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CFR PARTS AFFECTED IN THIS ISSUE

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

Rules and Regulations

Federal Register
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NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

RIN 3150–AF99

Transfer for Disposal and Manifests; Minor Technical Conforming Amendment

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations concerning low-level waste shipment manifest information. The currently effective codified regulations (CFR) include a dual implementation procedure that allows use of one of two manifesting procedures. The use of new manifesting requirements, which were promulgated on March 27, 1995, became mandatory on March 1, 1998. Therefore, this action is necessary to remove expired provisions from the regulations. An additional correction is being made to the scope section of this part to rectify an inadvertent change.

EFFECTIVE DATE: November 20, 1998.

FOR FURTHER INFORMATION CONTACT: Mark Haisfield, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6196, e-mail MFH@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

The purpose of these amendments to 10 CFR Part 20 are to: (1) Issue technical conforming changes to §§ 20.1009 and 20.2006 and appendix F; and (2) correct an inadvertent change made to § 20.1002. The amendments are necessary to restore the most current and complete version of the section concerning the information collection requirements approved by the Office of Management and Budget (OMB) and to remove information that refers to a time period that has now passed, and therefore is no longer applicable. The final rule entitled ''Low-Level Waste Shipment Manifest Information and Reporting'' (60 FR 15649; March 27, 1995) established a compliance period of almost 3 years before the use of the new manifesting requirements became mandatory. The mandatory effective date was March 1, 1998. Until the rule became mandatory, the NRC permitted the continued use of manifest requirements that were in effect before March 27, 1995. Therefore, Part 20 contains a dual implementation procedure that allows the use of either the old manifesting requirements or the new manifesting requirements. Because the use of the new requirements became mandatory on March 1, 1998, reference to the previous manifesting requirements is inappropriate and might cause confusion to users. This amendment will simplify the appropriate sections of the CFR by removing the now obsolete procedures.

The requirements in § 20.1009, ''Information collection requirements: OMB approval,'' published as part of the final rule on March 27, 1995, became effective on March 1, 1998. However, in between its promulgation on March 27, 1995, and March 1, 1998, other changes have been made to Part 20 that required corresponding changes to this section. Therefore, when the March 27, 1995, rule became effective, it superseded approved changes to § 20.1009 made since March 27, 1995. This final rule will update § 20.1009 to restore the changes made to this section between March 27, 1995 and March 1, 1998.

Section 20.2006, ''Transfer for disposal and manifests,'' is being revised to eliminate the option to use either appendix F or appendix G, eliminate reference to appendix F, and to require the use of appendix G, since appendix F is now obsolete.

Appendix F to Part 20, ''Requirements for Low-Level Waste Transfer for Disposal at Land Disposal Facilities and Manifests,'' is being entirely removed and appendix F will be noted as ''Reserved.''

An additional amendment deals with an inadvertent change that was made to the scope section of Part 20 during the final rulemaking, ''Criteria for the Release of Individuals Administered Radioactive Material'' (62 FR 4132 dated 1/29/97). The inadvertent change to this section eliminated the proper reference to Part 36, ''Licenses and Radiation Safety Requirements for Irradiators'' and to § 76.60 dealing with certification of gaseous diffusion plants.

Because these amendments deal with agency organization, practice, and procedure, the notice and comment provisions of the Administrative Procedure Act do not apply pursuant to 5 U.S.C. 553(b)(A). The amendments will be effective 60 days after publication in the **Federal Register**.

Compatibility of Agreement State Regulations

Under ''Policy Statement on Adequacy and Compatibility of Agreement State Programs,'' approved by the Commission on June 30, 1997, § 20.2006 and appendix F are listed as compatibility category ''B.'' Under compatibility category B, the program elements have significant direct transboundary implications that the State should adopt with essentially identical language. Section 20.1009 is not applicable to the Agreement States. Section 20.1002 is listed as compatibility category ''D.'' Under compatibility category D, this section is not required for purposes of compatibility; however, if adopted by the State, should be compatible with NRC.

Environmental Impact: Categorical Exclusion

The Commission has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(2). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paper Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, approval 3150–0014.

Public Protection Notification

If an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to

respond to, the collection of information.

Regulatory Analysis

A regulatory analysis has not been prepared for this final rule because this rule is considered a minor non-substantive amendment. It has no economic impact on NRC licensees or the public.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this rule, and therefore, a backfit analysis is not required because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

List of Subjects in 10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR Part 20.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955 as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

2. Section 20.1002 is revised to read as follows:

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under parts 30 through 36, 39, 40, 50, 60, 61, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under Part 76 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with § 35.75, or to exposure from voluntary participation in medical research programs.

3. Section 20.1009 is revised to read as follows:

§ 20.1009 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150–0014.

(b) The approved information collection requirements contained in this part appear in §§ 20.1003, 20.1101, 20.1202, 20.1203, 20.1204, 20.1206, 20.1208, 20.1301, 20.1302, 20.1403, 20.1404, 20.1406, 20.1501, 20.1601, 20.1703, 20.1901, 20.1902, 20.1904, 20.1905, 20.1906, 20.2002, 20.2004, 20.2006, 20.2102, 20.2103, 20.2104, 20.2105, 20.2106, 20.2107, 20.2108, 20.2110, 20.2201, 20.2202, 20.2203, 20.2204, 20.2205, 20.2206, 20.2301, and appendix G to 10 CFR Part 20.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 20.2104, NRC Form 4 is approved under control number 3150–0005.

(2) In §§ 20.2106 and 20.2206, NRC Form 5 is approved under control number 3150–0006.

(3) In § 20.2006 and appendix G to 10 CFR Part 20, NRC Form 540 and 540A is approved under control number 3150–0164.

(4) In § 20.2006 and appendix G to 10 CFR Part 20, NRC Form 541 and 541A is approved under control number 3150–0166.

(5) In § 20.2006 and appendix G to 10 CFR Part 20, NRC Form 542 and 542A is approved under control number 3150–0165.

4. Section 20.2006 is revised to read as follows:

§ 20.2006 Transfer for disposal and manifests.

(a) The requirements of this section and appendix G to 10 CFR Part 20 are designed to—

(1) Control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in this part, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility (as defined in Part 61 of this chapter);

(2) Establish a manifest tracking system; and

(3) Supplement existing requirements concerning transfers and recordkeeping for those wastes.

(b) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to 10 CFR Part 20.

(c) Each shipment manifest must include a certification by the waste generator as specified in section II of appendix G to 10 CFR Part 20.

(d) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in section III of appendix G to 10 CFR Part 20.

Appendix F To Part 20 [Reserved]

5. Appendix F to part 20 is removed and reserved.

Dated at Rockville, Maryland this 8th day of September, 1998.

For the Nuclear Regulatory Commission.

Hugh L. Thompson, Jr.,

Acting Executive Director for Operations.

[FR Doc. 98–25176 Filed 9–18–98; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–15–AD; Amendment 39–10770; AD 98–20–04]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A319, A320, and A321 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Airbus Model A319, A320, and A321 series airplanes, that requires replacing certain toilet rinse valves with modified rinse valves. This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by this AD are intended to prevent water contamination of the avionics computers, which could result in the display of erroneous or misleading information to the flightcrew, and consequent reduced controllability of the airplane.

DATES: Effective October 26, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 26, 1998.

ADDRESSES: The service information referenced in this AD may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Airbus Model A319, A320, and A321 series airplanes was published in the **Federal Register** on March 20, 1998 (63 FR 13570). That action proposed to require replacing certain Monogram toilet rinse valves with modified rinse valves.

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 proposed rule.

Two commenters express their concerns that additional sources of fluid contamination of avionics computers exist. One commenter specifies that other possible fluid sources include water supply and drain lines, coffee makers, water boilers, water filters, hot-cups, beverage containers, trash cans, rain, snow, waste tanks, waste tank rinse systems, hydraulic lines, fuel lines, and de-icing fluid systems. The other commenter states that, since the avionics computers probably have cooling air holes in their cases and are not intrinsically tolerant of moisture ingress, it may be desirable to provide additional protection of the avionics computers such as installing drip shields. The commenter further suggests that the need for such additional protection could be verified by a safety analysis conducted to consider the probability of failure of the rinse valve, the probability of overflow fluids entering the computers, and the probability of hazardous malfunction of the computers due to moisture ingress.

The FAA acknowledges the commenters' concern that other potential sources of fluid contamination may exist. However, an existing unsafe condition (water contamination of the avionics computers due to malfunction of the toilet rinse valve) has been identified and a corrective action required in this rule. The FAA finds that to delay issuance of this final rule would be inappropriate, since issuance of an AD is the means by which the identified unsafe condition will be addressed. Therefore, no change to this final rule is necessary.

However, the FAA has been advised that additional safety analyses have been conducted to address other probabilities of contamination of the avionics computers. Additionally, the FAA is reviewing additional information received from the Direction Générale de l'Aviation Civile (DGAC), the airworthiness authority for France, concerning contamination of the avionics computers. After review of the findings of this information, the FAA may consider further rulemaking.

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.

Cost Impact

The FAA estimates that 16 airplanes of U.S. registry will be affected by this AD, that it will take approximately 6 work hours per airplane to accomplish the required actions, and that the average labor rate is $60 per work hour. Required parts will be provided by the manufacturer at no cost to the operators. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $5,760, or $360 per airplane.

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

Regulatory Impact

The regulations 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. 106(g), 40113, 44701.

§ 39.13 [Amended]

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

98–20–04 Airbus Industrie: Amendment 39–10770. Docket 98-NM–15–AD.

Applicability: Model A319, A320, and A321 series airplanes; equipped with Monogram rinse valves having part number (P/N) 15800–348, Revision C; and on which Airbus Modification 26145 (reference Airbus Service Bulletin A320–38–1049) has not been accomplished; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent water contamination of the avionics computers, which could result in the display of erroneous or misleading information to the flightcrew, and consequent reduced controllability of the airplane, accomplish the following:

(a) Within 12 months after the effective date of this AD, replace all Monogram toilet rinse valves having P/N 15800–348, Revision C, with modified rinse valves, in accordance with Airbus Service Bulletin A320–38–1049, dated January 22, 1997.

(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, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

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

(d) The actions shall be done in accordance with Airbus Service Bulletin A320–38–1049, dated January 22, 1997. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in French airworthiness directive 97–269–103(B), dated September 24, 1997.

(e) This amendment becomes effective on October 26, 1998.

Issued in Renton, Washington, on September 11, 1998.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–24901 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–28–AD; Amendment 39–10769; AD 98–20–03]

RIN 2120–AA64

Airworthiness Directives; Fokker Model F.28 Mark 1000, 2000, 3000, and 4000 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all Fokker Model F.28 Mark 1000, 2000, 3000, and 4000 series airplanes, that requires repetitive inspections of the center joint of the main landing gear (MLG) torque link and the MLG assembly for excessive free-play; and correction, if necessary. This AD also requires installation of new MLG torque link dampers, which constitutes terminating action for the repetitive inspections; and revision of the FAA-approved maintenance program to incorporate inspections and overhaul of the new torque link dampers. This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by this AD are intended to prevent the failure of MLG torque links, which could result in reduced controllability of the airplane on the ground during takeoff or landing.

DATES: Effective October 26, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 26, 1998.

ADDRESSES: The service information referenced in this AD may be obtained from Fokker Services B.V., Technical Support Department, P.O. Box 75047, 1117 ZN Schiphol Airport, the Netherlands. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to all Fokker Model F.28 Mark 1000, 2000, 3000, and 4000 series airplanes was published in the **Federal Register** on April 2, 1998 (63 FR 16177). That action proposed to require repetitive inspections of the center joint of the main landing gear (MLG) torque link and the MLG assembly for excessive free-play; and correction, if necessary. That action also proposed to require installation of new MLG torque link dampers, which would constitute terminating action for the repetitive inspections; and revision of the FAA-approved maintenance program to incorporate inspections and overhaul of the new torque link dampers.

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

Request That Final Rule Not Be Issued

The single commenter, an operator, states that the requirements of the proposed rule are unnecessary. The commenter states that the incident that initiated the Dutch airworthiness directive was caused by certain operators' failure to adequately maintain their landing gear, wheels, brakes, and tires. The commenter further notes that accomplishment of the proposed installation of a shimmy damper could allow airlines to lengthen the time between replacement and repair of those worn parts, which would exacerbate the

condition. The commenter concludes that the requirements of the proposed rule would unfairly penalize operators who have adequately maintained their airplanes and have no problems with vibration.

The FAA does not concur that the requirements of this AD are unnecessary. As explained in the preamble of the proposed rule, the Dutch airworthiness authority [Rijksluchtvaartdienst (RLD)] advised the FAA that it received numerous reports of MLG torque link failure on in-service airplanes. The cause of these failures has been attributed to one or more deficiencies, such as excessive play in hinges and bearings, worn or non-approved tires, or nitrogen or tire pressure that is too high. Such deficiencies caused reduced natural stability of the MLG in a lateral and torsional mode during landing, resulting in vibration and consequent failure of the MLG torque links.

Although the deficiencies are maintenance-related, the FAA considers that the large number of deficiencies reported is sufficient evidence that an unsafe condition exists. Therefore, this AD action addresses certain identified deficiencies that may result in an unsafe condition (reduced controllability of the airplane on the ground during takeoff or landing), and requires corrective action, if necessary.

Request for Approval of Alternative Method of Compliance

The commenter also requests approval of an alternative method of compliance that consists of an enhanced maintenance program for landing gear components. The commenter provided correspondence indicating that Transport Canada Aviation (the airworthiness authority for Canada) has approved the commenter's request for an alternative method of compliance based on the enhanced maintenance program.

The FAA does not concur that this final rule should be revised to reflect approval of an alternative method of compliance. The information submitted by the commenter is insufficient for the FAA to evaluate the commenter's suggestion. However, under the provisions of paragraph (d) of this final rule, the FAA may consider requests for approval of an alternative method of compliance if sufficient data are submitted to substantiate that such a design change would provide an acceptable level of safety.

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.

Cost Impact

The FAA estimates that 27 airplanes of U.S. registry will be affected by this AD. It will take approximately 3 work hours per airplane to accomplish the required inspections, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the inspections required by this AD on U.S. operators is estimated to be $4,860, or $180 per airplane, per inspection cycle.

It will take approximately 18 work hours per airplane to accomplish the required installation/modification, at an average labor rate of $60 per work hour. Required parts will cost approximately $90,000 per airplane. Based on these figures, the cost impact of the installation/modification required by this AD on U.S. operators is estimated to be $2,459,160, or $91,080 per airplane.

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

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. 106(g), 40113, 44701.

§ 39.13 [Amended]

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

98–20–03 Fokker Services B.V.: Amendment 39–10769. Docket 98–NM–28–AD.

Applicability: All Model F.28 Mark 1000, 2000, 3000, and 4000 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 request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent the failure of main landing gear (MLG) torque links, which could result in reduced controllability of the airplane on the ground during takeoff or landing, accomplish the following:

(a) Within 1,000 flight cycles after the effective date of this AD, perform a visual inspection of the center joint of the MLG torque link for excessive free play, in accordance with Part 1.D. of the Accomplishment Instructions of Fokker Service Bulletin F28/32–151, Revision 1, dated March 12, 1997.

(1) If no discrepancy is detected, repeat the visual inspection thereafter at intervals not to exceed 1,000 flight cycles.

(2) If any discrepancy is detected, prior to further flight, correct the discrepant condition in accordance with Part 1.D. of the Accomplishment Instructions of the service bulletin. Repeat the visual inspection thereafter at intervals not to exceed 1,000 flight cycles.

Note 2: Part 1.D. of the Accomplishment Instructions of Fokker Service Bulletin F28/32–151, Revision 1, dated March 12, 1997, references Fokker F.28 Airplane Maintenance Manual (AMM), Chapter 32–10–04, as an additional source of service information to accomplish the actions required by this AD.

(b) Within 3,000 flight cycles after the effective date of this AD, perform a visual inspection of the MLG assembly for excessive free play, in accordance with Parts 1.A., 1.B., and 1.C. of the Accomplishment Instructions of Fokker Service Bulletin F28/32–151, Revision 1, dated March 12, 1997.

(1) If no discrepancy is detected, repeat the visual inspection thereafter at intervals not to exceed 3,000 flight cycles.

(2) If any discrepancy is detected, prior to further flight, correct the discrepant condition in accordance with Parts 1.A., 1.B., and/or 1.C. of the Accomplishment Instructions of the service bulletin, as applicable. Repeat the visual inspection thereafter at intervals not to exceed 3,000 flight cycles.

Note 3: Parts 1.A., 1.B., and 1.C. of the Accomplishment Instructions of Fokker Service Bulletin F28/32–151, Revision 1, dated March 12, 1997, reference Fokker F.28 AMM, Chapters 32–10–01, 32–10–00, and 32–10–04, as additional sources of service information to accomplish the actions required by this AD.

(c) Within 30 months after the effective date of this AD, accomplish paragraphs (c)(1) and (c)(2) of this AD.

(1) Install torque link dampers and associated sub-assemblies in accordance with Part 2 of the Accomplishment Instructions of Fokker Service Bulletin F28/32–151, Revision 1, dated March 12, 1997. Accomplishment of the installation constitutes terminating action for the repetitive inspection requirements of this AD.

(2) Revise the FAA-approved maintenance program to incorporate a visual inspection of the oil level of the torque-link dampers thereafter at intervals not to exceed 250 flight hours, and incorporate a scheduled overhaul of each damper concurrent with the overhaul of the MLG on which it is installed, in accordance with Part 2 of the Accomplishment Instructions of Fokker Service Bulletin F28/32–151, Revision 1, dated March 12, 1997.

Note 4: After the maintenance program is revised to include the required inspection and overhaul actions in accordance with paragraph (c)(2) of this AD, operators do not need to make a maintenance log entry to show compliance with this AD each time those actions are accomplished thereafter.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 5: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

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

(f) The actions shall be done in accordance with Fokker Service Bulletin F28/32–151, Revision 1, dated March 12, 1997, which includes the following list of effective pages:

Page No.	Revision level shown on page	Date shown on page
1–6, 10	1	March 12, 1997.
7–9, 11–13 ...	Original	August 9, 1996.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Fokker Services B.V., Technical Support Department, P.O. Box 75047, 1117 ZN Schiphol Airport, the Netherlands. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 6: The subject of this AD is addressed in Dutch airworthiness directive BLA 1996–103(A), dated August 30, 1996.

(g) This amendment becomes effective on October 26, 1998.

Issued in Renton, Washington, on September 11, 1998.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–24902 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–44–AD; Amendment 39–10772; AD 98–20–06]

RIN 2120–AA64

Airworthiness Directives; Aerospatiale Model ATR42 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Aerospatiale Model ATR42 series airplanes, that requires modification of the electrical power supply for the standby horizon indicator. This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by this AD are intended to prevent loss of the standby horizon indicator in the event of failure of emergency direct current (DC) power, which could result in reduced controllability of the airplane during instrument flight rules conditions.

DATES: Effective October 26, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 26, 1998.

ADDRESSES: The service information referenced in this AD may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Aerospatiale Model ATR42 series airplanes was published in the **Federal Register** on May 12, 1998 (63 FR 26106). That action proposed to require modification of the electrical power supply for the standby horizon indicator.

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

The commenter, an operator of the affected airplanes, requests that the proposed rule be revised as follows:

—For airplanes on which Aerospatiale Modification 03059 has not been accomplished, allow accomplishment of the actions specified in the original issue of Avions de Transport Regional Service Bulletin ATR42–34–0090.

—For all other airplanes, Revision 1 of that service bulletin should be required to be accomplished.

The commenter notes that Revision 1 of the service bulletin is specified in the proposed rule as the appropriate source of service information for all affected airplanes. The commenter states that, from a technical standpoint, there is no difference between the original issue and Revision 1 of the service bulletin in regard to installations accomplished on

its fleet. The commenter adds that Revision 1 integrates additional wiring options in Figures 9, 19, and 20 of the service bulletin (in regard to the commenter's fleet) for airplanes on which Aerospatiale Modification 03059 has been accomplished; that modification does not apply to the commenter's fleet.

The FAA does not concur with the commenter's request. The FAA has confirmed that some airplanes on which Aerospatiale Modification 03059 has not been accomplished that have been modified in accordance with the original issue of the service bulletin do not require additional work in accordance with Revision 1. However, other such airplanes do require additional work because of certain changes in the wiring design contained in Revision 1.

An operator of airplanes that have been modified previously in accordance with the original issue of the service bulletin should review the work specified in Revision 1 to determine what additional work is necessary for its affected fleet. If no additional work is necessary to conform to Revision 1 of the service bulletin, those airplanes would be considered to be in compliance with the AD, as provided by the phrase, ''unless accomplished previously'', in the compliance provision of the AD. No change to this final rule is necessary.

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.

Cost Impact

The FAA estimates that 88 airplanes of U.S. registry will be affected by this AD, that it will take approximately 10 to 55 work hours per airplane to accomplish the required modification (depending on how many kits are needed for each airplane), and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be between $52,800 and $290,400, or between $600 and $3,300 per airplane.

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

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. 106(g), 40113, 44701.

§ 39.13 [Amended]

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

98–20–06 Aerospatiale: Amendment 39–10772. Docket 98–NM–44–AD.

Applicability: Model ATR42–200, –300, and –320 series airplanes on which Aerospatiale Modification 4647 has not been accomplished; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent loss of the standby horizon indicator in the event of failure of emergency direct current (DC) power, which could result in reduced controllability of the airplane during instrument flight rules conditions, accomplish the following:

(a) Within 12 months after the effective date of this AD, modify the electrical power supply for the standby horizon indicator in accordance with Avions de Transport Regional Service Bulletin ATR42–34–0090, Revision 1, dated April 22, 1997.

(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, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

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

(d) The actions shall be done in accordance with Avions de Transport Regional Service Bulletin ATR42–34–0090, Revision 1, dated April 22, 1997, which contains the following list of effective pages:

Page No.	Revision level shown on page	Date shown on page
1–4, 15, 29–37, 49–52, 55–62, 69–72.	1	April 22, 1997.
5–14, 16–28, 38–48, 52, 53, 63–68, 73, 74.	Original	December 6, 1997.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in French airworthiness directive 96–230–066(B), dated October 23, 1996.

(e) This amendment becomes effective on October 26, 1998.

Issued in Renton, Washington, on September 11, 1998.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–24903 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–63–AD; Amendment 39–10768; AD 98–20–02]

RIN 2120–AA64

Airworthiness Directives; Saab Model SAAB 2000 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Saab Model SAAB 2000 series airplanes, that requires repetitive inspections to detect chafing of the hydraulic pipe on the emergency uplock release system of the main landing gear (MLG); testing of the hydraulic pipe for leaks, if necessary; and repair of the hydraulic pipe, if necessary. This amendment also requires modification of the attachment bolt and attachment hole on the structural panel, which terminates the repetitive inspection requirements of this AD. This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by this AD are intended to prevent chafing between the hydraulic pipe on the emergency uplock release system of the MLG and an attachment bolt on a structural panel, which could result in rupture of the hydraulic pipe, loss of hydraulic pressure, and consequent inability to activate the emergency MLG extension.

DATES: Effective October 26, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 26, 1998.

ADDRESSES: The service information referenced in this AD may be obtained from Saab Aircraft AB, SAAB Aircraft Product Support, S–581.88, Linköping, Sweden. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Saab Model SAAB 2000 series airplanes was published in the **Federal Register** on April 21, 1998 (63 FR 19675). That action proposed to require repetitive inspections to detect chafing of the hydraulic pipe on the emergency uplock release system of the main landing gear (MLG); testing of the hydraulic pipe for leaks, if necessary; and repair of the hydraulic pipe, if necessary. That action also proposed to require modification of the attachment bolt and attachment hole on the structural panel, which would terminate the repetitive inspection requirements of this AD.

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

The commenter, the manufacturer, indicates that it has issued Saab Service Bulletin 2000–29–007, Revision 02, dated May 8, 1998. (The proposed AD references Revision 01 of the service bulletin as the appropriate source of service information for accomplishment of the actions required by the AD.) The commenter notes that Revision 02 of the service bulletin contains no changes to compliance or technical items; it only specifies a change to the aircraft effectivity. The commenter indicates that this effectivity changes does not affect any U.S.-registered airplane.

Based on this comment, the FAA has revised this final rule to include Revision 02 of the service bulletin as an additional source of service information for accomplishment of the requirements of the AD. Additionally, the applicability of this final rule has been revised to add airplane serial number –060 (which is not on the U.S. Register), and to exclude certain airplane serial numbers, as specified in the effectivity of Revision 02 of the service bulletin.

Conclusion

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the change described previously. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

The FAA estimates that 3 Saab Model SAAB 2000 series airplanes of U.S. registry will be affected by this AD, that it will take approximately 3 work hours per airplane to accomplish the required inspection, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the inspection on U.S. operators is estimated to be $540, or $180 per airplane, per inspection cycle.

It will take approximately 6 work hours per airplane to accomplish the required modification, at an average labor rate of $60 per work hour. Required parts will be supplied by the manufacturer at no cost to the operators. Based on these figures, the cost impact of the modification required by this AD on U.S. operators is estimated to be $1,080, or $360 per airplane.

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

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. 106(g), 40113, 44701.

§ 39.13 [Amended]

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

98–20–02 Saab Aircraft AB: Amendment 39–10768. Docket 98–NM–63–AD.

Applicability: Model SAAB 2000 series airplanes, serial numbers –002 through –050 inclusive, and –052, –053, and –060; excluding serial number –051; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

Note 2: Accomplishment of the actions required by this AD prior to the effective date of this AD in accordance with Saab Service Bulletin 2000–29–007, dated April 29, 1997, is considered acceptable for compliance with the applicable actions specified in this AD.

To prevent chafing between the hydraulic pipe on the emergency uplock release system of the main landing gear (MLG) and an attachment bolt on a structural panel, which could result in rupture of the hydraulic pipe, loss of hydraulic pressure, and consequent inability to activate the emergency MLG extension, accomplish the following:

(a) Within 300 flight hours after the effective date of this AD, perform a visual inspection to detect chafing of the hydraulic pipe on the emergency uplock release system of the MLG, in accordance with Saab Service Bulletin 2000–29–007, Revision 01, dated August 18, 1997, or Revision 02, dated May 8, 1998.

(1) If no chafing is detected, repeat the visual inspection thereafter at intervals not to exceed 300 flight hours.

(2) If any chafing is detected, prior to further flight, perform a test of the hydraulic pipe to detect leaks in accordance with the service bulletin.

(i) If no leaking is detected, repeat the actions required by paragraph (a) of this AD thereafter at intervals not to exceed 300 flight hours.

(ii) If any leaking is detected, prior to further flight, repair the hydraulic pipe and accomplish paragraph (b) of this AD, in accordance with the service bulletin.

(b) Within 900 flight hours after the effective date of this AD, modify the attachment bolt and attachment hole on the structural panel, in accordance with Saab Service Bulletin 2000–29–007, Revision 01, dated August 18, 1997, or Revision 02, dated May 8, 1998. Accomplishment of this modification constitutes terminating action for the repetitive inspection requirements of this AD.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

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

(e) The actions shall be done in accordance with Saab Service Bulletin 2000–29–007, Revision 01, dated August 18, 1997, or Saab Service Bulletin 2000–29–007, Revision 02, dated May 8, 1998. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Saab Aircraft AB, SAAB Aircraft Product Support, S–581.88, Linköping, Sweden. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in Swedish airworthiness directives (SAD) 1–112R1, dated August 21, 1997, and 1–112R2, dated May 8, 1998.

(f) This amendment becomes effective on October 26, 1998.

Issued in Renton, Washington, on September 11, 1998.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–24904 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–310–AD; Amendment 39–10771; AD 98–20–05]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A310 and A300–600 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Airbus Model A310 and A300–600 series airplanes, that currently requires, among other things, repetitive inspections to ensure correct synchronization of the hydraulic control valves of the trimmable horizontal stabilizer (THS) actuator; replacement of the horizontal stabilizer actuator motors with new or serviceable motors and resynchronization of the valves, or adjustment of the synchronization, if necessary; and a functional test of the THS. This amendment adds a requirement to replace the hydraulic motor of the THS with an improved motor, which constitutes terminating action for the repetitive inspections. This amendment also expands the applicability to include additional airplanes. This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by this AD are intended to prevent desynchronization of the hydraulic control valves, which could result in runaway of the horizontal stabilizer to its full up or down position, subsequent reduced maneuvering capability, and potential pitch upset.

DATES: Effective October 26, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 26, 1998.

The incorporation by reference of Airbus All Operators Telex (AOT) 27–21, Revision 1, dated January 5, 1996, as listed in the regulations, was approved previously by the Director of the Federal

Register as of February 5, 1996 (61 FR 2697, January 29, 1996).

ADDRESSES: The service information referenced in this AD may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 96–01–52, amendment 39–9491 (61 FR 2697, January 29, 1996), which is applicable to certain Airbus Model A310 and A300–600 series airplanes, was published in the **Federal Register** on April 30, 1998 (63 FR 23690). The action proposed to continue to require, among other things, repetitive inspections to ensure correct synchronization of the hydraulic control valves of the trimmable horizontal stabilizer (THS) actuator; replacement of the horizontal stabilizer actuator motors with new or serviceable motors and resynchronization of the valves, or adjustment of the synchronization, if necessary; and a functional test of the THS. The action also proposed to add a requirement to replace the hydraulic motor of the THS with an improved motor, which would constitute terminating action for the repetitive inspections.

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

The Air Transport Association (ATA) of America, on behalf of one of its members, requests that the proposed compliance time for the replacement of the hydraulic motor of the trimmable horizontal stabilizer actuator be extended from 1 year to 18 months. The commenter bases its request on the limitations of the overhaul vendor, the equivalent level of safety provided by the frequent inspections, and the lack of findings during those inspections.

The commenter has established an aggressive motor replacement program, but has been limited by the ability of the overhaul vendor to modify and return the units. Due to the limited number of spares available and a turnaround time of 20 days, the commenter is only able to accomplish the replacement on one or two airplanes per month. At that rate of accomplishment, this commenter believes 18 months to be the minimum amount of time in which it can accomplish the replacement on its entire fleet.

The commenter also states that, for the past two years, it has been performing the inspection required by AD 96–01–52 at intervals of 500 hours time-in-service on unmodified units, and has yet to find any desynchronized motors. Further, the commenter notes that, since the issuance of AD 96–01–52, the Direction Générale de l'Aviation Civile, (DGAC), which is the airworthiness authority for France, revised the inspection interval to 1,200 flight hours; however, AD 96–01–52 was not revised to reflect this relaxation of the inspection interval.

The FAA concurs with the commenter's request. The FAA has confirmed that the DGAC is in the process of revising its related airworthiness directive to extend the compliance time for accomplishment of the replacement. In light of this, and in consideration of the fact that a more stringent inspection interval of 500 hours time-in-service is retained in this AD, the FAA finds that the compliance time for motor replacement can be extended to 18 months without compromising the safety of the affected fleet. The final rule has been revised accordingly.

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 with the change previously described. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 88 airplanes of U.S. registry that will be affected by this AD.

The actions that are currently required by AD 96–01–52, and retained in this AD, take approximately 1 work hour per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the requirements of the existing AD on U.S. operators is estimated to be $5,280, or $60 per airplane.

The new actions that are required by this new AD will take approximately 4 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts will be provided by the manufacturer at no cost to operators. Based on these figures, the cost impact of the new requirements of this AD on U.S. operators is estimated to be $21,120, or $240 per airplane.

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

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. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–9491 (61 FR 2697, January 29, 1996), and by adding a new airworthiness directive (AD), amendment 39–10771, to read as follows:

98–20–05 Airbus: Amendment 39–10771. Docket 97–NM–310–AD. Supersedes AD 96–01–52, Amendment 39–9491.

Applicability: Model A310 and A300–600 series airplanes on which Airbus Modification 11607 has not been installed, certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent desynchronization of the hydraulic control valves, which could result in runaway of the horizontal stabilizer to its full up or down position, subsequent reduced maneuvering capability, and potential pitch upset, accomplish the following:

Restatement of Requirements of AD 96–01–52

(a) Within 12 days after February 5, 1996 (the effective date of AD 96–01–52, amendment 39–9491), perform an inspection to ensure correct synchronization of the hydraulic control valves of the trimmable horizontal stabilizer (THS) actuator, in accordance with paragraph 4.2.2.1 of Airbus All Operators Telex (AOT) 27–21, Revision 1, dated January 5, 1996.

(1) If the actuator is synchronized correctly, prior to further flight, perform a functional test of the THS in accordance with paragraph 4.2.2.1 of the AOT. Thereafter, repeat the inspection required by paragraph (a) of this AD at intervals not to exceed 500 hours time-in-service.

(2) If the actuator is desynchronized slightly, as specified in the AOT, prior to further flight, adjust the synchronization, and perform a functional test of the THS, in accordance with paragraph 4.2.2.2 of the AOT. Thereafter, repeat the inspection required by paragraph (a) of this AD at intervals not to exceed 500 hours time-in-service.

(3) If the actuator is desynchronized significantly, as specified in the AOT, prior to further flight, accomplish either paragraph (a)(3)(i) or (a)(3)(ii) of this AD. Prior to further flight following the accomplishment of either of those paragraphs, adjust the synchronization, and perform a functional test of the THS, in accordance with paragraph 4.2.2.3 of the AOT. Thereafter, repeat the inspection required by paragraph (a) of this AD at intervals not to exceed 500 hours time-in-service.

(i) Remove and replace the hydraulic motors of the horizontal stabilizer actuator (HSA) with new or serviceable motors in accordance with procedures specified in the Airplane Maintenance Manual. Or

(ii) Remove the hydraulic motors of the HSA and perform the various follow-on actions specified in paragraph 4.2.2.4 of the AOT, in accordance with that paragraph. (The follow-on actions include checking the motors and the cam seats, assembling the motors, and metal stamping the modification plate of the motors.) If any discrepancy is found during the check, prior to further flight, repair in accordance with paragraph 4.2.2.4 of the AOT.

(b) For airplanes on which any maintenance action relating to a hydraulic motor or a hydraulic valve block of the HSA has occurred since the airplane was new: Within 12 days after February 5, 1996, accomplish either paragraph (b)(1) or (b)(2) of this AD.

(1) Replace both hydraulic motors of the HSA with new or serviceable motors in accordance with the procedures specified in the Airplane Maintenance Manual. Adjust the synchronization, and perform a functional test of the THS in accordance with paragraph 4.2.2.3 of Airbus AOT 27–21, Revision 1, dated January 5, 1996. Thereafter, perform the repetitive inspections required by paragraph (a) of this AD at intervals not to exceed 500 hours time-in-service. Or

(2) Remove the hydraulic motors of the HSA and perform the various follow-on actions specified in paragraph 4.2.2.4 of the AOT, in accordance with that paragraph of the AOT. Adjust the synchronization, and perform a functional test of the THS in accordance with paragraph 4.2.2.3 of the AOT. (The follow-on actions include checking the motors and the cam seats, assembling the motors, and metal stamping the modification plate of the motors.) If any discrepancy is found during the check, prior to further flight, repair in accordance with paragraph 4.2.2.4 of the AOT. Thereafter, perform the repetitive inspections required by paragraph (a) of this AD at intervals not to exceed 500 hours time-in-service.

New Requirements of This AD

(c) Within 18 months after the effective date of this AD, replace the hydraulic motors of the THS actuator with improved motors, in accordance with Airbus Service Bulletin A310–27–2081 (for Model A310 series airplanes) or A300–27–6035 (for Model A300–600 series airplanes), both dated November 26, 1996, as applicable. Accomplishment of this action constitutes terminating action for the repetitive inspection requirements of this AD.

(d) As of the effective date of this AD, no person shall install on any airplane a THS actuator having part number 47142–201/–203.

(e)(1) 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, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

(e)(2) Alternative methods of compliance, approved previously in accordance with AD 96–01–52, amendment 39–9491, are approved as alternative methods of compliance with paragraphs (a) and (b) of this AD.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

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

(g) Except as provided by paragraphs (a)(3)(i) and (b)(1) of this AD, the actions shall be done in accordance with Airbus All Operators Telex (AOT) 27–21, Revision 1, dated January 5, 1996; Airbus Service Bulletin A310–27–2081, dated November 26, 1996; or Airbus Service Bulletin A300–27–6035, dated November 26, 1996; as applicable.

(1) The incorporation by reference of Airbus Service Bulletin A310–27–2081, dated November 26, 1996, and Airbus Service Bulletin A300–27–6035, dated November 26, 1996, is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of Airbus All Operators Telex (AOT) 27–21, Revision 1, dated January 5, 1996, was approved previously by the Director of the Federal Register as of February 5, 1996 (61 FR 2697, January 29, 1996).

(3) Copies may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in French airworthiness directive 97–081–217(B), dated March 12, 1997.

(h) This amendment becomes effective on October 26, 1998.

Issued in Renton, Washington, on September 11, 1998.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–24906 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–152–AD; Amendment 39–10774; AD 98–20–07]

RIN 2120–AA64

Airworthiness Directives; British Aerospace (Jetstream) Model 4101 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain British Aerospace (Jetstream) Model 4101 airplanes, that currently requires an inspection to determine the data on the label of certain hose assemblies, and replacement of all hose assemblies from any discrepant batch with certain new hose assemblies. This amendment requires a one-time inspection for different data on the label of certain hose assemblies, and replacement of all hose assemblies from any discrepant batch with certain new hose assemblies. This action also adds airplanes to the applicability of the existing AD. This amendment is prompted by a report of the failure of a hose assembly in the fire extinguisher system of the engine nacelle due to cracks, caused during manufacture of the hose assemblies, in the swaged ferrule that attaches the hose to the end fitting. The actions specified by this AD are intended to prevent failure of hose assemblies, which could prevent the proper distribution of fire extinguishing agent within the engine nacelle in the event of a fire.

DATES: Effective October 26, 1998.

The incorporation by reference of Jetstream Alert Service Bulletin J41–A26–007, Revision 1, dated May 21, 1997, as listed in the regulations, is approved by the Director of the Federal Register as of October 26, 1998.

ADDRESSES: The service information referenced in this AD may be obtained from AI(R) American Support, Inc., 13850 Mclearen Road, Herndon, Virginia 20171. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 97–15–05, amendment 39–10078 (62 FR 38015, July 16, 1997), which is applicable to certain British Aerospace (Jetstream) Model 4101 airplanes, was published in the **Federal Register** on July 14, 1998 (63 FR 37793). That action proposed to add a one-time inspection for different data on the label of certain hose assemblies, and replacement of all hose assemblies from any discrepant batch with certain new hose assemblies. That action also proposed to add airplanes to the applicability of the existing AD.

Comments

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

The commenter supports the proposed rule.

Conclusion

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

Cost Impact

The FAA estimates that approximately 57 airplanes of U.S. registry will be affected by this AD.

The new inspection that is required in this AD will take approximately 1 work hour per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the inspection required by this AD on U.S. operators is estimated to be $3,420, or $60 per airplane.

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

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. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–10078 (62 FR 38015, July 16, 1997), and by adding a new airworthiness directive (AD), amendment 39–10774, to read as follows:

98–20–07 British Aerospace Regional Aircraft [Formerly Jetstream Aircraft Limited; British Aerospace (Commercial Aircraft) Limited]: Amendment 39–10774. Docket 98–NM–152–AD. Supersedes AD 97–15–05, Amendment 39–10078.

Applicability: Model Jetstream 4101 airplanes, constructors numbers 41004 through 41100 inclusive; certificated in any category.

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

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

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of hose assemblies, which could prevent the proper distribution of fire extinguishing agent within the engine nacelle in the event of a fire, accomplish the following:

(a) Within 30 days after the effective date of this AD, perform a one-time detailed visual inspection to determine the data on the label of the two hose assemblies having part number 14191001–56, in accordance with Jetstream Alert Service Bulletin J41–A26–007, Revision 1, dated May 21, 1997.

(1) If the data on any hose assembly are not identical to the data shown on either Label 1 or Label 2 of Figure 2 of the Accomplishment Instructions of the alert service bulletin, no further action is required by this AD.

(2) If the data on any hose assembly are identical to the data shown on either Label 1 or Label 2 of Figure 2 of the Accomplishment Instructions of the alert service bulletin, prior to the accumulation of 60 flight hours following accomplishment of the inspection required by paragraph (a) of this AD, replace the hose assembly with a new hose assembly that has different data on the identification label, in accordance with the alert service bulletin.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

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

(d) The inspection and replacement shall be done in accordance with Jetstream Alert Service Bulletin J41–A26–007, Revision 1, dated May 21, 1997. This incorporation by reference is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from AI(R) American Support, Inc., 13850 Mclearen Road, Herndon, Virginia 20171. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on October 26, 1998.

Issued in Renton, Washington, on September 11, 1998.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–24907 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. 29334; Amendment No. 71–30]

Airspace Designations; Incorporation By Reference

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends FAA regulations relating to airspace designations to reflect the approval by the Director of the Federal Register of the incorporation by reference of FAA Order 7400.9F, Airspace Designations and Reporting Points. This action also explains the procedures the FAA will use to amend the listings of Class A, Class B, Class C, Class D, and Class E airspace areas and reporting points incorporated by reference.

DATES: These regulations are effective September 16, 1998, through September 15, 1999. The incorporation by reference of FAA Order 7400.9F is approved by the Director of the Federal Register as of September 16, 1998, through September 15, 1999.

FOR FURTHER INFORMATION CONTACT: Donna Danhauer, Brenda Brown or Janet Glivings, Airspace and Rules Division (ATA–400), Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

FAA Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, listed Class A, Class B, Class C, Class D, and Class E airspace areas and reporting points. Due to the length of these descriptions, the FAA requested approval from the Office of the Federal Register to incorporate the material by reference in the Federal Aviation Regulations section 71.1 (14 CFR 71.1). The Director of the Federal Register approved the incorporation by reference of FAA Order 7400.9E in section 71.1, effective September 16, 1997, through September 15, 1998. During the incorporation by reference period, the FAA processed all proposed changes of the airspace listings in FAA Order 7400.9E in full text as proposed rule documents in the **Federal Register**. Likewise, all amendments of these listings were published in full text as final rules in the **Federal Register**. This rule reflects the periodic integration of these final rule amendments into a revised edition of Airspace Designations and Reporting Points, Order 7400.9F. The Director of the Federal Register has approved the incorporation by reference of FAA Order 7400.9F in § 71.1, as of September 16, 1998, through September 15, 1999. This rule also explains the procedures the FAA will use to amend the airspace designations incorporated by reference in part 71. Sections 71.5, 71.31, 71.33, 71.41, 71.51, 71.61, 71.71, 71.79, and 71.901 are also updated to reflect the incorporation by reference of FAA Order 7400.9F.

The Rule

This action amends part 71 of the Federal Aviation Regulations (14 CFR part 71) to reflect the approval by the Director of the Federal Register of the incorporation by reference of FAA Order 7400.9F, effective September 16, 1998, through September 15, 1999. During the incorporation by reference period, the FAA will continue to process all proposed changes of the airspace listings in FAA Order 7400.9F in full text as proposed rule documents in the **Federal Register**. Likewise, all amendments of these listings will be published in full text as final rules in the **Federal Register**. The FAA will periodically integrate all final rule amendments into a revised edition of the Order, and submit the revised edition to the Director of the Federal Register for approval for incorporation by reference in § 71.1.

The FAA has determined 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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. This action neither places any new restrictions or requirements on the public, nor changes the dimensions or operating requirements of the airspace listings incorporated by reference in part 71. Consequently, notice and public procedure under 5 U.S.C. 553(b) are unnecessary. Because this action will continue to update the changes to the airspace designations, which are depicted on aeronautical charts, and to avoid any unnecessary pilot confusion,

I find that good cause exists, under 5 U.S.C. 553(d), for making this amendment effective in less than 30 days.

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—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

2. Section 71.1 is added to read as follows:

§ 71.1 Applicability.

The complete listing for all Class A, Class B, Class C, Class D, and Class E airspace areas and for all reporting points can be found in FAA Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The approval to incorporate by reference FAA Order 7400.9F is effective September 16, 1998, through September 15, 1999. During the incorporation by reference period, proposed changes to the listings of Class A, Class B, Class C, Class D, and Class E airspace areas and to reporting points will be published in full text as proposed rule documents in the **Federal Register**. Amendments to the listings of Class A, Class B, Class C, Class D, and Class E airspace areas and to reporting points will be published in full text as final rules in the **Federal Register**. Periodically, the final rule amendments will be integrated into a revised edition of the Order and submitted to the Director of the Federal Register for approval for incorporation by reference in this section. Copies of FAA Order 7400.9F may be obtained from the Airspace and Rules Division, ATA–400, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, (202) 267–8783. Copies of FAA Order 7400.9F may be inspected in Docket No. 29334 at the Federal Aviation Administration, Office of the Chief Counsel, AGC–200, Room 915G, 800 Independence Avenue, SW., Washington, D.C., weekdays between 8:30 a.m. and 5:00 p.m., or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. This section is effective September 16, 1998, through September 15, 1999.

§ 71.5 [Amended]

3. Section 71.5 is amended by removing the words ''FAA Order 7400.9E'' and adding, in their place, the words ''FAA Order 7400.9F.''

§ 71.31 [Amended]

4. Section 71.31 is amended by removing the words ''FAA Order 7400.9E'' and adding, in their place, the words ''FAA Order 7400.9F.''

§ 71.33 [Amended]

5. Paragraph (c) of § 71.33 is amended by removing the words ''FAA Order 7400.9E'' and adding, in their place, the words ''FAA Order 7400.9F.''

§ 71.41 [Amended]

6. Section 71.41 is amended by removing the words ''FAA Order 7400.9E'' and ''FAA Order 7400.9B'' and adding, in their place, the words ''FAA Order 7400.9F.''

§ 71.51 [Amended]

7. Section 71.51 is amended by removing the words ''FAA Order 7400.9E'' and ''FAA Order 7400.9B'' and adding, in their place, the words ''FAA Order 7400.9F.''

§ 71.61 [Amended]

8. Section 71.61 is amended by removing the words ''FAA Order 7400.9E'' and ''FAA Order 7400.9B'' and adding, in their place, the words ''FAA Order 7400.9F.''

§ 71.71 [Amended]

9. Paragraphs (b), (c), (d), (e), and (f) of § 71.71 are amended by removing the words ''FAA Order 7400.9E'' and adding, in their place, the words ''FAA Order 7400.9F.''

§ 71.79 [Amended]

10. Section 71.79 is amended by removing the words ''FAA Order 7400.9E'' and adding, in their place, the words ''FAA Order 7400.9F.''

§ 71.901 [Amended]

11. Paragraph (a) of § 71.901 is amended by removing the words ''FAA Order 7400.9E'' and adding, in their place, the words ''FAA Order 7400.9F.''

Issued in Washington, DC, September 10, 1998.

Reginald C. Matthews,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 98–25071 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98–AWP–21]

Revision of Class D Airspace; San Diego-Gillespie Field, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action will revise the Class D airspace at San Diego-Gillespie Field, CA by lowering the ceiling of the Class D airspace area from 2,900 feet Mean Sea Level (MSL) to 2,400 feet MSL. The proposed modification of the San Diego, CA, Class B airspace area would create a narrow 300 foot corridor northeast of Gillespie Field. This corridor would reduce the available airspace for aircraft that are approaching or overflying Gillespie Field from the northeast. Lowering the Gillespie Field Class D airspace ceiling will create an 800 foot corridor along this same route, thereby increasing navigable airspace for aircraft operating under Visual Flight Rules (VFR).

EFFECTIVE DATE: 0901 UTC December 31, 1998. *Comment date:* Comments for inclusion in the Rules Docket must be received on or before October 21, 1998.

ADDRESSES: Send comments on the direct final rule in triplicate to: Federal Aviation Administration, Attn: Manager, Airspace Branch, AWP–520, Docket No. 98–AWP–21, Air Traffic Division, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009.

The official docket may be examined in the Office of the Assistant Chief Counsel, Western-Pacific Region, Federal Aviation Administration, Room 6007, 15000 Aviation Boulevard, Lawndale, California 90261.

An informal docket may also be examined during normal business hours at the Office of the Manager, Airspace Branch, Air Traffic Division at the above address.

FOR FURTHER INFORMATION CONTACT: Debra Trindle, Air Traffic Division, Airspace Specialist, AWP–520.10, Western-Pacific Region, Federal

Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6613.

SUPPLEMENTARY INFORMATION: This amendment to 14 CFR 71 revises the Class D airspace at San Diego-Gillespie Field, CA by lowering the ceiling of the Class D from 2,900 feet Mean Sea Level (MSL) to 2,400 feet MSL. On May 19, 1998, the FAA published a Notice of Proposed Rulemaking (NPRM) to modify the San Diego, CA, Class B airspace area. A comment on the NPRM was received indicating that the proposed modification to the San Diego Class B airspace would create a 300 foot corridor northeast of Gillespie Field. This corridor will result from lowering the floor of the San Diego Class B airspace area ''I'' from 3,800 feet MSL to 3,200 feet MSL. The above mentioned corridor would exist over the upper limit of the Gillespie Field Class D airspace area when aircraft are approaching or overflying Gillespie Field from the northeast. After careful analysis of the Gillespie Field Class D airspace area and the adjacent San Diego Class B airspace area, the FAA agrees with the comment and proposes lowering the Gillespie Field Class D airspace ceiling to create an 800 foot corridor, thereby increasing navigable airspace for aircraft operating under Visual Flight Rules (VFR). Class D airspace areas are published in Paragraph 5000 of FAA Order 7400.9F dated September 10, 1998, and effective September 16, 1998, which is incorporated by reference in 14 CFR 71.1. The Class D airspace designation listed in this document will be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and therefore is issuing it as a direct final rule. This action revises controlled airspace associated with San Diego-Gillespie Field, CA. The intended effect of this action is to remove controlled airspace where no longer required and to increase navigable airspace for aircraft operating VFR. Unless a written adverse or negative comment or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

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

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 98–AWP–21.'' The postcard will be date stamped and returned to the commenter.

Agency Findings

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.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this 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 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—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; ROUTES; AND REPORTING POINTS.

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

Paragraph 5000 Class D Airspace

* * * * *

AWP CA D San Diego-Gillespie Field, CA [Revised]

San Diego-Gillespie Field, CA
(Lat. 32°49′34″N, long. 116°58′21″W)

That airspace extending upward from the surface to and including 2,400 feet MSL within a 4.3 mile radius of San Diego-Gillespie Field, excluding that airspace within the San Diego, CA, Class B airspace area and the Miramar NAS, CA, Class E airspace area. This Class D airspace area is effective during the dates and times established in advance by a Notice to

Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in Los Angeles, California, on September 11, 1998.

Leonard A. Mobley,

Acting Manager, Air Traffic Division Western-Pacific Region.

[FR Doc. 98–25208 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–ASW–23]

Modification to the Gulf of Mexico Low Offshore Airspace Area

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Gulf of Mexico Low Offshore Airspace Area. Specifically, this action modifies the Gulf of Mexico Low Offshore Airspace Area by extending the boundaries further south and southwest of the current location to the Houston Air Route Traffic Control Center (ARTCC) Flight Information Region/Control Area (FIR/CTA). The FAA is taking this action to provide additional airspace in which domestic air traffic control procedures may be used to separate and manage aircraft operations. This change will enhance the efficient utilization of that airspace.

EFFECTIVE DATE: 0901 UTC, October 8, 1998.

FOR FURTHER INFORMATION CONTACT: Ms. Sheri Edgett Baron, Airspace and Rules Division, ATA–400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Background

On March 2, 1993, the FAA published a final rule (58 FR 12128) which, in part, redesignated certain control areas over international waters as offshore airspace areas. The redesignations were necessary to comply with the Airspace Reclassification final rule issued on December 17, 1991 (56 FR 65638).

One of the areas affected by the March 2, 1993, final rule was the Gulf of Mexico Control Area. This area was divided vertically into two areas, one of which was redesignated as the Gulf of Mexico Low Offshore Airspace Area.

In June 1996 the FAA completed an evaluation of the airspace over the Gulf of Mexico. The evaluation was a combined effort with representatives from the FAA, Servicios a la Navegacion en El Espacio Aereo Mexicano, and other airspace users. The objective of the evaluation was, in part, to identify areas where air traffic services, air traffic operations, and utilization of airspace could be improved. One conclusion of this evaluation was the determination that system capacity would be enhanced by modifying air traffic control (ATC) procedures used to control aircraft operations in the airspace over the Gulf of Mexico.

Currently, International Civil Aviation Organization (ICAO) oceanic ATC procedures are used to separate and manage aircraft operations that extend beyond the lateral boundary of the existing Gulf of Mexico Low Offshore Airspace Area. Modifying the Gulf of Mexico Low Offshore Airspace Area by extending the boundaries further south and southwest of the current location to the Houston ARTCC FIR/CTA, allows the application of domestic ATC separation procedures over a larger area. This action to modify the offshore airspace area will enhance system capacity and allow for more efficient utilization of that airspace.

On August 5, 1998, the FAA proposed to amend 14 CFR part 71 to modify the Gulf of Mexico Low Offshore airspace area (63 FR 41752). Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments were received. Except for editorial changes, this amendment is the same as that proposed in the notice.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) modifies the Gulf of Mexico Low Offshore Airspace Area by extending the present airspace boundaries further south and southwest of the current location to the Houston ARTCC FIR/CTA. This modification will allow the application of domestic ATC separation procedures, in lieu of ICAO separation procedures, which will enhance system capacity and allow for more efficient utilization of that airspace.

This modification to the Gulf of Mexico Low Offshore Airspace Area will be effective on October 8, 1998. In order to avoid pilot confusion and to make pilots immediately aware of the modification to the Gulf of Mexico Low Offshore Airspace Area, the FAA finds that good cause exists, pursuant to 5 U.S.C. (d), for making this amendment effective in less than 30 days.

Offshore airspace area designations are published in paragraph 6007 of FAA Order 7400.9F, dated September 10, 1998, and effective September 16, 1998, which is incorporated by reference in 14 CFR 71.1. The offshore airspace area designation listed in this document will 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 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 rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

ICAO Considerations

As part of this proposal relates to navigable airspace outside the United States, this notice is submitted in accordance with the ICAO International Standards and Recommended Practices.

The application of International Standards and Recommended Practices by the FAA, Office of Air Traffic Airspace Management, in areas outside U.S. domestic airspace is governed by the Convention on International Civil Aviation. Specifically, the FAA is governed by Article 12 and Annex 11, which pertain to the establishment of necessary air navigational facilities and services to promote the safe, orderly, and expeditious flow of civil air traffic. The purpose of the document is to ensure that civil aircraft operations on international air routes are performed under uniform conditions.

The International Standards and Recommended Practices in Annex 11 apply to airspace under the jurisdiction of a contracting state, derived from ICAO. Annex 11 provisions apply when air traffic services are provided and a contracting state accepts the responsibility of providing air traffic services over high seas or in airspace of undetermined sovereignty. A contracting state accepting this responsibility may apply the International Standards and Recommended Practices that are

consistent with standards and practices utilized in its domestic jurisdiction.

In accordance with Article 3 of the Convention, state owned aircraft are exempt from the Standards and Recommended Practices of Annex 11. The United States is a contracting state to the Convention. Article 3(d) of the Convention provides that participating state aircraft will be operated in international airspace with due regard for the safety of civil aircraft.

Since this action involves, in part, the designation of navigable airspace outside the United States, the Administrator is consulting with the Secretary of State and the Secretary of Defense in accordance with the provisions of Executive Order 10854.

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— DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

Paragraph 6007 Offshore Airspace Areas

* * * * *

Gulf of Mexico Low [Revised]

That airspace extending upward from 1,200 feet MSL bounded on the west, north, and east by a line 12 miles offshore and parallel to the Texas, Louisiana, Mississippi, Alabama, and Florida shorelines; bounded on the south from east to west by the southern boundary of the Jacksonville Air Route Traffic Control Center, Miami Oceanic CTA/FIR; Merida UTA/UIR, Houston CTA/FIR; Monterrey UTA/UIR, Houston CTA/FIR; to the point of beginning.

* * * * *

Issued in Washington, DC, on September 15, 1998.

Reginald C. Matthews,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 98–25209 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8782]

RIN 1545–AV90

Source Rules for Foreign Sales Corporation Transfer Pricing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance to taxpayers who have made an election to be treated as a foreign sales corporation (FSC). The regulations clarify that the special source rule under section 927(e)(1) applies only to income of related suppliers from sales of export property giving rise to foreign trading gross receipts of a FSC.

DATES: *Effective date.* These regulations are effective March 3, 1998.

Applicability date. These regulations apply to taxable years beginning after December 31, 1997.

FOR FURTHER INFORMATION CONTACT: Elizabeth Beck (202) 622–3880 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under section 927 which was added by the Deficit Reduction Act of 1984, applicable for taxable years of foreign sales corporations beginning after December 31, 1984. Temporary regulations (TD 8126) were published in the **Federal Register** (52 FR 6468) on March 3, 1987. These temporary regulations were amended by temporary regulations published in the **Federal Register** (63 FR 10305) as a Treasury decision (TD 8764) on March 3, 1998. On the same date, a notice of proposed rulemaking cross-referencing TD 8764 was published in the **Federal Register** (63 FR 10351). The proposed rule proposed changes to the grouping and source rules for foreign sales corporation transfer pricing. Comments responding to this notice were received. On June 24, 1998, a public hearing was held limited to the proposed changes to the grouping rules, since no hearing was requested with respect to the source rule. After consideration of all comments received, the proposed regulations regarding the source rule are adopted as revised by this Treasury decision.

Explanation of Provisions

A. Current Temporary Regulations

Section 927(e)(1) provides that ''under regulations, the income of a person described in section 482 from a transaction giving rise to foreign trading gross receipts of a FSC which is treated as from sources outside the United States shall not exceed the amount which would be treated as foreign source income earned by such person if the pricing rule under section 994 which corresponds to the rule used under section 925 with respect to such transaction applied to such transaction.'' Transactions giving rise to foreign trading gross receipts include qualifying sales, leases, licenses and services. Because TD 8126 could be interpreted to apply the special foreign source limit only to sales of export property, § 1.927(e)–1T was amended by TD 8764 to clarify that the regulation applies to any transaction giving rise to foreign trading gross receipts of a FSC, including but not limited to sales, leases, licenses and services. TD 8764 also made conforming changes, added special rules and gave examples regarding the special source rule.

B. Discussion of Comments

No comments were received on the special rules added in proposed § 1.927(e)–1(a)(3)(ii). These rules clarify how the corresponding DISC transfer pricing rules are to be applied for purposes of the foreign source limit and are generally taxpayer favorable. No comments were received on Examples (1) and (3) set forth in proposed § 1.927(e)–1(b). These examples illustrate how the limit is applied under different transfer pricing methods for sales transactions.

Comments received did suggest that the rule distinguish between the foreign source income limitation applicable to sales and the limitation applicable to other transactions giving rise to foreign trading gross receipts. In light of these comments, Treasury and the IRS believe that additional consideration should be given to the appropriate scope of the special source rule of section 927(e)(1) and that the expanded special source rule should be withdrawn. Accordingly, the final regulation applies the special source rule only to sales of export

property. Example (2) of the proposed regulation, which addressed a licensing transaction, has been removed.

Special Analyses

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

Drafting Information

The principal author of these regulations is Elizabeth Beck of the Office of the Associate Chief Counsel (International). Other personnel from the IRS and Treasury Department also participated in the development of these regulations.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by removing the entry for § 1.927(e)–1T and adding an entry in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * * Section 1.927(e)–1 also issued under 26 U.S.C. 927(e)(1). * * *

§ 1.927(e)–1T [Removed]

Par. 2. Section 1.927(e)–1T is removed.

Par. 3. Section 1.927(e)–1 is added to read as follows:

§ 1.927(e)–1 Special sourcing rule.

(a) *Source rules for related persons*—(1) *In general.* The income of a person described in section 482 from a sale of export property giving rise to foreign trading gross receipts of a FSC that is treated as from sources outside the United States shall not exceed the amount that would be treated as foreign source income earned by such person if the pricing rule under section 994 that corresponds to the rule used under section 925 with respect to such transaction applied to such transaction. This special sourcing rule also applies if the FSC is acting as a commission agent for the related supplier with respect to the transaction described in the first sentence of this paragraph (a)(1) that gives rise to foreign trading gross receipts and the transfer pricing rules of section 925 are used to determine the commission payable to the FSC. No limitation results under this section with respect to a transaction to which the section 482 pricing rule under section 925(a)(3) applies.

(2) *Grouping of transactions.* If, for purposes of determining the FSC's profits under the administrative pricing rules of sections 925(a) (1) and (2), grouping of transactions under § 1.925(a)–1T(c)(8) was elected, the same grouping shall be used for making the determinations under the special sourcing rule in this section.

(3) *Corresponding DISC pricing rules*—(i) *In general.* For purposes of this section—

(A) The DISC gross receipts pricing rule of section 994(a)(1) corresponds to the gross receipts pricing rule of section 925(a)(1);

(B) The DISC combined taxable income pricing rule of section 994(a)(2) corresponds to the combined taxable income pricing rule of section 925(a)(2); and

(C) The DISC section 482 pricing rule of section 994(a)(3) corresponds to the section 482 pricing rule of section 925(a)(3).

(ii) *Special rules.* For purposes of this section—

(A) The DISC pricing rules of section 994(a)(1) and (2) shall be determined without regard to export promotion expenses;

(B) Qualified export receipts under section 994(a)(1) and

(2) shall be deemed to be an amount equal to the foreign trading gross receipts arising from the transaction; and

(C) Combined taxable income for purposes of section 994(a)(2) shall be deemed to be an amount equal to the combined taxable income for purposes of section 925(a)(2) arising from the transaction.

(b) *Examples.* The provisions of this section may be illustrated by the following examples:

Example 1. (i) R and F are calendar year taxpayers. R, a domestic manufacturing company, owns all the stock of F, which is a FSC acting as a commission agent for R. For the taxable year, R and F used the combined taxable income pricing rule of section 925(a)(2). For the taxable year, the combined taxable income of R and F is $100 from the sale of export property, as defined in section 927(a), manufactured by R using production assets located in the United States. Title to the export property passed outside of the United States.

(ii) Under section 925(a)(2), 23 percent of the $100 combined taxable income of R and F ($23) is allocated to F and the remaining $77 is allocated to R. Absent the special sourcing rule, under section 863(b) the $77 income allocated to R would be sourced $38.50 U.S. source and $38.50 foreign source. Under the special sourcing rule, the amount of foreign source income earned by a related supplier of a FSC shall not exceed the amount that would result if the corresponding DISC pricing rule applied. The DISC combined taxable income pricing rule of section 994(a)(2) corresponds to the combined taxable income pricing rule of section 925(a)(2). Under section 994(a)(2), $50 of the combined taxable income ($100 x .50) would be allocated to the DISC and the remaining $50 would be allocated to the related supplier. Under section 863(b), the $50 income allocated to the DISC's related supplier would be sourced $25 U.S. source and $25 foreign source. Accordingly, under the special sourcing rule, the foreign source income of R shall not exceed $25.

Example 2. (i) Assume the same facts as in *Example 1* except that R and F used the gross receipts pricing rule of section 925(a)(1). In addition, for the taxable year foreign trading gross receipts derived from the sale of the export property are $2,000.

(ii) Under section 925(a)(1), 1.83 percent of the $2,000 foreign trading gross receipts ($36.60) is allocated to F and the $63.40 remaining combined taxable income ($100 − $36.60) is allocated to R. Absent the special sourcing rule, under section 863(b) the $63.40 income allocated to R would be sourced $31.70 U.S. source and $31.70 foreign source. Under the special sourcing rule, the amount of foreign source income earned by a related supplier of a FSC shall not exceed the amount that would result if the corresponding DISC pricing rule applied. The DISC gross receipts pricing rule of section 994(a)(1) corresponds to the gross receipts pricing rule of section 925(a)(1). Under section 994(a)(1), $80 ($2,000 × .04) would be allocated to the DISC and the $20 remaining combined taxable income would be allocated to the related supplier. Under section 863(b), the $20 income allocated to the DISC's related supplier would be sourced $10 U.S. source and $10 foreign source. Accordingly, under the special sourcing rule, the foreign source income of R shall not exceed $10.

(c) *Effective date.* The rules of this section are applicable to taxable years beginning after December 31, 1997.

Michael P. Dolan,

Deputy Commissioner of Internal Revenue.

Approved: August 18, 1998.

Donald C. Lubick,

Assistant Secretary of the Treasury.

[FR Doc. 98–25045 Filed 9–17–98; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF JUSTICE

28 CFR Part 92

RIN 1105–AA58

FY 1998 Police Recruitment Program

AGENCY: Office of Community Oriented Policing Services, U.S. Department of Justice.

ACTION: Interim rule with requests for comments.

SUMMARY: This rule establishes a framework for the Police Recruitment Project, authorized by the Police Recruitment Act, Subtitle H of the Violent Crime Control and Law Enforcement Act of 1994. For Fiscal Year 1998, Congress has appropriated $1 million for the funding of pilot projects under the Police Recruitment Program. This regulation is being published under the statutory grant of authority of the Police Recruitment Act to issue guidelines governing the content and results of programs receiving grants under the Police Recruitment Program.

DATES: This interim rule is effective on September 21, 1998. All comments must be received by close of business (5:30 p.m. EST) on October 21, 1998.

ADDRESSES: All comments should be addressed to Rob Chapman, Program Coordinator, Office of Community Oriented Policing Services, U.S. Department of Justice, 1100 Vermont Avenue, N.W., Washington, D.C. 20530.

FOR FURTHER INFORMATION CONTACT: The Department of Justice Response Center at 1–800–421–6770 or (202) 307–1480, or Rob Chapman, Community Oriented Policing Services, at (202) 633–1295.

SUPPLEMENTARY INFORMATION: The purpose of this rule is to provide guidance to the non-profit community groups interested in applying to participate in the Police Recruitment Program. The rule addresses program purposes and goals, and project and eligibility requirements. The rule is not intended to be a comprehensive compilation of the administrative requirements of the Police Recruitment Program. Other program requirements and procedures will be formulated by the participating community organizations and police departments in light of their circumstances and needs.

The rule amends 28 CFR Part 92 by designating existing section 92.1 through 92.6 as Subpart A to read as follows: ''Police Corps Eligibility and Selection Criteria.'' The rule further amends 28 CFR Part 92 by adding Subpart B to read as follows: ''Police Recruitment Program Guidelines.''

Overview

The Office of Community Oriented Policing Services administers the Police Recruitment Program, U.S. Department of Justice. This program is designed to develop pilot projects to meet the ongoing need for additional improvement in recruiting, selecting and retaining police officer applicants. The Police Recruitment program will make grants to a limited number of qualified community organizations to assist in meeting the cost of qualified programs designed to recruit and retain applicants to police departments.

To do this, applicants under this program are expected to utilize innovative and effective methods in meeting the program guidelines. Successful applicants will be funded for a total of up to $500,000 for a one-year grant period only, though two additional years of no-cost extensions will be permitted.

The successful applicants funded under the Police Recruitment program will ultimately design programs to enhance opportunities and increase inroads for individuals within their local police agencies. These advances will be accomplished through a variety of methods, including, but not limited to, targeted recruitment efforts; tutorial programs to enable individuals to meet police force academic requirements and pass entrance examinations; counseling for those applicants who may encounter problems throughout the application process; and programs to aid in the retention of these applicants throughout the application and hiring process.

Request for Comment: The COPS Office seeks comments on any aspect of this rule.

Administrative Requirements

Administrative Procedure Act 5 U.S.C. 553

The rule is implemented as an Interim Rule based on the good cause exceptions of the Administrative Procedure Act found at 5 U.S.C. 553, with provision of post-promulgation public comments. The COPS Office will address any comments received in a final rule. Immediate implementation is necessary to expedite the availability of funds to qualified community organizations to provide recruiting and retention services through qualified programs to police department candidates. The immediate implementation of the rules serves the public benefit of ensuring that funds flow as quickly as possible to support the costs of programs involving tutorial, counseling, and retention services for such individuals. The length of the comment period has been limited to thirty days in order to provide qualified non-profit community groups timely access to the available program funds. It would be contrary to the public interest to delay implementation of the program.

Regulatory Flexibility Act

The Director of the Office of Community Oriented Policing Services, in accordance with the Regulatory Flexibility Act, codified at 5 U.S.C. 605(b), has reviewed this regulation and, by approving it, certifies that this regulation will not have a significant economic impact on a substantial number of small entities. This Interim Rule builds upon the statutory outline of a program providing federal grant assistance to programs sponsored by non-profit organizations providing recruiting and retention services to police department applicants. The award of such grants imposes no significant economic impacts on substantial numbers of small businesses or other entities.

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, section 1(b), Principles of Regulation. The Office of Community Oriented Policing Services has determined that this Interim Rule is not a significant regulatory action under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget.

Executive Order 12612

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

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

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

Paperwork Reduction Act

The interim rule is not subject to the Paperwork Reduction Act requirements because the information collected as part of the grant application process will be collected from fewer than ten respondents.

List of Subjects in 28 CFR Part 92

Law enforcement officers, Scholarships and fellowships.

Accordingly, chapter I of title 28 of the Code of Federal Regulations is amended as follows:

PART 92 HEADING [REVISED]

PART 92—OFFICE OF COMMUNITY ORIENTED POLICING SERVICES (COPS)

1. The heading for part 92 is revised as set forth above.

2. The authority citation for part 92 is revised to read as follows:

Authority: 42 U.S.C. 13811–13812; 42 U.S.C. 14091–14102.

3. Existing sections 92.1 through 92.6 are designated as Subpart A and a new subpart heading is added to read as follows:

Supart A—Police Corps Eligibility and Selection Criteria

4. Part 92 is amended by adding a new Subpart B to read as follows:

Subpart B—Police Recruitment Program Guidelines

Sec.

Subpart B—Police Recruitment Program Guidelines

§ 92.7 Scope.

(a) The Police Recruitment program offers funds to qualified community organizations to assist in meeting the costs of programs which are designed to recruit and train police applicants from a variety of neighborhoods and localities.

(b) Individual participants encountering problems throughout the police department application process shall receive counseling, tutorials, and other academic assistance as necessary to assist them in the application process of a police department.

(c) Program goals should include increasing the retention in the hiring process for police applicants participating in the program.

(d) Programs funded under the Police Recruitment program will have a one-year grant period, with allowances for two additional years of no-cost extensions.

§ 92.8 Providing recruitment services.

The non-profit community organizations that wish to receive a grant under this program should provide for an overall program design with the objective of recruiting and retaining applicants from a variety of populations to a police department. The recruitment strategies employed may include:

(a) A process for recruiting applicants for employment by a police department. These processes should include working in cooperation with a local law enforcement department to develop selection criteria for the participants. The selection criteria may include, but are not limited to:

(1) Demonstrated interest in policing as a career;

(2) Scholastic record (except that failure to meet the satisfactory academic scores shall not disqualify the applicant since the program is designed to provide tutorial service so to help applicant pass the required examinations);

(3) Background screening;

(4) Work experience;

(5) Letters of recommendation.

(b) The recruitment services must ensure that applicants possess the necessary mental and physical capabilities and emotional characteristics to be an effective law enforcement officer.

§ 92.9 Publicizing the Police Recruitment Program.

Participating organizations should have experience in or an ability to develop procedures to publicize the availability of like programs. These programs should be widely publicized throughout the affected geographic area. The methods for publicizing the Police Recruitment programs may include, but are not limited to:

(a) Sending press releases to community bulletins, college and local newspapers, and television stations, as well as public service announcements to local and college radio stations;

(b) Sending information to and/or making presentations at:

(1) Local community colleges;

(2) Colleges and universities serving populations in the geographic area of the program;

(3) Local nonprofit groups;

(4) Academic counseling departments within public and private nonprofit colleges and universities;

(5) Academic counseling departments within public and private nonprofit high schools;

(6) High school and college student associations;

(7) Local religious groups;

(8) Local social services agencies.

(c) Disseminating press releases and/or translated materials to non-English language newspapers and magazines; and

(d) Maintaining toll-free or other easy-access telephone numbers for obtaining application materials.

§ 92.10 Providing tutorials and other academic assistance programs.

(a) The program designed by the community organization must include academic counseling, tutorials and other academic assistance programs to enable individuals to meet police force academic requirements, pass entrance examinations, and meet other requirements. The program should include:

(1) Processes for evaluating educational assistance needs of young adults and adults. These processes should include, but are not limited to: screening procedures and testing batteries to assess individual needs;

(2) Tutorial programs designed to meet the specific and varied academic needs of individual applicants; and

(3) Academic and guidance counseling for adults. Specific counseling programs must be designed for individuals who encounter problems with passing the entrance examinations, and may include specialized counseling in self discipline, study habits, taking written and oral exams, and physical fitness.

(b) These tutorial and academic assistance programs must be provided by individuals or groups that have experience in developing and providing

tutorial programs for young adults and adults.

(c) The program provider must also have experience in providing counseling for participants who encounter other problems with the police department application process.

§ 92.11 Content of the recruitment and retention programs.

Applicants must describe in detail the intended program strategies for providing academic and guidance counseling activities for members of the community, as described in §§ 92.2 through 92.4. A review of mandatory topics to be addressed in a detailed concept paper/application to be provided by all applicants follows.

(a) Applicants must address program strategies for responding to program and applicant needs throughout the recruitment process. The process should be based on an examination and understanding of the needs of the population in meeting the qualification requirements of the police department. The project strategy should subsequently be tailored based on the understanding of the current and anticipated problems in meeting police department requirements.

(b) Applicants must describe the manner in which academic services and tutorials, and guidance counseling programs that would assist applicants to pass the entrance examination and related tests will be provided. This should also include the anticipated length of the academic and guidance counseling programs, qualifications of the counselors, and the content of the counseling programs.

(c) Applicants must provide retention services to assist in keeping individuals in the application process of a police department. These may include:

(1) Counseling programs aimed at meeting the needs of potential police applicants before they are eligible to apply for a sworn position;

(2) Pre-police employment programs, such as junior police cadet programs, reserve programs, and police volunteer activities and

(3) Mentoring activities utilizing sworn officers.

(d) Applicants must estimate the number of police applicants to be served by the prospective program, along with an estimation of the total number of potential or actual applicants who will be successfully hired and eventually deployed as police officers.

§ 92.12 Program funding length.

Funding for these programs will be for one year only, but will allow for two additional years of no-cost extension.

§ 92.13 Program eligibility.

(a) Eligible organizations for the Police Recruitment program grant are certified nonprofit organizations that have training and/or experience in:

(1) Working with a police department and with teachers, counselors, and similar personnel;

(2) Providing services to the community in which the organization is located;

(3) Developing and managing services and techniques to recruit and train individuals, and in assisting such individuals in meeting requisite standards and provisions;

(4) Developing and managing services and techniques to assist in the retention of applicants to like programs; and

(5) Developing other programs that contribute to the community.

(b) A program is qualified to receive a grant if:

(1) The overall design of the program is to recruit and retain applicants to a police department;

(2) The program provides recruiting services that include tutorial programs to enable individuals to meet police force academic requirements and to pass entrance examinations;

(3) The program provides counseling to applicants to police departments who may encounter problems throughout the application process; and

(4) The program provides retention services to assist in retaining individuals to stay in the application process of the police department.

(c) To qualify for funding under the Police Recruitment program, the intended activities must support the recruitment services, tutorial and other academic assistance programs, and retention services for individuals. The qualified non-profit organization must submit an application which identifies the law enforcement department with which it will work and includes documentation showing:

(1) The need for the grant;

(2) The intended use of the funds;

(3) Expected results from the use of grant funds;

(4) Demographic characteristics of the population to be served, including age, disability, race, ethnicity, and languages used;

(5) Status as a non-profit organization; and

(6) Contains satisfactory assurances that the program for which the grant is made will meet the applicable requirements of the program guidelines prescribed in this document.

Dated: September 2, 1998.

Joseph E. Brann,

Director.

[FR Doc. 98–25143 Filed 9–18–98; 8:45 am]

BILLING CODE 4410–AT–M

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Part 103

RIN 1506–AA12

Amendment to the Bank Secrecy Act Regulations—Exemptions from the Requirement To Report Transactions in Currency—Phase II

AGENCY: Financial Crimes Enforcement Network, Treasury.

ACTION: Final rule.

SUMMARY: This document contains a final rule that further reforms and simplifies the process by which depository institutions may exempt transactions of retail and other businesses from the requirement to report transactions in currency in excess of $10,000, and restates generally, to reflect such changes, the text of the Bank Secrecy Act regulation requiring the reporting by financial institutions of transactions in currency. The final rule, as issued by the Financial Crimes Enforcement Network (''FinCEN''), constitutes a further step in achieving the reduction set by the Money Laundering Suppression Act of 1994 in the number of currency transaction reports required to be filed annually by depository institutions, as part of a continuing program to reduce unnecessary burdens imposed upon financial institutions by the Bank Secrecy Act and increase the cost-effectiveness of the counter-money laundering policies of the Department of the Treasury.

DATES: Effective date. October 21, 1998.

Applicability date. See § 103.22(d)(11) of the final rule contained in this document.

FOR FURTHER INFORMATION CONTACT: Peter Djinis, Associate Director, FinCEN, (703) 905–3930; Charles Klingman, Financial Institutions Policy Specialist, FinCEN, (703) 905–3602; Stephen R. Kroll, Chief Counsel, Cynthia L. Clark, Deputy Chief Counsel, and Albert R. Zarate, Attorney-Advisor, Office of Chief Counsel, FinCEN, (703) 905–3590.

SUPPLEMENTARY INFORMATION:

I. Statutory Provisions

The Bank Secrecy Act, Titles I and II of Pub. L. 91–508, as amended, codified at 12 U.S.C. 1829b, 12 U.S.C. 1951–1959, and 31 U.S.C. 5311–5330, authorizes the Secretary of the Treasury, *inter alia*, to issue regulations requiring financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, and regulatory matters, and to implement counter-money laundering programs and compliance procedures. Regulations implementing Title II of the Bank Secrecy Act (codified at 31 U.S.C. 5311–5330) appear at 31 CFR Part 103. The authority of the Secretary to administer Title II of the Bank Secrecy Act has been delegated to the Director of FinCEN.

The reporting by financial institutions of transactions in currency in excess of $10,000 has long been a major component of the Department of the Treasury's implementation of the Bank Secrecy Act. The reporting requirement is imposed by 31 CFR 103.22, a rule issued under the broad authority granted to the Secretary of the Treasury by 31 U.S.C. 5313(a) to require reports of domestic coin and currency transactions.

Four new provisions (31 U.S.C. 5313(d) through (g)) concerning exemptions from the currency transaction reporting requirement were added to 31 U.S.C. 5313 by the Money Laundering Suppression Act of 1994 (the ''Money Laundering Suppression Act''), Title IV of the Riegle Community Development and Regulatory Improvement Act of 1994, Pub. L. 103–325 (September 23, 1994). 31 U.S.C. 5313(d) provides that the Secretary of the Treasury shall exempt a depository institution from the requirement to report currency transactions with respect to transactions between the depository institution and four categories of entities. The requirements of that subsection are at present reflected in the terms of 31 CFR 103.22(h) (which is amended and redesignated as 31 CFR 103.22(d) by the final rule published in this document).

31 U.S.C. 5313(e) authorizes the Secretary of the Treasury to exempt a depository institution from the requirement to report transactions in currency between a depository institution and a qualified business customer of the institution. Subsection (e)(2) defines a ''qualified business customer'' as a business that

(A) maintains a transaction account (as defined in section 19(b)(1)(C) of the Act) at the depository institution;

(B) frequently engages in transactions with the depository institution which are subject to the reporting requirements of subsection (a); and

(C) meets criteria which the Secretary determines are sufficient to ensure that the purposes of this subchapter are carried out without requiring a report with respect to such transactions.

Subsection (e)(3) provides that the Secretary of the Treasury shall establish, by regulation, the criteria for granting and maintaining an exemption under subsection (e)(1).

Subsection (e)(4)(A) provides that the Secretary of the Treasury shall establish guidelines for depository institutions to follow in selecting customers for an exemption under subsection (e). Under subsection (e)(4)(B), those guidelines may include a description of the type of businesses for which no exemption will be granted under this subsection.

Subsection (e)(5) provides that the Secretary of the Treasury shall prescribe regulations requiring each depository institution to

(A) review, at least once each year, the qualified business customers of such institution with respect to whom an exemption has been granted under this subsection; and

(B) upon the completion of such review, resubmit information about such customers, with such modifications as the institution determines to be appropriate, to the Secretary for the Secretary's approval.

Subsection (e)(6) states that during the two-year period beginning on the date of enactment of the Money Laundering Suppression Act, the discretionary exemption rules shall be applied by the Secretary of the Treasury on the basis of such criteria as the Secretary determines to be appropriate to achieve an orderly implementation of the requirements of this subsection.

Subsection (f) places limits on the liability of a depository institution in connection with a transaction that has been exempted from reporting under either 31 U.S.C. 5313 (d) or (e) and provides for the coordination of any exemption with other Bank Secrecy Act provisions, especially those relating to the reporting of suspicious transactions. Finally, subsection (g) defines ''depository institution'' for purposes of the new exemption provisions.

Section 402(b) of the Money Laundering Suppression Act states simply that in administering the new statutory exemption provisions:

The Secretary of the Treasury shall seek to reduce, within a reasonable period of time, the number of reports required to be filed in the aggregate by depository institutions pursuant to section 5313(a) of title 31 * * * by at least 30 percent of the number filed during the year preceding [September 23, 1994,] the date of enactment of [the Money Laundering Suppression Act].

The enactment of 31 U.S.C. 5313 (d) through (g) reflects a Congressional intention to ''reform * * * the procedures for exempting transactions between depository institutions and their customers.'' *See* H.R. Rep. 103–652, 103d Cong., 2d Sess. 186 (August 2, 1994). The administrative exemption procedures at which the statutory changes are directed are found in 31 CFR 103.22(b)(2) and (c) through (f); those procedures have not succeeded in eliminating the reporting of routine currency transactions by businesses.

Several reasons have been given for this lack of success. These include the retention by banks of liability for making incorrect exemption determinations, and the complexity of the administrative exemption procedures (which require banks, for example, to assign dollar limits to each exemption based on the amounts of currency projected to be needed for the customary conduct of the exempt customer's lawful business, and which increase the risk of liability to banks that grant exemptions). Finally, advances in technology have made it less costly for some banks simply to report all currency transactions rather than to incur the administrative costs (and risks) of exempting customers and then administering the terms of particular exemptions properly.

The problems created by the prior administrative exemption system also include that system's failure to provide the Treasury with information needed for thoughtful administration of the Bank Secrecy Act. Although banks are required to maintain a centralized list of exempt customers and to make that list available upon request, *see* 31 CFR 103.22(f) and (g), there is no way short of a bank-by-bank request for lists (with the time and cost such a request would entail both for banks and government) for Treasury to learn the extent to which routine transactions are effectively screened out of the system or (for that matter) the extent to which exemptions have been granted in situations in which they are not justified.

In crafting the 1994 statutory provisions relating to mandatory and discretionary exemptions, Congress sought to alter the burden of liability and uncertainty that the administrative exemption system created. The statutory provisions embraced several categories of transactions that were either already partially exempt or plainly eligible for

exemption under the prior administrative exemption system.[1]

II. Phase I—Final Rule

On September 8, 1997, a final rule revising paragraph (h) of 31 CFR 103.22 was published in the **Federal Register**. *See* 62 FR 47141. The final rule modified (and as modified, superseded) an interim rule on exemptions (collectively, ''Phase I'') that FinCEN published with request for comments in April 1996. *See* 61 FR 18204. The Phase I final rule exempted from the requirement to report transactions in currency in excess of $10,000, transactions between banks[2] and (i) other banks operating in the United States; (ii) government departments and agencies, and entities that otherwise exercise governmental authority; (iii) entities listed on certain national stock exchanges; and (iv) certain subsidiaries of those listed entities.

As FinCEN explained when the Phase I interim rule was published, the transactions in currency of bank customers in those categories were either required to be exempt from reporting by statute, were already effectively exempt from reporting under the terms of 31 CFR Part 103, or, in the case of listed entities and certain of their subsidiaries, involved enterprises whose routine currency transaction reports are of little or no value to law enforcement officials. Recognition of exemption under the Phase I interim and final rules required simply the filing of a single document identifying the exempt person and the depository institution that exempts it. Transactions in currency, like other transactions, remained subject to the requirement that banks report suspicious transactions.

III. Phase II—Notice of Proposed Rulemaking

On the same day the Phase I final rule was published in the **Federal Register**, FinCEN published a notice of proposed rulemaking (the ''Notice'') to further reform and simplify the process by which banks may exempt, from the requirement to report transactions in currency in excess of $10,000, transactions involving certain of their customers. *See* 62 FR 47156. As FinCEN stated in the Notice, the objective of the second stage reform (''Phase II'') was to provide, to the extent possible, a blanket relief, similar to that contained in Phase I, for those categories of business enterprise that could not easily be described in a single phrase and that were not subject to the sorts of regulatory and marketplace oversight that shape the environment of publicly-held companies. To accomplish that goal, while still providing federal authorities with the tools to monitor and prevent abuse, FinCEN proposed a pared-down exemption system.

In the Notice, FinCEN specifically proposed the following changes: (i) The addition of two new classes of exempt persons, non-listed businesses and payroll customers; (ii) the addition of special requirements governing the exemption of non-listed businesses and payroll customers, namely, an initial projection of such exempt person's annual currency needs and an annual filing listing the aggregate currency deposits and withdrawals of such exempt person during the preceding year; (iii) the addition of five new operating rules governing the exemption of non-listed businesses and payroll customers; (iv) the deletion of paragraphs (b) through (g) of present section 103.22 (the ''prior'' administrative exemption system); (v) the redesignation of paragraph (h) (reflecting the terms of the Phase I final rule) of section 103.22 as paragraph (d) of that section; and (vi) the addition of certain conforming changes to the redesignated paragraph (d).

On November 28, 1997, FinCEN published a notice (the ''November Extension'') in the **Federal Register** extending the comment period for the Notice and soliciting additional comments on certain matters relating to the Notice. *See* 62 FR 63298. The decision to extend the comment period and the request for additional comments resulted from discussions held at an open meeting to discuss the Notice on November 7, 1997.[3]

In the November Extension, FinCEN stated that, in light of the comments made at the open meeting, it did not believe additional comments concerning the proposed estimation and aggregate currency reporting provisions were necessary. FinCEN did, however, indicate that it was important that alternatives to those proposals be brought forward by interested parties, and it specifically sought comments on an alternative described in the November Extension. That alternative would have required a bank, when designating a non-listed business or a payroll customer as an exempt person, to (i) include on its initial designation form a statement of the manner in which it applies its ''know-your-customer'' standards to customers whose currency transactions it exempts from the currency transaction report requirements, and (ii) certify in an annual renewal of exempt status filing that during the preceding year there were no transactions involving any accounts of the person at the bank that would have required the filing of a suspicious activity report. FinCEN also sought comments on the impact of changing the word ''shall'' to ''may'' in proposed 103.22(d)(5)(v), to provide a bank with the option, but not the necessity, of exempting a customer on a bank-wide basis. Lastly, FinCEN repeated its request, made in the Notice, for comments relating to the treatment for exemption purposes of currency deposits that commingle funds derived from eligible business activities with funds derived from ineligible business activities.

IV. Summary of Comments and Revisions

A. Comments on the Notice—Overview

FinCEN received 70 written responses to the Notice. Of these, 51 were submitted by banks or bank holding companies, 8 by financial institution trade associations, 4 by credit unions, 2 by law firms, 2 by private individuals, and 1 by a compliance software designer.

Comments on the Notice focused primarily on the following proposed provisions: (i) The projection and annual aggregate currency reporting requirements (including possible alternatives); (ii) the twelve-month waiting period governing the designation of non-listed businesses and payroll customers as exempt persons; (iii) the operating rule making a sole proprietorship eligible for exemption only to the extent of its business (as opposed to personal) transactions; (iv) the operating rule making certain businesses ineligible for designation as exempt persons to the extent they engage in one or more listed ineligible business activities; and (v) the limitation on exemption with respect to

[1] As noted below, transactions in currency between domestic banks were already exempt from reporting, *see* 31 CFR 103.22(b)(1)(ii), and ''[d]eposits or withdrawals, exchanges of currency or other payments and transfers by local or state governments, or the United States or any of its agencies or instrumentalities'' were one of the categories of transactions specifically described as eligible for exemption by banks. *See* 31 CFR 103.22(b)(2)(iii).

[2] The Phase I interim and final rules, as well as the notice of proposed rulemaking to which the final rule contained in this document relates, used the term ''bank'' to define the class of financial institutions to which the rules respectively applied. As defined in 31 CFR 103.11(c), that term includes both commercial banks and other classes of depository institutions at which the language of 31 U.S.C. 5313 is directed. The final rule contained in this document continues to use the term ''bank,'' rather than depository institution.

[3] FinCEN announced the public meeting in the **Federal Register** on October 31, 1997. *See* 62 FR 58909.

transactions carried out by an exempt person as an agent for a third party. Regarding the latter three provisions, commenters expressed particular concern over the application of those provisions to situations where their customers commingle funds derived from personal transactions or ineligible business activities with eligible business activities.

After full and careful consideration of all of the comments, 31 CFR 103.22 is revised to read as stated in the final rule.

B. Final Rule

The format of the final rule is generally consistent with the Notice. The terms of the final rule, however, differ from the terms of the Notice in the following significant respects:

- Banks are not required to initially estimate and then report annually the aggregate currency deposits and withdrawals of any customer that is designated as a non-listed business or payroll customer;
- Banks are required to renew exemptions for non-listed business and payroll customers every two years rather than every year;
- Banks must maintain a system of monitoring the transactions in currency of each exempt customer for any and all reportable suspicious activity;
- As part of the required biennial renewal, banks must certify that they have complied with the requirement to maintain a system of monitoring for reportable suspicious activity;
- Banks may, but need not, treat all eligible accounts of a person at a single institution as exempt;
- Banks are not required to segregate funds derived from non-business activities when exempting a transaction in currency of a sole proprietorship; and
- Banks may treat a business that engages in multiple activities as a non-listed business so long as that business does not engage primarily in one or more of those activities described in paragraph (d)(6)(viii).

The changes adopted in the final rule are intended to improve, clarify, and refine the rule's provisions in light of the objectives for implementation of 31 U.S.C. 5313(d)–(g) that FinCEN outlined when the Phase I interim rule was published. Those objectives are reducing the burden of currency transaction reporting, requiring reporting only of information that is of value to law enforcement and regulatory authorities, and, perhaps most importantly, creating an exemption system that is cost-effective and that works. *See* 61 FR 18205.

Eliminating the administrative exemption system in section 103.22 requires the deletion of the bulk of that section, paragraphs (b)–(g). Because that is so, and because the structure and many of the rules of section 103.22(h) also apply to the proposed reformed exemption system for other customers, the final rule completely restates section 103.22 so that its terms may be presented clearly.

For convenience, the redistribution of the provisions of prior section 103.22 may be summarized as follows:

DISTRIBUTION TABLE

Prior 103.22	New 103.22
No provision	103.22(a).
103.22(a)(1):	
Sentences 1–2	Deleted in part; 103.22(b)(1).
Sentences 3–4	103.22(c)(2).
103.22(a)(2)(i)–(ii)	103.22(b)(2)(i)–(ii).
103.22(a)(2)(iii)	103.22(c)(3).
103.22(a)(3)	Deleted in part; 103.22(b)(1), 103.22(c)(2).
103.22(a)(4)	103.22(c)(1).
103.22(b)	Deleted, except 103.22(b)(1)(iii) and 103.22(b)(2)(iv).
103.22(b)(1)(iii)	103.22(d)(1).
103.22(b)(2)(iv)	103.22(d)(2)(vii).
103.22(c)	Deleted.
103.22(d)	Deleted.
103.22(e)	Deleted.
103.22(f)	Deleted.
103.22(g)	Deleted.
103.22(h)(1)[4]	Deleted in part; 103.22(d)(1).
103.22(h)(2)(i)–(iii)	103.22(d)(2)(i)–(iii).
103.22(h)(2)(iv), (vi)	103.22(d)(2)(iv).
103.22(h)(2)(v), (vi)	103.22(d)(2)(v).
No provision	103.22(d)(2)(vi).
No provision	103.22(d)(2)(vii).
103.22(h)(3)(i)–(ii)	103.22(d)(3)(i).
103.22(h)(3)(iii)	103.22(d)(3)(ii).
103.22(h)(3)(iv)	103.22(d)(3)(i).
No provision	103.22(d)(4).
No provision	103.22(d)(5)(i)–(ii).
103.22(h)(4)(i)–(iv)	103.22(d)(6)(i)–(iv).
103.22(h)(4)(v)	103.22(d)(6)(x).
No provision	103.22(d)(6)(v)–(ix).
103.22(h)(5)	103.22(d)(7).
103.22(h)(6)(i)	103.22(d)(8)(i).
103.22(h)(6)(ii)	103.22(d)(8)(ii).
103.22(h)(6)(iii)	103.22(d)(8)(iii).
103.22(h)(7)	103.22(d)(9)(i).
No provision	103.22(d)(9)(ii).
103.22(h)(8)	103.22(d)(10).
103.22(h)(9)	Deleted.

DISTRIBUTION TABLE—Continued

Prior 103.22	New 103.22
No provision	103.22(d)(11).

[4] All references to paragraph (h) of section 103.22 are to the final rule that was published in the FEDERAL REGISTER on September 8, 1997. *See* 62 FR 47141.

V. Section-by-Section Analysis

A. 103.22(a)—General

Paragraph (a) continues to describe generally the scope and organization of restated § 103.22. One commenter asked that FinCEN add language to this paragraph indicating that banks are not required to exempt certain transactions from the requirement to report transactions in currency in excess of $10,000. FinCEN believes that such a change is unnecessary; the last sentence of paragraph (a) (as proposed and as adopted in the final rule) already refers to rules ''permitting'' banks to exempt certain transactions from the reporting requirement.

B. 103.22(b)—Filing Obligations

Paragraph (b) continues to contain the blanket statement of the obligation of financial institutions to report transactions in currency in excess of $10,000, as well as a separate statement describing the filing obligations of casinos.

Paragraph (b) also continues to state that the general obligation to report transactions in currency in excess of $10,000 does not apply to payments or transfers made solely in connection with the purchase of postage or philatelic products from the Postal Service. As stated in the Notice, this change from the administrative exemption system reflects a proposed amendment to the treatment of the Postal Service, for purposes of the Bank Secrecy Act, that was published as part of a set of proposed rules relating to money services businesses (''MSBs'') on May 21, 1997. *See* 62 FR 27890. FinCEN received no comment on this change.

C. 103.22(c)—Aggregation

Paragraph (c) continues to restate the reporting rules applicable to multiple branches of financial institutions and multiple transactions of their customers. Those rules reflect, with one exception relating to recordkeeping facilities, the terms of prior paragraphs (a)(1) and (a)(4) of section 103.22. As an analogue to a change (discussed below) that permits affiliated banks to make a single designation of each exempt person, the Notice proposed a change clarifying that for purposes of the currency transaction reporting requirements, a financial institution includes not only all domestic branch offices, but also any recordkeeping facility, wherever located, that contains records relating to the transactions of the institution's domestic branch offices. The only comment that FinCEN received concerning recordkeeping facilities stated that the change would create an excessive burden on large banks because such banks typically have central recordkeeping facilities. Given the utility of treating a recordkeeping facility as a financial institution, particularly in cases in which affiliated banks make a single designation of exempt person, and that the commenter did not explain how central recordkeeping could lead to an excessive reporting burden on banks, the proposal regarding recordkeeping facilities is adopted in the final rule.

D. 103.22(d)—Transactions of Exempt Persons

1. General

Paragraph (d)(1) continues to state generally that, subject to the limitation on exemption set forth in paragraph (d)(7), no bank is required to file a currency transaction report otherwise required by paragraph (b) with respect to any transaction in currency between an exempt person and such bank.[5] This paragraph also adopts the language set forth in the Notice that states that a non-bank financial institution need not file a currency transaction report with respect to a transaction in currency between the institution and a commercial bank. That provision is reflected in paragraph (b)(1)(iii) of prior section 103.22.

At least one commenter suggested that FinCEN clarify, in light of, *inter alia*, the Right to Financial Privacy Act, 12 USC 3413 *et seq.*, that a bank must continue to file currency transaction reports for particular customers otherwise eligible for treatment as exempt persons if it elects not to use the reformed exemption system for those customers. The retention in paragraph (d)(1) of the phrase ''otherwise required by paragraph (b)'' is meant to convey that very point—namely, that a bank is required to file a currency transaction report regarding a transaction in currency in excess of $10,000 unless the bank follows the procedures set forth in paragraph (d) for designating the customer involved as an exempt person so that transactions by that customer are exempt from the currency transaction reporting requirement.

2. Exempt Person

The final rule adopts the two classes of exempt person introduced in the Notice—namely, non-listed businesses and payroll customers. In addition, the final rule restates, with two minor technical changes, the existing classes of exempt person (set forth in prior section 103.22(h)(2)). First, the phrase ''or analogous equity interest'' has been added after the term ''common stock'' in paragraph (d)(2)(v) to make clear that any subsidiary of any listed entity may be treated as an exempt person, regardless of whether the subsidiary has adopted the corporate form of business. Thus, any subsidiary of a listed entity may be treated as an exempt person so long as 51 per cent of the subsidiary's equity interest is owned by the listed entity. Second, the terms of prior paragraph (h)(2)(vi), stating that in the case of non-bank financial institutions, listed entities and their subsidiaries may be treated as exempt persons only to the extent of their domestic operations, have been incorporated into paragraphs (d)(2)(iv) and (v).

Paragraphs (d)(2)(vi) and (vii) continue to require that any business must have been a bank customer for twelve months before it is eligible for exemption as a non-listed business or a payroll customer. Several commenters argued that this twelve-month period was excessive (particularly compared to the two-month minimum period that has evolved administratively under prior paragraphs (b)(2) and (d) of section 103.22) and would discourage customers from changing banks.

As stated in the Notice, the ten-month difference in time periods is justified by the elimination of virtually all of the

[5] FinCEN anticipates that Internal Revenue Service Form 4789 (the form currently used to file a currency transaction report) may be revised at some point to require that a bank check a box when it files a currency transaction report with respect to a transaction conducted by an exempt person. The purpose of such a requirement would be to provide FinCEN with a more accurate estimate of the number of currency transactions reports required to be filed under the revised exemption system.

other requirements of the prior administrative exemption system. Under the reformed system, a bank will be able to exempt the transactions in currency of a non-listed business or payroll customer simply by the one-time filing of a form that identifies the exempt person and the exempting bank, and by renewing that initial designation every two years. Thus, banks no longer will be confined to exempting only those transactions falling within certain ''permitted'' ranges. In addition, banks will no longer be required to prepare and submit signed exempt statements, or to maintain mandatory exemption lists. Given the removal of these time-consuming procedures, coupled with the need to keep some ''tension'' in the liberalized exemption system so that it does not become a vehicle for more efficient money laundering, FinCEN believes that a ten-month difference is warranted.

The final rule also adopts in paragraph (d)(2)(vi), with one minor change, the definition of a non-listed business set forth in the Notice. The definition, based in large part on 31 U.S.C. 5313(e)(2), confines permissible exemptions to bank customers located in the United States that have transaction account relationships with the exempting bank involving the recurring use of currency in amounts exceeding $10,000. The term ''United States'' has been added to the clause after the comma in paragraph (d)(2)(vi)(C), to make clear that a non-listed business must be incorporated or organized under the laws of the United States or a State, or must be registered as and eligible to do business within the United States or a State. The term ''United States'' is specifically defined in 31 CFR 103.11(nn) to include, among other things, the District of Columbia and the Territories and Insular Possessions of the United States.

The final rule also continues to track the structure described above in the context of defining a payroll customer. Thus, paragraph (d)(2)(vii) requires that any person must have been a bank customer for at least twelve months before it is eligible for exemption as a payroll customer, and limits such designation to bank customers who regularly withdraw more than $10,000 to pay their United States employees. For consistency with the preceding paragraph, and in response to at least one comment that sought clarification of the term ''U.S. resident'' in the Notice, paragraph (d)(2)(vii) has been changed to state that an exemptible payroll customer must be incorporated or organized under the laws of the United States or a State, or must be registered as and eligible to do business within the United States or a State.

3. Initial Designation of Exempt Persons

Paragraph (d)(3) continues to state generally that, when initially designating one of its customers as an exempt person, a bank must make a one-time filing (using the form now used to file a currency transaction report, until such time as FinCEN issues a form specifically for this purpose) that identifies the exempt person and the exempting bank. With respect to its bank customers who are themselves banks, the exempting bank will have the option in the future of filing its current list of bank customers in such a format and manner as FinCEN may specify.

The Notice included a provision that would have required a bank, when designating a non-listed business or payroll customer as an exempt person, to include a projection of the exempt person's annual currency deposits and withdrawals. Most commenters objected to this proposal. According to these commenters, any projections of currency activity would amount to ''little more than guesswork'' because banks do not have in place the systems capable of tracking currency activity in this manner. A few commenters also expressed apprehension over a bank incurring liability if it should significantly underestimate the currency activity of one of its customers.

Several commenters also expressed reservations about the alternative that FinCEN outlined in the November Extension. That alternative would have required a bank to describe the manner in which it applies its ''know-your-customer'' standards to the tracking of currency deposits of its commercial customers. At least one commenter noted that this requirement would be superfluous, given that a bank's exemption process and currency tracking system is reviewed in detail during its BSA examination and that any application of a bank's know-your-customer policy will be monitored by bank examiners in any event.

Based on these comments, and mindful of the goal to create a reformed exemption system that is cost-effective and efficient, the final rule includes neither a requirement that a bank include in its initial designation a projection of its exempt customers' currency activity, nor a requirement that the bank describe in that designation the manner in which the bank applies its ''know-your-customer'' policies to exempt customers.

4. Annual Review

Paragraph (d)(4) makes explicit the requirement that a bank verify, at least once each year, the status of all those entities it has designated as exempt persons. This annual review requirement was implicit in the terms of proposed paragraph (d)(7)(iii), which would have required that, absent specific knowledge of any information that would be grounds for revocation, a bank verify the status of those entities it has designated as exempt persons only once each year. FinCEN notes that this requirement to annually review customers designated as exempt persons is reflected both in the terms of 31 U.S.C. 5313(e)(5) and in the administrative practice surrounding the superseded exemption system.

Paragraph (d)(4) also states that a bank must review at least annually the application to each account of a non-listed business or payroll customer of the monitoring system required to be maintained by paragraph (d)(9)(ii). This language has been added to help ensure that the reformed system is not exploited by criminals as a more efficient vehicle for money laundering.

5. Biennial Filing With Respect to Certain Exempt Persons

The Notice would have required banks, in the case of non-listed businesses and payroll customers, to file annual updates containing a statement of the exempt person's annual currency deposits and withdrawals through all transaction accounts for the preceding year.

Many commenters argued adamantly against an annual aggregate currency reporting requirement. Those commenters stressed that banks do not have the automated systems in place to comply with such a requirement, and that the cost of implementing such systems would be unreasonably high. Many commenters also maintained that, rather than comply with an annual aggregate currency reporting requirement, banks would choose to continue to file currency transaction reports on transactions involving exempt persons.

Several commenters also voiced their dissatisfaction with the alternative that FinCEN outlined in the November Extension. That alternative would have required a bank to certify that, during the preceding year, there was no transaction involving any accounts of the exempt person at the bank that would have required the bank to file a suspicious transaction report with respect to that person under 31 CFR 103.21. At least one commenter

expressed the fear that this certification would be viewed as a warranty that no suspicious activity occurred, and that banks would be unwilling to risk civil or criminal liability by making such a statement.

In response to these comments, FinCEN has deleted the provision requiring annual statements of the aggregate currency deposits and withdrawals of non-listed businesses and payroll customers. Instead of requiring annual currency statements, the final rule requires simply that banks maintain a system of monitoring the transactions in currency of non-listed businesses and payroll customers for suspicious activity, see paragraph (d)(9)(ii), and renew the exempt status of those customers every two years. *See* paragraph (d)(5)(ii). As part of that biennial renewal, banks must certify that their system of monitoring the transactions in currency of such exempt persons for suspicious activity has been applied as necessary, but at least annually, to the account of the exempt person to whom the biennial renewal applies. *See id.*

The filing required by paragraph (d)(5) need only be made once every two years. While the terms of 31 U.S.C. 5313(e)(5) contemplate an annual review, the statute does not explicitly set a time for the filing of updated information garnered as a result of that review. In light of at least a few comments suggesting that banks be required to file updated information less frequently than once a year, the final rule requires banks to renew exemption status every two years.

The date on which renewals must be filed also has changed from the Notice. At least one commenter suggested that the proposed date of February 28 be changed because it coincides with the time period in which banks must make other regulatory filings. The final rule therefore adopts the date of March 15 as the date on which biennial renewals must be filed.

Consistent with the Notice, paragraph (d)(5) states that biennial renewals also must include information about any change in control of the exempt person of which the bank knows or should know based on its records. At least one commenter contended that the ''should know'' standard essentially requires a bank to review constantly the information it possesses on each of its exempt customers, and therefore would unreasonably burden large banks where there are potentially many points of contact between the customer and the bank.

That the ''should know'' standard requires a bank to exercise some degree of due diligence when renewing the exempt status of one of its customers is wholly intentional. This concept of due diligence is entirely consistent with the language set forth in the Phase I final rule, which states that a bank must, when applying the terms of the reformed exemption system, take such steps that a reasonable and prudent bank would take and document to protect itself from loan or other fraud or loss based on misidentification of a person's status. Indeed, as one commenter noted, ''no institution would exempt a customer, either under the new or old system, without first engaging in extensive due diligence.'' Thus, the final rule requires biennial renewals to include information concerning a change in control of which a bank knows or should know based on its records.

6. Operating Rules

The final rule adopts, with a few modifications, the five operating rules introduced in the Notice relating to the Phase II rules.

a. Paragraph (d)(6)(v) states that a bank may aggregate all customer accounts to apply the exemption provisions to that customer. In response to several comments, the word ''shall'' in the Notice has been changed to ''may,'' to provide a bank with the option of exempting a customer on a bank-wide basis and counting all accounts to determine, for example, whether a customer's cash withdrawals or deposits exceed $10,000. To ensure consistency in the treatment of their exempt customers by banks, a sentence has been added in the final rule that makes clear that if a bank elects to treat all transaction accounts of a customer as a single account, the bank must continue to treat the accounts as a single account for Bank Secrecy Act purposes thereafter.

b. Paragraph (d)(6)(vi) permits affiliated banks to make a single designation of an exempt person, that will apply to all accounts of the person at all banks within the affiliated group. The language in the Notice pertaining to projected and annual currency transaction activity has been deleted.

c. Paragraph (d)(6)(vii) states that sole proprietorships may be treated as either non-listed businesses or payroll customers if they otherwise meet the requirements for treatment as such exempt persons. The Notice included provisions that would have made certain accounts of a sole proprietorship ineligible for exemption to the extent they are ''personal'' accounts, or otherwise commingle personal and business funds. Several commenters argued against these limitations, stating that it would be difficult, if not impossible, for banks to distinguish between personal and business-related transactions in currency. Again, mindful of the goal to create a reformed exemption system that works, and given that banks are under an obligation to report suspicious activity concerning the transactions in currency of their exempt customers, including sole proprietorships, the final rule does not include a provision that would require banks to track commingled funds. However, it should be noted that only ''commercial accounts'' are eligible; nothing in the final rule permits the exemption of a sole proprietor's personal bank accounts.

d. Paragraph (d)(6)(viii) lists those businesses that may not be exempted under the reformed exemption system as non-listed companies (although they may qualify for exemption under the more limited payroll customer definition). The Notice sought comments on the treatment of businesses with multiple activities of which one is an activity for which an exemption is barred. In addition, both the Notice and the November Extension solicited comments on the advisability of requiring multiple-activity businesses to segregate funds derived from eligible business activity from those derived from ineligible business activity, in order to be eligible for treatment as an exempt person.

Several commenters suggested that a multiple-activity business should be eligible for treatment as an exempt person because a contrary rule would make many of its customers ineligible for treatment as exempt persons, in particular grocery stores. According to those commenters, such multiple-activity businesses, as a matter of common practice, commingle funds derived from different activities, and would not pay the cost of maintaining multiple accounts in order to avail themselves of the advantages of the reformed exemption system.

In light of these comments, the final rule simply states that a business that engages in multiple business activities may be treated as a non-listed business so long as that business does not engage primarily in one or more of those activities described in paragraph (d)(6)(viii)—i.e., no more than 50% of its gross revenues is derived from ineligible business activity. FinCEN believes that this change will benefit banks by providing them with a bright-line test (the same one, FinCEN notes, that has evolved around the administrative practice surrounding the prior exemption system) for determining

whether to treat multi-activity businesses as exemptible non-listed businesses. To further facilitate the use of the reformed exemption system, the final rule does not include a provision that would require a multiple-activity business to segregate commingled funds to be eligible for treatment as an exempt person.

e. Paragraph (d)(6)(ix) defines a transaction account for purposes of proposed paragraph (d) as any account described in section 19(b)(1)(C) of the Act, 12 U.S.C. 461(b)(1)(C). As stated in the Notice, this definition does not include any other accounts not described in 12 U.S.C. 461(b)(1)(C), such as money market accounts. Thus, the definition of a transaction account in the proposed rule is narrower than the definition of the same term that is set forth at 31 CFR 103.11(hh). Paragraph (d)(6)(ix) also provides, consistent with the Notice, that a person may be exempt either as a non-listed business or as a payroll customer only to the extent of such person's transaction accounts.

FinCEN received several comments requesting that the definition of a transaction account be broadened. Because the terms of 31 U.S.C. 5313(e)(2)(A) specifically define a transaction account by reference to 12 U.S.C. 461(b)(1)(C), the final rule adopts the definition of a transaction account set forth in the Notice. Should the above definition of a transaction account prove too difficult to apply, FinCEN will entertain requests for administrative relief from the application of that definition.

7. Limitation on Exemption

Paragraph (d)(7) carries over the terms of prior paragraph 103.22(h)(5) and states that the exemption from reporting contained in paragraph (d)(1) does not apply to a transaction carried out by an exempt person as an agent of another person who is the beneficial owner of the funds that are the subject of a transaction in currency.[6] With regard to exempt customers acting as agents for third parties, a few commenters noted that it was common practice for those customers to commingle the funds derived from their agent activities with those funds derived from their other business activities. Because of the difficulty in distinguishing between the two kinds of funds, FinCEN was asked not to adopt a rule that would require customers to segregate funds derived from agent activities to be eligible for treatment as an exempt person.

Given these comments, the final rule does not require that an exempt person segregate agent-derived funds to be eligible for treatment as an exempt person. However, the language of paragraph (d)(7)(relating to transactions carried out by an exempt person as an agent for another), has not been deleted. The exemption procedures will apply only to transactions conducted for the account of the exempt person, not for the account of a third party who is not otherwise an exempt person. *See* 31 U.S.C. 5313(f)(1)(B) and paragraph (d)(8)(ii) of the final rule.

It should be noted that a bank customer that commingles funds from, *e.g.*, the sale of money orders or of goods sold on consignment, with its normal business receipts, for deposit purposes into its own general account engages in a transaction that is exempt or not depending upon the customer's own status, regardless of the fact that a portion of the funds are subject to a potential equitable or other lien by a third party (the issuer of the money orders or the consignor of the goods) if the customer does not pay an amount equal to the money order or consignment sales proceeds over to the issuer or consignor. If instead, the business selling the money orders or consigned goods deposits the funds directly into an account opened by the money order issuer or the goods' consignor, the eligibility of the transaction for exemption would depend upon the status of the issuer or consignor.

8. Limitation on Liability

Paragraph (d)(8)(i) generally states, consistent with the Notice, that once a bank has complied with the requirements of paragraph (d), it is protected from any penalty for failure to file a currency transaction report concerning a transaction in currency by an exempt person.

Paragraph (d)(8)(ii) states that subject to the specific terms of paragraph (d), and absent any specific knowledge of any information indicating that a customer no longer meets the requirements of an exempt person, a bank satisfies the requirements of paragraph (d) if it continues to treat that customer as an exempt person until the date of that customer's next periodic review. This language is meant to harmonize the requirement, contained in paragraph (d)(4), that banks review the status of their exempt customers at least once a year, with the provisions relating to the revocation of a customer's exempt status that are set forth at paragraph (d)(10).

9. Obligations to File Suspicious Activity Reports and Maintain a System to Monitor Transactions in Currency

Paragraph 103.22(d)(9)(i) states that the reformed exemption system does not create any exemption from, or have any negative effect at all on, the requirement that banks file suspicious transaction reports with respect to transactions that satisfy the requirements of the rules of FinCEN (31 CFR 103.21), the federal bank supervisory agencies, or both, relating to suspicious activity reporting. *See* 12 CFR 21.11 (Office of the Comptroller of the Currency); 12 CFR 208.20 (Federal Reserve System); 12 CFR 353.3 (Federal Deposit Insurance Corporation); 12 CFR 563.180 (Office of Thrift Supervision); 12 CFR 748.1 (National Credit Union Administration). Indeed, as pointed out in the notice of proposed rulemaking, the operation of a coordinated and uniform suspicious transaction reporting system is a basis for the revision and simplification of the exemption rules contained in this final rule. In the context of the revised CTR exemption system, the indicia of suspicious activity can include both specific transactions and overall transaction volume substantially inconsistent with the sort in which the particular customer normally would be expected to engage. Thus, as stated in the text of the rule itself, anomalous transaction trends or patterns (such as a sharp increase from one year to the next in the gross total of currency transactions made by an exempt person) may trigger the obligations of a bank under section 103.21.

Paragraph (d)(9)(ii) has been added to make explicit that the continuing obligation to file suspicious activity reports (where appropriate) necessarily requires a bank to establish and maintain a monitoring system for non-listed business and payroll customers that is reasonably designed to detect those transactions in currency that would require a bank to file a suspicious transaction report with respect to an exempt person.[7] FinCEN purposely has not attempted to describe the exact contours of an acceptable monitoring system. Because the situation of each bank and each customer are different, FinCEN believes that mandating a uniform monitoring system would be ill-advised. From FinCEN's perspective, a monitoring system meets the requirements of paragraph (d)(9)(ii) if it

[6] FinCEN indicated that it would consider additional comments on this subject when it issued the Phase I final rule. *See* 62 FR 47141, 47146.

[7] The Bank Secrecy Act provides Treasury with the authority to condition the grant of discretionary exemptions. *See* 31 U.S.C. 5313(e).

is reasonably designed to detect, for each exempt account, those transactions in currency that would require a bank to file a suspicious transaction report.

The adoption of the monitoring system requirement is intended to advance the objectives of creating an exemption system that is simple and as cost-effective as possible, while still keeping some tension in the liberalized system. FinCEN believes that an increased emphasis on suspicious activity reporting with respect to transactions in currency of exempt persons should provide that needed tension. FinCEN further notes that maintaining a monitoring system reasonably designed to detect suspicious activity, and certifying compliance with that requirement, should not pose additional burdens on banks, because they remain subject in any event to the requirement to file reports of suspicious activity with respect to any transaction they exempt from the requirement to file currency transaction reports under the reformed exemption system. As explained above, the statement of the requirement to maintain a specific currency transaction monitoring program for accounts of exempt persons is limited to accounts of non-listed businesses and payroll customers, the classes of exempt persons with respect to which annual review requirements are specifically imposed by the final rule. However, banks are required to report suspicious transactions, including transactions in currency, in the accounts of all exempt persons (as in all other accounts) and paragraph (d)(9)(ii)'s more detailed specification does not by implication lessen the suspicious transaction reporting obligations or procedures of banks generally under paragraph (d)(9)(i) and 31 CFR 103.21.

10. Revocation

Paragraph (d)(10) states that the status of an exempt person automatically ceases, without any action by the Department of the Treasury, when an entity ceases to be listed on the applicable stock exchange or a subsidiary of a listed entity ceases to have at least 51 per cent of its common stock or analogous equity interest owned by a listed entity. The phrase ''analogous equity interest'' has been added to reflect the change made to the definition of an exempt subsidiary set forth in paragraph (d)(2)(v).

11. Transitional Rule

Paragraph 103.22(d)(11) states the transitional rules governing the use of the reformed exemption system. A few commenters requested that FinCEN provide ample time for banks to move from the prior administrative exemption system to the reformed system, particularly given that banks will need some time to address year 2000 computer issues. In light of these comments, the transition period stated in the Notice—that, in effect, provides banks until the end of the calendar year 1999 to make the transition to the reformed system—has been extended in the final rule to July 1, 2000. Provided that banks comply with the transition period set forth in the final rule, they may treat a customer as exempt under either the prior administrative exemption rules or the reformed exemption procedures set forth in paragraph 103.22(d) (so long as they do so consistently) during the transitional period.

V. Executive Order 12866

The Department of the Treasury has determined that this final rule is not a significant regulatory action under Executive Order 12866.

VI. Unfunded Mandates Act of 1995 Statement

Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), Pub. L. 104–4 (March 22, 1995), requires that an agency prepare a budgetary impact statement before promulgating a rule that includes a federal mandate that may result in expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, section 202 of the Unfunded Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. FinCEN has determined that it is not required to prepare a written statement under section 202 and has concluded that on balance this final rule provides the most cost-effective and least burdensome alternative to achieve the objectives of the rule.

VII. Regulatory Flexibility Act

FinCEN certifies that this amendment to the regulations implementing the Bank Secrecy Act will not have a significant, adverse financial impact on a substantial number of small depository institutions. By adding two new classes of customers, non-listed businesses and payroll customers, to the list of exempt persons, the final rule represents a significant decrease in the reporting burden imposed on all depository institutions. FinCEN anticipates that the addition of these two new classes of exempt persons can contribute to at least a 2 million reduction in the number of currency transaction reports filed annually, and a cost reduction to depository institutions of $16 million. Further, the requirements placed upon depository institutions under the reformed exemption system, as laid out in the final rule, represent a substantial net decrease in the burdens associated with the prior exemption process. For example, depository institutions will no longer be required to prepare and submit signed exemption statements, or to maintain customer exempt lists. Under the reformed system, a depository institution will be able to exempt the transactions in currency of an exempt person simply by the one-time filing of a currency transaction report form that identifies the exempt customer and the exempting depository institution, and, in the case of non-listed businesses and payroll customers, renewing the exempt status of its exempt customers every two years.

VIII. Paperwork Reduction Act

In accordance with requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*, and its implementing regulations, 5 CFR part 1320, the following information concerning the collection of information on Internal Revenue Service Form 4789 is presented to assist those persons wishing to comment on the information collection.

FinCEN anticipates that this final rule, if used by banks, can result in at least a 2 million reduction in the number of currency transaction reports required to be filed annually, and a cost reduction to banks of $16 million. FinCEN believes that these estimated reductions are reasonable, and probably conservative.

Title: Currency Transaction Report.

OMB Number: 1506–0004.

Description of Respondents: All financial institutions, except casinos.

Estimated Number of Respondents: 250,000.

Frequency: As required.

Estimate of Burden: Reporting average of 19 minutes per response; recordkeeping average of 5 minutes per response.

Estimate of Total Annual Burden on Respondents: 10,000,000 responses. Reporting burden estimate = 3,166,667 hours; recordkeeping burden estimate = 833,333 hours. Estimated combined total of 4,000,000 hours.

Estimate of Total Annual Cost to Respondents for Hour Burdens: Based on $20 per hour, the total cost to the public is estimated to be $80,000,000.

Estimate of Total Other Annual Costs to Respondents: None.

Type of Review: Extension.

In accordance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*, and its implementing regulations, 5 CFR part 1320, the following information concerning the collection of information as required by 31 CFR 103.22 is presented to assist those persons wishing to comment on the information collection.

FinCEN anticipates that this final rule will result in a reduction in hours spent complying with exemption requirements of 350,000 hours, and a reduction in cost to banks of $7,500,000. This is a conservative estimate, based on comments and discussions with banking industry representatives of the cost of complying with the administrative exemption system requirements.

Title: Currency transaction reporting exemption recordkeeping (31 CFR 103.22).

OMB Number: 1506–0009.

Description of Respondents: All banks.

Estimated Number of Respondents: 19,000.

Frequency: As required.

Estimate of Burden: Recordkeeping average of 2 hours per respondent.

Estimate of Total Annual Burden on Respondents: Recordkeeping burden estimate = 38,000 hours.

Estimate of Total Annual Cost to Respondents for Hour Burdens: Based on $20 per hour, the total cost to the public is estimated to be $760,000.

Estimate of Total Other Annual Costs to Respondents: None.

Type of Request: Extension.

List of Subjects in 31 CFR Part 103

Administrative practice and procedure, Authority delegations (Government agencies), Banks and banking, Currency, Foreign banking, Foreign currencies, Gambling, Investigations, Law enforcement, Penalties, Reporting and recordkeeping requirements, Securities, Taxes.

Amendment

For the reasons set forth above in the preamble, 31 CFR part 103 is amended as follows:

PART 103—FINANCIAL RECORDKEEPING AND REPORTING OF CURRENCY AND FOREIGN TRANSACTIONS

1. The authority citation for part 103 continues to read as follows:

Authority: 12 U.S.C. 1829b and 1951–1959; 31 U.S.C. 5311–5330.

2. Section 103.22 is revised to read as follows:

§ 103.22 Reports of transactions in currency.

(a) *General.* This section sets forth the rules for the reporting by financial institutions of transactions in currency. The reporting obligations themselves are stated in paragraph (b) of this section. The reporting rules relating to aggregation are stated in paragraph (c) of this section. Rules permitting banks to exempt certain transactions from the reporting obligations appear in paragraph (d) of this section.

(b) *Filing obligations*—(1) *Financial institutions other than casinos.* Each financial institution other than a casino shall file a report of each deposit, withdrawal, exchange of currency or other payment or transfer, by, through, or to such financial institution which involves a transaction in currency of more than $10,000, except as otherwise provided in this secction. In the case of the Postal Service, the obligation contained in the preceding sentence shall not apply to payments or transfers made solely in connection with the purchase of postage or philatelic products.

(2) *Casinos.* Each casino shall file a report of each transaction in currency, involving either cash in or cash out, of more than $10,000.

(i) Transactions in currency involving cash in include, but are not limited to:

(A) Purchases of chips, tokens, and plaques;

(B) Front money deposits;

(C) Safekeeping deposits;

(D) Payments on any form of credit, including markers and counter checks;

(E) Bets of currency;

(F) Currency received by a casino for transmittal of funds through wire transfer for a customer;

(G) Purchases of a casino's check; and

(H) Exchanges of currency for currency, including foreign currency.

(ii) Transactions in currency involving cash out include, but are not limited to:

(A) Redemptions of chips, tokens, and plaques;

(B) Front money withdrawals;

(C) Safekeeping withdrawals;

(D) Advances on any form of credit, including markers and counter checks;

(E) Payments on bets, including slot jackpots;

(F) Payments by a casino to a customer based on receipt of funds through wire transfer for credit to a customer;

(G) Cashing of checks or other negotiable instruments;

(H) Exchanges of currency for currency, including foreign currency; and

(I) Reimbursements for customers' travel and entertainment expenses by the casino.

(c) *Aggregation*—(1) *Multiple branches.* A financial institution includes all of its domestic branch offices, and any recordkeeping facility, wherever located, that contains records relating to the transactions of the institution's domestic offices, for purposes of this section's reporting requirements.

(2) *Multiple transactions—general.* In the case of financial institutions other than casinos, for purposes of this section, multiple currency transactions shall be treated as a single transaction if the financial institution has knowledge that they are by or on behalf of any person and result in either cash in or cash out totaling more than $10,000 during any one business day (or in the case of the Postal Service, any one day). Deposits made at night or over a weekend or holiday shall be treated as if received on the next business day following the deposit.

(3) *Multiple transactions—casinos.* In the case of a casino, multiple currency transactions shall be treated as a single transaction if the casino has knowledge that they are by or on behalf of any person and result in either cash in or cash out totaling more than $10,000 during any gaming day. For purposes of this paragraph (c)(3), a casino shall be deemed to have the knowledge described in the preceding sentence, if: any sole proprietor, partner, officer, director, or employee of the casino, acting within the scope of his or her employment, has knowledge that such multiple currency transactions have occurred, including knowledge from examining the books, records, logs, information retained on magnetic disk, tape or other machine-readable media, or in any manual system, and similar documents and information, which the casino maintains pursuant to any law or regulation or within the ordinary course of its business, and which contain information that such multiple currency transactions have occurred.

(d) *Transactions of exempt persons*—(1) *General.* No bank is required to file a report otherwise required by paragraph (b) of this section with respect to any transaction in currency between an exempt person and such bank, or, to the extent provided in paragraph (d)(6)(vi) of this section, between such exempt person and other banks affiliated with such bank. In addition, a non-bank financial institution is not required to file a report

otherwise required by paragraph (b) of this section with respect to a transaction in currency between the institution and a commercial bank. (A limitation on the exemption described in this paragraph (d)(1) is set forth in paragraph (d)(7) of this section.)

(2) *Exempt person.* For purposes of this section, an exempt person is:

(i) A bank, to the extent of such bank's domestic operations;

(ii) A department or agency of the United States, of any State, or of any political subdivision of any State;

(iii) Any entity established under the laws of the United States, of any State, or of any political subdivision of any State, or under an interstate compact between two or more States, that exercises governmental authority on behalf of the United States or any such State or political subdivision;

(iv) Any entity, other than a bank, whose common stock or analogous equity interests are listed on the New York Stock Exchange or the American Stock Exchange or whose common stock or analogous equity interests have been designated as a Nasdaq National Market Security listed on the Nasdaq Stock Market (except stock or interests listed under the separate ''Nasdaq Small-Cap Issues'' heading), provided that, for purposes of this paragraph (d)(2)(iv), a person that is a financial institution, other than a bank, is an exempt person only to the extent of its domestic operations;

(v) Any subsidiary, other than a bank, of any entity described in paragraph (d)(2)(iv) of this section (a ''listed entity'') that is organized under the laws of the United States or of any State and at least 51 percent of whose common stock or analogous equity interest is owned by the listed entity, provided that, for purposes of this paragraph (d)(2)(v), a person that is a financial institution, other than a bank, is an exempt person only to the extent of its domestic operations;

(vi) To the extent of its domestic operations, any other commercial enterprise (for purposes of this paragraph (d), a ''non-listed business''), other than an enterprise specified in paragraph (d)(6)(viii) of this section, that:

(A) Has maintained a transaction account at the bank for at least 12 months;

(B) Frequently engages in transactions in currency with the bank in excess of $10,000; and

(C) Is incorporated or organized under the laws of the United States or a State, or is registered as and eligible to do business within the United States or a State; or

(vii) With respect solely to withdrawals for payroll purposes from existing transaction accounts, any other person (for purposes of this paragraph (d), a ''payroll customer'') that:

(A) Has maintained a transaction account at the bank for at least 12 months;

(B) Operates a firm that regularly withdraws more than $10,000 in order to pay its United States employees in currency; and

(C) Is incorporated or organized under the laws of the United States or a State, or is registered as and eligible to do business within the United States or a State.

(3) *Initial designation of exempt persons*—(i) *General.* A bank must designate each exempt person with which it engages in transactions in currency by the close of the 30-day period beginning after the day of the first reportable transaction in currency with that person sought to be exempted from reporting under the terms of this paragraph (d). Except where the person sought to be exempted is another bank as described in paragraph (d)(2)(i) of this section, designation by a bank of an exempt person shall be made by a single filing of Internal Revenue Service Form 4789, in which line 36 is marked ''Designation of Exempt Person'' and items 2–14 (Part I, Section A) and items 37–49 (Part III) are completed, or by filing any form specifically designated by FinCEN for this purpose. The designation must be made separately by each bank that treats the person in question as an exempt person, except as provided in paragraph (d)(6)(vi) of this section. The designation requirements of this paragraph (d)(3) apply whether or not the particular exempt person to be designated has previously been treated as exempt from the reporting requirements of prior § 103.22(a) under the rules contained in 31 CFR 103.22(a) through (g), as in effect on October 20, 1998 (see 31 CFR Parts 0 to 199 revised as of July 1, 1998). A special transitional rule, which extends the time for initial designation for customers that have been previously treated as exempt under such prior rules, is contained in paragraph (d)(11) of this section.

(ii) *Special rules for banks.* When designating another bank as an exempt person, a bank must either make the filing required by paragraph (d)(3)(i) of this section or file, in such a format and manner as FinCEN may specify, a current list of its domestic bank customers. In the event that a bank files its current list of domestic bank customers, the bank must make the filing as described in paragraph (d)(3)(i) of this section for each bank that is a new customer and for which an exemption is sought under this paragraph (d).

(4) *Annual review.* The information supporting each designation of an exempt person, and the application to each account of an exempt person described in paragraphs (d)(2)(vi) or (d)(2)(vii) of this section of the monitoring system required to be maintained by paragraph (d)(9)(ii) of this section, must be reviewed and verified at least once each year.

(5) *Biennial filing with respect to certain exempt persons*—(i) *General.* A biennial filing, as described in paragraph (d)(5)(ii) of this section, is required for continuation of the treatment as an exempt person of a customer described in paragraph (d)(2)(vi) or (vii) of this section. No biennial filing is required for continuation of the treatment as an exempt person of a customer described in paragraphs (d)(2)(i) through (v) of this section.

(ii) *Non-listed businesses and payroll customers.* The designation of a non-listed business or a payroll customer as an exempt person must be renewed biennially, beginning on March 15 of the second calendar year following the year in which the first designation of such customer as an exempt person is made, and every other March 15 thereafter, on such form as FinCEN shall specify. Biennial renewals must include a statement certifying that the bank's system of monitoring the transactions in currency of an exempt person for suspicious activity, required to be maintained by paragraph (d)(9)(ii) of this section, has been applied as necessary, but at least annually, to the account of the exempt person to whom the biennial renewal applies. Biennial renewals also must include information about any change in control of the exempt person involved of which the bank knows (or should know on the basis of its records).

(6) *Operating rules*—(i) *General rule.* Subject to the specific rules of this paragraph (d), a bank must take such steps to assure itself that a person is an exempt person (within the meaning of the applicable provision of paragraph (d)(2) of this section), to document the basis for its conclusions, and document its compliance, with the terms of this paragraph (d), that a reasonable and prudent bank would take and document to protect itself from loan or other fraud or loss based on misidentification of a person's status, and in the case of the monitoring system requirement set forth in paragraph (d)(9)(ii) of this section, such steps that a reasonable and prudent bank would take and document

to identify suspicious transactions as required by paragraph (d)(9)(ii) of this section.

(ii) *Governmental departments and agencies.* A bank may treat a person as a governmental department, agency, or entity if the name of such person reasonably indicates that it is described in paragraph (d)(2)(ii) or (d)(2)(iii) of this section, or if such person is known generally in the community to be a State, the District of Columbia, a tribal government, a Territory or Insular Possession of the United States, or a political subdivision or a wholly-owned agency or instrumentality of any of the foregoing. An entity generally exercises governmental authority on behalf of the United States, a State, or a political subdivision, for purposes of paragraph (d)(2)(iii) of this section, only if its authorities include one or more of the powers to tax, to exercise the authority of eminent domain, or to exercise police powers with respect to matters within its jurisdiction. Examples of entities that exercise governmental authority include, but are not limited to, the New Jersey Turnpike Authority and the Port Authority of New York and New Jersey.

(iii) *Stock exchange listings.* In determining whether a person is described in paragraph (d)(2)(iv) of this section, a bank may rely on any New York, American or Nasdaq Stock Market listing published in a newspaper of general circulation, on any commonly accepted or published stock symbol guide, on any information contained in the Securities and Exchange Commission ''Edgar'' System, or on any information contained on an Internet World-Wide Web site or sites maintained by the New York Stock Exchange, the American Stock Exchange, or the National Association of Securities Dealers.

(iv) *Listed company subsidiaries.* In determining whether a person is described in paragraph (d)(2)(v) of this section, a bank may rely upon:

(A) Any reasonably authenticated corporate officer's certificate;

(B) Any reasonably authenticated photocopy of Internal Revenue Service Form 851 (Affiliation Schedule) or the equivalent thereof for the appropriate tax year; or

(C) A person's Annual Report or Form 10-K, as filed in each case with the Securities and Exchange Commission.

(v) *Aggregated accounts.* In determining the qualification of a customer as an exempt person, a bank may treat all transaction accounts of the customer as a single account. If a bank elects to treat all transaction accounts of a customer as a single account, the bank must continue to treat such accounts consistently as a single account for purposes of determining the qualification of the customer as an exempt person.

(vi) *Affiliated banks.* The designation required by paragraph (d)(3) of this section may be made by a parent bank holding company or one of its bank subsidiaries on behalf of all bank subsidiaries of the holding company, so long as the designation lists each bank subsidiary to which the designation shall apply.

(vii) *Sole proprietorships.* A sole proprietorship may be treated as a non-listed business if it otherwise meets the requirements of paragraph (d)(2)(vi) of this section, as applicable. In addition, a sole proprietorship may be treated as a payroll customer if it otherwise meets the requirements of paragraph (d)(2)(vii) of this section, as applicable.

(viii) *Ineligible businesses.* A business engaged primarily in one or more of the following activities may not be treated as a non-listed business for purposes of this paragraph (d): serving as financial institutions or agents of financial institutions of any type; purchase or sale to customers of motor vehicles of any kind, vessels, aircraft, farm equipment or mobile homes; the practice of law, accountancy, or medicine; auctioning of goods; chartering or operation of ships, buses, or aircraft; gaming of any kind (other than licensed parimutuel betting at race tracks); investment advisory services or investment banking services; real estate brokerage; pawn brokerage; title insurance and real estate closing; trade union activities; and any other activities that may be specified by FinCEN. A business that engages in multiple business activities may be treated as a non-listed business so long as no more than 50% of its gross revenues is derived from one or more of the ineligible business activities listed in this paragraph (d)(6)(viii).

(ix) *Transaction account.* A transaction account, for purposes of paragraph (d) of this section, is any account described in section 19(b)(1)(C) of the Federal Reserve Act, 12 U.S.C. 461(b)(1)(C). For purposes of paragraphs (d)(2)(vi) and (d)(2)(vii) of this section, a person is an exempt person only to the extent of such person's eligible transaction accounts.

(x) *Documentation.* The records maintained by a bank to document its compliance with and administration of the rules of this paragraph (d) shall be maintained in accordance with the provisions of § 103.38.

(7) *Limitation on exemption.* A transaction carried out by an exempt person as an agent for another person who is the beneficial owner of the funds that are the subject of a transaction in currency is not subject to the exemption from reporting contained in paragraph (d)(1) of this section.

(8) *Limitation on liability.* (i) No bank shall be subject to penalty under this part for failure to file a report required by paragraph (b) of this section with respect to a transaction in currency by an exempt person with respect to which the requirements of this paragraph (d) have been satisfied, unless the bank:

(A) Knowingly files false or incomplete information with respect to the transaction or the customer engaging in the transaction; or

(B) Has reason to believe that the customer does not meet the criteria established by this paragraph (d) for treatment of the transactor as an exempt person or that the transaction is not a transaction of the exempt person.

(ii) Subject to the specific terms of this paragraph (d), and absent any specific knowledge of information indicating that a customer no longer meets the requirements of an exempt person, a bank satisfies the requirements of this paragraph (d) to the extent it continues to treat that customer as an exempt person until the date of that customer's next periodic review, which, as required by paragraph (d)(4) of this section, shall occur no less than once each year.

(iii) A bank that files a report with respect to a currency transaction by an exempt person rather than treating such person as exempt shall remain subject, with respect to each such report, to the rules for filing reports, and the penalties for filing false or incomplete reports that are applicable to reporting of transactions in currency by persons other than exempt persons.

(9) *Obligations to file suspicious activity reports and maintain system for monitoring transactions in currency.* (i) Nothing in this paragraph (d) relieves a bank of the obligation, or reduces in any way such bank's obligation, to file a report required by § 103.21 with respect to any transaction, including any transaction in currency that a bank knows, suspects, or has reason to suspect is a transaction or attempted transaction that is described in § 103.21(a)(2)(i), (ii), or (iii), or relieves a bank of any reporting or recordkeeping obligation imposed by this part (except the obligation to report transactions in currency pursuant to this section to the extent provided in this paragraph (d)). Thus, for example, a sharp increase from one year to the next in the gross total of currency transactions made by an exempt customer, or similarly anomalous transaction trends or

patterns, may trigger the obligations of a bank under § 103.21.

(ii) Consistent with its annual review obligations under paragraph (d)(4)of this section, a bank shall establish and maintain a monitoring system that is reasonably designed to detect, for each account of a non-listed business or payroll customer, those transactions in currency involving such account that would require a bank to file a suspicious transaction report. The statement in the preceding sentence with respect to accounts of non-listed and payroll customers does not limit the obligation of banks generally to take the steps necessary to satisfy the terms of paragraph (d)(9)(i) of this section and § 103.21 with respect to all exempt persons.

(10) *Revocation*. The status of any person as an exempt person under this paragraph (d) may be revoked by FinCEN by written notice, which may be provided by publication in the **Federal Register** in appropriate situations, on such terms as are specified in such notice. Without any action on the part of the Treasury Department and subject to the limitation on liability contained in paragraph (d)(8)(ii) of this section:

(i) The status of an entity as an exempt person under paragraph (d)(2)(iv) of this section ceases once such entity ceases to be listed on the applicable stock exchange; and

(ii) The status of a subsidiary as an exempt person under paragraph (d)(2)(v) of this section ceases once such subsidiary ceases to have at least 51 per cent of its common stock or analogous equity interest owned by a listed entity.

(11) *Transitional rule*. (i) No accounts may be newly granted an exemption or placed on an exempt list on or after October 21, 1998, under the rules contained in 31 CFR 103.22(b) through (g), as in effect on October 20, 1998 (see 31 CFR Parts 0 to 199 revised as of July 1, 1998).

(ii) If a bank properly treated an account (a ''previously exempted account'') as exempt on October 20, 1998 under the rules contained in 31 CFR 103.22(b) through (g), as in effect on October 20, 1998 (see 31 CFR Parts 0 to 199 revised as of July 1, 1998), it may continue to treat such account as exempt under such prior rules with respect to transactions in currency occurring on or before June 30, 2000, provided that it does so consistently until the earlier of June 30, 2000, and the date on which the bank makes the designation or the determination described in paragraph (d)(11)(iii) of this section. A bank that continues to treat a previously exempted account as exempt under the prior rules, and for the period, specified in the preceding sentence, shall remain subject to such prior rules, and to the penalties for failing to comply therewith, with respect to transactions in currency occurring during such period.

(iii) A bank must, on or before July 1, 2000, either designate the holder of a previously exempted account as an exempt person under paragraph (d)(2) of this section or determine that it may not or will not treat such holder as an exempt person under paragraph (d)(2) of this section (so that it will be required to make reports under paragraph (a) of this section with respect to transactions in currency by such person occurring on or after the date of determination, but no later than July 1, 2000). A bank that initially does not designate the holder of a previously exempted account as an exempt person for periods beginning after June 30, 2000, may later make such a designation, to the extent otherwise permitted to do so by this paragraph (d), for periods after the effective date of such designation.

Approved by the Office of Management and Budget under control number 1506–0009.)

Dated: September 14, 1998.

William F. Baity,

Acting Director,

Financial Crimes Enforcement Network.

[FR Doc. 98–24969 Filed 9–18–98; 8:45 am]

BILLING CODE 4820–03–P

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 357

[Department of the Treasury Circular, Public Debt Series, No. 2–86]

Regulations Governing Book-Entry Treasury Bonds, Notes, and Bills; Determination Regarding State Statutes; Wisconsin, New Hampshire and Michigan

AGENCY: Bureau of the Public Debt, Fiscal Service, Treasury.

ACTION: Determination of substantially identical state statutes.

SUMMARY: The Department of the Treasury is announcing that it has reviewed the statutes of Wisconsin, New Hampshire and Michigan which have recently enacted laws adopting Revised Article 8 of the Uniform Commercial Code—Investment Securities (''Revised Article 8'') and determined that they are substantially identical to the uniform version of Revised Article 8 for purposes of interpreting the rules in 31 CFR Part 357, Subpart B (the ''TRADES'' regulations). Therefore, that portion of the TRADES rule requiring application of Revised Article 8 if a state has not adopted Revised Article 8 will no longer be applicable for those 3 states.

EFFECTIVE DATE: September 21, 1998.

FOR FURTHER INFORMATION CONTACT: Sandy Dyson, Attorney-Advisor (202) 219–3320, or Cynthia E. Reese, Deputy Chief Counsel (202) 219–3320.

ADDRESSES: Copies of this notice are available for downloading from the Bureau of the Public Debt home page at: http://www.publicdebt.treas.gov.

SUPPLEMENTARY INFORMATION: On August 23, 1996, The Department published a final rule to govern securities held in the commercial book-entry system, now referred to as the Treasury/Reserve Automated Debt Entry System (''TRADES''), 61 FR 43626.

In the commentary to the final regulations, Treasury stated that for the 28 states that had by then adopted Revised Article 8, the versions enacted were ''substantially identical'' to the uniform version for purposes of the rule. Therefore, for those states, that portion of the TRADES rule requiring application of Revised Article 8 was not invoked. Treasury also indicated in the commentary that as additional states adopt Revised Article 8, notice would be provided in the **Federal Register** as to whether the enactments are substantially identical to the uniform version so that the federal application of Revised Article 8 would no longer be in effect for those states. Treasury adopted this approach in an attempt to provide certainty in application of the rule in response to public comments. Notices have subsequently been published setting forth Treasury's determination concerning 19 additional states' enactment of Revised Article 8. See (62 FR 26, January 2, 1997, 62 FR 34010, June 18, 1997, 62 FR 61912, November 20, 1997, 63 FR 20099, April 23, 1998 and 63 FR 35807, July 1, 1998). Thus, a total of 50 states, including the three states addressed herein, the District of Columbia and Puerto Rico, have enacted statutes substantially identical to the uniform version of Revised Article 8.

This notice addresses the recent adoption of Article 8 by Wisconsin, New Hampshire and Michigan.

Treasury has reviewed the three state enactments and has concluded all of them are substantially identical to the uniform version of Revised Article 8.

Accordingly, if either § 357.10(b) or § 357.11(b) directs a person to Wisconsin, New Hampshire and Michigan, the provisions of §§ 357.10(c) and 357.11(d) of the TRADES rule are not applicable.

Dated: September 15, 1998.

Van Zeck,

Commissioner of the Public Debt.

[FR Doc. 98–25213 Filed 9–17–98; 8:45 am]

BILLING CODE 4810–39–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR 100

[CGD08–98–060]

RIN 2115–AE46

Special Local Regulations: 2nd Annual Hobbs Island Regatta, Tennessee River Mile 333.5 to 336.5, Huntsville, Alabama

AGENCY: Coast Guard, DOT.

ACTION: Temporary Final Rule.

SUMMARY: Special local regulations are being adopted for the 2nd Annual Hobbs Island Regatta. This event will be held on September 26, 1998 from 9:00 a.m. until 4:00 p.m. at the riverfront in Huntsville, AL. These regulations are needed to provide for the safety of life on navigable waters during the event.

DATES: These regulations are effective from 9 a.m. until 4 p.m. on September 26, 1998.

FOR FURTHER INFORMATION CONTACT: LTJG Tom Boyles, Marine Safety Office, Paducah, KY. Tel: (502) 442–1621 ext. 310.

SUPPLEMENTARY INFORMATION:

Drafting Information

The drafters of this regulation are LTJG Tom Boyles, Project Officer, Marine Safety Office Paducah, and LTJG Michele Woodruff, Project Attorney, Eighth Coast Guard District Legal Office.

Regulatory History

In accordance with 5 U.S.C. 553, a notice of proposed rule making for these regulations has not been published, and good cause exists for making them effective in less than 30 days from the date of publication. Following normal rule making procedures would have been impracticable. The details of the event were not finalized with sufficient time remaining to publish proposed rules in advance of the event or to provide for a delayed effective date.

Background and Purpose

The marine event requiring this regulation is the 2nd Annual Hobbs Island Regatta. The Rocket City Rowing Club sponsors this event. The event will consist of a three-mile rowing race involving rowing shells of up to 60 feet in length with nine person crews. The sponsor expects approximately 300 to 350 participants and between 10 and 15 spectator boats. Spectators will be able to view the event from areas designated by the sponsor.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary because of the event's short duration.

Small Entities

The Coast Guard finds that the impact on small entities, if any, is not substantial. Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 et seq) that this temporary rule will not have a significant economic impact on a substantial number of small entities because of the event's short duration.

Collection of Information

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

Federalism Assessment

The Coast Guard has analyzed this action in accordance with the principles and criteria of Executive Order 12612 and has determined that this rule does not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard considered the environmental impact of this rule and concluded that under section 2–1, paragraph (34)(h) of Commandant Instruction M16475.1C this rule is excluded from further environmental documentation.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements.

Temporary Regulations

In consideration of the foregoing, part 100 of Title 33, Code of Federal Regulations, is amended as follows:

PART 100—[AMENDED]

1. The authority citation of part 100 continues to read as follows:

Authoirty: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. A temporary section 100.35–T09–060 is added to read as follows:

§ 100.35–T08–060 Tennessee River at Huntsville, Alabama.

(a) *Regulated Area:* A regulated area is established on the Tennessee River between miles 333.5 and 336.5.

(b) *Special Local Regulation:* All persons and/or vessels not registered with the sponsors as participants or official patrol vessels are considered spectators. The ''official patrol'' consists of any Coast Guard, public, state or local law enforcement and/or sponsor provided vessels assigned to patrol the event.

(1) No spectators shall anchor, block, loiter in, or impede the through transit of participants or official patrol vessels in the regulated area during effective dates and times, unless cleared for such entry by or through an official patrol vessel.

(2) When hailed and/or signaled by an official patrol vessel, a spectator shall come to an immediate stop. Vessels shall comply with all directions given: failure to do so may result in a citation.

(3) The Patrol Commander is empowered to forbid and control the movement of all vessels in the regulated area. The Patrol Commander may terminate the event at any time it is deemed necessary for the protection of life and/or property and can be reached on VHF–FM Channel 16 by using the call sign ''PATCOM''.

Effective Date: These regulations will be effective on September 26, 1998 from 9:00 a.m. until 4:00 p.m.

Dated: September 4, 1998.

A. L. Gerfin, Jr.,

Captain, U.S. Coast Guard,

Acting Commander, 8th Coast Guard Dist.

[FR Doc. 98–25160 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–15–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07–98–008]

RIN 2115–AE46

Special Local Regulations; Around Alone Sailboat Race, Charleston, SC

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is revising the temporary special local regulations that created a regulated area in the coastal waters off Charleston, SC, for the Around Alone single-handed sailboat race, sponsored by Great Adventures, Ltd. The revisions to the dimensions of the regulated area include extending the area further offshore and will ensure a more controlled start and safer passage for the participants once the race has begun. These regulations are necessary to provide for the safety of life on navigable waters because of the expected presence of numerous spectator craft.

DATES: This section becomes effective from 10 am until 2 pm (EDT) on September 26, 1998.

FOR FURTHER INFORMATION CONTACT: LTJG S. Brisco, Project Manager, Coast Guard Group Charleston at (843) 724–7628.

SUPPLEMENTARY INFORMATION:

Regulatory History

The Coast Guard published a Notice of Proposed Rulemaking in the **Federal Register** on March 30, 1998 (63 FR 15115) and the Final Rule on July 2, 1998 (63 FR 36181).

Background and Purpose

These regulations revised the size and location of the regulated area and are needed to provide for the safety of life during the start of the Around Alone 1998–99 sailing race. These revised regulations are intended to promote safe navigation offshore of Charleston Harbor immediately before, during, and after the start of the race, by creating a larger area to control the traffic entering, exiting, and traveling within the regulated area. The anticipated concentration of commercial traffic, spectator vessels, and participating vessels associated with the race poses a safety concern.

The regulated area will encompasses an area south of Charleston Harbor entrance lighted buoy 7 (LLNR 2405). Eight conspicuous markers will indicate the boundaries of the regulated area. These regulations prohibit the movement of spectator vessels and other non-participants within the regulated area on September 26, 1998, between 10 a.m. and 2 p.m., at the discretion of the Coast Guard Patrol Commander.

In accordance with 5 U.S.C. 533, a notice of proposed rulemaking has not been published for these revised regulations and good cause exists for making them effective in less than 30 days from the date of publication in the **Federal Register**. Following normal rulemaking procedures would have been impracticable. The decision to increase the size of the regulated area for safety purposes was not made with sufficient time remaining to publish proposed rules in advance of the event or to provide for delayed effective date.

Regulatory Evaluation

This revised rule is not a major significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. The Office of Management and Budget has exempted it from review under that order. It is not significant under the regulatory polices and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary. The revised regulations will only be in effective for approximately 4 hours on September 26, 1998.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this revised rule will have a significant economic impact on a substantial number of small entities. ''Small entities'' include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their field, and governmental jurisdictions with populations of less than 50,000.

Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this revised rule will not have a significant economic impact on a substantial number of small entities because the increase in the size of the regulated area is not significant, and it would be in effect for only 4 hours in a limited area outside Charleston harbor.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3051 *et seq.*)

Federalism

The Coast Guard has analyzed this action in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this revised rule, and has determined pursuant figure 2–1, paragraph #34(h) of Commandant Instruction M16475.1C, that this proposal is categorically excluded from further environmental documentation. A Categorical Exclusion Determination is available in the docket for inspection and copying.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

Temporary Regulations

In consideration of the foregoing, the Coast Guard amends Part 100 of Title 33, Code of Federal Regulations, as follows:

PART 100—[AMENDED]

1. The authority citation for Part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. Revise section 100.35T–07–008 to read as follows:

§ 100.35T–07–008 Around Alone 1998–99 Sailing Race; Charleston, SC.

(a) *Definitions:*

(1) *Regulated area.* The regulated area includes the waters off Charleston, SC, in an area bounded by eight points located at 32–42.112N, 79–48.008W; 32–41.711N, 79–47.329W; 32–41.676N, 79–46.730W; 32–41.169N, 79–45.737W; 32–40.033N, 79–46.709W; 32–40.619N, 79–47.671W; 32–41.091N, 79–47.867W; 32–41.554N, 79–48.591W. All coordinates reference Datum: NAD 83. Each of these eight points will be conspicuously marked with a marker.

(2) *Coast Guard Patrol Commander.* The Coast Guard Patrol Commander is a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Commander, Coast Guard Group Charleston, SC.

(b) *Special Local Regulations.* (1) Entry into the regulated area by other than event participants is prohibited, unless otherwise authorized by the Coast Guard Patrol Commander.

(2) The Coast Guard Patrol Commander may delay, modify, or cancel the race as conditions or circumstances require. The Coast Guard Patrol Commander shall monitor the start of the race with the race committee, to allow for a window of opportunity for the race participants to depart the harbor with minimal interference with inbound or outbound commercial traffic.

(3) Spectator and other non-participating vessels may only follow the participants out of Charleston

Harbor to the race starting area if they maintain a minimum distance of 500 yards behind the last participant, at the discretion of the Patrol Commander. Upon completion of the start of the race and when the last race participant has passed the outermost boundary of the regulated area, all vessels may resume normal operations.

(4) The regulations specified in this paragraph apply only within the navigable waters of the United States. In the waters within the regulated area that are outside the navigable waters of the United States, the following nonobligatory guidelines apply.

(i) All unaffiliated vessels should remain clear of the regulated area and avoid interfering with any Around Alone participant or Coast Guard vessel. Interference with participants or any race activity may constitute a safety hazard warranting cancellation or termination of all or part of the Around Alone activities by the Captain of the Port.

(ii) Any unauthorized entry into the zone by unaffiliated vessels constitutes a risk to the safety of marine traffic. Such entry will constitute a factor to be considered in determining whether a person has operated a vessel in a negligent manner in violation of 46 U.S.C. 2302.

(c) *Date.* This section becomes effective at 10 a.m. and terminates at 2 p.m. EDT on September 26, 1998.

Dated: September 10, 1998.

Norman T. Saunders,

Rear Admiral, U.S. Coast Guard Commander, Seventh Coast Guard District.

[FR Doc. 98–25161 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–15–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[TN–AT–98–01; FRL–6163–4]

New Stationary Sources; Supplemental Delegation of Authority to Tennessee and Nashville-Davidson, Tennessee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Delegation of Authority.

SUMMARY: The State of Tennessee and Nashville-Davidson County, Tennessee have requested that EPA delegate authority for implementation and enforcement of existing New Source Performance Standards (NSPS) which have been previously adopted by the State, but have remained undelegated by EPA, and to approve the mechanism for delegation (automatic) of future NSPS. The purpose of the agency requests for approval of their delegation mechanism is to streamline the existing administrative procedures by eliminating unnecessary steps involved in taking delegation of federal NSPS regulations. With the new NSPS delegation mechanism in place, once a new or revised NSPS is promulgated by EPA, delegation of authority from EPA to the Tennessee Department of Environment and Conservation and the Metropolitan Health Department of Nashville and Davidson County will become effective on the date the NSPS is promulgated. No further State or local requests for delegation will be necessary. Likewise, no further **Federal Register** notices will be published. The EPA's review of each of the agencies' pertinent laws, rules, and regulations indicate that adequate and effective procedures are in place for the implementation and enforcement of these Federal standards. This document was written to inform the public of delegations that were made to the above mentioned agencies for which a **Federal Register** notice was not previously written and to inform the public of the agencies' new mechanism for delegation of future NSPS.

EFFECTIVE DATE: The effective date is September 21, 1998.

ADDRESSES: Copies of the request for delegation of authority and EPA's letter of delegation are available for public inspection during normal business hours at the following locations:

Environmental Protection Agency, Region 4, Air & Radiation Technology Branch, 61 Forsyth Street, S.W., Atlanta, Georgia 30303

Tennessee Department of Environment and Conservation, Division of Air Pollution Control, 9th Floor L&C Annex, 401 Church Street, Nashville, Tennessee 37243–1531

Metropolitan Health Department of Nashville and Davidson County, Bureau of Environmental Health Services, 311—23rd Avenue, North, Nashville, Tennessee 37203,

Effective immediately, all requests, applications, reports and other correspondence required pursuant to the delegated standards should not be submitted to the Region 4 office, but should instead be submitted to the following addresses:

Tennessee Department of Environment and Conservation, Division of Air Pollution Control, 9th Floor L&C Annex, 401 Church Street, Nashville, Tennessee 37243–1531

Metropolitan Health Department of Nashville and Davidson County, Bureau of Environmental Health Services, 311—23rd Avenue, North, Nashville, Tennessee 37203.

FOR FURTHER INFORMATION CONTACT: Ms. Katy Forney, Air & Radiation Technology Branch, Environmental Protection Agency, Region 4, 61 Forsyth St. SW, Atlanta, Georgia 30303, 404–562–9130.

SUPPLEMENTARY INFORMATION: Section 301, in conjunction with Sections 110 and 111(c)(1) of the Clean Air Act as amended November 15, 1990, authorizes EPA to delegate authority to implement and enforce the standards set out in 40 CFR Part 60, New Source Performance Standards (NSPS).

On April 11, 1980, the EPA initially delegated the authority for implementation and enforcement of the NSPS program to the State of Tennessee and on May 25, 1977, the NSPS program was initially delegated to the Nashville-Davidson County local program. These agencies have subsequently requested a delegation of authority for implementation and enforcement of the previously adopted, undelegated Part 60 NSPS categories listed below as well as future NSPS categories codified in 40 CFR Part 60.

The State of Tennessee:

Currently, no NSPS regulations are waiting delegation.

Nashville-Davidson County, Tennessee:

Delegation Requested on October 24, 1996:

- 40 CFR part 60, Subpart Ea, as amended 12–19–95
- 40 CFR part 60, Subpart Eb, promulgated 12–19–95
- 40 CFR part 60, Subpart WWW, promulgated 3–12–96

Delegation Requested on October 6, 1997:

- 40 CFR part 60, Subpart Ec, promulgated 9–15–97

All current NSPS categories are delegated with the exception of the following sections within those subparts that may not be delegated. Future NSPS regulations will contain a list of sections that will not be delegated for that subpart.

1. Subpart A—§§ 60.8(b) (1) through (5), § 60.11(e) (7) and (8), § 60.13 (g), (i) and (j)(2)
2. Subpart B—§§ 60.22, § 60.27, and § 60.29
3. Subpart Da—§ 60.45a
4. Subpart Db—§ 60.44b(f), § 60.44b(g), § 60.49b(a)(4)
5. Subpart Dc—§ 60.48c(a)(4)
6. Subpart Ec—§ 60.56(c)(i)
7. Subpart J—§ 60.105(a)(13)(iii), § 60.106(i)(12)
8. Subpart Ka—§ 60.114a

9. Subpart Kb—§ 60.111b(f)(4), § 60.114b, § 60.116b(e)(3) (iii) and (iv), § 60.116b(f)(2)(iii)
10. Subpart O—§ 60.153(e)
11. Subpart EE—§ 60.316(d)
12. Subpart GG—§ 60.334(b)(2), § 60.335(f)(1)
13. Subpart RR—§ 60.446(c)
14. Subpart SS—§ 60.456(d)
15. Subpart TT—§ 60.466(d)
16. Subpart UU—§ 60.474(g)
17. Subpart VV—§ 60.482–1(c)(2) and § 60.484
18. Subpart WW—§ 60.496(c)
19. Subpart XX—§ 60.502(e)(6)
20. Subpart AAA—§ 60.533, § 60.534, § 60.535, § 60.536(i)(2), § 60.537, § 60.538(e), § 60.539
21. Subpart BBB—§ 60.543(c)(2)(ii)(B)
22. Subpart DDD—§ 60.562–2(c)
23. Subpart III—§ 60.613(e)
24. Subpart NNN—§ 60.663(e)
25. Subpart RRR—§ 60.703(e)
26. Subpart SSS—§ 60.711(a)(16), § 60.713(b)(1)(i), § 60.713(b)(1)(ii), § 60.713(b)(5)(i), § 60.713(d), § 60.715(a), § 60.716
27. Subpart TTT—§ 60.723(b)(1), § 60.723(b)(2)(i)(C), § 60.723(b)(2)(iv), § 60.724(e), § 60.725(b)
28. Subpart VVV—§ 60.743(a)(3)(v)(A) and (B), § 60.743(e), § 60.745(a), § 60.746

After a thorough review of the request, the Regional Administrator determined that such a delegation was appropriate for all source categories. All sources subject to the requirements of 40 CFR Part 60 will now be under the jurisdiction of the appropriate above mentioned agency.

Since review of the pertinent laws, rules, and regulations for the State and local agencies have shown them to be adequate for implementation and enforcement of existing, previously adopted, undelegated NSPS and future NSPS, EPA hereby notifies the public that it has delegated the authority for existing, previously adopted and undelegated NSPS as well as the mechanism for delegation (automatic) of future NSPS source categories upon publication of this **Federal Register** notice.

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule, as that term is defined in 5 U.S.C. 804(3).

Authority: This notice is issued under the authority of sections 101, 110, 111, 112 and 301 of the Clean Air Act, as amended (42 U.S.C. 7401, 7410, 7411, 7412 and 7601).

Dated: September 8, 1998.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 98–25202 Filed 9–18–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[FL–AT–98–01; FRL–6163–5]

New Stationary Sources; Supplemental Delegation of Authority to the State of Florida

AGENCY: Environmental Protection Agency (EPA).

ACTION: Delegation of Authority.

SUMMARY: The State of Florida has requested that EPA delegate authority for implementation and enforcement of existing New Source Performance Standards (NSPS) which have been previously adopted by the State, but have remained undelegated by EPA, and to approve the mechanism for delegation (adopt-by-reference) of future NSPS. The purpose of Florida's request for approval of their delegation mechanism is to streamline the existing administrative procedures by eliminating unnecessary steps involved in taking delegation of federal NSPS regulations. With the new NSPS delegation mechanism in place, once a new or revised NSPS is promulgated by EPA, formal delegation of authority from EPA to the Florida Department of Environmental Protection will become effective on the date that the NSPS is adopted by the State of Florida without change. No further State requests for delegation will be necessary. Likewise, no further **Federal Register** notices will be published. If an NSPS regulation is adopted with changes, EPA reserves the right to review and comment on the adopted NSPS. The State will notify EPA, and in return, EPA will review any State revisions and reserve the option to implement the NSPS regulation directly, in which case a **Federal Register** notice will advise accordingly. The EPA's review of Florida's pertinent laws, rules, and regulations indicates that adequate and effective procedures are in place for the implementation and enforcement of these Federal standards. This document was written to inform the public of delegations made to the State of Florida for which a **Federal Register** notice was not previously written and to inform the public of Florida's new mechanism for delegation of future NSPS.

EFFECTIVE DATE: The effective date is September 21, 1998.

ADDRESSES: Copies of the request for delegation of authority and EPA's letter of delegation are available for public inspection during normal business hours at the following locations:

Environmental Protection Agency, Region 4, Air & Radiation Technology Branch, 61 Forsyth Street, S.W., Atlanta, Georgia 30303

Florida Department of Environmental Protection, Division of Air Resources Management, 2600 Blair Stone Road, Tallahassee, Florida 32399–2400.

Effective immediately, all requests, applications, reports and other correspondence required pursuant to the delegated standards should not be submitted to the Region 4 office, but should instead be submitted to the following address: Florida Department of Environmental Protection, Division of Air Resources Management, 2600 Blair Stone Road, Tallahassee, Florida 32399–2400.

FOR FURTHER INFORMATION CONTACT: Ms. Katy Forney, Air & Radiation Technology Branch, Environmental Protection Agency, Region 4, 61 Forsyth St. SW, Atlanta, Georgia 30303, 404–562–9130.

SUPPLEMENTARY INFORMATION: Section 301, in conjunction with Sections 110 and 111(c)(1) of the Clean Air Act as amended November 15, 1990, authorizes EPA to delegate authority to implement and enforce the standards set out in 40 CFR Part 60, New Source Performance Standards (NSPS).

On June 10, 1982, the EPA initially delegated the authority for implementation and enforcement of the NSPS program to the State of Florida. The State of Florida subsequently requested a delegation of authority for implementation and enforcement of the previously adopted, undelegated Part 60 NSPS categories listed below as well as future NSPS categories codified in 40 CFR Part 60.

1. Subpart Eb, adopted June 5, 1996
2. Subpart VV, adopted June 5, 1996
3. Subpart NNN, adopted June 5, 1996
4. Subpart QQQ, adopted June 5, 1996
5. Subpart RRR, adopted June 5, 1996
6. Subpart A, adopted October 7, 1996
7. Subpart Dc, adopted October 7, 1996
8. Subpart J, adopted October 7, 1996
9. Subpart VV, adopted October 7, 1996
10. Subpart WWW, adopted October 17, 1996
11. Subpart A, adopted February 24, 1997
12. Subpart X, adopted October 23, 1997
13. Subpart OOO, adopted October 23, 1997
14. Subpart Eb, adopted March 2, 1998
15. Subpart Ec, adopted March 2, 1998

All current NSPS categories are delegated with the exception of the

following sections within those subparts that may not be delegated. Future NSPS regulations will contain a list of sections that will not be delegated for that subpart.

1. Subpart A—§ 60.8(b) (1) thru (5), § 60.11(e) (7) and (8), § 60.13 (g), (i) and (j)(2)
2. Subpart B—§ 60.22, § 60.27, and § 60.29
3. Subpart Da—§ 60.45a
4. Subpart Db—§ 60.44b(f), § 60.44b(g), § 60.49b(a)(4)
5. Subpart Dc—§ 60.48c(a)(4)
6. Subpart Ec—§ 60.56(c)(i)
7. Subpart J—§ 60.105(a)(13)(iii), § 60.106(i)(12)
8. Subpart Ka—§ 60.114a
9. Subpart Kb—§ 60.111b(f)(4), § 60.114b, § 60.116b(e)(3) (iii) and (iv), § 60.116b(f)(2)(iii)
10. Subpart O—§ 60.153(e)
11. Subpart EE—§ 60.316(d)
12. Subpart GG—§ 60.334(b)(2), § 60.335(f)(1)
13. Subpart RR—§ 60.446(c)
14. Subpart SS—§ 60.456(d)
15. Subpart TT—§ 60.466(d)
16. Subpart UU—§ 60.474(g)
17. Subpart VV—§ 60.482–1(c)(2) and § 60.484
18. Subpart WW—§ 60.496(c)
19. Subpart XX—§ 60.502(e)(6)
20. Subpart AAA—§ 60.533, § 60.534, § 60.535, § 60.536(i)(2), § 60.537, § 60.538(e), § 60.539
21. Subpart BBB—§ 60.543(c)(2)(ii)(B)
22. Subpart DDD—§ 60.562–2(c)
23. Subpart III—§ 60.613(e)
24. Subpart NNN—§ 60.663(e)
25. Subpart RRR—§ 60.703(e)
26. Subpart SSS—§ 60.711(a)(16), § 60.713(b)(1)(i), § 60.713(b)(1)(ii), § 60.713(b)(5)(i), § 60.713(d), § 60.715(a), § 60.716
27. Subpart TTT—§ 60.723(b)(1), § 60.723(b)(2)(i)(C), § 60.723(b)(2)(iv), § 60.724(e), § 60.725(b)
28. Subpart VVV—§ 60.743(a)(3)(v)(A) and (B), § 60.743(e), § 60.745(a), § 60.746

After a thorough review of the request, the Regional Administrator has determined that such a delegation request was appropriate for all source categories. All sources subject to the requirements of 40 CFR Part 60 will now be under the jurisdiction of the State of Florida.

Since review of the pertinent laws, rules, and regulations for the State agency has shown them to be adequate for implementation and enforcement of existing, previously adopted, undelegated NSPS and future NSPS, EPA hereby notifies the public that it has delegated the authority for existing, previously adopted and undelegated NSPS as well as the mechanism for delegation of future NSPS source categories upon publication of this **Federal Register** notice.

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule, as that term is defined in 5 U.S.C. 804(3).

Authority: This notice is issued under the authority of sections 101, 110, 111, 112 and 301 of the Clean Air Act, as Amended (42 U.S.C. 7401, 7410, 7411, 7412 and 7601).

Dated: September 8, 1998.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 98–25203 Filed 9–18–98; 8:45 am]

BILLING CODE 6560–50–P

NATIONAL SCIENCE FOUNDATION

45 CFR Part 670

RIN 3145–AA34

Conservation of Antarctic Animals and Plants

AGENCY: National Science Foundation (NSF).

ACTION: Final rule.

SUMMARY: NSF is issuing a final rule that amends its existing regulations for the conservation and protection of Antarctic animals and plants. These revisions implement amendments to the Antarctic Conservation Act of 1978 contained in the Antarctic Science Tourism and Conservation Act of 1996.

EFFECTIVE DATE: November 5, 1998.

FOR FURTHER INFORMATION CONTACT: Anita Eisenstadt, Office of the General Counsel, at 703–306–1060.

SUPPLEMENTARY INFORMATION: On June 2, 1998, the National Science Foundation (NSF) published a proposed rule to revise its existing regulations for the conservation and protection of Antarctic animals and plants and invited public comment on the rule. (63 FR 29963). The only public comment concerned a typographical error in the **Federal Register** notice.

Since the proposed rule was published, the Antarctic Treaty Parties adopted a measure to establish three additional specially protected areas. At the 22nd Antarctic Treaty Consultative Meeting (ATCM) held in Tromso, Norway from May 25, 1998 to June 5, 1998, the Parties adopted Measure 1 (1998) which added as specially protected areas the historic sites at Cape Royds, Hut Point, and Cape Adare. Accordingly, the final rule has been revised to incorporate these three new specially protected areas. No public comment is needed because the addition of these three sites merely implements measures adopted at the ATCM.

Determinations

NSF has determined, under the criteria set forth in Executive Order 12866, that this rule is not a significant regulatory action requiring review by the Office of Information and Regulatory Affairs. As required by the Regulatory Flexibility Act, it is hereby certified that this rule will not have a significant impact on a substantial number of small businesses. For purposes of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the permit application and reporting collection of information requirements have been approved by the Office of Management and Budget (OMB No. 3145–0034). Finally, NSF has reviewed this rule in light of section 2 of Executive Order 12778 and I certify for the National Science Foundation that this rule meets the applicable standards provided in sections 2(a) and 2(b) of that order.

List of Subjects in 45 CFR Part 670

Administrative practice and procedure, Antarctica, Exports, Imports, Reporting and recordkeeping requirements, Wildlife.

Dated: September 9, 1998

Lawrence Rudolph,

General Counsel, National Science Foundation.

For the reasons set forth in the preamble, the National Science Foundation hereby revises 45 CFR part 670 to read as follows:

PART 670—CONSERVATION OF ANTARCTIC ANIMALS AND PLANTS

Subpart A—Introduction

Sec.

Subpart B—Prohibited Acts, Exceptions

Subpart C—Permits

Authority: 16 U.S.C. 2405, as amended.

Subpart A—Introduction

§ 670.1 Purpose of regulations.

The purpose of the regulations in this part is to conserve and protect the native mammals, birds, plants, and invertebrates of Antarctica and the ecosystem upon which they depend and to implement the Antarctic Conservation Act of 1978, Public Law 95–541, as amended by the Antarctic Science, Tourism, and Conservation Act of 1996, Public Law 104–227.

§ 670.2 Scope.

The regulations in this part apply to:

(a) Taking mammals, birds, or plants native to Antarctica.

(b) Engaging in harmful interference of mammals, birds, invertebrates, or plants native to Antarctica.

(c) Entering or engaging in activities within Antarctic Specially Protected Areas.

(d) Receiving, acquiring, transporting, offering for sale, selling, purchasing, importing, exporting or having custody, control, or possession of any mammal, bird, or plant native to Antarctica that was taken in violation of the Act.

(e) Introducing into Antarctica any member of a non-native species.

§ 670.3 Definitions.

In this part:

Act means the Antarctic Conservation Act of 1978, Public Law 95–541 (16 U.S.C. 2401 *et seq.*) as amended by the Antarctic Science, Tourism, and Conservation Act of 1996, Public Law 104–227.

Antarctic Specially Protected Area means an area designated by the Antarctic Treaty Parties to protect outstanding environmental, scientific, historic, aesthetic, or wilderness values or to protect ongoing or planned scientific research, designated in subpart F of this part.

Antarctica means the area south of 60 degrees south latitude.

Director means the Director of the National Science Foundation, or an officer or employee of the Foundation designated by the Director.

Harmful interference means—

(a) Flying or landing helicopters or other aircraft in a manner that disturbs concentrations of birds or seals;

(b) Using vehicles or vessels, including hovercraft and small boats, in a manner that disturbs concentrations of birds or seals;

(c) Using explosives or firearms in a manner that disturbs concentrations of birds or seals;

(d) Willfully disturbing breeding or molting birds or concentrations of birds or seals by persons on foot;

(e) Significantly damaging concentrations of native terrestrial plants by landing aircraft, driving vehicles, or walking on them, or by other means; and

(f) Any activity that results in the significant adverse modification of habitats of any species or population of native mammal, native bird, native plant, or native invertebrate.

Import means to land on, bring into, or introduce into, or attempt to land on, bring into or introduce into, any place subject to the jurisdiction of the United States, including the 12-mile territorial sea of the United States, whether or not such act constitutes an importation within the meaning of the customs laws of the United States.

Management plan means a plan to manage the activities and protect the special value or values in an Antarctic Specially Protected Area designated by the United States as such a site consistent with plans adopted by the Antarctic Treaty Consultative Parties.

Native bird means any member, at any stage of its life cycle, of any species of the class Aves which is indigenous to Antarctica or occurs there seasonally through natural migrations, that is designated in subpart D of this part. It includes any part, product, egg, or offspring of or the dead body or parts thereof excluding fossils.

Native invertebrate means any terrestrial or freshwater invertebrate, at any stage of its life cycle, which is indigenous to Antarctica. It includes any part thereof, but excludes fossils.

Native mammal means any member, at any stage of its life cycle, of any species of the class Mammalia, which is indigenous to Antarctica or occurs there seasonally through natural migrations, that is designated in subpart D of this part. It includes any part, product, offspring of or the dead body or parts thereof but excludes fossils.

Native plant means any terrestrial or freshwater vegetation, including bryophytes, lichens, fungi, and algae, at any stage of its life cycle which is indigenous to Antarctica that is designated in subpart D of this part. It includes seeds and other propagules, or parts of such vegetation, but excludes fossils.

Person has the meaning given that term in section 1 of title 1, United States Code, and includes any person subject to the jurisdiction of the United States and any department, agency, or other instrumentality of the Federal Government or of any State or local government.

Protocol means the Protocol on Environmental Protection to the Antarctic Treaty, signed October 4, 1991, in Madrid, and all annexes thereto, including any future amendments to which the United States is a Party.

Specially Protected Species means any native species designated as a Specially Protected Species that is designated in subpart E of this part.

Take or taking means to kill, injure, capture, handle, or molest a native mammal or bird, or to remove or damage such quantities of native plants that their local distribution or abundance would be significantly affected or to attempt to engage in such conduct.

Treaty means the Antarctic Treaty signed in Washington, D.C. on December 1, 1959.

United States means the several states of the Union, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, the Virgin Islands, Guam, the Commonwealth of the

Northern Mariana Islands, and other commonwealth, territory, or possession of the United States.

Subpart B—Prohibited Acts, Exceptions

§ 670.4 Prohibited acts.

Unless a permit has been issued pursuant to subpart C of this part or unless one of the exceptions stated in §§ 670.5 through 670.9 is applicable, it is unlawful to commit, attempt to commit, or cause to be committed any of the acts described in paragraphs (a) through (g) of this section.

(a) *Taking of native mammal, bird or plants.* It is unlawful for any person to take within Antarctica a native mammal, a native bird, or native plants.

(b) *Engaging in harmful interference.* It is unlawful for any person to engage in harmful interference in Antarctica of native mammals, native birds, native plants or native invertebrates.

(c) *Entry into Antarctic specially designated areas.* It is unlawful for any person to enter or engage in activities within any Antarctic Specially Protected Area.

(d) *Possession, sale, export, and import of native mammals, birds, and plants.* It is unlawful for any person to receive, acquire, transport, offer for sale, sell, purchase, export, import, or have custody, control, or possession of, any native bird, native mammal, or native plant which the person knows, or in the exercise of due care should have known, was taken in violation of the Act.

(e) *Introduction of non-indigenous animals and plants into Antarctica.* It is unlawful for any person to introduce into Antarctica any animal or plant which is not indigenous to Antarctica or which does not occur there seasonally through natural migrations, as specified in subpart H of this part, except as provided in §§ 670.7 and 670.8.

(f) *Violations of regulations.* It is unlawful for any person to violate the regulations set forth in this part.

(g) *Violation of permit conditions.* It is unlawful for any person to violate any term or condition of any permit issued under subpart C of this part.

§ 670.5 Exception in extraordinary circumstances.

(a) *Emergency exception.* No act described in § 670.4 shall be unlawful if the person committing the act reasonably believed that the act was committed under emergency circumstances involving the safety of human life or of ships, aircraft, or equipment or facilities of high value, or the protection of the environment.

(b) *Aiding or salvaging native mammals or native birds.* The prohibition on taking shall not apply to any taking of native mammals or native birds if such action is necessary to:

(1) Aid a sick, injured or orphaned specimen;

(2) Dispose of a dead specimen; or

(3) Salvage a dead specimen which may be useful for scientific study.

(c) *Reporting.* Any actions taken under the exceptions in this section shall be reported promptly to the Director.

§ 670.6 Prior possession exception.

(a) *Exception.* Section 670.4 shall not apply to:

(1) any native mammal, bird, or plant which is held in captivity on or before October 28, 1978; or

(2) Any offspring of such mammal, bird, or plant.

(b) *Presumption.* With respect to any prohibited act set forth in § 670.4 which occurs after April 29, 1979, the Act creates a rebuttable presumption that the native mammal, native bird, or native plant involved in such act was not held in captivity on or before October 28, 1978, or was not an offspring referred to in paragraph (a) of this section.

§ 670.7 Food exception.

Paragraph (e) of § 670.4 shall not apply to the introduction of animals and plants into Antarctica for use as food as long as animals and plants used for this purpose are kept under carefully controlled conditions. This exception shall not apply to living species of animals. Unconsumed poultry or its parts shall be removed from Antarctica unless incinerated, autoclaved or otherwise sterilized.

§ 670.8 Foreign permit exception.

Paragraphs (d) and (e) of § 670.4 shall not apply to transporting, carrying, receiving, or possessing native mammals, native plants, or native birds or to the introduction of non-indigenous animals and plants when conducted by an agency of the United States Government on behalf of a foreign national operating under a permit issued by a foreign government to give effect to the Protocol.

§ 670.9 Antarctic Conservation Act enforcement exception.

Paragraphs (a) through (d) of § 670.4 shall not apply to acts carried out by an Antarctic Conservation Act Enforcement Officer (designated pursuant to 45 CFR 672.3) if undertaken as part of the Antarctic Conservation Act Enforcement Officer's official duties.

§ 670.10 [Reserved]

Subpart C—Permits

§ 670.11 Applications for permits.

(a) *General content of permit applications.* All applications for a permit shall be dated and signed by the applicant and shall contain the following information:

(1) The name and address of the applicant;

(i) Where the applicant is an individual, the business or institutional affiliation of the applicant must be included; or

(ii) Where the applicant is a corporation, firm, partnership, or institution, or agency, either private or public, the name and address of its president or principal officer must be included.

(2) Where the applicant seeks to engage in a taking,

(i) The scientific names, numbers, and description of native mammals, native birds or native plants to be taken; and

(ii) Whether the native mammals, birds, or plants, or part of them are to be imported into the United States, and if so, their ultimate disposition.

(3) Where the applicant seeks to engage in a harmful interference, the scientific names, numbers, and description of native birds or native seals to be disturbed; the scientific names, numbers, and description of native plants to be damaged; or the scientific names, numbers, and description of native invertebrates, native mammals, native plants, or native birds whose habitat will be adversely modified;

(4) A complete description of the location, time period, and manner in which the taking or harmful interference would be conducted, including the proposed access to the location;

(5) Where the application is for the introduction of non-indigenous plants or animals, the scientific name and the number to be introduced;

(6) Whether agents as referred to in § 670.13 will be used; and

(7) The desired effective dates of the permit.

(b) *Content of specific permit applications.* In addition to the general information required for permit applications set forth in this subpart, the applicant must submit additional information relating to the specific action for which the permit is being sought. These additional requirements are set forth in the sections of this part dealing with the subject matter of the permit applications as follows:

Native Mammals, Birds, Plants, and Invertebrates—Section 670.17

Specially Protected Species—Section 670.23
Specially Protected Areas—Section 670.27
Import and Export—Section 670.31
Introduction of Non-Indigenous Plants and Animals—Section 670.36

(c) *Certification.* Applications for permits shall include the following certification:

I certify that the information submitted in this application for a permit is complete and accurate to the best of my knowledge and belief. Any false statement will subject me to the criminal penalties of 18 U.S.C. 1001.

(d) *Address to which applications should be sent.* Each application shall be in writing, addressed to:

Permit Officer, Office of Polar Programs, National Science Foundation, Room 755, 4201 Wilson Boulevard, Arlington, Virginia 22230.

(e) *Sufficiency of application.* The sufficiency of the application shall be determined by the Director. The Director may waive any requirement for information, or request additional information as determined to be relevant to the processing of the application.

(f) *Withdrawal.* An applicant may withdraw an application at any time.

(g) *Publication of permit applications.* The Director shall publish notice in the **Federal Register** of each application for a permit. The notice shall invite the submission by interested parties, within 30 days after the date of publication of the notice, of written data, comments, or views with respect to the application. Information received by the Director as a part of any application shall be available to the public as a matter of public record.

§ 670.12 General issuance criteria.

Upon receipt of a complete and properly executed application for a permit and the expiration of the applicable public comment period, the Director will decide whether to issue the permit. In making the decision, the Director will consider, in addition to the specific criteria set forth in the appropriate subparts of this part:

(a) Whether the authorization requested meets the objectives of the Act and the requirements of the regulations in this part;

(b) The judgment of persons having expertise in matters germane to the application; and

(c) Whether the applicant has failed to disclose material information required or has made false statements about any material fact in connection with the application.

§ 670.13 Permit administration.

(a) *Issuance of the permits.* The Director may approve any application in whole or part. Permits shall be issued in writing and signed by the Director. Each permit may contain such terms and conditions as are consistent with the Act and this part.

(b) *Denial.* The applicant shall be notified in writing of the denial of any permit request or part of a request and of the reason for such denial. If authorized in the notice of denial, the applicant may submit further information or reasons why the permit should not be denied. Such further submissions shall not be considered a new application.

(c) *Amendment of applications or permits.* An applicant or permit holder desiring to have any term or condition of his application or permit modified must submit full justification and supporting information in conformance with the provisions of this subpart and the subpart governing the activities sought to be carried out under the modified permit. Any application for modification of a permit that involves a material change beyond the terms originally requested will normally be subject to the same procedures as a new application.

(d) *Notice of issuance or denial.* Within 10 days after the date of the issuance or denial of a permit, the Director shall publish notice of the issuance or denial in the **Federal Register**.

(e) *Agents of the permit holder.* The Director may authorize the permit holder to designate agents to act on behalf of the permit holder.

(f) *Marine mammals, endangered species, and migratory birds.* If the Director receives a permit application involving any native mammal which is a marine mammal as defined by the Marine Mammal Protection Act of 1972 (16 U.S.C. 1362(5)), any species which is an endangered or threatened species under the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*) or any native bird which is protected under the Migratory Bird Treaty Act (16 U.S.C. 701 *et seq.*), the Director shall submit a copy of the application to the Secretary of Commerce or to the Secretary of the Interior, as appropriate. If the appropriate Secretary determines that a permit should not be issued pursuant to any of the cited acts, the Director shall not issue a permit. The Director shall inform the applicant of any denial by the appropriate Secretary and no further action shall be taken on the application. If, however, the appropriate Secretary issues a permit pursuant to the requirements of the cited acts, the Director still must determine whether the proposed action is consistent with the Act and the regulations in this part.

§ 670.14 Conditions of permits.

(a) *Possession of permits.* Permits issued under the regulations in this part, or copies of them, must be in the possession of persons to whom they are issued and their agents when conducting the authorized action.

(b) *Display of permits.* Any permit issued shall be displayed for inspection upon request to the Director, designated agents of the Director, or any person with enforcement responsibilities.

(c) *Filing of reports.* Permit holders are required to file reports of the activities conducted under a permit. Reports shall be submitted to the Director not later than June 30 for the preceding 12 months.

§ 670.15 Modification, suspension, and revocation.

(a) The Director may modify, suspend, or revoke, in whole or in part, any permit issued under this subpart:

(1) In order to make the permit consistent with any change to any regulation in this part made after the date of issuance of this permit;

(2) If there is any change in conditions which make the permit inconsistent with the purpose of the Act and the regulations in this part; or

(3) In any case in which there has been any violation of any term or condition of the permit, any regulation in this part, or any provision of the Act.

(b) Whenever the Director proposes any modifications, suspension, or revocation of a permit under this section, the permittee shall be afforded opportunity, after due notice, for a hearing by the Director with respect to such proposed modification, suspension or revocation. If a hearing is requested, the action proposed by the Director shall not take effect before a decision is issued by him after the hearing, unless the proposed action is taken by the Director to meet an emergency situation.

(c) Notice of the modification, suspension, or revocation of any permit by the Director shall be published in the **Federal Register**, within 10 days from the date of the Director's decision.

§ 670.16 [Reserved]

Subpart D—Native Mammals, Birds, Plants, and Invertebrates

§ 670.17 Specific issuance criteria.

With the exception of specially protected species of mammals, birds, and plants designated in subpart E of this part, permits to engage in a taking or harmful interference:

(a) May be issued only for the purpose of providing—

(1) Specimens for scientific study or scientific information; or

(2) Specimens for museums, zoological gardens, or other educational or cultural institutions or uses; or

(3) For unavoidable consequences of scientific activities or the construction and operation of scientific support facilities; and

(b) Shall ensure, as far as possible, that—

(1) No more native mammals, birds, or plants are taken than are necessary to meet the purposes set forth in paragraph (a) of this section;

(2) No more native mammals or native birds are taken in any year than can normally be replaced by net natural reproduction in the following breeding season;

(3) The variety of species and the balance of the natural ecological systems within Antarctica are maintained; and

(4) The authorized taking, transporting, carrying, or shipping of any native mammal or bird is carried out in a humane manner.

§ 670.18 Content of permit applications.

In addition to the information required in subpart C of this part, an applicant seeking a permit to take a native mammal or native bird shall include a complete description of the project including the purpose of the proposed taking, the use to be made of the native mammals or native birds, and the ultimate disposition of the native mammals and birds. An applicant seeking a permit to engage in a harmful interference shall include a complete description of the project including the purpose of the activity which will result in the harmful interference. Sufficient information must be provided to establish that the taking, harmful interference, transporting, carrying, or shipping of a native mammal or bird shall be humane.

§ 670.19 Designation of native mammals.

The following are designated native mammals:

Pinnipeds:
- Crabeater seal—*Lobodon carcinophagus.*
- Leopard seal—*Hydrurga leptonyx.*
- Ross seal—*Ommatophoca rossi.*[1]
- Southern elephant seal—*Mirounga leonina.*
- Southern fur seals—*Arctocephalus spp.*[1]
- Weddell seal—Leptonychotes weddelli.

Large Cetaceans (Whales):
- Blue whale—*Balaenoptera musculus.*
- Fin whale—*Balaenoptera physalus.*
- Humpback whale—*Megaptera novaeangliae.*
- Minke whale—*Balaenoptera acutrostrata.*
- Pygmy blue whale—*Balaenoptera musculus brevicauda*
- Sei whale—*Balaenoptera borealis*
- Southern right whale—*Balaena glacialis australis*
- Sperm whale—*Physeter macrocephalus*

Small Cetaceans (Dolphins and porpoises):
- Arnoux's beaked whale—*Berardius arnuxii.*
- Commerson's dolphin—*Cephalorhynchus commersonii*
- Dusky dolphin—*Lagenorhynchus obscurus*
- Hourglass dolphin—*Lagenorhynchus cruciger*
- Killer whale—*Orcinus orca*
- Long-finned pilot whale—*Globicephala melaena*
- Southern bottlenose whale—*Hyperoodon planifrons.*
- Southern right whale dolphin—*Lissodelphis peronii*
- Spectacled porpoise—*Phocoena dioptrica*

[1] These species of mammals have been designated as specially protected species and are subject to subpart E of this part.

§ 670.20 Designation of native birds.

The following are designated native birds:

Albatross:
- Black-browed—*Diomedea melanophris.*
- Gray-head—*Diomedea chrysostoma.*
- Light-mantled sooty—*Phoebetria palpebrata.*
- Wandering—*Diomedea exulans.*

Fulmer:
- Northern Giant—*Macronectes halli.*
- Southern—*Fulmarus glacialoides.*
- Southern Giant—*Macronectes giganteus.*

Gull:
- Southern Black-backed—*Larus dominicanus.*

Jaeger:
- Parasitic—*Stercorarius parasiticus.*
- Pomarine—*Stercorarius pomarius.*

Penguin:
- Adelie—*Pygoscelis adeliae.*
- Chinstrap—*Pygoscelis antarctica.*
- Emperor—*Aptenodytes forsteri.*
- Gentoo—*Pygoscelis papua.*
- King—*Aptenodytes patagonicus.*
- Macaroni—*Eudyptes chrysolophus.*
- Rockhopper—*Eudyptes crestatus.*

Petrel:
- Antarctic—*Thalassoica antarctica.*
- Black-bellied Storm—*Fregatta tropica.*
- Blue-*Halobaena caerulea.*
- Gray—*Procellaria cinerea.*
- Great-winged—*Pterodroma macroptera.*
- Kerguelen—*Pterodroma macroptera.*
- Kerguelen—*Pterodroma brevirostris.*
- Mottled—*Pterodroma inexpectata.*
- Snow—*Pagodroma nivea.*
- Soft-plumaged—*Pterodroma mollis.*
- South-Georgia Diving—*Pelecanoides georgicus.*
- White-bellied Storm—*Fregetta grallaria.*
- White-chinned—*Procellaria aequinoctialis.*
- White-headed—*Pterodroma lessonia.*
- Wilson's Storm—*Oceanites oceanicus.*

Pigeon:
- Cape—*Daption capense.*

Pintail:
- South American Yellow-billed—*Anas georgica spinicauda.*

Prion:
- Antarctic—*Pachyptila desolata.*
- Narrow-billed—*Pachyptila belcheri.*

Shag:
- Blue-eyed—*Phalacrocorax atriceps.*

Shearwater:
- Sooty—*Puffinus griseus.*

Skua:
- Brown—*Catharacta lonnbergi*
- South Polar—*Catharacta maccormicki.*

Swallow:
- Barn—*Hirundo rustica.*

Sheathbill:
- American—*Chionis alba.*

Tern:
- Antarctic—*Sterna vittata.*
- Arctic—*Sterna paradisaea.*

§ 670.21 Designation of native plants.

All plants whose normal range is limited to, or includes Antarctica are designated native plants, including:

Bryophytes

Freshwater algae

Fungi

Lichens

Marine algae

Vascular Plants

§ 670.22 [Reserved]

Subpart E—Specially Protected Species of Mammals, Birds and Plants

§ 670.23 Specific issuance criteria.

Permits authorizing the taking of mammals, birds, or plants designated as a Specially Protected Species of mammals, birds, and plants in § 670.25 may only be issued if:

(a) There is a compelling scientific purpose for such taking;

(b) The actions allowed under any such permit will not jeopardize the existing natural ecological system, or the survival of the affected species or population;

(c) The taking involves non-lethal techniques, where appropriate; and

(d) The authorized taking, transporting, carrying or shipping will be carried out in a humane manner.

§ 670.24 Content of permit applications.

In addition to the information required in subpart C of this part, an applicant seeking a permit to take a Specially Protected Species shall include the following in the application:

(a) A detailed scientific justification of the need for taking the Specially Protected Species, including a discussion of possible alternative species;

(b) Information demonstrating that the proposed action will not jeopardize the existing natural ecological system or the survival of the affected species or population; and

(c) Information establishing that the taking, transporting, carrying, or shipping of any native bird or native mammal will be carried out in a humane manner.

§ 670.25 Designation of specially protected species of native mammals, birds and plants.

The following two species have been designated as Specially Protected Species by the Antarctic Treaty Parties and are hereby designated Specially Protected Species:

Common Name and Scientific Name
Kerguelen Fur Seal—*Arctocephalus tropicales gazella.*
Ross Seal—*Ommatophoca rossi.*

§ 670.26 [Reserved].

Subpart F—Antartic Specially Protected Areas

§ 670.27 Specific issuance criteria.

Permits authorizing entry into any Antarctic Specially Protected Area designated in § 670.29 may only be issued if:

(a) The entry and activities to be engaged in are consistent with an approved management plan, or

(b) A management plan relating to the area has not been approved by the Antarctic Treaty Parties, but

(1) There is a compelling scientific purpose for such entry which cannot be served elsewhere, and

(2) The actions allowed under the permit will not jeopardize the natural ecological system existing in such area.

§ 670.28 Content of permit application.

In addition to the information required in subpart C of this part, an applicant seeking a permit to enter an Antarctic Specially Protected Area shall include the following in the application:

(a) A detailed justification of the need for such entry, including a discussion of alternatives;

(b) Information demonstrating that the proposed action will not jeopardize the unique natural ecological system in that area; and

(c) Where a management plan exists, information demonstrating the consistency of the proposed actions with the management plan.

§ 670.29 Designation of Antarctic specially protected areas.

The following areas have been designated by the Antarctic Treaty Parties for special protection and are hereby designated as Antarctic Specially Protected Areas. Detailed maps and descriptions of the sites and complete management plans can be obtained from the National Science Foundation, Office of Polar Programs, National Science Foundation, Room 755, 4201 Wilson Boulevard, Arlington, Virginia 22230.

ASPA 101, Taylor Rookery, MacRobertson Land.
ASPA 102, Rookery Islands, Holme Bay.
ASPA 103, Ardrey Island and Odbert Island, Budd Coast.
ASPA 104, Sabrina Island, Balleny Islands.
ASPA 105, Beaufort Island, Ross Sea.
ASPA 106, Cape Hallett, Victoria Land.
ASPA 107, Dion Islands, Marguerite Bay, Antarctic Peninsula.
ASPA 108, Green Island, Berthelot Islands, Antarctic Peninsula.
ASPA 109, Moe Island, South Orkney Islands.
ASPA 110, Lynch Island, South Orkney Islands.
ASPA 111, Southern Powell Island and adjacent islands, South Orkney Islands.
ASPA 112, Coppermine Peninsula, Robert Island.
ASPA 113, Litchfield Island, Arthur Harbor, Palmer Archipelago.
ASPA 114, North Coronation Island, South Orkney Islands.
ASPA 115, Lagotellerie Island, Marguerite Bay.
ASPA 116, 'New College Valley', Caughley Beach, Cape Bird, Ross Island.
ASPA 117, Avian Island, Northwest Marguerite Bay.
ASPA 118, Cryptogam Ridge, Mount Melbourne, Victoria Land.
ASPA 119, Forlidas Pond and Davis Valley Ponds.
ASPA 120, Pointe-Geologie Archipelago
ASPA 121, Cape Royds, Ross Island.
ASPA 122, Arrival Heights, Hut Point Peninsula, Ross Island.
ASPA 123, Barwick Valley, Victoria Land.
ASPA 124, Cape Crozier, Ross Island.
ASPA 125, Fildes Peninsula, King George Island, South Shetland Islands.
ASPA 126, Byers Peninsula, Livingston Island, South Shetland Islands.
ASPA 127, Haswell Island.
ASPA 128, Western Shore of Admiralty Bay, King George Island.
ASPA 129, Rothera Point, Adelaide Island.
ASPA 130, Tramway Ridge, Mt. Erebus, Ross Island.
ASPA 131, Canada Glacier, Lake Fryxell, Taylor Valley, Victoria Land.
ASPA 132, Potter Peninsula, King George Island, South Shetland Islands.
ASPA 133, Harmony Point.
ASPA 134, Cierva Point and nearby islands, Danco Coast, Antarctic Peninsula.
ASPA 135, Bailey Peninsula, Budd Coast, Wilkes Land.
ASPA 136, Clark Peninsula, Budd Coast, Wilkes Land.
ASPA 137, Northwest White Island, McMurdo Sound.
ASPA 138, Linnaeus Terrace, Asgard Range, Victoria Land.
ASPA 139, Biscoe Point, Anvers Island, Palmer Archipelago.
ASPA 140, Shores of Port Foster, Deception Island, South Shetland Islands.
ASPA 141, Yukidori Valley, Langhovde, Lutzow-Holm Bay.
ASPA 142, Svarthamaren Mountain, Muhlig-Hofmann Mountains, Queen Maud Land.
ASPA 143, Marine Plain, Mule Peninsula, Vestfold Hills, Princess Elizabeth Land.
ASPA 144, Chile Bay (Discovery Bay), Greenwich Island, South Shetland Islands.
ASPA 145, Port Foster, Deception Island, South Shetland Islands.
ASPA 146, South Bay, Doumer Island, Palmer Archipelago.
ASPA 147, Ablation Point-Ganymede Heights, Alexander Island.
ASPA 148, Mount Flora, Hope Bay, Antarctic Peninsula.
ASPA 149, Cape Shirreff, Livingston Island, South Shetland Islands.
ASPA 150, Ardley Island, Maxwell Bay, King George Island, South Shetland Islands.
ASPA 151, Lions Rump, King George Island, South Shetland Islands.
ASPA 152, Western Bransfield Strait, off Low Island, South Shetland Islands.
ASPA 153, East Dallmann Bay, off Brabant Island.
ASPA 154, Cape Evans Historic Site.
ASPA 155, Lewis Bay Tomb.
ASPA 156, Hut and associated artifacts, Backdoor Bay, Cape Royds, Ross Island.
ASPA 157, Discovery Hut, Hut Point, Ross Island.
ASPA 158, Huts and associated artifacts, Cape Adare.

§ 670.30 [Reserved].

Subpart G—Import into and Export From the United States

§ 670.31 Specific issuance criteria for imports.

Subject to compliance with other applicable law, any person who takes a native mammal, bird, or plant under a permit issued under the regulations in this part may import it into the United States unless the Director finds that the importation would not further the purpose for which it was taken. If the importation is for a purpose other than that for which the native mammal, bird, or plant was taken, the Director may permit importation upon a finding that importation would be consistent with the purposes of the Act, the regulations in this part, or the permit under which they were taken.

§ 670.32 Specific issuance criteria for exports.

The Director may permit export from the United States of any native mammal, bird, or native plants taken within Antarctica upon a finding that exportation would be consistent with the purposes of the Act, the regulations in this part, or the permit under which they were taken.

§ 670.33 Content of permit applications.

In addition to the information required in subpart C of this part, an applicant seeking a permit to import into or export from the United States a native mammal, a native bird, or native plants taken within Antarctica shall include the following in the application:

(a) Information demonstrating that the import or export would further the purposes for which the species was taken;

(b) Information demonstrating that the import or export is consistent with the purposes of the Act or the regulations in this part;

(c) A statement as to which U.S. port will be used for the import or export, and

(d) Information describing the intended ultimate disposition of the imported or exported item.

§ 670.34 Entry and exit ports.

(a) Any native mammal, native bird, or native plants taken within Antarctica that are imported into or exported from the United States must enter or leave the United States at ports designated by the Secretary of Interior in 50 CFR part 14. The ports currently designated are:

(1) Los Angeles, California.
(2) San Francisco, California.
(3) Miami, Florida.
(4) Honolulu, Hawaii.
(5) Chicago, Illinois.
(6) New Orleans, Louisiana.
(7) New York, New York.
(8) Seattle, Washington.
(9) Dallas/Fort Worth, Texas.
(10) Portland, Oregon.
(11) Baltimore, Maryland.
(12) Boston, Massachusetts.
(13) Atlanta, Georgia.

(b) Permits to import or export at non-designated ports may be sought from the Secretary of Interior pursuant to subpart C, 50 CFR part 14.

§ 670.35 [Reserved].

Subpart H—Introduction of Non-Indigenous Plants and Animals

§ 670.36 Specific issuance criteria.

For purposes consistent with the Act, only the following plants and animals may be considered for a permit allowing their introduction into Antarctica:

(a) Domestic plants; and

(b) Laboratory animals and plants including viruses, bacteria, yeasts, and fungi.

Living non-indigenous species of birds shall not be introduced into Antarctica.

§ 670.37 Content of permit applications.

Applications for the introduction of plants and animals into Antarctica must describe:

(a) The species, numbers, and if appropriate, the age and sex, of the animals or plants to be introduced into Antarctica;

(b) The need for the plants or animals;

(c) What precautions the applicant will take to prevent escape or contact with native fauna and flora; and

(d) How the plants or animals will be removed from Antarctica or destroyed after they have served their purpose.

§ 670.38 Conditions of permits.

All permits allowing the introduction of non-indigenous plants and animals will require that the animal or plant be kept under controlled conditions to prevent its escape or contact with native fauna and flora and that after serving its purpose the plant or animal shall be removed from Antarctica or be destroyed in manner that protects the natural system of Antarctica.

§ 670.39 [Reserved].

[FR Doc. 98–24993 Filed 9–18–98; 8:45 am]
BILLING CODE 7555–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

RIN 1018–AE93

Migratory Bird Hunting; Early Seasons and Bag and Possession Limits for Certain Migratory Game Birds in the Contiguous United States, Alaska, Hawaii, Puerto Rico, and the Virgin Islands; Correction

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule; correction.

SUMMARY: The U.S. Fish and Wildlife Service published a document in the **Federal Register** of August 31, 1998, prescribing the hunting seasons, hours, areas, and daily bag and possession limits of mourning, white-winged, and white-tipped doves; band-tailed pigeons; rails; moorhens and gallinules; woodcock; common snipe; sandhill cranes; sea ducks; early (September) waterfowl seasons; migratory game birds in Alaska, Hawaii, Puerto Rico, and the Virgin Islands; and some extended falconry seasons. The document contained incorrect information concerning the date of the youth waterfowl hunting day in Nebraska.

DATES: This rule is effective on September 1, 1998.

FOR FURTHER INFORMATION CONTACT: Robert J. Blohm, Acting Chief, Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, (703) 358–1838.

SUPPLEMENTARY INFORMATION: In the **Federal Register** issue of August 31, 1998 (63 FR 46336), on page 46350, in the second column, the entry for Nebraska's Youth Waterfowl Hunting Day is corrected to read September 19.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

Dated: September 14, 1998.

Donald Barry,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 98–25118 Filed 9–18–98; 8:45 am]
BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 971208297–8054–02; I.D. 091598B]

Fisheries of the Exclusive Economic Zone Off Alaska; Pollock in Statistical Area 630 of the Gulf of Alaska

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

ACTION: Closure.

SUMMARY: NMFS is prohibiting directed fishing for pollock in Statistical Area 630 of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 1998 total allowable catch (TAC) of pollock in this area.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), September 16, 1998, until 2400 hrs, A.l.t., December 31, 1998.

FOR FURTHER INFORMATION CONTACT: Thomas Pearson, 907–486-6919.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

In accordance with § 679.20(c)(3)(ii), the Final 1998 Harvest Specifications of Groundfish for the GOA (63 FR 12027, March 12, 1998) established the amount of the 1998 TAC of pollock in Statistical Area 630 of the GOA as 39,315 metric tons (mt).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 1998 TAC for pollock will be reached. Therefore, the Regional Administrator is establishing a

directed fishing allowance of 38,815 mt, and is setting aside the remaining 500 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for pollock in Statistical Area 630 of the GOA.

Maximum retainable bycatch amounts for applicable gear types may be found in the regulations at § 679.20(e) and (f).

Classification

This action responds to the best available information recently obtained from the fishery. It must be implemented immediately to prevent overharvesting the 1998 TAC of pollock for Statistical Area 630 of the GOA. A delay in the effective date is impracticable and contrary to the public interest. Further delay would only result in overharvest. NMFS finds for good cause that the implementation of this action should not be delayed for 30 days. Accordingly, under 5 U.S.C. 553(d), a delay in the effective date is hereby waived.

This action is required by 50 CFR 679.20 and is exempt from review under E.O. 12866.

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

Dated: September 16, 1998.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 98–25167 Filed 9–16–98; 4:03 pm]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 63, No. 182
Monday, September 21, 1998

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1150

[DA–98–05]

Dairy Promotion and Research Order; Invitation to Submit Comments on Proposed Amendment to the Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This document invites written comments on a proposal to amend the Dairy Promotion and Research Order (Order). A proposed amendment, requested by the National Dairy Promotion and Research Board (Board), which administers the Order, would modify the number of members from geographic regions in accordance with the provisions of the Order in order to best reflect the geographic distribution of milk production volume in the United States.

DATES: Comments are due no later than October 5, 1998.

ADDRESSES: Comments (two copies) should be filed with the USDA/AMS/Dairy Programs, Promotion and Research Branch, 1400 Independence Avenue, SW, Stop 0233, Room 2734 South Building, Washington, DC 20250–0233. Comments, which should reference the docket number and the date and page number of the issue of the **Federal Register**, will be made available for public inspection in Room 2734 South Building during regular business hours.

FOR FURTHER INFORMATION CONTACT: David R. Jamison, Chief, USDA/AMS/Dairy Programs, Promotion and Research Branch, 1400 Independence Avenue, S.W., Stop 0233, Room 2734 South Building, Washington, DC 20250–0233, (202) 720–6909, E-Mail address: David__Jamison@usda.gov.

SUPPLEMENTARY INFORMATION: The Department is issuing this proposed rule in conformance with Executive Order 12866.

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

The Dairy and Tobacco Adjustment Act of 1983 (7 USC 4501—4513) (Act), as amended, authorizes the Order. The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 118 of the Act, any person subject to the Order may file with the Secretary a petition stating that the Order, any provision of the Order, or any obligation imposed in connection with the Order is not in accordance with the law and request a modification of the Order or to be exempted from the Order. A person subject to an order is afforded the opportunity for a hearing on the petition. After a hearing, the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the person is an inhabitant, or has his principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided a complaint is filed not later than 20 days after the date of the entry of the ruling.

In accordance with the Paperwork Reduction Act (44 U.S.C. Chapter 35), the forms and reporting and recordkeeping requirements that are included in the Order have been approved previously by the Office of Management and Budget (OMB) and were assigned OMB No. 0581–0093, except for Board members' nominee background information sheets that were assigned OMB No. 0505–0001.

Statement of Consideration

The Order specified in § 1150.131(c) that the Board shall review the geographic distribution of milk production volume throughout the United States and, if warranted, shall recommend to the Secretary a reapportionment of the regions and/or modification of the number of members from regions in order to best reflect the geographic distribution of milk production volume in the United States. Section 1150.131(d) of the Order specifies the formula to be used to determine the number of Board seats to represent each of the 13 geographic regions of the country designated in the Order. Under the formula, total milk production for the 48 States for the previous calendar year is divided by 36 to determine a factor of pounds of milk represented by each Board member. The resulting factor is then divided into the pounds of milk produced in each region to determine the number of Board members for each region. The initial Board that was established in 1984 was based on 1983 milk production. The Board was last modified in 1994 based on the 1992 milk production. In 1983, each Board member represented about 3,875 million pounds of the 139,509 million pounds of milk produced in the 48 States. During 1997, total milk production increased to 156,464 million pounds which indicated that each of the Board members would represent 4,346 million pounds of milk.

Based on a review of the 1997 geographic distribution of milk production, the Board has concluded that the number of Board members for four of the 13 geographic regions should be changed. Milk production in Region 2 (California) increased to 27,628 million pounds in 1997 up from 22,084 million pounds in 1992, indicating 6.36 Board members based on 1997 production (27,628 divided by 4,346 = 6.36) compared to 5.24 Board members based on 1992 production (22,084 divided by 4,211 = 5.24). Also, milk production in Region 3 (Arizona, Colorado, Idaho, Montana, Nevada, Utah, and Wyoming) increased to 11,929 million pounds in 1997 up from 8,470 in 1992, indicating 2.74 Board members based on 1997 production (11,929 divided by 4,346 = 2.74) compared to 2.01 Board members based on 1992 production (8,470 divided by 4,211 = 2.01). Milk production in Region 6 (Wisconsin) decreased to 22,368 million pounds in 1997 from 24,103 million pounds in 1992, indicating 5.15 Board members based on 1997 production (22,368 divided by 4,346 = 5.15) compared to 5.72 Board members based on 1992 production (24,103 divided by 4,211 = 5.72). Also, milk production in Region 7 (Illinois, Iowa, Missouri, and Nebraska) decreased to 9,699 million pounds from 11,168 million pounds in 1992, indicating 2.23 Board members based on 1997 production (9,699 divided by 4,346 = 2.23) compared to 2.65 Board

members based on 1992 production (11,168 divided by 4,211 = 2.65). Thus, the Board proposed that the number of Board members from Region 2 be increased from five to six, that the number of Board members from Region 3 be increased from two to three, that the number of Board members from Region 6 be decreased from six to five, and that the number of Board members from Region 7 be decreased from three to two so that the Board will best reflect the geographic distribution of milk production volume throughout the United States.

A 14-day comment period is provide for interested persons to comment on this proposed rule. Terms of the existing Board members expire October 31, 1998. To be able to appoint new Board members based on the redistribution, the 14-day comment period is appropriate.

Small Business Consideration

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires the Agency to examine the impact of a proposed rule on small entities. Small businesses in the dairy industry have been defined by the Small Business Administration as those employing less than 500 employees. There are approximately 99,413 dairy farmers subject to the provisions of the Order. Most of the parties subject to the Order are considered small entities.

Changes are proposed to a provision of the Order (7 CFR Part 1150). This change is to the number of members representing four geographic regions on the Board to reflect the volume of milk produced within the specified regions. The Order is authorized under the Act, as amended (7 USC 4501–4513).

Currently, the Order provides for a 36-member board with members representing 13 geographic regions. Section 1150.131(c) states that the Board is required at least every five years, and not more than every three years, to review the geographic distribution of milk production volume throughout the United States and if necessary recommend modification of regional representation. The last modification was made in 1994. Section 1150.131(d) of the Order specifies the formula to be used to determine the number of Board seats to represent each of the 13 geographic regions of the country designated in the Order. Under the formula, total milk production for the 48 States for the previous calendar year is divided by 36 to determine a factor of pounds of milk represented by each Board member. The resulting factor is then divided into the pounds of milk produced in each region to determine the number of Board members for each region. The initial Board that was established in 1984 was based on 1983 milk production. The Board was last modified in 1994 based on the 1992 milk production. In 1983, each Board member represented about 3,875 million pounds of the 139,509 million pounds of milk produced in the 48 States. During 1997, total milk production increased to 156,464 million pounds which indicated that each of the Board members would represent 4,346 million pounds of milk.

Based on a review of the 1997 geographic distribution of milk production, the Board has concluded that the number of Board members for four of the 13 geographic regions should be changed. Milk production in Region 2 (California) increased to 27,628 million pounds in 1997 up from 22,084 million pounds in 1992, indicating 6.36 Board members based on 1997 production (27,628 divided by 4,346 = 6.36) compared to 5.24 Board members based on 1992 production (22,084 divided by 4,211 = 5.24). Also, milk production in Region 3 (Arizona, Colorado, Idaho, Montana, Nevada, Utah, and Wyoming) increased to 11,929 million pounds in 1997 up from 8,470 in 1992, indicating 2.74 Board members based on 1997 production (11,929 divided by 4,346 = 2.74) compared to 2.01 Board members based on 1992 production (8,470 divided by 4,211 = 2.01). Milk production in Region 6 (Wisconsin) decreased to 22,368 million pounds in 1997 from 24,103 million pounds in 1992, indicating 5.15 Board members based on 1997 production (22,368 divided by 4,346 = 5.15) compared to 5.72 Board members based on 1992 production (24,103 divided by 4,211 = 5.72). Also, milk production in Region 7 (Illinois, Iowa, Missouri, and Nebraska) decreased to 9,699 million pounds from 11,168 million pounds in 1992, indicating 2.23 Board members based on 1997 production (9,699 divided by 4,346 = 2.23) compared to 2.65 Board members based on 1992 production (11,168 divided by 4,211 = 2.65). Thus, the Board proposed that the number of Board members from Region 2 be increased from five to six, that the number of Board members from Region 3 be increased from two to three, that the number of Board members from Region 6 be decreased from six to five, and that the number of Board members from Region 7 be decreased from three to two so that the Board will best reflect the geographic distribution of milk production volume throughout the United States.

This amendment to the Order will not add any burden to regulated parties because they relate to provisions concerning membership of the Board. The proposed change would not impose additional reporting or collecting requirements. No relevant Federal rules have been identified that duplicate, overlap, or conflict with the rule.

Accordingly, pursuant to 5 U.S.C. 605(b), the Agricultural Marketing Service has certified that this rule would not have a significant economic impact on a substantial number of small entities.

List of Subjects in 7 CFR Part 1150

Dairy Products, Reporting and Recordkeeping Requirements, Research.

For the reasons set forth in the preamble, it is proposed that 7 CFR part 1150 be amended as follows:

PART 1150—NATIONAL DAIRY PROMOTION AND RESEARCH PROGRAM

1. The authority citation for 7 CFR Part 1150 continues to read as follows:

Authority: 7 U.S.C. 4501–4513.

2. In § 1150.131, paragraphs (a)(2), (a)(3), (a)(6), and (a)(7) are revised to read as follows:

§ 1150.131 Establishment and membership.

(a) * * *

(2) Six members from region number two comprised of the following State: California.

(3) Three members from region number three comprised of the following States: Arizona, Colorado, Idaho, Montana, Nevada, Utah, and Wyoming.

* * * * *

(6) Five members from region number six comprised of the following State: Wisconsin.

(7) Two members from region number seven comprised of the following States: Illinois, Iowa, Missouri, and Nebraska.

* * * * *

Dated: September 16, 1998.

Enrique E. Figueroa,

Administrator, Agricultural Marketing Service.

[FR Doc. 98–25212 Filed 9–18–98; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–CE–152–AD]

RIN 2120–AA64

Airworthiness Directives; The New Piper Aircraft, Inc. Models PA–31, PA–31–300, PA–31–325, PA–31–350, and PA–31P–350 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to supersede Airworthiness Directive (AD) 81–15–04 R1, which applies to certain The New Piper Aircraft, Inc. (Piper) Models PA–31, PA–31–300, PA–31–325, PA–31–350, and PA–31P–350 airplanes and currently requires repetitively inspecting for cracks at the elevator outboard hinge attachment on the horizontal stabilizer rear spar, and if cracks are found, incorporating a spar and hinge bracket assembly kit. The proposed action would require repetitively inspecting the horizontal rear spar in the area of the outboard hinge attachment and the outboard hinge attach bracket for cracks. When cracks are found or at a certain accumulation of time-in-service (TIS), the proposed AD would require modifying the horizontal stabilizer spar by incorporating an improved stabilizer spar and hinge bracket assembly kit that would terminate the repetitive inspections. The proposed AD is prompted by several field reports of cracks found during routine inspections on airplanes already in compliance with AD 81–15–04 R1. The actions specified by the proposed AD are intended to prevent failure of the horizontal stabilizer rear spar caused by cracks at the elevator outboard hinge attachment, which could result in loss of control of the airplane.

DATES: Comments must be received on or before November 20, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 97–CE–152–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 New Piper Aircraft, Inc., Customer Services, 2926 Piper Drive, Vero Beach, Florida 32960. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. William Herderich, Aerospace Engineer, FAA, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; telephone: (770) 703-6084; facsimile: (770) 703–6097.

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. 97-CE–152-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 Regional Counsel, Attention: Rules Docket No. 97–CE–152–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

Airworthiness Directive (AD) 81–15–04 R1, Amendment 39–4200, currently requires repetitively inspecting certain Piper Model PA–31, PA–31–300, PA–31-325, PA–31–350, and PA–31P–350 airplanes for cracks in the horizontal stabilizer rear spar and the outboard hinge attach bracket and, if cracks are found, incorporating Piper Stabilizer Rear Spar Modification and Outboard Hinge Replacement Kit.

Actions Since Issuance of Previous Rule

Since the issuance of AD 81–15–04 R1, the FAA has received several reports of cracks developing in the horizontal stabilizer rear spar and the elevator outboard hinge attach brackets on airplanes that are in compliance with this AD. The results of the investigation of these reports show that the onset of cracks is believed to be caused by improper fit of the hinge assembly in the spar channel and the method of attaching the hinge bracket assembly to the rear spar.

Based on this new information, the manufacturer elected to redesign the hinge bracket assembly and change the method of attaching the hinge bracket assembly to the rear spar. This new design and change in the attaching method should alleviate any further need for inspecting the rear spar and hinge bracket assembly.

Relevant Service Information

Piper has issued Service Bulletin (SB) No. 1007, dated September 30, 1997, which specifies procedures for repetitively inspecting for cracks in the elevator outboard hinge bracket and the horizontal stabilizer rear spar. If cracks are found, the service information also specifies following the instructions provided in Piper Kit No. 766–646 which is referenced in Piper SB No. 1007, dated September 30, 1997, which provides procedures for modifying the rear spar and elevator outboard hinge attachment by incorporating Piper Kit No. 766–646.

The FAA's Determination

After examining the circumstances and reviewing all available information related to the incidents described above, the FAA has determined that AD action should be taken to prevent failure of the horizontal stabilizer rear spar caused by cracks at the elevator outboard hinge attachment, which could result in loss of control of the airplane.

Explanation of the Provisions of the Proposed AD

Since an unsafe condition has been identified that is likely to exist or develop in other Piper Models PA–31, PA–31–300, PA–31–325, PA–31–350, and PA–31P–350 airplanes of the same type design, the proposed AD would supersede AD 81–15–04 R1 with a new AD that would require:

- Inspecting the horizontal stabilizer rear spar at the outboard hinge

attachment and outboard hinge attach bracket for cracks,

• If no cracks are found, the proposed AD would require repetitively inspecting this area until cracks are found, and

• If cracks are found or upon the accumulation of 500 hours TIS, whichever occurs first, the proposed AD would require modifying the horizontal stabilizer rear spar by incorporating Piper Kit No. 766–646.

The incorporation of this kit would terminate the currently required repetitive inspections. Accomplishment of the proposed modification would be in accordance with the Instructions in Piper Kit No. 766–646 which is referenced in Piper Service Bulletin No. 1007, dated September 30, 1997.

Differences Between the Service Information and the Proposed AD

The compliance time specified in the Piper Service Bulletin No. 1007, dated September 30, 1997, is different than the compliance time in the proposed AD. The FAA is not using the 50 hours time-in-service (TIS) as the initial and repetitive inspection times, as specified in the service bulletin. Fifty hours TIS or less is normally reserved for urgent safety of flight conditions. The proposed AD is not considered an urgent safety of flight condition, it is superseding an action that already requires repetitive inspections. Based on engineering judgment and the service history received from the field, the FAA is proposing the initial and repetitive inspection time be increased to 100 hours TIS in order to allow operators a reasonable amount of time to accomplish the proposed action.

Cost Impact

The FAA estimates that 1,739 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 11 workhours to per airplane to accomplish the proposed actions, and that the average labor rate is approximately $60 an hour. Parts cost approximately $478 per airplane. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $1,978,982, or $1,138 per airplane. This cost estimate does not take into account the number of repetitive inspections that may be incurred over the life of the airplane. These figures are based on the presumption that no owner/operator of the affected aircraft has accomplished this replacement.

Regulatory Impact

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

For the reasons discussed above, I certify that this 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 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Airworthiness Directive 81–15–04 R1, Amendment 39–4200, and by adding a new AD to read as follows:

The New Piper Aircraft, Inc.: Docket No. 97–CE–152–AD; Supersedes AD 81–15–04 R1, Amendment 39–4200.

Applicability: The following airplane models and serial numbers, certificated in any category:

Models	Serial Nos.
PA–31, PA–31–300, and PA–31–325.	31–2 through 31–8312019
PA–31–350	31–5001 through 31–8553002
PA–31P–350	31P–8414001 through 31P–8414050

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

Compliance: As indicated in the body of this AD, unless already accomplished.

To prevent failure of the horizontal stabilizer rear spar caused by cracks at the elevator outboard hinge attachment, which could result in loss of control of the airplane:

(a) Within the next 100 hours time-in-service (TIS) after the effective date of this AD, inspect the horizontal stabilizer rear spar in the area of the outboard hinge attachment and the outboard hinge attach bracket for cracks in accordance with the INSTRUCTIONS section of Piper Service Bulletin (SB) No. 1007, dated September 30, 1997.

(b) If cracks are found, prior to further flight, modify the horizontal stabilizer rear spar by incorporating Piper Kit No. 766–646 in accordance with the INSTRUCTIONS contained in Piper Kit No. 766–646 which is referenced in Piper SB No. 1007, dated September 30, 1997.

(c) If no cracks are found, continue to inspect in accordance with paragraph (a) of this AD at intervals not to exceed 100 hours TIS. Upon the accumulation of 500 hours TIS after the effective date of this AD or when cracks are found, whichever occurs first, modify the horizontal stabilizer rear spar by incorporating Piper Kit No. 766–646 which is referenced in Piper SB No. 1007, dated September 30, 1997.

(d) Modifying the affected airplane by incorporating Piper Kit No. 766–646 is considered a terminating action to the inspections required in paragraphs (a) and (c) of this AD.

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

(f) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349.

(1) The request shall be forwarded through an appropriate FAA Maintenance Inspector,

who may add comments and then send it to the Manager, Atlanta ACO.

(2) Alternative methods of compliance approved in accordance with AD 81–15–04 R1, are not considered approved as alternative methods of compliance for this AD.

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

(g) All persons affected by this directive may obtain copies of the documents referred to herein upon request to The New Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, Florida 32960; or may examine this document at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

(h) This amendment supersedes AD 81–15–04 R1, Amendment 39–4200.

Issued in Kansas City, Missouri, on September 14, 1998.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–25127 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement (OSM)

30 CFR Part 920

[MD–045–FOR]

Maryland Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement. DOI.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: OSM is announcing the receipt of a proposed amendment to the Maryland Regulatory Program (hereinafter referred to as the Maryland Program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA), 30 U.S.C. 1201 *et seq.*, as amended. This proposed amendment provides that administrative review and award of costs decisions formerly appealed to the Board of Review will now be reviewed in accordance with State Government Article, § 10–215, Annotated Code of Maryland. The amendment is intended to revise the Maryland program to be consistent with the corresponding Federal regulations.

DATES: Written comments must be received by 4:00 p.m., E.D.T., October 21, 1998. If requested, a public hearing on the proposed amendment will be held on October 16, 1998. Requests to speak at the hearing must be received by 4:00 p.m., E.D.T., on October 6, 1998.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to George Rieger, Manager, at the address listed below.

Copies of the Maryland program, the proposed amendment, a listing of any scheduled public hearings, 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 contracting OSM's Appalachian Regional Coordinating Center.

George Rieger, Manager, Pittsburgh Oversight and Inspection Office, OSM, Appalachian Regional Coordinating Center, 3 Parkway Center, Pittsburgh, PA 15220, Telephone: (412) 937–2153, Maryland Bureau of Mines, 160 South Water Street, Frostburg, Maryland 21532, Telephone: (301) 689–4136.

FOR FURTHER INFORMATION CONTACT: George Rieger, Manager, Appalachian Regional Coordinating Center, at (412) 937–2153.

SUPPLEMENTARY INFORMATION:

I. Background on the Maryland Program

On December 1, 1980, the Secretary of the Interior conditionally approved the Maryland program. Background information on the Maryland program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the December 1, 1980, **Federal Register** (45 FR 79449). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 920.12, 920.15, and 920.16.

II. Description of the Proposed Amendment

By letter dated August 25, 1998, (Administrative Record No. MD–580–00), the Maryland Department of the Environment (MDDOE) submitted the proposed amendment to its program. This proposal supersedes an existing proposed amendment Maryland submitted on May 7, 1991, to satisfy the requirements of 30 CFR 920.16(a). The 1991 proposed amendment resulted in a final rule published in the **Federal Register** on January 10, 1992, (57 FR 1104) approving the revisions. The final rule indicated that 30 CFR 920.16(a) was removed and reserved. However, Maryland did not promulgate the revisions approved by OSM. Since that time, the Bureau of Mines has been transferred from the Department of Natural Resources to the Department of the Environment and the Code of Maryland Regulations (COMAR) has been recodified. The Board of Review was abolished in 1990 and the right to appeal administrative review and award of costs decisions is now authorized by § 10–215 of the State Government Article.

The provisions of COMAR that Maryland proposed to amend are as follows:

1. COMAR 26.20.34.06 Procedure after Testimony is Concluded.

In Section G. Maryland proposes to delete the phrase, ''may appeal the decision to the Board of Review pursuant to COMAR 08.16.01'' and replace it with the phrase, ''is entitled to judicial review in accordance with State Government Article, § 10–215, Annotated Code of Maryland.''

2. COMAR 26.20.34.09 Award of Costs.

In Section G. Maryland proposes to delete the phrase, ''may appeal to the Board of Review pursuant to COMAR 08.16.01'' and replaces it with the phrase, ''is entitled to judicial review in accordance with State Government Article, § 10–215, Annotated Code of Maryland.''

3. COMAR 26.20.06.02 Administrative Appeal.

This section has been deleted.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is now seeking comment on whether the amendment proposed by Maryland satisfies the applicable requirements for the approval of State program amendments. If the amendment is deemed adequate, it will become part of the Maryland program.

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 Appalachian Regional Coordinating Center will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by close of business on October 6, 1998. If no one requests an opportunity to comment at a 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 comment have been heard. Persons in the audience who have not been scheduled to comment and who wish to do so will be heard following those scheduled. The hearing will end after all persons who desire to comment have been heard.

Public Meeting

If only one person requests an opportunity to comment 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

Executive Order 12866

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

Executive Order 12988

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, 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 of SMCRA (30 U.S.C. 1253 and 1255) and 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.

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)).

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.*).

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 which is the subject of this rule is based upon corresponding 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 in the analyses for the corresponding Federal regulations.

Unfunded Mandates

This rule will not impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 938

Intergovernmental relations, Surface mining, Underground mining.

Dated: September 10, 1998.

Allen D, Klein,

Regional Director, Appalachian Regional Coordinating Center.

[FR Doc. 98–25117 Filed 9–18–98; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 934

[ND–038–FOR, Amendment NO. XXVII]

North Dakota Regulatory Program

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

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: Office of Surface Mining Reclamation and Enforcement (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 the addition of the: definition of water supply, and revision of existing rules on: rulemaking notices, consolidation of information in permits, water management design plans, annual maps, wildlife monitoring reports, subsoil removal approvals, soil respreading requirements, sedimentation pond performance standards, and noncoal waste disposal. In addition to the above, the U.S. Office of Surface Mining is proposing to: remove the program requirement at 30 CFR 934.16(n) concerning the submission of specific fish and wildlife resource information.

The amendment is intended to revise the North Dakota program to be consistent with the corresponding Federal regulations and incorporate the additional flexibility afforded by the revised Federal regulations and provide additional safeguards, and clarify ambiguities, and improve operational efficiency.

DATES: Written comments must be received by 4:00 p.m., m.d.t. October 21, 1998. If requested, a public hearing on the proposed amendment will be held on October 16, 1998. Requests to present oral testimony at the hearing must be received by 4:00 p.m., m.d.t. on October 6, 1998.

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 East ''B'' Street, Federal Building, Room 2128, Casper, Wyoming 82601–1918, Telephone: 307/261–6550

Jim Deutsch, Director, Reclamation Division, North Dakota Public Service Commission, Capitol Building, 600 E. Boulevard Ave., Bismarck, North Dakota 58505–0480, Telephone: 701/328–2251

FOR FURTHER INFORMATION CONTACT: Guy Padgett, Telephone: 307/261–6550; Internet: GPadgett@OSMRE.GOV

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 conditions of approval of the North Dakota program can be found in the December 15, 1980 **Federal Register** (45 FR 82214). Subsequent actions concerning North Dakota's program and program amendments can be found at 30 CFR 934.15 and 934.16.

II. Proposed Amendment

By letter dated September 2, 1998, North Dakota submitted a proposed amendment to its program pursuant to SMCRA (Amendment number XXVII, administrative record No. ND–BB–01, 30 U.S.C. 1201 *et seq.*). North Dakota submitted the proposed amendment in response to a July 17, 1997 letter (administrative record No. ND–BB–02) that OSM sent to North Dakota in accordance with 30 CFR 732.17(c), and in response to the required program amendments at 30 CFR 934.16(cc) and at its own initiative. The provisions of the North Dakota Administrative Code (NDAC) that North Dakota proposed to revise and add were: (1) NDAC 69–05.2–01–02.90, Replacement of water supply; (2) NDAC 69–05.2–01–03, publication of hearing notices; (3) NDAC 69.05.2–05–09, Permit Applications—Consolidation for multiple permit operations; (4) NDAC 69–05.2–09–09, Permit applications—Operation plans—Surface water management—Ponds, impoundments, banks, dams, embankments, and diversions; (5) NDAC 69–05.2–13–02, Performance standards—General requirements—Annual map; (6) NDAC 69–05.2–13–08, Performance standards—General requirements Protection of fish, wildlife, and related environmental values; (7) NDAC 69–05.2–15–02, Performance standards—Suitable plant growth material—Removal; (8) NDAC 69–05.2–15–04, Performance standards—Suitable plant growth material—Redistribution; (9) NDAC 69–05.2–16–09, Performance standards—Hydrologic balance—Sedimentation ponds; and (10) NDAC 69–05.2–19–04, Performance standards—Waste materials—Disposal of noncoal wastes. In addition, the U.S. Office of Surface Mining is proposing to remove the program requirement at 30 CFR 934.16(n) which would have revised NDAC 69–05.2–08–15(3)(a), to require the submission of site-specific fish and wildlife resource information when the permit or adjacent areas are likely to include species listed or proposed to be listed by North Dakota under State statutes similar to the Endangered Species Act.

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. on October 6, 1998. 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 requested 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 12988

The Department of the Interior had conducted the reviews required by section 3 of Executive Order 12988 (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 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 State 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 date and assumptions for the counterpart Federal regulations.

6. Unfunded Mandates

This rule will not impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 934

Intergovernmental relations, Surface mining, Underground mining.

Dated: September 10, 1998.

Richard J. Seibel,

Regional Director, Western Regional Coordinating Center.

[FR Doc. 98–25116 Filed 9–18–98; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07–98–041]

RIN 2115–AE46

Special Local Regulations; Hillsborough Bay, Tampa, FL

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: Permanent Special Local Regulations are being proposed for the Gasparilla Marine Parade on Hillsborough Bay in Tampa, Florida. This event will be held annually on the first Saturday in February between 10 a.m. and 1:30 p.m. Eastern Standard Time (EST). These regulations are needed to provide for the safety of life on navigable waters during the event.

DATES: Comments must be received on or before November 20, 1998.

ADDRESSES: Comments may be mailed to Commander Coast Guard Group St. Petersburg, 600 8th Avenue SE, St. Petersburg, FL 33701, or may be delivered to the above address between 7:30 a.m. and 4 p.m. Monday through Friday, except Federal holidays. Comments will become part of this docket and will be available for inspection or copying at the above address.

FOR FURTHER INFORMATION CONTACT: LTJG Brian Hill, (305) 536–4250, or Assistant Operations Officer, Coast Guard Group St. Petersburg, FL, (813) 824–7533.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking [CGD07–98–041] and the specific section of this proposal to which each comment applies and give the reason for each comment.

The Coast Guard shall consider all comments received during the comment period. It may change this proposal in view of the comments. The Coast Guard plans no public hearing. Persons may request a public hearing by writing to Assistant Operations Officer, Coast Guard Group Saint Petersburg at the address under **ADDRESSES**. The request should include the reasons why a hearing would be beneficial. If the Coast Guard determines that the opportunity for oral presentations will aid this rulemaking, it will hold a public hearing at a time and place announced by a notice in the **Federal Register**.

Background and Purpose

These regulations are needed to provide for the safety of life, to protect vessels participating in the parade, and to protect marine mammals during the Gasparilla Marine Parade. There will be approximately 750 participants, afloat and ashore, participating in the marine parade. Also, 200–400 spectator craft are expected. The resulting congestion of navigable channels creates an extra or unusual hazard in the navigable waters.

The regulated area will prohibit commercial vessels, jet skis, and vessels without propulsion from entering Hillsborough Bay during the parade, and will establish an idle speed no wake zone inside the regulated area.

Regulatory Evaluation

This proposal is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of the order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This regulation will only be in effect for approximately four hours in a limited area.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this proposed rule, if adopted, will have a significant economic impact on a substantial number of small entities. ''Small entities'' include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their field, and governmental jurisdictions with populations of less than 50,000.

Therefore, the Coast Guard certifies under section 605(b) that this proposed rule, if adopted will not have a significant effect upon a substantial number of small entities as these regulations will be in effect in a limited area for five hours only one day each year. If, however, you think that your business or organization qualifies as a small entity and that this proposed rule will have a significant economic impact on your business or organization, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and in what way and to what degree this proposed rule will economically affect your business.

Collection of Information

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

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the rulemaking does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this proposal and has determined pursuant to Figure 2–1, paragraph 34(h) of Commandant Instruction M16475.1C, that this action is categorically excluded from further environmental documentation. A Categorical Exclusion Determination document will be completed during the comment period.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

Proposed Regulations: In consideration of the foregoing, the Coast Guard proposes to amend Part 100 of Title 33, Code of Federal Regulations as follows:

PART 100—[Amended]

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. A new § 100.734 is added to read as follows:

§ 100.734 Annual Gasparilla Marine Parade; Hillsborough Bay, Tampa, FL.

(a) *Regulated Area.* A regulated area is established consisting of all waters of Hillsborough Bay and its tributaries north of a line drawn along latitude 27° 51′30″ N. The regulated area includes the following in their entirety: Hillsborough Cut ''D'' Channel, Sparkman Channel, Ybor Channel and the Hillsborough River south of the John F. Kennedy Bridge. Coordinates Reference Datum: NAD 1983.

(b) *Special Local Regulations.* (1) Entry into the regulated area is prohibited to all commercial marine traffic from 9 a.m. to 2:30 p.m. EST on the first Saturday in February.

(2) The regulated area is an idle speed, ''no wake'' zone.

(3) All vessels within the regulated area shall stay clear of and give way to all vessels in parade formation in the Gasparilla Marine Parade.

(4) When within the marked channels of the parade route, vessels participating in the Gasparilla Marine Parade may not exceed the minimum speed necessary to maintain steerage.

(5) Jet skis and vessels without mechanical propulsion are prohibited from the parade route.

(6) Northbound vessels in excess of 80 feet in length without mooring arrangements made prior to the first Saturday in February, are prohibited from entering Seddon Channel unless the vessel is officially entered in the Gasparilla Marine Parade. All northbound vessels in excess of 80 feet without prior mooring arrangements not officially entered in the Gasparilla Marine Parade, must use the alternate route through Sparkman Channel.

(c) *Dates.* This section becomes effective annually at 9 a.m. and terminate at 2:30 p.m. EST on the first Saturday in February.

Dated: July 9, 1998.

R.C. Olsen, Jr.,

Acting Captain U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 98–25162 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–15–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NH004–01–5814; A–1–FRL–6163–2]

Approval and Promulgation of Air Quality Implementation Plans; New Hampshire; Gasoline Dispensing Facilities and Gasoline Tank Trucks

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of New Hampshire on November 24, 1992. This revision consists of regulations to control volatile organic compound (VOC) emissions from gasoline dispensing facilities and from gasoline tank trucks. The intended effect of this action is to propose approval of these regulations. This action is being taken under the Clean Air Act.

DATES: Comments must be received on or before October 21, 1998. Public comments on this document are requested and will be considered before taking final action on this SIP revision.

ADDRESSES: Comments may be mailed to Susan Studlien, Deputy Director, Office of Ecosystem Protection, U.S. Environmental Protection Agency, Region I, JFK Federal Bldg., Boston, MA 02203. Copies of the State submittal and EPA's technical support document are available for public inspection during normal business hours, by appointment at the Office of Ecosystem Protection, U.S. Environmental Protection Agency, Region I, One Congress Street, 11th floor, Boston, MA and Air Resources Division, Department of Environmental Services, 64 North Main Street, Caller Box 2033, Concord, NH 03302–2033.

FOR FURTHER INFORMATION CONTACT: Anne E. Arnold, (617) 565–3166.

SUPPLEMENTARY INFORMATION: On November 25, 1992, EPA received a formal SIP submittal from New Hampshire containing a new regulation Part Env-A 1205 ''Volatile Organic Compounds (VOC): Gasoline Dispensing Facilities and Gasoline Tank Trucks.''

I. Background

Under the pre-amended Clean Air Act (CAA), ozone nonattainment areas were required to adopt reasonably available control technology (RACT) rules for sources of VOC emissions. EPA issued three sets of control technique guidelines (CTGs) documents, establishing a ''presumptive norm'' for RACT for various categories of VOC sources. The three sets of CTGs were (1) Group I—issued before January 1978 (15 CTGs); (2) Group II—issued in 1978 (9 CTGs); and (3) Group III—issued in the early 1980's (5 CTGs). Those sources not covered by a CTG were called non-CTG sources. EPA determined that the area's SIP-approved attainment date established which RACT rules the area needed to adopt and implement. Under section 172(a)(1), ozone nonattainment areas were generally required to attain the ozone standard by December 31, 1982. Those areas that submitted an attainment demonstration projecting attainment by that date were required to adopt RACT for sources covered by the Group I and II CTGs. Those areas that sought an extension of the attainment date under section 172(a)(2) to as late as December 31, 1987 were required to adopt RACT for all CTG sources and for all major (i.e., 100 ton per year or more of VOC emissions) non-CTG sources.

On November 15, 1990, amendments to the 1977 CAA were enacted. Pub. L. 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q. Section 182(b)(2) of the amended Act requires States to adopt RACT rules for all areas designated nonattainment for ozone and classified as moderate or above. There are three parts to the section 182(b)(2) RACT requirement: (1) RACT for sources covered by an existing CTG—i.e., a CTG issued prior to the enactment of the CAAA of 1990; (2) RACT for sources covered by a post-enactment CTG; and (3) all major sources not covered by a CTG. This RACT requirement applies to nonattainment

areas that previously were exempt from certain RACT requirements to ''catch up'' to those nonattainment areas that became subject to those requirements during an earlier period. In addition, it requires newly designated ozone nonattainment areas to adopt RACT rules consistent with those for previously designated nonattainment areas.

Pursuant to the amended CAA, two areas in New Hampshire were classified as serious ozone nonattainment areas and one area was classified as a marginal ozone nonattainment area. 56 FR 56694 (Nov. 6, 1991). The serious areas are subject to the section 182(b)(2) RACT catch-up requirement. Also, the State of New Hampshire is located in the Northeast Ozone Transport Region (OTR). The entire state is, therefore, subject to section 184(b) of the amended CAA. Section 184(b) requires that RACT be implemented for all VOC sources covered by a CTG issued before or after enactment of the CAAA of 1990 and for all major VOC sources (defined as 50 tons per year for sources in the OTR). CTGs have been issued for several VOC source categories including gasoline tank trucks and gasoline dispensing facilities (Stage I vapor recovery) which are the source categories addressed in today's action.

Furthermore, the CAA requires serious and above ozone nonattainment areas to adopt regulations which require owners and operators of gasoline dispensing facilities to install and operate so called ''Stage II'' vapor recovery equipment designed to control vapors emitted when vehicles are refueled (section 182(b)(3) as modified by section 202(a)(6)). Under section 182(b)(3), New Hampshire was required to submit Stage II vapor recovery rules for its two serious ozone nonattainment areas by November 15, 1992.

Also, section 184(b)(2) of the amended Act requires that states in the OTR adopt Stage II or comparable measures within one year of EPA completion of a study identifying control measures capable of achieving emissions reductions comparable to those achievable through section 182(b)(3) Stage II vapor recovery controls. On January 13, 1995, EPA completed its study ''Stage II Comparability Study for the Northeast Ozone Transport Region'' (EPA–452/R–94–011). Therefore, states in the OTR must adopt Stage II or comparable measures and submit them to EPA as a SIP revision by January 13, 1996. EPA has recently received New Hampshire's Stage II comparability SIP revision. New Hampshire's November 24, 1992 SIP submittal which is the subject of today's document is not intended to satisfy that requirement.

In response to sections 182(b)(2), 182(b)(3), and 184(b)(1)(B) of the CAA, New Hampshire adopted Part Env-A 1205 ''Volatile Organic Compounds (VOC): Gasoline Dispensing Facilities and Gasoline Tank Trucks'' and submitted this regulation to EPA as a SIP revision. New Hampshire's regulation is briefly summarized below.

New Hampshire's Env-A 1205

This regulation requires that all gasoline storage tanks with a capacity equal to or greater than 250 gallons be equipped with a submerged fill pipe and that all storage tanks at facilities with an annual throughput of greater than or equal to 120,000 gallons be equipped with Stage I vapor recovery controls. These requirements apply statewide. In addition, this regulation also requires that gasoline tank trucks operating in the State be maintained vapor-tight and be tested annually. Furthermore, this rule requires that owners or operators of gasoline dispensing facilities, which have an annual throughput equal to or greater than 420,000 gallons and are located in the counties of Hillsborough, Merrimack, Rockingham, and Strafford, install and operate Stage II vapor recovery controls.

EPA has reviewed this regulation against the applicable statutory requirements and for consistency with EPA guidance. New Hampshire's regulation and EPA's evaluation are detailed in a memorandum dated April 29, 1998, entitled ''Technical Support Document—New Hampshire—Gasoline Dispensing Facilities and Gasoline Tank Trucks.'' Copies of that document are available, upon request, from the EPA Regional Office listed in the **ADDRESSES** section of this document. A summary of EPA's evaluation is provided below.

EPA's Evaluation of New Hampshire's Submittal

In determining the approvability of a VOC RACT rule, EPA must evaluate the rule for consistency with the requirements of the Act and EPA regulations, as found in section 110 and part D of the Act and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). The EPA interpretation of these requirements, which forms the basis for today's action, appears in various EPA policy guidance documents. For the purpose of assisting State and local agencies in developing RACT rules, EPA prepared a series of Control Technique Guidelines (CTG) documents. The CTGs are based on the underlying requirements of the Act and specify the presumptive norms for RACT for specific source categories. EPA has not yet developed CTGs to cover all sources of VOC emissions. Further interpretations of EPA policy are found in: (1) Those portions of the proposed Post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); (2) the document entitled ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to Appendix D of November 24, 1987 **Federal Register** document'' (Blue Book) (notice of availability was published in the **Federal Register** on May 25, 1988); (3) the existing CTGs; and (4) the ''Model Volatile Organic Compound Rules for Reasonably Available Control Technology'' issued as a staff working draft in June 1992. In general, these guidance documents have been set forth to ensure that VOC rules are fully enforceable and strengthen or maintain the SIP.

EPA has evaluated the Stage I vapor recovery and gasoline tank truck requirements of New Hampshire's Env-A 1205 and has found that they are consistent with EPA model regulations and the following EPA guidance documents: ''Leaks from Gasoline Tank Trucks and Vapor Collection Systems'' (EPA–450/2–78–051); ''Guidance to State and Local Agencies in Preparing Regulations to Control Volatile Organic Compounds from Ten Stationary Source Categories'' (EPA–450/2–79–004); and ''Hydrocarbon Control Strategies for Gasoline Marketing Operations'' (EPA–450/3–78–017). As such, EPA believes that New Hampshire's regulation constitutes RACT for these source categories.

EPA has also evaluated the Stage II vapor recovery requirements of New Hampshire's regulation for consistency with the requirements of the Act and EPA guidance. Under section 182(b)(3), EPA was required to issue guidance as to the effectiveness of Stage II systems. In November 1991, EPA issued technical and enforcement guidance to meet this requirement.[1] In addition, on April 16, 1992, EPA published the ''General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990'' (General Preamble) (57 FR 13498). The guidance documents and the General Preamble interpret the Stage II statutory requirement and indicate what EPA

[1] These two documents are entitled ''Technical Guidance—Stage II Vapor Recovery Systems for Control of Vehicle Refueling Emissions at Gasoline Dispensing Facilities'' (EPA–450/3–91–022) and ''Enforcement Guidance for Stage II Vehicle Refueling Control Programs.''

believes a State submittal needs to include to meet that requirement.

Section 182(b)(3)(A) of the Act specifies that Stage II controls must apply to any facility that dispenses more than 10,000 gallons of gasoline per month or, in the case of an independent small business marketer (ISBM), as defined in section 324(c) of the Act, any facility that dispenses more than 50,000 gallons of gasoline per month. The scope of the control requirement in New Hampshire's rule differs from the formula specified in the CAA in two respects. First, the rule applies to facilities with an *annual* throughput of 420,000 gallons of gasoline, rather than measuring throughput on a monthly basis as provided in section 182(b)(3)(A). It is possible that a monthly threshold would capture more gas stations in the program by catching stations with seasonal variations in their throughput. But EPA and New Hampshire have documented that seasonal variation of gasoline sales across the state is not great, approximately three percent. Therefore, EPA has determined that the annual throughput threshold in New Hampshire's rule does not allow gas stations to go uncontrolled that might otherwise be captured by a monthly threshold. Moreover, along the New Hampshire seacoast, where one might expect to see seasonal variation due to summer tourist traffic, the New Hampshire stage II regulation covers a higher percentage of gas stations selling gasoline to the public than it does in inland communities. Finally, in 1992 New Hampshire estimated that its rule would require controls for about 84.3 percent of gasoline throughput in the program area. Data from 1996 demonstrate that the program actually controls 88.5 percent of all throughput. Second, the rule imposes one threshold for all gasoline stations. As noted above, the CAA specifies a lower threshold of 10,000 gallons per month for regular stations and a higher threshold of 50,000 gallons for ISBM's. If one assumes that New Hampshire's rule covers facilities that on average pump 35,000 gallons of gasoline a month, then the rule fails to control emissions from regular stations that pump between 10,000 and 35,000 gallons of fuel a month as compared with the CAA's minimum requirement. Correspondingly, the rule does control emissions from ISBM's that pump between 35,000 and 50,000 gallons a month that the State could allow to go uncontrolled under the CAA's formula.[2]

Although the applicability cut-off in New Hampshire's rule differs from the CAA-required cut-offs, New Hampshire's SIP submittal includes a Stage II Equivalency Demonstration which shows that implementation of its applicability cut-off in the four county area results in equivalent VOC reductions as compared with implementation of the CAA-required applicability cut-offs in the four county area. Also, New Hampshire's Stage II requirements apply to the Manchester previously classified marginal ozone nonattainment area, whereas section 182(b)(3) of the CAA only requires that New Hampshire implement Stage II requirements in the state's two serious areas. New Hampshire's rule, therefore, results in an additional environmental benefit as compared with the section 182(b)(3) CAA-required program. Thus, this rule creates emission reduction credits that are consistent with the principles outlined in EPA's Economic Incentive Program (EIP) rules (59 FR 16690).

Section 182(b)(3)(B) of the Act specifies the time by which certain facilities must comply with the State regulation. For facilities that are not owned or operated by an ISBM, these times, calculated from the time of State adoption of the regulation, are: (1) 6 months for facilities for which construction began after November 15, 1990, (2) 1 year for facilities that dispense greater than 100,000 gallons of gasoline per month, and (3) 2 years for all other facilities. The Stage II compliance schedule in New Hampshire's regulation is consistent with this CAA requirement.

In accordance with EPA's guidance, New Hampshire requires the use of Stage II systems that have been tested and certified by the California Air Resources Board (CARB) as meeting a 95 percent emission reduction efficiency. The State also requires sources to verify proper installation and function of Stage II equipment through the use of a liquid blockage test and a leak test prior to system operation and upon major modification of a facility or upon written notification from the State. In addition, New Hampshire's rule contains recordkeeping requirements consistent with those recommended in EPA's guidance.

EPA is proposing to approve the November 24, 1992 New Hampshire SIP revision. EPA is soliciting public comments on the issues discussed in this proposal or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to the EPA Regional office listed in the **ADDRESSES** section of this action.

II. Proposed Action

EPA is proposing to approve New Hampshire's Env-A 1205 ''Volatile Organic Compounds (VOC): Gasoline Dispensing Facilities and Gasoline Tank Trucks'' as meeting the section 182(b)(2) and section 184(b)(1)(B) VOC RACT requirements of the CAA for the gasoline dispensing facility and gasoline tank truck source categories. EPA is also proposing to approve New Hampshire's Env-A 1205 as achieving the emission reductions required under section 182(b)(3) for Stage II vapor recovery in serious ozone nonattainment areas.

III. Administrative Requirements

A. Executive Orders 12866 and 13045

The Office of Management and Budget (OMB) has exempted this regulatory action from review under Executive Order 12866.

The proposed rule is not subject to Executive Order 13045, entitled ''Protection of Children form Environmental Health Risks and Safety Risks,'' because it is not an ''economically significant'' action under Executive Order 12866.

B. Regulatory Flexibility Act

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

SIP approvals under section 110 and subchapter I, Part D of the 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, the Administrator certifies that it does not have a significant impact on any small entities affected.

C. Unfunded Mandates

To reduce the burden of Federal regulations on States and small governments, President Clinton issued Executive Order 12875 on October 26,

[2] Section 182(b)(3)(A) does not preclude states from establishing more stringent applicability thresholds. Under sections 116 and 324(b) states retain their authority to require Stage II controls at facilities in addition to those covered by section 182(b)(3)(A).

1993, entitled ''Enhancing the Intergovernmental Partnership.'' Under Executive Order 12875, EPA may not issue a regulation which is not required by statute unless the Federal Government provides the necessary funds to pay the direct costs incurred by the State and small governments or EPA provides to the Office of Management and Budget a description of the prior consultation and communications the agency has had with representatives of State and small governments and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected and other representatives of State and small governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

The present action satisfies the requirements of Executive Order 12875 because it does not contain a significant unfunded mandate. This rule approves preexisting state requirements and does not impose new federal mandates binding on State or small governments. Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

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

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.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Ozone, Reporting and recordkeeping requirements.

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

Dated: September 11, 1998.

John P. DeVillars,

Regional Administrator, Region I.

[FR Doc. 98–25195 Filed 9–18–98; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

43 CFR Part 414

RIN 1006–AA40

Offstream Storage of Colorado River Water and Interstate Redemption of Storage Credits in the Lower Division States

AGENCY: Bureau of Reclamation, Interior.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Department of the Interior (''the Department'' or ''we'') hereby gives notice that we are reopening the comment period on our proposed rule entitled ''Offstream Storage of Colorado River Water and Interstate Redemption of Storage Credits in the Lower Division States.'' We originally published the proposed rule on December 31, 1997, at 62 FR 68492, and accepted public comments until April 3, 1998.

DATES: We must receive your comments at the address below on or before October 21, 1998.

ADDRESSES: If you wish to submit comments, you may do so by any one of three methods. You may mail comments to Bureau of Reclamation, Administrative Record, Lower Colorado Regional Office, P.O. Box 61470, Boulder City, NV 89006–1470. You may comment via the internet at bjohnson@lc.usbr.gov Or, you may hand-deliver comments to Bureau of Reclamation, Administrative Record, Lower Colorado Regional Office, 400 Railroad Avenue, Boulder City, NV.

FOR FURTHER INFORMATION CONTACT: Mr. Dale Ensminger, (702) 293–8659.

SUPPLEMENTARY INFORMATION: We request that interested parties provide comments on whether an authorized entity in a Storing State under the rule must hold an ''entitlement'' to use Colorado River water pursuant to court decree, contract with the United States, or reservation of water from the Secretary of the Interior. As published on December 31, 1997, section 414.2 of the proposed rule defined ''authorized entity'' as ''a State water banking authority, or other entity of a Lower Division State holding entitlements to Colorado River water. * * *'' Section 414.2 of the proposed rule defined ''Entitlement'' as ''an authorization to benefically use Colorado River water pursuant to: (1) a decreed right, (2) a contract with the United States through the Secretary, or (3) a reservation of water from the Secretary.''

The Department received differing comments on these definitions and other technical matters during the previous comment period. For example, differing comments on the definition of ''authorized entity'' revealed that some read the definition as allowing a State Water Bank to participate in activities under the rule without holding an entitlement to Colorado River water, while others did not. We invite comment on whether the definition of ''authorized entity'' should be revised to clarify that an ''authorized entity,'' including a State water bank, must hold an entitlement to Colorado River water in order to ensure consistency with the Law of the River, including specifically section 5 of the Boulder Canyon Project Act, 43 U.S.C. 617d, as interpreted by the *Supreme Court in Arizona* v. *California*, 373 U.S. 546 (1963).

We also invite comment on whether efficiency, flexibility, and certainty in Colorado River management may result combining an approval Interstate Storage Agreement and a contract under Section 5 of the Boulder Canyon Project Act into one document, thus making the parties entitlement holders upon execution of the Agreement. And, we invite comment on whether, if the documents are not combined, the Interstate Storage Agreements and any separate Section 5 contract (or amendments to an existing contract) should be processed and approved simultaneously to eliminate duplication of any administrative and compliance procedures.

Dated: September 15, 1998.

Patricia J. Beneke,

Assistant Secretary—Water and Science.

[FR Doc. 98–25139 Filed 9–18–98; 8:45 am]

BILLING CODE 4310–94–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[ET Docket No. 98–153; FCC 98–208]

Revision of the Rules Regarding Ultra-Wideband Transmission Systems

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: By this *Notice of Inquiry*, the Commission is initiating a proceeding to investigate the possibility of permitting the operation of ultra-wideband (UWB) radio systems on an unlicensed basis under its rules. Comments are requested on the standards and operating requirements that should be applied to UWB systems to prevent interference to other radio services.

DATES: Comments are due December 7, 1998, reply comments are due January 4, 1999.

ADDRESSES: Federal Communications Commission, 1919 M Street, N.W., Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: John A. Reed, Office of Engineering and Technology, (202) 418–2455.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Inquiry* in ET Docket No. 98–153, adopted August 20, 1998, and released September 1, 1998. The complete text of this *Notice of Inquiry* is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, N.W., Washington, D.C., and also may be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 2100 M Street, NW, Suite 140, Washington, D.C. 20037.

Summary of the Notice of Inquiry

1. The Commission is initiating this inquiry on its own motion to investigate the possibility of permitting the operation of ultra-wideband (UWB) radio systems on an unlicensed basis under part 15 of its rules. Through this inquiry, we are seeking input to help us evaluate UWB technology and to determine what standards and operating requirements are necessary to prevent interference to other users of the radio spectrum. Upon review of the responses to this inquiry, we will determine whether to propose any changes to the rules.

2. UWB radio systems typically use extremely narrow pulse (impulse) modulation or swept frequency modulation that employs a fast sweep over a wide bandwidth. Because of the type of modulation employed, the emission bandwidths of UWB devices generally exceed one gigahertz and may be greater than ten gigahertz. In some cases, these pulses do not modulate a carrier. Instead, the radio frequency emissions generated by the pulses are applied to an antenna, the resonant frequency of which determines the center frequency of the radiated emission.

3. UWB systems could provide an improved method for providing radar applications where precise distance resolution is required and for providing covert voice or data communications that overcome multipath problems. Radar systems are currently being developed to detect buried objects such as plastic gas pipes or hidden flaws in airport runways or highways. Other radar systems would be used as fluid level sensors in difficult-to-measure situations such as oil refinery tanks and other storage tanks. Public safety personnel have expressed a desire for radar systems that can detect people hidden behind walls or covered with debris, such as from an earthquake. Public safety personnel also have expressed a need for UWB communications systems that can operate covertly. These communications systems could also be employed by heavy industrial manufacturers to overcome multipath and machinery-generated radio noise.

4. *Applications and general characteristics.* What types of UWB devices can we expect to be developed? What are the frequency ranges and bandwidths expected to be used by UWB devices? What are the expected total power levels and spectral power densities, peak and average, of UWB devices? What are the expected or desired operating distances?

5. *Regulatory treatment.* We understand that UWB systems will operate at very low spectral power densities, producing noise-like signals. Further, it appears that UWB systems will operate over very short distances. Because of this, it appears appropriate to provide for UWB technologies under part 15 of the rules. We invite comments on whether it would be appropriate to apply our part 15 rules to UWB technologies. Are there certain types of UWB devices or applications that should be regulated on a licensed basis under some other rule part? If so, which rule parts? If provisions are made for UWB technology under part 15, how should we define UWB technology?

6. *TV broadcast and restricted bands.* Part 15 designates certain sensitive and safety-related frequency bands as restricted bands. Only spurious emissions not exceeding the general emission limits are permitted within these restricted bands or, with few exceptions, within the frequency bands allocated for TV broadcasting. However, it is difficult, if not impossible, for UWB systems to avoid placing fundamental emissions within the restricted bands or the TV broadcast bands. Accordingly, comments are requested on whether the Commission should eliminate the requirement that only spurious emissions be permitted to fall within the restricted bands and the TV broadcast bands. Should the rules generally continue to prohibit operation of UWB systems within the restricted bands and the TV broadcast bands? Are there certain restricted bands where operation could be permitted, but not others? If so which bands and what is the justification? If certain restricted bands were retained, what impact would this have on the viability of UWB technology?

7. *Emission limits.* The current part 15 rules are based on the equivalent of a spectral power density, *i.e.*, a field strength limit is specified along with a measurement bandwidth. In most cases, emissions at or below 1000 MHz are based on the use of a quasi-peak detector which employs a designated measurement bandwidth. Above 1000 MHz, emissions are based on average field strength limits with a minimum measurement bandwidth of one megahertz. Where an average limit applies, there is also a limit on peak emission levels. Are the existing general emission limits sufficient to protect other users of the spectrum, especially radio operations in the restricted bands, from harmful interference? Should different limits be applied to UWB systems? Should we specify a different standard for UWB devices based on spectral power density? Should these standards be designed to ensure that the emissions appear to be broadband noise? What is the potential for harmful interference due to the cumulative impact of emissions if there is a large proliferation of UWB devices? Could the cumulative impact result in an unacceptably high increase in the background noise level? Should the Commission limit proliferation by restricting the types of products or should the rules permit manufacturers to design products for any application as long as the equipment meets the standards? Should a limit on the total peak level apply to UWB devices? Can emissions below or above a certain frequency range be further filtered to reduce the potential for interference to

other users of the radio spectrum without affecting the performance of the UWB systems? Are the existing limits on the amount of energy permitted to be conducted back onto the AC power lines appropriate for UWB devices? What operational restrictions, if any, should be required to protect existing users? Is the use of UWB modulation techniques necessary for certain types of communication systems; if so, for what purposes?

8. *Measurements.* Part 15 references the specific measurement procedure to be employed, the frequency range over which measurements are to be made, and the measurement detector functions and bandwidths to be employed. Comments are requested on whether the peak output level continues to be indicative of the interference potential of a UWB system. Is a pulse desensitization correction factor appropriate for measuring emissions from a UWB device? Should any modifications be made to this measurement procedure for UWB devices? Would another measurement procedure that does not apply a pulse desensitization correction factor be more appropriate for determining the interference potential of an UWB device? The frequency range over which measurements are required to be made depends on the frequency of the fundamental emission. Is the frequency of the fundamental emission readily discernible for UWB devices? Are the current frequency measurement ranges specified in the rules appropriate for UWB devices or should these ranges be modified? Are the measurement detector functions and bandwidths appropriate for UWB devices? Should these standards be modified and, if so, how? Are there any other changes to the measurement procedures that should be applied to UWB devices?

9. *Other matters.* There is a prohibition in the rules against the use of a Class B, damped wave emission. This prohibition stems from a similar International Telecommunication Union regulation and is a throwback to the days when spark gap transmitters were employed. There is no longer a clear definition of a Class B, damped wave emission. Should the prohibition against Class B, damped wave emissions apply to UWB systems or is the prohibition irrelevant, especially in light of the relatively low power levels employed by UWB devices? Comments are invited on any other matters or issues that may be pertinent to the operation of UWB systems.

10. This is a non-restricted notice and comment rule making proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda period, provided they are disclosed as provided in the Commission's rules. *See generally* 47 CFR 1.1202, 1.1203, and 1.2306(a).

11. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998). Comments filed through the ECFS can be sent as an electronic file via the Internet to <http://www.fcc.gov/e-file/ecfs.html<. Generally, only one copy of an electronic submission must be filed. If multiple docket or rule making numbers appear in the cation of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rule making number referenced in the caption. In completing the transmittal screen, commenters should include their full name, Postal Service mailing address, and the applicable docket or rule making number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to ecfs@fcc.gov, and should including the following words in the body of the message, ''get form <your e-mail address.'' A sample form and directions will be sent in reply.

12. Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rule making number appear in the caption of this proceeding, commenters must submit two additional copies for each additional docket or rule making number. All filings must be sent to the Commission's Secretary, Magalie Roman Salas, Office of Secretary, Federal Communications Commission, 1919 M St., N.W., Room 222, Washington, D.C. 20554.

13. The proposed action is authorized under sections 4(i), 301, 302, 303(e), 303(f), 303(r), 304 and 307 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 301, 302, 303(e), 303(f), 303(r), 304, and 307.

List of Subjects: 47 CFR Part 15

Communications equipment, Radio, Reporting and recordkeeping requirements.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 98–25113 Filed 9–18–98; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[ET Docket 98–156; FCC 98–209]

Certification of Equipment in the 24.05–24.25 GHz band at Field Strengths up to 2500 mV/m

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: By this *Notice of Proposed Rulemaking* (''NPRM''), the Federal Communications Commission proposes to amend its rules to allow the operation of fixed point-to-point transmitters in the 24.05–24.25 GHz band at field strengths of up to 2500 mV/m, measured at 3 meters. Devices operating at these field strength levels will be required to use highly directionalized antennas to minimize the possibility of creating harmful interference to other services in the band. This action is taken in response to a *Petition for Rulemaking* (''Petition'') filed by Sierra Digital Communications, Inc. (''Sierra'').

DATES: Comments must be filed on or before December 7, 1998, and reply comments must be filed on or before January 4, 1999.

ADDRESSES: Address all comments concerning this proposed rule to the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, FCC, 1919 M Street NW., Room 222, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Neal McNeil, Office of Engineering and Technology, (202) 418–2408, TTY (202) 418–2989, e-mail: nmcneil@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rule Making,* ET Docket 98–156, FCC 98–209, adopted August 21, 1998 and released September 1, 1998. The full text of this document is available for inspection and copying during regular business hours in the FCC Reference Center, Room 239, 1919 M Street, NW, Washington, DC. The complete text of this document also may be purchased from the Commission's duplication contractor, International Transcription Service, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

Summary of Notice of Proposed Rulemaking

1. Section 15.249 of the Commission's rules, 47 CFR 15.249, permits devices to operate in the 24.00–24.25 GHz band with field strengths up to 250 mV/m. However, in its Petition, Sierra notes

that Section 15.245 permits field disturbance sensors to operate in the central 100 MHz of this band, 24.075–24.175 GHz, with a field strength of up to 2500 mV/m. Sierra requests that the Commission amend Section 15.249 to permit fixed point-to-point operations in the 24.00–24.25 GHz band at a field strength of 2500 mV/m. Under this proposal, peak emission limits would remain unchanged at 2500 mV/m. Sierra proposes that devices operating at this higher limit be required to use antennas with gains of at least 33 dBi. Higher antenna gains would be permitted if transmitter output power is reduced to maintain a maximum field strength of 2500 mV/m. According to Sierra, a directional antenna with a minimum gain of 33 dBi will produce a smaller area of potential interference than an omnidirectional antenna operating at 250 mV/m.

2. We tentatively conclude that the rule changes requested by Sierra will provide additional flexibility to establish point-to-point operations under part 15 and will not pose an increased risk of interference to other users of the spectrum. We observe that Sierra is requesting to operate at the same signal levels that are already permitted for part 15 field disturbance sensors that operate in the 24.075–24.175 GHz band segment. We do not believe that granting Sierra's request will pose any greater risk of interference than these devices. Further, the services operating in the range of frequencies covered by Sierra's request are the same as those that exist in the 24.075–24.175 GHz segment, except for the 24.00–24.05 GHz segment where there is a primary allocation for the Amateur Service and Amateur Satellite Service.

3. The American Radio Relay League, Inc. (ARRL) filed comments in opposition to Sierra's Petition. ARRL objects to the proposal on the basis of potential interference to Amateur operations, particularly Amateur Satellite operations. We do not believe that ARRL has demonstrated that there will be a significant risk of interference to Amateur operations in the 24.05–24.25 GHz band segment. The point-to-point operations proposed by Sierra will still use relatively low powers and will be highly directional. If interference occurs to Amateur operations, it would be relatively simple to identify the source due to the fixed use of the part 15 operations. Furthermore, we believe that the risk of interference remains substantially less than from industrial, scientific, and medical (ISM) equipment that is permitted to operate in the 24.00–24.25 GHz band without any radiated emissions limits.

4. At the same time, we are concerned that Amateur Satellite operations in the 24.00–24.05 GHz band segment rely on the reception of weak signals. We note that Sierra suggests imposing additional conditions to facilitate sharing the 24.00–24.05 GHz band segment. However, we are not convinced that the conditions suggested by Sierra will provide sufficient protection to amateur satellite operations. Further, it does not appear that disallowing use of the 24.00–24.05 GHz segment would have a significant impact on part 15 point-to-point operations. Therefore, we are not proposing to permit point-to-point operations as requested by Sierra in the 24.00–24.05 GHz segment.

Initial Regulatory Flexibility Analysis

5. As required by Section 603 of the Regulatory Flexibility Act, 5 U.S.C. § 603, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the expected significant economic impact on small entities by the policies and rules proposed in this *Notice of Proposed Rule Making* (''NPRM''). Written public comments are requested on the IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the NPRM provided above. The Commission shall send a copy of this NPRM, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with paragraph 603(a) of the Regulatory Flexibility Act.

A. Reason for Action

6. This rule making proceeding is initiated to obtain comment regarding proposed changes to the regulations for non-licensed transmitters. The Commission seeks to determine if the standards should be amended as sought in the *Petition for Rulemaking* (''Petition'') filed by Sierra Digital Communications, Inc.

B. Legal Basis

7. The proposed action is taken pursuant to Sections 4(i), 301, 302, 303(e), 303(f), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. Sections 154(i), 301, 302, 303(e), 303(f), and 303(r).

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

8. For the purposes of this NPRM, the RFA defines a ''small business'' to be the same as a ''small business concern'' under the Small Business Act, 15 U.S.C. 632, unless the Commission has developed one or more definitions that are appropriate to its activities. *See* 5 U.S.C. 601(3). Under the Small Business Act, a ''small business concern'' is one that: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) meets any additional criteria established by the Small Business Administration (SBA). *See* 15 U.S.C. 632. SBA has defined a small business for Standard Industrial Classification (SIC) category 4812 (Radiotelephone Communications) to be small entities when they have fewer than 1500 employees. *See* 13 CFR 121.201. Given this definition, nearly all such companies are considered small.

D. Description of Projected Reporting, Recordkeeping and Other Compliance Requirements

9. Part 15 transmitters are already required to be authorized under the Commission's certification procedure as a prerequisite to marketing and importation. The changes proposed in this proceeding would not change any of the current reporting or recordkeeping requirements. Further, the proposed regulation adds permissible methods of operation and would not require the modification of any existing products.

E. Significant Alternatives to Proposed Rules Which Minimize Significant Economic Impact on Small Entities and Accomplish Stated Objectives

10. None.

F. Federal Rules that May Duplicate, Overlap, or Conflict With the Proposed Rule

11. None.

List of Subjects in 47 CFR Part 15

Communications equipment.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 98–24909 Filed 9–18–98; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 227

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. 980806212–8212–01; I.D. 073098C]

Endangered and Threatened Wildlife and Plants; One-year Finding for a Petition To List the Atlantic Sturgeon (Acipenser oxyrinchus oxyrinchus) in the United States as Endangered or Threatened

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce; Fish and Wildlife Service (FWS), Interior.

ACTION: Notice of 1-year petition finding.

SUMMARY: NMFS and the FWS (collectively, the Services), under the Endangered Species Act of 1973, as amended (ESA), announce a 1-year finding for a petition to add Atlantic sturgeon (*Acipenser oxyrinchus oxyrinchus*), in areas where it continues to exist in the United States, to the list of threatened and endangered wildlife and to designate critical habitat. After review of all available scientific and commercial information, the Services find that listing Atlantic sturgeon in the United States is not warranted at this time.

DATES: This finding becomes effective on September 15, 1998.

ADDRESSES: A complete list of references used in the preparation of this 12-month finding is contained in the status review, which is available upon request from the Protected Resources Division, National Marine Fisheries Service, One Blackburn Drive, Gloucester, MA 01930.

FOR FURTHER INFORMATION CONTACT: Mary Colligan, NMFS (978–281–9116), Ray Santos, NMFS (978–281–9103) or Anne Hecht, FWS (978–443–4325).

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(B) of the ESA (16 U.S.C. 1531 *et seq.*) requires that for any petition to revise the Lists of Endangered and Threatened Wildlife and Plants that contains substantial information, a finding be made within 12 months of the date of receipt of the petition on whether the petitioned action is (1) not warranted, (2) warranted, or (3) warranted but precluded from immediate proposal by other pending proposals. Such 12-month findings are to be published promptly in the **Federal Register**.

On June 2, 1997, the Services received a petition dated May 29, 1997, from the Biodiversity Legal Foundation requesting the Services to list Atlantic sturgeon in the United States, where it continues to exist, as threatened or endangered and to designate critical habitat within a reasonable period of time following the listing. The petitioner acknowledged NMFS' lead for Atlantic sturgeon under the ESA, but cited the species' life history and joint FWS/NMFS responsibility for the species under the Fish and Wildlife Conservation Act to encourage the Services to work together in reviewing the petition. The Services agreed that to use each Service's respective expertise in cooperation would be in the best interest of the species and, therefore, conducted this review jointly. Threats to the species cited in the petition include the following: (1) environmental degradation and habitat loss, especially the presence of dams blocking access to former spawning habitat, and water pollution; (2) overfishing; and (3) inadequacy of existing regulatory mechanisms, especially the lack of Federal requirements to specifically consider Atlantic sturgeon when authorizing developments and the absence of centralized direction and funding for research that is essential to identification and arrest of factors contributing to the species' decline.

On October 17, 1997, the Services published a notice in the **Federal Register** of their October 2, 1997, finding that substantial information existed indicating that the petitioned action may be warranted (62 FR 54018). The **Federal Register** notice announced initiation of a status review to determine whether listing of the Atlantic sturgeon in its North American range, including Atlantic Canada, is warranted. The Services formed a team, comprising six Federal and three state agency biologists, to conduct the status review.

In the October 17, 1997, notice (62 FR 54018), the Services solicited information and data on Atlantic sturgeon to assure a comprehensive review of all available information. The Services received information and data from 13 sources. This information included relevant genetics research and information specific to Atlantic sturgeon in Rhode Island, Maine, New Hampshire, and Connecticut. A number of the comments identified the existing regulatory framework under the Atlantic States Marine Fisheries Commission (ASMFC) as a more appropriate management mechanism than the ESA. The Services included this information and data in the status review.

The Services find that listing Atlantic sturgeon is not warranted at this time. This finding is based on the following: (1) evidence that the historic range of the species has not been substantially reduced and that its current range is not likely to be significantly reduced in the foreseeable future; (2) persistence of at least 14 spawning populations; (3) existing prohibitions on harvest and possession in all 15 states comprising the species' U.S. range; (4) detailed evaluation of current habitat conditions and threats to habitat showing that conditions are adequate to sustain the species and are likely to remain so in the foreseeable future; (5) lack of substantial information indicating that overutilization for commercial, recreational, scientific or educational purposes is currently significantly affecting the species; (6) lack of information indicating that disease or predation are causing significant losses of individuals of the species; (7) existing regulatory mechanisms which provide adequate protection and further the conservation of the species (8) lack of information indicating that artificial propagation is currently posing a threat to the species.

The petition and finding address the subspecies, *Acipenser oxyrinchus oxyrinchus*, one of two subspecies of Atlantic sturgeon. This subspecies, referenced hereafter in this notice as ''Atlantic sturgeon,'' is distributed along the eastern coast of North America. Sightings have been reported from Hamilton Inlet, Labrador, south to the St. Lucie River, Florida.

Atlantic sturgeon are late-maturing, anadromous fish that may live up to 60 years, reach lengths up to 14 feet (4.3 m), and weigh over 800 pounds (364 kg). They are distinguished by armor-like plates and a long snout. Sturgeon are opportunistic benthic feeders, filtering quantities of mud along with their food. Spawning occurs in flowing fresh or estuarine waters with a hard bottom. After hatching, juveniles may remain in fresh/estuarine waters for several years, then head seaward to grow to maturity and join the sub-adult migration run, which can reach many miles from their home rivers. Age at maturity increases with increasing latitude along the Atlantic Coast; sexual maturity for males ranges from 5 to 24 years, and, for females, from 7 to 30 years.

The Services' status review addressed the status of the Atlantic sturgeon population in the U.S., which was the subject of the petition, but also considered whether there is evidence that U.S. and Canadian stocks interbreed and whether activities conducted in Canada threaten Atlantic sturgeon of U.S. origin. Review of currently available information failed to show that there is an interbreeding population segment spanning the U.S.-Canadian border or that Canadian fisheries pose a meaningful threat to U.S. Atlantic sturgeon stocks. Evaluation of the U.S. Atlantic sturgeon population regarding the Services' Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act (61 FR 4722) showed that Atlantic sturgeon in the U.S. constitute a discrete and significant population segment and that consideration of its conservation status in relationship to the ESA's standards for listing is appropriate.

Historically, Atlantic sturgeon populations in the U.S. ranged from the Penobscot River, Maine, to the St. Johns River, Florida (although it is unclear whether spawning occurred in the latter river). The presence of Atlantic sturgeon was documented in 34 rivers; however, the number of historical spawning populations is unknown. Their range in the U.S. has contracted slightly, and now extends from the Kennebec River, Maine (and absence from the Penobscot River has not been conclusively determined), to the Satilla River, Georgia. Presence is documented in 32 rivers. Currently, 14 spawning populations are confirmed, and 5 others are suspected. Thus, current distributional information is inconsistent with the petitioner's claim, based on a 1996 ASMFC document, that reproducing populations are present in six or fewer rivers.

Historical records from the 1700s to 1800s document large numbers of sturgeon in many rivers along the Atlantic Coast. It is clear that Atlantic sturgeon underwent significant range-wide declines from historical abundance levels due to overfishing in the late 1800s. Sturgeon stocks may have been further impacted through environmental degradation, especially in the early to mid-1900s. However, the species persisted in many rivers, and populations rebounded to the point where commercial fisheries were active in many rivers during all or some of the years from 1962 to 1996. Many of these contemporary fisheries resulted in overfishing, depressing populations to the point where management authorities have now closed all directed fisheries and prohibited retention of bycatch.

Recent quantitative estimates of species abundance and population trends derive from stock assessments conducted in conjunction with the now-closed directed fisheries in New York and New Jersey. Although these assessments show substantial declines in population numbers in both the Delaware and Hudson River populations, they also document the presence of multiple year-classes in both systems, as do more qualitative surveys conducted elsewhere in the species' range, including the Chesapeake Bay, Cape Fear River, and Edisto River.

The petition and other sources (i.e., ASMFC, 1990, Smith and Clugston, 1997) have cited habitat loss and degradation as contributors to the decline of Atlantic sturgeon, but none of these documents contains a comprehensive analysis of the overall effect of current habitat conditions on the species. A thorough review of the effects of three habitat-related factors—dams, dredging, and water quality on U.S. Atlantic sturgeon populations—demonstrates that, while habitat alterations have occurred historically and some deleterious conditions persist, the conclusion that current habitat conditions imperil the species is unsupported by the available information.

Dams for hydropower generation, flood control, and navigation have the potential to adversely modify Atlantic sturgeon habitat. However, a detailed analysis of the locations of dams and the proportion of historical habitat rendered inaccessible to specific Atlantic sturgeon populations indicates that dams have had a limited effect on Atlantic sturgeon populations. Many dams on rivers inhabited by Atlantic sturgeon are located at the fall line, where natural waterfalls and rapids limited pre-dam upstream access to all, but occasional, occurrences of mature Atlantic sturgeon. Of 25 rivers for which current habitat accessibility can be quantified, only 3 (the Merrimack, Housatonic, and Susquehanna) currently suffer loss of > 30 percent of their habitat to dams. Dams impede access to 10–30 percent of habitat on another three rivers (Kennebec, Penobscot, and Salmon Falls). Quantitative estimates of habitat accessibility are not available for the Roanoke, Tar-Pamlico, or Cape Fear rivers, but spawning continues to occur on these rivers. Qualitative information indicates that a substantial portion of habitat on the Santee River is blocked by Wilson Dam. With the exception of Rodman Dam on a tributary of the St. Johns River (FL), all extant dams in Atlantic sturgeon habitat have been in place for more than 50 years. Several dams in the historical range of the Atlantic sturgeon have been removed or are in the process of being removed. The Services are not aware of any proposals to construct new dams within current or historical Atlantic sturgeon habitat.

Potential harm to Atlantic sturgeon from dredging includes the destruction of benthic feeding areas, disruption of spawning migrations, and deposition of resuspended fine sediments in spawning habitat. The most serious potential impacts are those that might affect spawning habitats during the actual spawning season, but a river-by-river review of dredging activity demonstrates that this potential is limited to a few specific rivers. No dredging has occurred within Atlantic sturgeon spawning habitats in 21 rivers during the last 20 to 25 years. Only six rivers with extant spawning populations where dredging might be on-going within spawning habitat in recent years were identified, and seasonal restrictions are in place to protect most sensitive spawning habitats on all but one of these.

While sturgeon are clearly susceptible to a variety of water quality problems, including changes in water temperature, decreases in levels of dissolved oxygen, additions in nutrients, and the presence of a variety of contaminants, available evidence shows that overall water quality in Atlantic sturgeon habitats is substantially better than it was through the 1970s and is continuing to improve, especially in the Northeast and Mid-Atlantic states. While acknowledging residual water quality issues, the status review noted substantial improvements in water quality in a number of rivers. Additionally, the Services examined long-term habitat trends in relation to the populations of the Atlantic sturgeon. Loss and degradation of habitat, especially the degradation of water quality that accompanied the rise of industry along much of the Eastern seaboard in the late 1800s through the 1970s, clearly contributed to past declines of Atlantic sturgeon populations. While current habitat conditions are not pristine, overall current spawning and nursery habitat conditions are substantially better than those under which this species recovered from collapse of stocks (due to overharvest) in the late 1800s and persisted during the first half of the 20th century. Important improvements in habitat quality have been effected through elimination of point and nonpoint sources of pollution, seasonal

restrictions on dredging operations in spawning and nursery habitats, and (in a few cases) dam removal. Recent increases in populations of the endangered shortnose sturgeon (*Acipenser brevirostrum*), which co-occurs with the Atlantic sturgeon over much of its range and shares many of its life history characteristics, also testify to the general capability of riverine sturgeon habitat to facilitate and support increasing populations of the latter species. Further habitat improvements could accelerate rebuilding of stocks, however, the Services conclude that current habitat conditions are above the threshold at which the Atlantic sturgeon is likely to become endangered in the foreseeable future throughout all or a significant portion of its range.

Commercial exploitation was the major cause of the early 20th century decline in Atlantic sturgeon abundance, as well as the primary cause of recent downward trends in the Hudson and Delaware River populations. The life history of Atlantic sturgeon (late age at maturity) and high commercial value make the species vulnerable to overexploitation. Many authors (i.e., Smith *et al.*, 1984, Smith and Clugston, 1997, Waldman and Wirgin, 1998) have cited past overharvesting by commercial fisheries as the major cause of the species' current low abundance.

By 1990, six jurisdictions within the Atlantic sturgeon's U.S. range (Pennsylvania, District of Columbia, Potomac River Fisheries Commission, Virginia, South Carolina, and Florida) had prohibited landings. The 1990 ASMFC Fisheries Management Plan (FMP) for Atlantic Sturgeon required all states to implement (1) a total closure on harvest, (2) a minimum length on harvestable fish of 7 feet (2.2 m) total length, or (3) alternative measures that could be submitted to the ASMFC for determination of conservation equivalency. All jurisdictions complied with this requirement, and, by 1995, the list of jurisdictions with total closures had expanded to include Maine, New Hampshire, Massachusetts, and North Carolina. Two states, New York and New Jersey that opted for conservation equivalency under the 1990 ASMFC plan closed their fisheries in 1995 and 1996, respectively (New Jersey by setting a quota of zero fish). Reported landings from the states that adopted the 7–foot (2.2–m) minimum (Georgia, Delaware, Connecticut, Maryland, and Rhode Island) were very low, and all of those states formally closed their fisheries between 1996 and 1998. The last state within the species' U.S. range to implement a complete prohibition on harvest and possession was Delaware, which implemented regulations on May 1, 1998.

The current ban on harvest of Atlantic sturgeon in all 17 jurisdictions has also been formalized in Amendment 1 to the ASMFC's Atlantic Sturgeon FMP as a long-term moratorium, enforceable under the terms of the Atlantic Coastal Fisheries Cooperative Management Act. This ban requires a complete closure, through prohibition on possession of Atlantic sturgeon (including any and all parts thereof) that must be maintained until the FMP is formally modified. The FMP Amendment, adopted by the ASMFC on June 11, 1998, anticipates that the moratorium remains in place until there are at least 20 protected age classes of females in each spawning stock. For the Hudson River population, the duration of the moratorium is anticipated to be approximately 41 years from its initiation. The ASMFC ban on harvest and possession includes any current or future recreational fishing.

In addition to the ban on harvest and possession in all state jurisdictions, including state waters, the 1998 FMP Amendment contains a request to the Secretary of Commerce to ban harvest and possession of Atlantic sturgeon in the exclusive economic zone (EEZ). This would extend protected waters from the boundary of state waters, 3 miles (1.8 km) from the coast, to the 200–mile (120–km) limit. The Services support this additional measure of protection for Atlantic sturgeon stocks in coastal waters, and the NMFS has started preparing the necessary documents to effect this closure. However, in view of the fact that any fish taken in the EEZ could not be landed or sold in any state from Maine to Florida, the Services do not believe that the current lack of such a closure in the EEZ represents a meaningful threat to the species and are not relying on its future implementation in this finding.

Atlantic sturgeon are susceptible to capture in a wide range of gear types that target other species, particularly gill nets and trawls. Potential threats from bycatch, including variable effects due to area, season, and gear types and population/species level impacts were examined in detail in ASMFC (1998) and in the status review. The only available assessment of population impacts of bycatch derived for the Hudson River population, 1991 through 1996, shows bycatch mortality rates that are well below the threshold likely to preclude population increases. Bycatch rates (based on first-year recapture reports from tagged fish) also showed a declining trend over the period for which data are available. Furthermore, any incentives for retention of bycatch have been eliminated through the range-wide prohibition on possession and sale of Atlantic sturgeon.

Several studies indicate that shortnose and Atlantic sturgeon, sympatric throughout most of their range, generally partition habitat spatially and demonstrate differences in dietary preferences. Little is known about natural predators of Atlantic sturgeon, but its bony scutes and large size are effective adaptations for minimizing predation of fish 2 or more years old. There is no evidence that current impacts of predation or competition are above ''natural'' levels.

While Atlantic sturgeon, like all organisms, are susceptible to disease, there is no evidence that disease currently poses an elevated or unnatural threat to this species. Although the recent widespread and devastating outbreaks of the toxic dinoflagellate, *Pfiesteria piscicida*, in North Carolina estuaries and in the Chesapeake Bay affected large numbers of fish, sturgeon were not affected; this may be attributable to the preference of Atlantic sturgeon for deep waters in swift currents and/or lack of susceptibility to this disease. In addition, anadromous species such as Atlantic sturgeon have a buffer against disease outbreaks that might be more catastrophic for fish populations that spend their entire life cycles in a single environment.

The major potential source of disease-related concern for Atlantic sturgeon is the possible introduction of non-indigenous sturgeon pathogens through the release to the wild of fish from aquaculture operations or aquarium fish. However, there are currently no commercial aquaculture operations for Atlantic sturgeon within the species' U.S. range, and the ban on possession of the species will preclude development of any such facilities unless and until an appropriate addendum to the ASMFC's FMP is adopted. The few public facilities working on development of propagation techniques maintain strict disease screening and management procedures. Although there is no range-wide ban on commercial aquaculture of non-indigenous sturgeons, no known commercial facilities are currently in existence.

The recently adopted amendment to the ASMFC Atlantic Sturgeon FMP formalizes a long-term coast-wide prohibition on harvest and possession of Atlantic sturgeon and any and all parts, including eggs. These prohibitions are already in effect via state regulations in every jurisdiction in the species' range. Under the provisions of 1993 amendments to the Atlantic Coastal Fisheries Cooperative Management Act

(P.L. 81–721), the Secretary of Commerce is empowered to enforce such mandatory compliance requirements in approved ASMFC plans by declaring a moratorium on the fishing of the applicable species. Under the terms of Amendment 1, the moratorium became mandatory on June 30, 1998, and will remain in place until the FMP is further amended through the formal procedures of the ASMFC. Even an addendum to the amended FMP (such as might be proposed to allow possession of imported or cultured Atlantic sturgeon) would require preparation of a written draft addendum, distribution to all states for review and comment, a public hearing in any state that requests one, and a 30-day review period prior to formal adoption by ASMFC's Sturgeon Management Board.

While the Services believe that the ASMFC moratorium on harvest and possession of Atlantic sturgeon is the critical component ensuring that this species is not likely to become endangered within the foreseeable future throughout all or a significant portion of its range, the FMP also contains other valuable recommendations for conservation (in its generic sense, not as defined in the ESA) and restoration of the species. These include measures for preservation of existing habitat, habitat restoration and improvement, monitoring and assessment of future bycatch, monitoring and assessment of stock recovery, and important protocols for any breeding and stocking activities. The FMP requires annual reporting from each jurisdiction on results of bycatch monitoring, monitoring of stock status, habitat protection efforts, and regulation (or oversight, if regulatory authority does not rest with the marine resources agency in a particular state) of any future aquaculture facilities. The ASMFC Sturgeon Management Board, which includes representatives from both Services, reviews the status of state compliance with the FMP at least annually.

A wide variety of Federal laws (including, but not limited to, the Federal Power Act, Fish and Wildlife Coordination Act, Federal Water Pollution Control Act, Rivers and Harbor Act, and National Environmental Policy Act), state laws, and local regulations affect activities with potential to destroy or degrade Atlantic sturgeon habitat. Although these laws do not require specific consideration of Atlantic sturgeon during project review and permitting processes, Atlantic sturgeon have frequently been the focus of such reviews and, more importantly, the beneficiaries of project modifications or denials, even in many situations where the species' needs were not explicitly considered. Atlantic sturgeon are also the indirect beneficiaries of section 7 ESA requirements for Federal agency consultation for the endangered shortnose sturgeon, where their ranges and conservation needs coincide. Habitat improvements since the mid- to late–1970s is tangible proof of the efficacy of existing Federal, state, and local laws to protect and conserve Atlantic sturgeon habitat.

The Services also find that existing authorities provide for coordination and funding of Atlantic sturgeon research and conservation efforts. In particular, the 1998 ASMFC Atlantic Sturgeon FMP Amendment provides a comprehensive blueprint for biologically appropriate restoration of habitat, monitoring and evaluation of future bycatch, and safeguards to prevent adverse effects from aquaculture on wild stocks. Management research needs for Atlantic sturgeon are clearly identified and partially prioritized in section 6 of the amended FMP. Existing ASMFC management institutions also furnish review, coordination, and oversight for this long-term effort, and both Services are active participants on the Sturgeon Management Board, Atlantic Sturgeon Technical Committee, and Atlantic Sturgeon Plan Review Team.

Artificial propagation for use in restoration of extirpated populations or supplementation of severely depleted populations has the potential to be both a threat to the species and a tool for recovery. Potential risks include accidental transmission of disease to wild stocks and changes in intra-population and inter-population genetic structure. Disease risks can be avoided and minimized through the implementation of appropriate protocols, however. These have been provided through stringent disease screening and certification of all fish prior to transfer or release to the wild. Genetic risks have been addressed through the development of a breeding and stocking protocol, the salient provisions of which have been incorporated into the 1998 ASMFC FMP Amendment. This protocol includes standards for sources of brood stock, minimum effective population size, stocking numbers, tagging, monitoring, and reporting. The Services have reviewed this protocol and find that it provides for minimization of risks and maximization of potential benefits from artificial propagation for conservation purposes.

There is currently no known commercial aquaculture activity involving Atlantic sturgeon within the species' U.S. range. Furthermore, the current ban on possession of the species in all jurisdictions precludes establishment of such facilities unless, and until, an addendum to the 1998 ASMFC FMP Amendment is approved. Potential risks from such activities include confounding enforcement on the moratorium on harvest and possession of wild fish and accidental escapement to the wild with attendant concerns for disease transmission and/or genetic impacts. Future changes in regulations may be conditioned to avoid or minimize these risks through the use of appropriate requirements for marking of aquaculture-produced fish and record keeping, escapement prevention, and disease controls.

There is currently no commercial aquaculture of non-indigenous sturgeon in the U.S. Atlantic sturgeon range. Potential risks stem from escapement to the wild, with attendant concerns for possible hybridization with Atlantic (and shortnose) sturgeon and transmission of diseases to which Atlantic sturgeon might be susceptible. In the event that such activities are proposed and implemented in the future, these risks may be attenuated through appropriate regulation and management of facilities. However, these risks do not currently constitute a threat to Atlantic sturgeon.

The Services have reviewed the petition, status review, available literature, and public comments and have consulted with scientists and fishery resource managers familiar with Atlantic sturgeon. After reviewing the best scientific and commercial information available, the Services find that the Atlantic sturgeon in the U.S. is not likely to become endangered within the foreseeable future throughout all or a significant portion of its range and that listing as threatened or endangered is not warranted.

References Cited

A complete list of references used in the preparation of the 12-month finding for the Atlantic sturgeon is contained in the status review, available upon request from the Northeast Regional Office (see **ADDRESSES** section).

Authority

The authority for this section is the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: September 11, 1998.

Rolland A. Schmitten,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

Dated: September 15, 1998.

Jamie Rappaport Clark,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 98–25105 Filed 9–15–98; 4:48 pm]

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Notices

Federal Register

Vol. 63, No. 182

Monday, September 21, 1998

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

ENVIRONMENTAL PROTECTION AGENCY

Unified National Strategy for Animal Feeding Operations

AGENCY: Natural Resources Conservation Service (NRCS), U.S. Department of Agriculture; Environmental Protection Agency.

ACTION: Notice and request for comments.

SUMMARY: The U.S. Department of Agriculture (USDA) and the U.S. Environmental Protection Agency (EPA) are seeking comments on the draft Unified National Strategy for Animal Feeding Operations. USDA and EPA are asking for comments from individuals, the livestock industry, State, Tribal, and local governments or subgroups thereof, universities, colleges, environmental groups, and other organizations. These comments will assist USDA and EPA in the development and implementation of a final strategy to reduce environmental risks associated with animal feeding operations (AFOs). The draft strategy was developed as part of the Clean Water Action Plan, which was announced by President Clinton and Vice President Gore in February 1998.

DATES: Comments must be received by January 19, 1999.

ADDRESSES: Please send comments to: Denise C. Coleman, Program Analyst, Natural Resources Conservation Service, ATTN: AFO, P.O. Box 2890, Washington, D.C. 20013–2890.

FOR FURTHER INFORMATION CONTACT: Joseph DelVecchio, Natural Resources Conservation Service, 202–690–2632; fax: 202–720-8520; joe.delvecchio@usda.gov; or William Hall, EPA, Office of Water, 202–565–3030; fax: 202–260–1460; afogroup.strategy@epa.gov.

SUPPLEMENTARY INFORMATION: The draft strategy states that owners and operators of AFOs should take action to reduce pollutant runoff. The draft strategy establishes a national performance expectation for all AFOs to be met by developing and implementing Comprehensive Nutrient Management Plans on AFOs. It explains voluntary and regulatory programs and their relationship. The strategy proposes incentives for owners and operators of AFOs to take early and voluntary actions and highlights several issues that must be addressed to successfully implement the Strategy. The full text of the Strategy follows.

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U.S. Department of Agriculture

U.S. Environmental Protection Agency

Draft—Unified National Strategy for Animal Feeding Operations

September 11, 1998.

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Note: This document presents USDA and EPA's strategic plan for addressing the environmental and public health impacts associated with AFOs. It is not a substitute for existing Federal regulations and it does not impose any binding requirements on USDA, EPA, the States, Tribes, localities, or the regulated community. USDA and EPA's strategies for addressing AFOs may evolve and change as their understanding of the issues increases through further work and receipt of additional information.

Table of Contents

1.0 Introduction and Guiding Principles

1.1 Introduction

Over the past quarter century, the United States has made tremendous progress in cleaning up its rivers, lakes, and coastal waters. In 1972, the Potomac River was too dirty to swim in, Lake Erie was dying, and the Cuyahoga River was so polluted it burst into flames. Many rivers and beaches were little more than open sewers. Today, water quality has improved dramatically and many rivers, lakes, and coasts are thriving centers of healthy communities.

The improvement in the health of the nation's waters is a direct result of a concerted effort to enhance stewardship of natural resources and to implement the environmental provisions of Federal, State, Tribal and local laws. Pollution control and conservation programs have stopped billions of pounds of pollution from fouling the Nation's water, doubling the number of waters safe for fishing and swimming.

Despite tremendous progress, 40 percent of the Nation's waterways assessed by States still do not meet goals for fishing, swimming, or both. Pollution from factories and sewage treatment plants has been dramatically reduced, but runoff from city streets, agricultural activities, including animal feeding operations (AFOs), and other sources continues to degrade the environment and puts drinking water at risk.

A strong livestock industry (of which AFOs are a part) is essential to the nation's economic stability, the viability of many rural communities, and the sustainability of a healthful and high quality food supply for the American public.[1] USDA and EPA recognize that farmers and ranchers are primary stewards of many of our nation's natural resources, have played a key role in past efforts to improve water quality, and will be important partners in implementing measures to protect the environment and public health.

In February of this year, President Clinton released the Clean Water Action Plan (CWAP), which provides a blueprint for restoring and protecting water quality across the Nation. The CWAP describes over 100 specific actions to expand and strengthen existing efforts to protect water quality. It also identifies polluted runoff as the most important remaining source of water pollution and provides for a coordinated effort to reduce polluted runoff from a variety of sources. As part of this effort, the CWAP calls for the development of this USDA-EPA unified national strategy to minimize the water quality and public health impacts of AFOs.

1.2 Guiding Principles

This USDA–EPA Unified National Strategy for Animal Feeding Operations reflects several guiding principles:

(1) Minimize water quality and public health impacts from AFOs.

(2) Focus on AFOs that represent the greatest risks to the environment and public health.

(3) Ensure that measures to protect the environment and public health complement the long-term sustainability of livestock production in the United States.

(4) Establish a national goal and environmental performance expectation for all AFOs.

(5) Build on the strengths of USDA, EPA, State and Tribal agencies, and other partners and make appropriate use of diverse tools including voluntary, regulatory, and incentive-based approaches.

(6) Foster public confidence that AFOs are meeting their performance expectations and that USDA, EPA, local governments, States, and Tribes are ensuring the protection of water quality and public health.

(7) Coordinate activities among the USDA, EPA, and related State and Tribal agencies and other organizations that influence the management and operation of AFOs.

(8) Focus technical and financial assistance to support AFOs in meeting the national performance expectation established in this Strategy.

2.0 AFOs and Water Quality and Public Health Risks

2.1 Characteristics of AFOs

For purposes of this Strategy, AFOs are agricultural enterprises where animals are kept and raised in confined situations. AFOs congregate animals, feed, manure and urine, dead animals, and production operations on a small land area. Feed is brought to the animals rather than the animals grazing or otherwise seeking feed in pastures or fields.

Approximately 450,000 agricultural operations nationwide confine animals.[2] USDA data indicate that the vast majority of farms with livestock are small. About 85% of these farms have fewer than 250 animal units (AUs).[3] An AU is equal to roughly one beef cow, therefore 1,000 AUs is equal to 1,000 beef cows or equivalent number of other animals.[4] Of these, in 1992 about 6,600 had more than 1,000 AUs and are considered to be large operations.

As a result of domestic and export market forces, technological changes, and industry adaptations, the past several decades have seen substantial changes in America's animal production industries. These factors have promoted expansion of confined production units, with growth in both existing areas and new areas; integration and concentration of some of the industries; geographic separation of animal production and feed production operations; and the concentration of large quantities of manure and wastewater on farms and in some watersheds.

In terms of production, the total number of animal units (AUs) in the U.S. increased by about 4.5 million (approximately three percent) between 1987 and 1992. During this same period, however, the number of AFOs decreased, indicating a consolidation within the industry overall and greater production from fewer, larger AFOs.[5]

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[1] The livestock industry accounts for half of all sales in U.S. agriculture today (source: USDA, Economic Research Service. ''Key statistical indicators of the food and fiber sector''. Agricultural Outlook. March, 1998: 32).

[2] General Accounting Office. Animal Agriculture: Information on Waste Management and Water Quality Issues, June 1995.

[3] USDA–ERS. 1992 Farm Costs and Returns Survey.

[4] USDA and EPA currently use slightly different definitions for an animal unit, largely for the pork and poultry animal types.

[5] General Accounting Office. Animal Agriculture: Information on Waste Management and Water Quality Issues, June 1995.

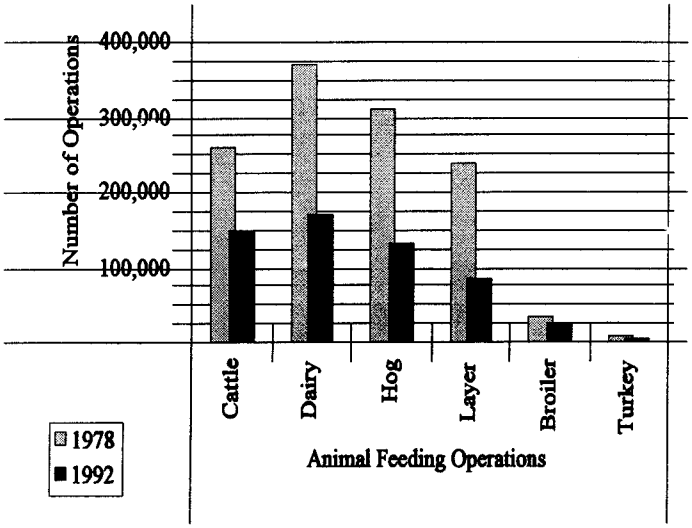

Figure 1: Industry Consolidation of Cattle, Dairy, Hog, Layer, Broiler and Turkey Animal Feeding Operations[6]

Table 1. Increase in the Average Number of Animal Units per Operation (1978-1992)	
Cattle	56%
Dairy	93%
Hog	134%
Layer	176%
Broiler	148%
Turkey	129%
Data source: *Animal Agriculture: Information on Waste Management and Water Issues*, General Accounting Office, 1995.	

2.2 Water Quality and Public Health Risks

[6] General Accounting Office. *Animal Agriculture: Information on Waste Management and Water Quality Issues*, June 1995

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Despite significant progress in reducing water pollution, serious water quality problems persist throughout the country. Recent State reports of water quality conditions indicate that:

- Of the rivers and streams surveyed (53 percent of all perennial stream miles) 36% were partially or fully impaired and another 8% were threatened;
- Of the surveyed lakes (40 percent of all lake acres) 39% were partially or fully impaired and another 10% were threatened; and
- Of the estuaries surveyed by coastal states (72 percent of all estuarine waters) 38% were impaired and another 4% were threatened;
- Of the Great Lakes shore miles surveyed (94 percent of all shore miles) 97% were impaired and another 1% were threatened.[7]

Based on this monitoring information, States have identified about 15,000 individual waterbodies in 1996 that did not meet clean water goals.

While many diverse sources contribute to water pollution, States report that agriculture is the most widespread source of pollution in the nation's surveyed rivers. In the 22 States that categorized impacts from specific types of agriculture, animal operations impact about 35,000 river miles of those miles assessed.

AFOs can pose a number of risks to water quality and public health, mainly because of the amount of animal manure and wastewater they generate.[8] Manure and wastewater from AFOs have the potential to contribute pollutants such as nutrients (e.g., nitrogen, phosphorus), sediment, pathogens, heavy metals, hormones, antibiotics, and ammonia to the environment. Excess nutrients in water can result in or contribute to eutrophication, anoxia (i.e., low levels of dissolved oxygen), and, in combination with other circumstances, have been associated with outbreaks of microbes such as *Pfiesteria piscicida.*

Pathogens, such as *Cryptosporidium*, have been linked to impairments in drinking water supplies and threats to human health. Pathogens in manure can create a food safety concern if manure is applied directly to crops at inappropriate times. In addition, pathogens are responsible for some shellfish bed closures. Nitrogen, in the form of nitrate, can contaminate drinking water supplies drawn from ground water. Nutrients can also cause toxic algal blooms which may be harmful to human health.

While there are other potential environmental impacts associated with AFOs (e.g., odor, habitat loss, ground water depletion), this Strategy focuses on addressing surface and ground water quality problems. This Strategy will indirectly benefit other resources.

3.0 The National Goal and Performance Expectation for AFOs

3.1 Defining the Goal and Performance Expectation

USDA and EPA's goal is for AFO owners and operators to take actions to minimize water pollution from confinement facilities and land application of manure. To accomplish this goal, this Strategy establishes a national performance expectation that all AFOs should develop and implement technically sound and economically feasible Comprehensive Nutrient Management Plans (CNMPs) to minimize impacts on water quality and public health.

3.2 Comprehensive Nutrient Management Planning

In general terms, a CNMP identifies actions or priorities that will be followed to meet clearly defined nutrient management goals at an agricultural operation. Defining nutrient management goals and identifying measures and schedules for attaining the goals is critical to reducing threats to water quality and public health from AFOs.

CNMPs should address, at a minimum, feed management, manure handling and storage, land application of manure, land management, record keeping, and other utilization options. While nutrients are often the major pollutants of concern, the plan should address risks from other pollutants, such as pathogens, to minimize water quality and public health impacts from AFOs. CNMPs should include a schedule to implement the management practices identified.

In addition to protecting water quality and public health, CNMPs should be site-specific and be written to address the goals and needs of the individual owner/operator, as well as the conditions on the farm (e.g., soils, crops). Plans should also be periodically reviewed and revised in cases where a facility increases in size, changes its method of manure management, or if other operating conditions change. CNMPs should encourage and facilitate technical innovation and new approaches to manure and nutrient management. Development and implementation of CNMPs is the ultimate responsibility of the AFO operator, with assistance as needed from certified industry staff, government agency specialists, private consultants and other qualified vendors.

The Natural Resources Conservation Service (NRCS) Field Office Technical Guide (FOTG) is the primary technical reference for the development of CNMPs for AFOs. It contains technical information about utilization and conservation of soil, water, air, plant, and animal resources. The FOTG used in an individual field office is localized to consider particular characteristics for the geographic area for which it is prepared. The FOTG is divided into five sections:

Section I General Resource References—References, maps, price bases, typical crop budgets, and other information for use in understanding the field office working area or in making decisions about resource use and resource management.

Section II Soil and Site Information—Soils are described and interpreted to help make decisions about land use and management. In most cases, this will be a electronic database.

Section III Conservation Management Systems (CMS)—Guidance for developing conservation management systems. A description of the resource considerations and their acceptable levels of quality or criteria.

Section IV Practice Standards, Specifications and Supplements—Contains standards and specifications for conservation practices used in the field office. The standards contained in the National Handbook of Conservation Practices (NHCP) may be supplemented to reflect local conditions. The NHCP contains standards and specifications for over 150 conservation practices, many of which are applicable to CNMPs for AFOs. These standards are based on sound science and over 65 years of NRCS experience. New standards can be added to this handbook using a procedure outlined in the handbook that includes a public review/input process. Practice standards establish the minimum level of acceptable quality for planning, installing, operating, and maintaining conservation practices.

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[7] U.S. EPA 1998. National Water Quality Inventory—1996 Report to Congress, Washington, DC.

[8] EPA, 1998, National Water Quality Inventory—1996 Report to Congress; Hunt, P.G., et al. 1995. Impact of animal waste on water quality in an eastern coastal plain watershed. *IN: Animal Waste and the Land-Water Interface,* Kenneth Steele, Ed., Lewis Publishers, Boca Raton, FL, 589 pp.; Ackerman and Taylor, 1995, Stream Impacts due to Feedlot Runoff. *IN: Animal Waste and the Land-Water Interface;* South Dakota Association of Conservation Districts, SD Department of Environment and Natural Resources, and USDA Natural Resources Conservation Service, 1996, Final Report—Animal Waste Management Team; EPA Office of the Inspector General, March 1997, Animal Waste Disposal Issues, Audit Report No. E1XWF7–13–0085–7100142.

Section V Conservation Effects—Contains Conservation Practice Physical Effects (CPPE) matrices which outline the impact of practices on various aspects of the five major resources—soil, air, water, plants, and animals.

3.3 Comprehensive Nutrient Management Plan Components

USDA and EPA agree that the following components should be included in a CNMP, as necessary. The specific practices used to implement each component may vary to reflect site-specific conditions or needs of the watershed.

Feed Management—Where possible, animal diets and feed should be modified to reduce the amounts of nutrients in manure. For example, enzymes such as phytase can be added to animal diets to increase the utilization of phosphorus. Greater utilization of phosphorus by the animal reduces the amount of phosphorus excreted and produces a manure with a nitrogen-phosphorus ratio closer to that required by crop and forage plants.

Manure Handling and Storage—Manure needs to be handled and stored properly to prevent water pollution from AFOs. Manure and wastewater handling and storage practices should also consider odor and other environmental and public health problems. Handling and storage considerations should include:

Divert clean water—Siting and management practices should divert clean water from contact with feed lots and holding pens, animal manure, or manure storage systems. Clean water can include rainfall falling on roofs of facilities, runoff from adjacent lands, or other sources.

Prevent leakage—Construction and maintenance of buildings, collection systems, conveyance systems, and storage facilities should prevent leakage of organic matter, nutrients, and pathogens to ground or surface water.

Provide adequate storage—Dry manure, such as that produced in certain poultry and beef operations, should be stored in production buildings, storage facilities, or otherwise covered to prevent precipitation from coming into direct contact with the manure. Liquid manure storage systems should safely store the quantity and contents of animal manure and wastewater produced, contaminated runoff from the facility, and rainfall. Location of manure storage systems should consider proximity to waterbodies, floodplains, and other environmentally sensitive areas.

Manure treatments—Manure should be handled and treated to reduce the loss of nutrients to the atmosphere during storage, to make the material a more stable fertilizer when land applied or to reduce pathogens, vector attraction and odors, as appropriate.

Management of dead animals—Dead animals should be disposed of in a way that does not adversely affect ground or surface water or create public health concerns. Composting, rendering, and other practices are common methods used to dispose of dead animals.

Land Application of Manure—Land application is the most common, and usually most desirable method of utilizing manure because of the value of the nutrients and organic matter. Land application should be planned to ensure that the proper amounts of all nutrients are applied in a way that does not cause harm to the environment or to public health. Land application in accordance with the CNMP should minimize water quality and public health risk. Considerations for appropriate land application should include:

Nutrient balance—The primary purpose of nutrient management is to achieve the level of nutrients required to grow the planned crop by balancing the nutrients that are already in the soil and from other sources with those that will be applied in manure, biosolids and fertilizer. At a minimum, nutrient management should prevent the application of nutrients at rates that will exceed the capacity of the soil and planned crops to assimilate nutrients and prevent pollution. Soils and manure should be tested to determine nutrient content.

Timing and methods of application—Care must be taken when land applying manure to prevent it from entering streams, other water bodies, or environmentally sensitive areas. The timing and method of application should prevent the loss of nutrients to ground or surface water and to minimize loss of nitrogen to the atmosphere. Manure application equipment should be calibrated to ensure that the quantity of material being applied is what is planned.

Land Management—Tillage, crop residue management, grazing management, and other conservation practices should be utilized to minimize movement to surface and ground water of soil, organic materials, nutrients, and pathogens from lands where manure is applied. Forest riparian buffers, filter strips, field borders, contour buffer strips, and other conservation buffer practices should be installed to intercept, store and utilize nutrients or other pollutants that may migrate from fields to which manure is applied.

Record Keeping—AFO operators should keep records that indicate the quantity of manure produced and ultimate utilization, including where, when, and amount of nutrients applied. Soil and manure testing should be incorporated into the records management system.

Other Utilization Options—In vulnerable watersheds, where the potential for environmentally sound land application is limited, alternative uses of manure, such as the sale of manure to other farmers, composting and sale of compost to home owners, and using manure for power generation may need to be considered. All manure utilization options should be designed and implemented to reduce the risk to all environmental resources and must comply with Federal, State, Tribal and local law.

3.4 Technical Assistance for CNMPs

AFO owners and operators may seek technical assistance for the development and implementation of CNMPs from qualified specialists, including staff from Federal agencies such as the NRCS, State, and Tribal agricultural and conservation agency staff, Cooperative Extension Service agents and specialists, Soil and Water Conservation Districts (SWCDs), integrators, industry associations, other AFO operators, and private consultants. Qualified specialists should assist in implementation and provide ongoing assistance through periodic reviews and revisions of CNMPs, as appropriate.

The successful implementation of this Strategy depends on the availability of qualified specialists from either the private or public sectors to assist in the development and implementation of CNMPs. Measures to expand technical assistance resources are discussed more thoroughly in Section 5.0, Strategic Issue #1.

4.0 Relationship of Voluntary and Regulatory Programs

Voluntary and regulatory programs serve complementary roles in providing AFO owners and operators and the animal agricultural industry with the assistance and certainty they need to achieve individual business and personal goals, and in ensuring protection of water quality and public health. The regulatory program focuses permitting and enforcement priorities on high risk operations, a small percentage of all AFOs (see Figure 2). For most AFOs, however, a variety of voluntary programs provide the technical and financial assistance to help producers meet technical standards and remain economically viable.

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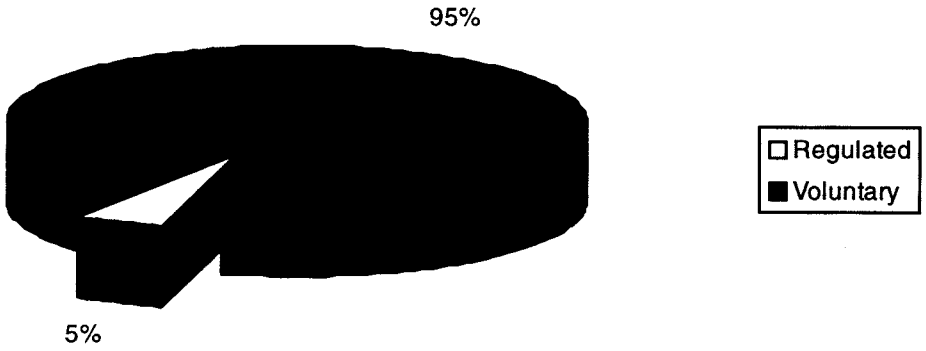

Figure 2: Estimated Percentage of Animal Feeding Operations Expected to be Regulated Under the Clean Water Act

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4.1 Voluntary Program for Most AFOs

Voluntary programs provide an enormous opportunity to help AFO owners and operators and communities address water quality and public health concerns surrounding AFOs. *For the vast majority of AFOs, voluntary efforts will be the principal approach to assist owners and operators in developing and implementing CNMPs, and in reducing water pollution and public health risks associated with AFOs.* While CNMPs are not required for AFOs participating in voluntary programs, they are strongly encouraged as the best possible means of managing potential water quality and public health impacts from these operations. For those CNMPs that are developed as part of a State, Tribal, or Federal voluntary technical or financial assistance program, the responsible agency, in consultation with the local Soil and Water Conservation Districts, will approve the plan to ensure that it is sufficient to meet requirements for participation in such programs. AFO owners and operators will be full partners in the development and implementation of CNMPs through voluntary programs and will agree to implement those plans before receiving financial assistance.

The voluntary approach is built on the ethic of land stewardship and sustainability. A sustainable society requires a sustainable environment-one depends upon the other. For generations, most producers have maintained agricultural productivity in harmony with a healthy land-the essence of land stewardship. Today, agricultural producers still have the responsibility to be good stewards of the land under their care. The voluntary development and implementation of a CNMP provide AFO operators with a way to embrace this stewardship ethic. USDA and EPA are proposing in this Strategy incentives to further the voluntary development and implementation of CNMPs.

Implementing voluntary programs requires the support of local leadership and full participation in planning and implementing conservation activities. Partnerships with Federal and State agencies, groups, SWCDs, Resource Conservation and Development (RC&D) Councils, private landowners; and between local leadership and science-based technical assistance are essential to success. Locally led conservation efforts, environmental education programs, and financial and technical assistance all help to build the land stewardship ethic that is fundamental to the success of a voluntary approach.

Locally Led Conservation—It is hard to overstate the importance of effective, locally led actions through the SWCDs in achieving national natural resource quality goals. This is particularly true for AFOs. USDA and EPA have a commitment to locally led conservation as one of the most effective ways to help individual landowners and communities achieve their conservation goals. Informed citizens are fundamental to making informed choices. Thus, locally led conservation is a logical complement to an investment in environmental education. Through the locally led approach, individuals can see how their actions fit with those of their neighbors.

Partnerships with grassroots organizations such as SWCDs, RC&D Councils, and others that promote the use of CNMPs, can help attain the goal of this Strategy. Through the locally led process, natural resource concerns are identified and proposals for local priorities are developed. SWCDs convene a local work group comprised of the district board members and key staff, NRCS staff; Farm Service Agency county committees and key staffs; and Cooperative Extension Service and other Federal, State, and local agencies interested in natural resource conservation. The SWCDs gather community input and bring the views of these local interests to work groups. These local work groups have the ability to identify problems and develop solutions locally. Also, they have knowledge of what resources are available to plan and implement the CNMPs.

Environmental Education—One of the best ways to help AFO operators or owners to participate in voluntary programs to reduce the potential impact of their operations on the environment is through education and outreach. There may be many well-managed AFOs, carefully following best management practices developed in the past, that are unintentionally contributing to water quality or other environmental degradation because of lack of access to the newest information. The agricultural research system continues to advance our understanding of the potential impacts of animal agriculture on the environment. USDA's Agricultural Research Service (ARS), Cooperative State Research, Education, and Extension Service (CSREES); EPA; State and Local governments; Land Grant Colleges and Universities and other institutions of higher learning; and the private sector are all actively involved in communicating knowledge gained through the agricultural research system to AFO owners and operators.

Through an aggressive environmental education and outreach effort, USDA and EPA believe that awareness of possible problems can be heightened and producers will be able to identify practices that may be contributing to water quality problems. Once producers have an understanding of potential problems and solutions, they can take a proactive role in developing their CNMP through the voluntary program.

Technical And Financial Assistance Programs—There are numerous sources of technical and financial assistance, such as USDA, EPA, SWCDs, RC&D Councils, State agencies, and the private sector, to assist AFO owners and operators in developing and implementing CNMPs. Through technical assistance, owners and operators can receive help in developing CNMPs and implementing solutions. Financial cost-share and loan programs can help defray the costs of approved/needed structures (e.g., waste storage facilities for small operations) or to implement other practices, such as installation of conservation buffers to protect water quality. An increasing number of States have financial assistance programs that supplement or enhance Federal assistance.

Conservation Technical Assistance (CTA), NRCS's base conservation program, is a potential tool in helping landowners develop CNMPs. The Conservation Reserve Program (CRP), Conservation Reserve Enhancement Program (CREP), and Environmental Quality Incentives Program (EQIP) are assisting AFOs across the Nation in nutrient management. The Small Watershed Protection Program (PL 83–566) provides comprehensive resource management planning on a watershed basis to assist local land users in addressing water quality concerns related to AFOs. RC&D assists States and local units of government in planning, developing, and implementing programs for resource conservation and development. Plans address water quality, community and economic development, and other concerns of interest to the local citizens. The Conservation Buffer Initiative and the Watershed Survey and Planning Program also offer opportunities to assist livestock producers in managing their potential environmental risks.

AFO owners and operators may also participate in other State and Federal programs to improve water quality and to develop and implement polluted runoff abatement activities, including State cost-share programs and EPA Section 319 nonpoint source grants and the State Revolving Fund (SRF) program authorized under the Clean Water Act

(CWA). Using all USDA, EPA, and other Federal, State and local programs together as tools helps leverage resources to help AFO owners and operators in voluntarily addressing water quality and public impacts.

4.2 Regulatory Program for Some AFOs

The Federal CWA provides general authority for water pollution control programs, including several programs related to animal feeding operations (AFOs). A number of primarily large AFOs (i.e. about 2,000 facilities) have been issued permits under section 402 of the CWA. These permits, called National Pollutant Discharge Elimination System (NPDES) permits, include conditions to limit pollution problems. In 42 States and the Virgin Islands, these NPDES permits are issued by States under authorization from EPA. These permits are generally written to implement national minimum standards (referred to as effluent guidelines) for large AFOs established in regulations. (A summary of the existing feedlots effluent limitations guidelines is included in Figure 3.) NPDES permits for AFOs must also include conditions that assure attainment of any applicable State- or Tribe-established water quality standards. These standards include designated uses, water quality criteria to protect these uses, and an antidegradation policy. Best management practices necessary to ensure compliance with the CWA, such as those included in CNMPs, may be imposed in NPDES permits. Where water quality standards are not attained, response actions are defined through the Total Maximum Daily Load (TMDL) process under Section 303(d) of the Act and implemented through revised NPDES permits and other measures.

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EPA's Effluent Limitations Guidelines for CAFOs

The effluent limitation allows no discharges to Waters of the U.S. except when chronic or catastrophic storm events cause an overflow from a facility designed, constructed, and operated to hold process generated wastewater plus runoff from a 25-year, 24-hour storm event. All NPDES permits for CAFOs with over 1,000 AUs other than non-producing facilities, must contain an equivalent or more stringent effluent limitation. See 40 CFR Part 412.

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The existing provisions of the CWA and related EPA regulations provide authority for including a significant number of AFOs in the permit program beyond those that now have permits. These statutory and regulatory authorities related to AFOs are described below along with the approach EPA will follow in setting priorities for carrying out these authorities.

The CWA provides that no person may ''discharge'' a pollutant except in accordance with a permit issued under section 402 of the Act. A ''discharge'' is defined as ''any addition of any pollutant to navigable waters from any point source.'' The term ''pollutant'' is broadly defined in the CWA and includes animal waste and related material.

The term ''point source'' as defined in the CWA includes any ''discernible, confined and discrete conveyance'' and specifically includes a ''concentrated animal feeding operation'' (CAFO). Thus, a discharge from a CAFO is prohibited except in accordance with an NPDES permit.

The term ''animal feeding operation'' or AFO is defined in EPA regulations as a ''lot or facility'' where animals ''have been, are, or will be stabled or confined and fed or maintained for a total of 45 days or more in any 12 month period and crops, vegetation, forage, growth or post harvest residues are not sustained in the normal growing season over any portion of the lot or facility.''

The regulations define a ''concentrated animal feeding operation'' or CAFO as an animal feeding operation where more than 1,000 ''animal units'' (as defined by the regulation) are confined at the facility; or more than 300 animal units are confined at the facility and:

- Pollutants are discharged into navigable waters through a manmade ditch, flushing system, or other similar man-made device; or
- Pollutants are discharged directly into waters that originate outside of and pass over, across, or through the facility or come into direct contact with the confined animals.

Poultry operations that remove waste from pens and stack it in areas exposed to rainfall or an adjacent watercourse have established a crude liquid manure system for process wastewater that may discharge pollutants. These facilities are CAFOs and therefore point sources under the NPDES program if the number of animals confined at the facility meets the regulatory definition at 40 CFR Part 122. Appendix B or if the facility is designated as a CAFO.

The regulations also provide, however, that no animal feeding operation is a CAFO as defined above if it discharges only in the event of a 25-year, 24-hour or larger storm event.

In addition, the NPDES permit issuing agency may, after conducting an on-site inspection, designate an animal feeding operation of any size as a CAFO based on a finding that the facility ''is a significant contributor of pollution to the waters of the United States.'' A

facility with 300 animal units or less, however, may not be designated as a CAFO under this authority unless pollutants are discharged from a man-made device or are discharged directly into waters passing over, across or through the facility or that otherwise come into direct contact with the confined animals.

Another regulatory program which addresses AFOs is the Coastal Nonpoint Pollution Control Program which is implemented under the authority of Section 6217 of the Coastal Zone Act Reauthorization Amendments (CZARA) of 1990. Section 6217 requires the 29 States and territories with NOAA-approved Coastal Zone Management Programs to develop enforceable policies and mechanisms to implement nonpoint source controls, known as management measures. Two management measures address facility wastewater and runoff from smaller AFOs, and another management measure addresses nutrient management on farms. In CZARA areas, permitted CAFOs are covered by the NPDES program while other AFOs would be covered by the CZARA management measures. EPA and NOAA should encourage States to consider the priorities of this Strategy when implementing their Coastal Nonpoint Pollution Control Programs.

4.3 Land Application of Manure

EPA and USDA recognize that manure and other animal waste from CAFOs is commonly applied to the land. Proper land application of these resources has agricultural benefits, but improper land application can cause water quality and potential public health impacts.

As noted above, the addition of pollutants from a discrete conveyance (e.g. natural channel or gullies) to the waters is regulated under the CWA as a point source discharge. At the same time, the Act exempts ''agricultural stormwater discharges'' from the definition of a point source. EPA has in the past, and will in the future, assume that discharges from the vast majority of agricultural operations are exempted from the NPDES program by this provision of the Act. The agricultural stormwater exemption, however, does not apply in a small number of circumstances that meet the following criteria:

- The discharge is associated with the land disposal of animal wastes (e.g. manure or other animal waste) originating from a CAFO (which is defined as a point source in the CWA and is regulated as a point source); and
- The discharge is not the result of proper agricultural practices (i.e., in general, the disposal occurred without a CNMP developed by a public official or a certified private party or in a manner inconsistent with the CNMP).

NPDES permits should assure that the animal waste from the CAFO will be utilized properly and require reporting on whether the permittee has a CNMP and whether it is being implemented properly.

4.4 Priorities for the Regulatory Program

The NPDES permit program authorized by the CWA will be used to address the relatively small number of AFOs that are now causing water quality or public health problems or that pose a significant risk to water quality or public health. EPA and USDA believe that AFOs in several situations are CAFOs and should be priorities for NPDES permitting:

Significant Manure Production—Large facilities (those with greater than 1000 animal units) produce quantities of manure that are a risk to water quality and public health whether the facilities are well managed or not. Because the amount of manure stored is so large, a spill while handling manure or a breach of a storage system can release large quantities of manure and wastewater into the environment causing catastrophic water quality impacts and threatening public health. Land application of large volumes of waste requires very careful planning to avoid water quality and public health impacts.

Of the estimated 450,000 animal feeding operations, only about 6,600 facilities had over 1,000 animal units as of 1992. Due to increases in the number of large facilities over the past six years, EPA and USDA believe that as many as 10,000 such facilities may exist today. EPA and USDA expect to update this estimate based on newer information. Based on size alone, these facilities are considered to be CAFOs and therefore are ''point sources'' subject to having an NPDES permit if they cause the addition of pollutants to waters. EPA believes that virtually all CAFOs with over 1,000 animal units are covered by the permit program and are a priority for permit issuance.

Unacceptable Conditions—Some facilities have unacceptable conditions that pose a significant risk of water pollution or public health problems. Specifically, facilities that have man-made conveyances that discharge animal waste to waters or have a direct discharge to waters that pass through the facility or come into direct contact with animals represent a significant risk to the environment and public health and are a priority for permit issuance. (As noted, AFOs with 300 or fewer AUs are CAFOs subject to permitting only where they have been designated as CAFOs by the permitting authority.)

There is insufficient data on which to base an estimate of the number of AFOs that have unacceptable conditions. EPA and USDA expect, however, that many, if not most, AFOs that now have unacceptable conditions will voluntarily address their unacceptable conditions to avoid the requirement to have a permit under the NPDES program.

Significant Contributors to Water Quality Impairment—In cases where water quality monitoring establishes that pollution from an individual facility with fewer than 1,000 animal units or a collection of facilities including those with fewer than 1,000 animal units is significantly contributing to, or is likely to significantly contribute to, impairment of a waterbody and nonattainment of a designated use, the facility or collection of facilities should be a priority for the NPDES permitting program.

Aggregate Water Quality Impacts on a Watershed Scale—EPA and USDA encourage States to use existing watershed assessment processes to determine whether a collection of AFOs is causing or contributing to watershed impairment. States should identify such watersheds for priority CAFO permitting. For example, the Clean Water Action Plan provides for a Unified Watershed Assessment Process to identify watersheds that are not meeting clean water and other natural resource goals.

In addition, States may consider identifying watersheds based on CWA section 303(d) lists or on assessments conducted by the interagency State technical committee. Such assessments may indicate, for example, that a high proportion of waters are impaired because of nutrient or pathogen problems attributable to animal manure or wastewater; that a watershed has more manure generated than there is land available to land apply manure in the watershed; or that water pollution associated with AFOs poses a significant threat to public health as a result of contamination of drinking water sources. EPA estimates that the number of AFOs that will be subject to the permit program as a result of identified watershed impairments to be between 1,000–3,000.

Site-specific Water Quality Impacts—Where the NPDES permitting authority has evidence that an individual AFO or group of AFOs significantly contribute to nonattainment of the designated use of an individual water body, these AFOs

should be a priority for permit issuance. Based on water quality assessment information from States, the number of facilities that meet these conditions is estimated to be between 1,000—3,000 facilities.

This section has described permitting and enforcement priorities for the regulatory program based on existing CAFO regulations. EPA and USDA expect that the total number of CAFOs in the situations described above that will be priorities for coverage under NPDES permits will be in the range 15,000—20,000. About 2,000 CAFOs now have NPDES permits. EPA plans to refine and strengthen the existing regulations during the next several years (see Section 5.0, Strategic Issue # 3).

4.5 CAFO CNMPs

NPDES permits for CAFOs will include conditions and other requirements that minimize the threat to water quality and public health and otherwise ensure compliance with the requirements of the CWA. EPA will issue guidance on the development of permits for CAFOs and will develop model permits. Among other things, the guidance will provide that permits include conditions that ensure compliance with national effluent guidelines applicable to CAFOs.

The EPA guidance will also recommend that CAFO permits require the development of a CNMP and its implementation on a schedule established in the permit. The guidance will incorporate NRCS's practice standards as the appropriate practice standards for CAFO CNMPs. Where elements of the CNMP are included in a NPDES permit, schedules for implementation of the practices or actions will be consistent with requirements of the CWA (i.e., compliance schedules will be consistent with State law and not exceed the five year term of the permit). Finally, permits will include any more stringent conditions that the permitting authority determines are necessary to meet State water quality standards.

CNMPs developed to meet the requirements of the NPDES permit program in general must be developed by a person certified to develop CNMPs, a qualified State agency official (e.g., cooperative extension agent), or by NRCS. Private parties may be certified by State or nonprofit groups (e.g., the Certified Crop Advisor Program of the American Society of Agronomy) approved by USDA, or certified directly by USDA through EQIP.

The ultimate responsibility for developing and implementing CNMPs resides with the CAFO owner and/or operator. If the CNMP is developed as a requirement of the NPDES permit program, the CNMP should be consistent with this Strategy and the regulatory agency will ensure that the CNMP meets the requirements of the CWA and is being implemented. State or Federal enforcement agencies will work to ensure compliance with permit requirements.

4.6 Smaller CAFOs Can Exit the Regulatory Program

Smaller CAFOs (those with fewer than 1000 AUs) that are not located in watersheds that are identified as impaired should be allowed to exit the permit program after the end of the five-year permit term. To exit the program these facilities must demonstrate that they have successfully addressed the initial condition that caused them to be designated as CAFOs, are fully implementing their CNMP, and offer evidence that they are in full compliance with their permit at the end of the permit term.

4.7 Good Faith Incentive

In many cases, AFOs are taking early voluntary actions in good faith to manage manure and wastewater in accordance with a CNMP. Some AFOs that are voluntarily implementing a CNMP may, however, have a discharge that makes them subject to the NPDES permitting program but does not cause them to be included in the permitting priorities described above (i.e., AFOs with 301–1000 AUs that do not discharge through a man-made conveyance or directly into waters of the U.S. that pass through their facility, and which are not significant contributors to nonattainment of a designated use as determined through water quality monitoring). NPDES permitting authorities will provide an opportunity for these AFOs to address the cause of the discharge before designating them as CAFOs.

5.0 Strategic Issues

Overview of Strategic Issues

This USDA/EPA Unified National Strategy on Animal Feeding Operations addresses seven major strategic issues:

Strategic Issue # 1—Building Capacity for CNMP Development and Implementation
Strategic Issue # 2—Accelerating Voluntary, Incentive-Based Programs
Strategic Issue # 3—Implementing and Improving the Existing Regulatory Program
Strategic Issue # 4—Coordinated Research, Technical Innovation, Compliance Assistance, and Technology Transfer
Strategic Issue # 5—Encouraging Industry Leadership
Strategic Issue # 6—Data Coordination
Strategic Issue # 7—Performance Measures and Accountability

Strategic Issue # 1 Building Capacity for CNMP Development and Implementation

Description

The successful implementation of this Strategy depends on the availability of qualified specialists from either the public or private sectors to assist in the development and implementation of CNMPs. AFO owners and operators will need substantially increased access to technical assistance from the private and public sectors to support a strengthened regulatory program and, at the same time, implement an accelerated effort to help owners and operators meet their stewardship responsibilities through early, voluntary action.

Through prior or existing voluntary programs, NRCS has developed CNMPs for AFOs. NRCS estimates that at least 300,000 AFOs need to develop CNMPs or revise existing CNMPs to meet the performance expectation of this Strategy. EPA estimates that between 15,000 to 20,000 operations will be considered CAFOs and be required to develop and implement CNMPs as part of a permit.

Desired Outcomes

- Increase the number of certified specialists to develop CNMPs.
- Ensure that CNMPs are implemented under the guidance of qualified specialists.
- Consistent quality of CNMP development and implementation.
- All AFO owners have a CNMP developed by a certified specialist by 2008.

Actions

USDA and EPA will take the following actions, to the extent permitted by available appropriations, to increase the supply of qualified technical specialists available to assist AFO owners and operators develop and implement CNMPs:

1. USDA and EPA will review available certification programs for those developing CNMPs for AFOs to ensure technical adequacy and will provide training and standards for these certification programs to improve their ability to certify CNMPs to AFOs.

2. Facilitate and encourage participation of private sector

consultants and technical advisors through certification, training, and other activities to ensure private sector sources of assistance can be effectively utilized by AFO owners and operators to develop and implement CNMPs.

3. Increase funding within the USDA NRCS Conservation Technical Assistance (CTA) Program and Cooperative Extension System to increase technically qualified field staff, train existing Federal and nonfederal staff, and provide enhanced technical support for Federal and nonfederal technical advisors.

4. Explore options for training and certifying AFO operators to develop and implement their own CNMPs.

5. USDA and EPA will facilitate the training of conservation contractors in the installation of practices specified in a CNMP.

6. USDA and EPA will provide assistance in the form of computer models or expert systems to assist in the development of CNMPs.

7. USDA and EPA will give priority to training those agencies and organizations that deliver services at the local level. The voluntary program is delivered at the local level through SWCDs, Cooperative Extension Service, USDA Service Centers, and the private sector. These local service providers should also be fully informed of the elements of the regulatory programs.

8. USDA and EPA will sponsor a national meeting to solicit ideas on how to build capacity for the development and implementation of CNMPs.

9. USDA will develop agreements with third-party vendors similar to the 1998 agreement with the Certified Crop Advisors (CCAs). CCAs will provide technical assistance to agricultural producers in nutrient management, pest management, and residue management. Any assistance provided under third party vendor agreements will meet NRCS standards and specifications, or State standards if more restrictive.

10. USDA, EPA, and the States should each analyze the potential impact of this Strategy on public and private resources and their availability to develop and implement CNMPs.

Strategic Issue #2—Accelerating Voluntary, Incentive-Based Programs

Description

USDA and EPA agree that the release of pollutants to surface or groundwater from an AFO is to be minimized regardless of size or management activity. *It is the ultimate responsibility of individual owners and operators, and the companies and industries they are involved with, to minimize the release of pollutants from their operations.* Under this Strategy, most AFOs will minimize the risk of pollution by voluntarily developing and implementing a CNMP.

Desired Outcomes

- All AFOs develop and implement CNMPs by 2008.
- Minimize pollution from AFOs to the greatest extent practical.
- Ensure the maximum environmental benefit is obtained per public dollar expended.
- Ensure adequate financial incentives are available to minimize the economic impact of implementing CNMPs.
- Ensure that limited resource, minority, and other underserved producers have the opportunity to participate fully in the voluntary programs.

Actions

1. National Standards

Develop and Revise Practice Standards—To ensure that conservation policies and practices are current and sufficient to address water quality risks associated with AFOs, NRCS, in consultation with EPA and with input from States and other stakeholders, will identify practice standards which need to be developed or revised and propose a schedule for development or revision by November 1998. The process of revising practice standards at both the national and local level involves the public review of new or revised standards. The process should be streamlined to the maximum extent possible.

2. Planning and Implementation

AFO CNMP Guidance—USDA's NRCS has national responsibility for conservation planning policy and procedures and will provide guidance, in consultation with EPA, by January 1999 that can be used by AFO owners, operators, and others to develop a CNMP.

Comprehensive Nutrient Management Planning requires that individuals, including AFO owners and operators, qualified in the technical issues associated with AFOs, should develop the CNMP. Good CNMPs are the result of a process that ensures all elements of an operation are considered and that causes of problems, rather than symptoms, are addressed. The CNMP guidance will indicate what should be contained in the CNMP (such as aerial photos or plan maps, planned conservation practices and schedule of implementation, engineering designs for any constructed facilities for storing or handling manure, records of soil and nutrient tests, appropriate rates of land application to prevent the application of nutrients at rates that will exceed the capacity of the soil and planned crops to assimilate nutrients and prevent pollution, and records of practices and actions).

3. Outreach and Program Delivery

Fair and equitable treatment—USDA and EPA agree and will ensure through aggressive outreach that the technical and financial assistance provided in the voluntary efforts recommended by this Strategy will be available to persons without regard to race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. These outreach efforts are already underway and will accelerate with the release of this Strategy.

4. Financial Assistance for CNMP Implementation

Financial assistance can ease the burden on AFO owners and operators who are implementing CNMPs. Financial assistance will be particularly important in helping existing AFOs improve the environmental performance of their operations. Failure to fully fund assistance at requested levels will seriously constrain our ability to accelerate progress through voluntary action and sometimes causes an economic hardship for AFOs. This is particularly true of limited resource farmers.

The primary source of USDA assistance to AFO owners and operators is the Environmental Quality Incentive Program (EQIP), which was initiated in the 1996 Farm Bill. The Conservation Reserve Program (CRP) and the Small Watershed Protection Program (PL 83–566) are also available to AFO owners and operators meeting program eligibility requirements. EQIP has been funded at $200 million in 1997 and 1998. Approximately 45 percent of the funds were spent in each of these years to fund contracts with AFOs to develop and provide cost share incentives to help implement CNMPs that consider most of the issues this Strategy recommends be addressed in a CNMP. The requests for funds for AFOs during each of those years was for approximately $230 million—three times the amount available. The Administration has requested $300 million for EQIP for FY 1999.

The CRP provides farmers rental payments to set aside lands for various environmental purposes. The continuous sign-up provision of CRP targets the establishment of conservation buffers which are

recognized as an important component of a CNMP. A provision of CRP, referred to as the Conservation Reserve Enhancement Program (CREP) allows States to join with the Federal government to increase rental rates paid to land owners by increasing funding for the CRP program with State funds. USDA established the Conservation Buffer Initiative in 1996 with the specific goal of establishing two million miles of buffers by 2002. In 1998, approximately $500 million was expended through CRP to establish an estimated 172,000 miles of buffers throughout the United States.

The PL 83–566 program received $86 million in FY 1997 and approximately $20 million was spent on 228 watershed plans that address water quality. A majority of these watershed plans address AFOs.

EPA has two funds that can be partially used to help many AFOs meet the performance expectation. The first is the 319 program, also known as the Nonpoint Source Management Program. Under section 319 of the CWA, States, Territories, and Tribes apply for and receive grants from EPA to implement nonpoint source pollution controls. Over $670 million have been available from this fund since 1990, with approximately 39 percent being directed toward agricultural issues, including AFOs.

The second EPA fund is the Clean Water SRF, which is a program used to make low interest loans (as low as zero percent) for important water quality projects. Managed by the States, the SRF program in each State can fund nonpoint source eligible implementation projects such as animal waste storage facilities. The SRF program is funding approximately three billion dollars in projects each year with a cumulative total over the years of $20 billion. Since 1997, the SRF program has funded over $650 million in nonpoint source-eligible projects to clean up polluted runoff (including AFOs).

Currently, many States have cost-share programs that address water quality issues. Funds from these programs are available to owners or operators to assist in development and implementation of CNMPs. USDA and EPA strongly support such programs.

Options to help provide Federal financial assistance to AFO operators to develop and implement CNMPs include:

- Continue and increase the USDA–EPA collaboration on AFO issues particularly at the field level, to better target and leverage available resources from all applicable programs to assist AFOs in addressing water quality issues.
- Target Federal financial assistance to existing AFOs who need to develop or revise CNMPs to meet the performance expectation established by this Strategy.
- Significantly increase EQIP funding as requested in the President's budget to meet the expressed demand from AFO owners and operators for financial assistance.
- Encourage AFO owners and operators to take full advantage of the CRP program and establish conservation buffers as part of their CNMPs. Also encourage States to collaborate with the Federal government through the CREP provision of the CRP program.
- Encourage States to use 319 funding in implementing programs that address management issues of AFOs. In particular, EPA will work with States to target the requested increase in 319 funds to impaired watersheds.
- EPA will work with States to increase the number and dollar amount of loans made through the Clean Water SRF for priority projects to prevent polluted runoff, with the goal of increasing the annual percentage of funds loaned for this purpose to at least 10 percent (or about $200 million) by the year 2001. EPA will also work with States toward the goal of increasing to 25 the number of States using integrated priority-setting systems to make clean water funding decisions by the year 2000. EPA will work with States to promote the use of these funds for AFO implementation measures.
- Encourage States and Tribes to address AFO issues as they work with the community to develop watershed restoration action strategies for priority watersheds under the CWAP.
- Develop a tool package of financial assistance programs that will be available so that AFO owners, counties, SWCDs, and States can assess options and understand how to receive financial assistance.

Strategic Issue #3 Implementing and Improving the Existing Regulatory Program

Description

The CWA provides that all ''point sources'' of water pollution that discharge or add pollution to waters are subject to having a National Pollutant Discharge Elimination System (NPDES) permit under section 402 of the Act. Section 502 of the Act defines ''concentrated animal feeding operations'' or CAFOs as point sources. EPA regulations provide detailed criteria for determining when an AFO is also a CAFO subject to the NPDES permit program (see also Section 4.2 and 4.4 of this Strategy).

This Strategy clarifies the applicability and the requirements of the existing regulatory program, identifies permitting and enforcement priorities, and describes EPA's plans to strengthen and improve existing regulations. For those facilities covered by the NPDES permitting program, CNMPs will identify steps to protect water quality and public health and will be a key element of the permit.

Desired Outcomes

- Minimize pollution from CAFOs to the greatest extent practicable.
- Ensure the maximum environmental benefit is obtained per public dollar expended.
- Develop draft comprehensive CAFO permitting guidance and model permits by October 1998 and final guidance by January 1999.
- Develop comprehensive State CAFO permitting strategies beginning in early 1999.
- Issue Round I NPDES permits to all CAFOs beginning in Spring 1999.
- Revise the NPDES CAFO permitting regulations by December 2001.
- Review and revise as appropriate the effluent limitation guideline for poultry and swine by December 2001 and for beef and dairy by December 2002.
- Large CAFOs (greater than 1,000 AUs) have developed and are implementing CNMPs by 2003.
- All CAFOs in States where EPA administers the NPDES program have developed and are implementing CNMPs by 2003.
- Issue Round II NPDES permits to all CAFOs beginning in 2005.
- All CAFOs in NPDES authorized States have developed and are implementing CNMPs in 2005.

Actions

1. Improve Implementation of the Existing CWA Permitting Program

EPA will work with States to establish a two-phase approach to permitting CAFOs. Round I of CAFO permitting will occur under EPA's existing CAFO regulations. In Round II permits, core permit elements may be expanded to reflect revisions to the effluent guideline, permit program regulations, and State-adopted water quality standards for nutrients.

A. Round I Permits

In Round I, EPA will work with NPDES-authorized States to issue Statewide general NPDES permits to cover all CAFOs with greater than 1000

AUs and CAFOs with between 300–1000 AUs that have unacceptable conditions. These general permits will be issued starting in Spring 1999 and affected CAFOs will be expected to submit a notice of intent to be covered by the permit. General permits will require facilities to develop and implement CNMPs on a schedule identified in the permit, develop record keeping procedures, and routinely report on the implementation of the CNMP.

EPA and the NPDES-authorized States should use individual NPDES permits in Round I for exceptionally large operations, new operations or those undergoing significant expansion, operations with historical compliance problems, or operations with significant environmental concerns. States have flexibility in determining which CAFOs should have individual NPDES permits and should address this topic in State CAFO permitting strategies (see Section 1D below).

Also in Round I, EPA will work with the States and Tribes to issue watershed general permits for facilities in selected watersheds, including those identified as not meeting clean water goals. States are encouraged to develop watershed general permits for watersheds where there are aggregate water quality impacts from AFOs on a watershed scale (see Section 4.4).

Watershed general permits are based on existing EPA and State permitting authority. EPA's regulations on general permits (40 CFR 122.28) allow the issuance of a single permit to cover facilities that share common elements (e.g., CAFOs) within a specific geographic area (e.g., watershed). To be covered under a watershed general permit during Round I, AFOs with fewer than 1000 AUs need to be individually designated as ''significant contributors'' of water pollution and AFOs with fewer than 301 AUs also need to meet specific criteria (e.g., have a man-made conveyance through which pollutants are discharged into navigable waters or a direct discharge to waters passing through the facility).

These watershed general permits will allow for tailoring of NPDES permit requirements to the needs of a watershed. Watershed general permits could also tailor permit requirements to the realities of manure and wastewater management practices in a given locality and promote more effective public participation than would a Statewide general permit. Watershed general permits must be written to reflect any TMDL developed for the watershed. EPA encourages permit writers to use their best judgment in developing such permits.

States should also issue individual permits to individual facilities that are significant contributors of water pollution to waters that do not attain water quality standards, due in whole or part to AFOs.

B. Round II Permits

Round II permitting will include reissuance of Statewide general permits, individual permits, and watershed general permits; will begin at the end of the five-year permit term of Round I (i.e., about 2005); and will incorporate new requirements resulting from revisions to the existing CAFO effluent guideline and NPDES permitting regulations.

In addition to potential regulatory revisions that may affect CAFO permitting, Round II CAFO permits will incorporate requirements that reflect ongoing activities related to nutrient water quality criteria development. On June 25, 1998, EPA announced a national strategy for the development of regional nutrient criteria. The strategy describes the approach EPA will take for development of scientific information related to nutrients and to working with States to ensure adoption of nutrient criteria into State water quality standards. EPA will establish numeric criteria for nutrients within three years of their issuance or by 2000, as specified in the Clean Water Action Plan. EPA expects all States and Tribes to adopt and implement numerical nutrient criteria into their water quality standards by December 31, 2003. All NPDES permits must be revised to incorporate requirements to meet State-adopted nutrient criteria as the permits are issued or reissued.

In Round II, EPA and States will continue to identify watersheds where cumulative effects of AFOs cause nonattainment of water quality standards and EPA and States will continue to identify as a priority for individual permits certain exceptionally large operations, those undergoing significant expansion or those with significant public interest.

Finally, in Round II, EPA will not include, and recommend that States not include, in reissued Statewide general permits any CAFO with fewer than 1000 AUs (or whatever appropriate threshold may exist because of revised regulations) that was included in a Round I permit if the CAFO is not located in a watershed that is identified as impaired and if the CAFO has successfully addressed the initial condition that caused them to be a CAFO, is fully implementing a CNMP, and offers evidence that it is in full compliance with its permit at the end of the permit term (See Section 4.6).

C. CAFO Permitting Guidance and Model Permits

EPA will develop comprehensive guidance on NPDES permitting of CAFOs including development of Statewide, individual, and watershed general permits. EPA will also develop model Statewide, individual, and watershed general permits. Guidance and model permits will be issued in draft by October 1998 and in final form by January 1999.

A key subject to be addressed in the guidance is the process for establishing schedules for development of CNMPs for those facilities covered by individual and general permits. These schedules for development of CNMPs should be appropriate to the circumstances in each State and should be described in detail in State-specific permitting strategies (see below). At a minimum, State-specific permitting strategies should provide for the development of CNMPs for the largest CAFOs (i.e., greater than 1,000 AUs) by 2003 and all CAFOs by 2005. In States where EPA administers the NPDES program, permits will require that all CAFOs have CNMPs by 2003.

The guidance will also address issues such as who is required to obtain a permit, elements of a permit (which may differ for new or expanding CAFOs and existing CAFOs), and different types of permits, including watershed general permits, consistent with the permitting priorities described in Section 4.4. EPA expects that permit elements will include specific performance measures for CNMP implementation, reporting (including reporting on CNMPs for land application and their implementation), and monitoring.

The model permits will provide that CNMPs developed pursuant to a permit, or that are directly related to issuance of a permit, should be provided to the permitting authority by the permittee. Some States have adopted approaches in their permitting programs that recognize the environmental responsibilities of corporate entities that participate in the operation of CAFOs. EPA will explore options for including such approaches in its model permits.

USDA and EPA agree that a CNMP developed by public sector parties or certified private parties should be a condition of an individual or general NPDES permit. EPA guidance will indicate that the CNMP should be the principal substantive pollution control provision of the permit and will

incorporate NRCS's practice standards as the appropriate practice standards for CAFO CNMPs. Permits will include other provisions including any more stringent conditions necessary to meet the requirements of the CWA (See Section 4.5).

D. State-Specific CAFO Permitting Strategies

EPA and USDA recognize that the current law and regulations provide authority to issue permits to a larger group of CAFOs than is identified in the priorities described in Section 4.4. However, States are asked to prioritize NPDES permit issuance to address AFOs that fall into the three priority permitting categories, at a minimum, and any other AFOs the State determines should have permits consistent with the authority of the current law, following the general guidelines for Round I and Round II permitting described above.

Some States have significantly greater numbers of AFOs requiring permits than do other States. The capacity for development of CNMPs in the public and private sector will vary from State to State. Resources available for the management of the NPDES program also vary from State to State. And, the extent to which smaller AFOs (i.e. under 1,000 animal units) are significant contributors to water quality problems on a site-specific or watershed basis will vary among States. State-specific CAFO permitting strategies should address timing and approaches to permitting, including the basis for using individual and general permits and should reflect stakeholder and public input to the extent practicable.

EPA will assist States in evaluating their CAFO permitting efforts and in developing, beginning in early 1999, comprehensive strategies consistent with this national Strategy to enhance permitting, inspection, and enforcement activities for CAFOs. EPA will also work with States to develop performance measures that track environmental progress and programmatic efforts. Finally, EPA will work to develop State-specific CAFO permitting strategies in cooperation with States that do not administer the NPDES program.

EPA will work with States to ensure that EPA enforcement priorities are designed to complement and ensure successful implementation of this Strategy and are otherwise consistent with State-specific permitting strategies. However, notwithstanding these priorities, it should also be recognized that EPA may initiate enforcement action at any facility at any time under the Agency's authorities to address imminent and substantial endangerments.

Several States have permitting or licensing programs that address environmental issues and requirements for AFOs that go beyond the NPDES program. EPA intends to work with States to ensure that State and Federal programs work together smoothly to protect water quality and public health. EPA will also work with States that are authorized to administer the NPDES program to ensure that State programs meet the NPDES substantive and procedural requirements and issue NPDES permits. However, this Strategy is not intended to preclude States from adopting more stringent approaches in their NPDES programs.

2. Review and Revision of Existing Regulations

A. Feedlots Effluent Limitations Guidelines

EPA will, with input from USDA, States, Tribes, other Federal Agencies and the public, review and revise as appropriate, the effluent limitation guideline for poultry and swine by December 2001 and for beef and dairy cattle by December 2002. NRCS and other USDA agencies will participate on the regulatory workgroup to revise the regulations.

In 1974, EPA promulgated the Effluent Limitation Guidelines and New Source Performance Standards for the Feedlots Point Source Category (40 CFR 412). The effluent guidelines for feedlots applies to a subset of operations in the following animal sectors: beef and dairy cattle, swine, sheep, horses, broiler and layer chickens, turkeys, and ducks.

The guideline establishes a ''no discharge'' requirement for process wastewater which, in general, includes the manure from the feedlot as well as any precipitation that comes into contact with the manure or any products used in or resulting from the production of animals or direct products (e.g., milk, eggs). The requirement prohibits discharges except those that result from chronic or catastrophic events, including from a 25-year, 24-hour or larger storm event where a facility has been appropriately designed and constructed. This ''no discharge'' standard applies to existing as well as new facilities.

EPA expects that revisions to the effluent guidelines will:

- Be closely coordinated with any changes to the NPDES permitting regulations.
- Consider innovative and alternative technologies including the viability of treatment and discharge technologies and technologies that do not involve storage of liquid manure.
- Assess different management practices that minimize the discharge of pollutants and the cross-media transfer of pollutants.
- Evaluate alternative use and disposal options for manure that nonetheless capture their nutrient/energy value.
- Evaluate options for regulating dry manure handling systems.
- Evaluate the need for different requirements for new or expanding and existing facilities.

B. NPDES Permit Regulations

EPA will, with input from USDA, States, Tribes, other Federal Agencies, and the public, revise the NPDES permit program regulations regarding CAFOs by December 2001.

EPA intends to revise the existing permitting regulations to clarify expectations and requirements for CAFOs as well as to reflect the changes in the industry. NRCS and other USDA agencies will participate on the regulatory workgroup to revise the regulations. Revision of the permitting regulations will be closely coordinated with the revision of the Feedlots Effluent Limitations Guideline (40 CFR Part 412) because of the commonality of issues and the administrative efficiencies for EPA, States and all interested groups. Permits in effect on the date of new regulations will remain in effect until subsequently changed to incorporate the new requirements.

Key permitting issues that EPA intends to consider during the regulatory revision process include:

- Establishing specific requirements for new and significantly expanding facilities and monitoring requirements for permitted facilities.
- Clarifying requirements for effective management of manure and wastewater from CAFOs whether they are handled on-site or off-site.
- Explore alternative ways of defining CAFOs.
- Consider requirements for CAFOs to conduct self-evaluations of CNMP implementation and keep records of such evaluations on-site.
- ÷ Considering large poultry operations, consistent with the size threshold for other animal sectors, as CAFOs, regardless of the type of watering or manure handling system.
- Clarifying who may designate and the criteria for designating certain AFOs as CAFOs.
- Providing for the protection of sensitive water bodies such as source water protection areas, Outstanding

National Water Resources, wetlands and other areas.

- Providing for expedited designation of smaller AFOs in watersheds identified for watershed general permits.
- ÷ Removing the exemption from permitting for AFOs that only discharge during a 24-hour 25-year or larger storm event.
- New, improved public review of general permit conditions applicable to individual facilities, including public notice of facilities to be covered.
- Consider defining all facilities regardless of size that have a man-made conveyance as a CAFO.
- Explore alternative approaches to ensuring that corporate entities support the efforts of individual AFOs to comply with permits and develop and implement CNMPs.

3. Improve Implementation of the Existing CWA Compliance and Enforcement Program

The following actions are designed to improve implementation of the existing CWA compliance and enforcement program for CAFOs and support implementation of this Strategy:

CAFO Compliance Assurance Implementation Plan Revisions—EPA will revise its CAFO Compliance Assurance Implementation Plan as necessary to ensure that EPA and State enforcement priorities support implementation of this Strategy. However, EPA may initiate emergency actions at any time against any AFO that presents an imminent or substantial endangerment.

Compliance Assistance—EPA will continue and expand compliance assistance efforts led by the National Agricultural Compliance Assistance Center consistent with the Strategy and changes to the regulatory program. As regulations are revised and implemented, EPA's initial efforts will focus on compliance assistance and later shift to a greater focus on enforcement activities.

CAFO Inspections—EPA will work with States to establish commitments for inspection of CAFOs with the goal of inspecting existing CAFOs (including unannounced periodic inspections to determine if CAFO CNMPs are being implemented) and other facilities that may need to be designated as CAFOs because they may fall into one of the categories that are priorities for NPDES permitting. EPA expects that training will be necessary for inspectors and will engage specialists familiar with AFOs and associated management practices to assist in this training.

Strategic Issue # 4 Coordinated Research, Technical Innovation, Compliance Assistance, and Technology Transfer

Description

Coordinated research, technical innovation, compliance assistance, and technology transfer relative to the environmental management of AFOs are critical components of this Strategy. USDA and EPA, together with other Federal partners, will establish coordinated research, technical innovation, and technology transfer activities, and compliance assistance, and establish a single point information center.

Knowledge gaps exist in our understanding of the effects of AFOs on natural resources and environmental quality. Some of this lack of understanding is due to the fragmented structure of our research and data collection efforts, information residing in multiple locations with much of the information obtained with objectives different from those of this Strategy and different information being used by AFO managers, technical assistance specialists and regulators. For example, research is done primarily from an animal production and natural resource management perspective by the Agricultural Research Service (ARS), Economic Research Service (ERS), and the land-grant colleges and universities, among others. These entities also do research on economic issues such as economic impact, cost/benefit analyses, policy analyses, and resource use and environmental implications. EPA, U.S. Geological Survey (USGS), and university researchers conduct research on AFOs from an environmental quality viewpoint. EPA and USDA will, in coordination with the private sector, the land grant colleges and universities and others, develop a coordinated plan for research, development, and assessment.

Desired Outcomes

A coordinated approach to research, technical innovation, compliance assistance, and technology transfer.

Actions

A. Coordinated Research Plan—USDA and EPA will develop a coordinated AFO research plan by October 1999. This plan will establish priorities for future research including:

1. Methods to better manage manure to address nutrients, pathogens, and other pollutants.
2. Modification of animal diets to reduce nutrients in manure.
3. Mitigation of sites with excessive pollutants.
4. Evaluation of impacts of best management practices from farm and watershed perspectives.
5. Educational materials for all audiences that meet their conservation, regulatory, and production needs.
6. Alternative uses of animal manure, such as for energy production or for high value, low volume fertilizers.
7. Assessment of the climate change effects of methane and NOx emissions from AFOs.
8. Assessment of the problem of air deposition of nutrients.
9. Assessment of food safety impacts from AFOs including pathogens, hormones, antibiotics, and metals and the water quality impacts resulting from the discharge of these and other compounds to the environment.
10. Assessment of the quality of existing monitoring data.
11. Alternatives to production methods that use animal confinement.
12. Establishment of soil phosphorous threshold levels.
13. Alternatives for transporting manure, manure distribution, and composting.
14. Water quality risk of dry manure management.

B. Coordinated Technology Transfer Plan—USDA and EPA will develop a coordinated AFO technology transfer plan by October 1999. The plan will describe how to disseminate the results of all research conducted by the agencies. The plan will also describe the establishment of a website on which to post all data results, analyses of the resulting information, comments or responses to the results or analyses, automated nutrient management tools, and any scholarly papers about the research project or related information.

C. Virtual Center—USDA and EPA will develop a Virtual Center with the goal of creating a single point of reference for both agencies, the individual producers, the livestock industry, and the general public. EPA and USDA will commit to developing a process for setting research priorities, coordinating research activities, participating in joint research endeavors, and sharing research results. The Virtual Center will consist of a website to be maintained by personnel from both USDA and EPA where research results, analyses, comments and responses to the research and scholarly papers on the research project or related information would be available to all.

Options

There are two options for realizing the three actions described above in this section. Regardless of which option is

chosen, EPA and USDA will coordinate with the National Agricultural Library in Beltsville, Maryland, which currently serves as a USDA repository for research data and results, as well as the National Agriculture Compliance Assistance Center. These options are not mutually exclusive nor exhaustive:

1. Develop a National AFO Information and Research Center.

USDA and EPA would develop a National AFO Information and Research Center. Appropriate EPA offices and USDA agencies would provide support to the Center. Other Federal agencies (e.g., USGS, Department of Energy) that are conducting relevant research, information management, and technical assistance activities would be invited to join as associated members. Members of the Center would contribute both financial and personnel support to the Center's activities. The Center would develop and manage a coordinated research program, compliance assistance, data exchange and coordinated technical assistance. In the short term, the Center would be tasked to complete the three action items described above.

2. Establish a National AFO Information and Research Working Group.

USDA and EPA would establish a National AFO Information and Research Working Group. Appropriate EPA offices and USDA agencies would provide support to the working group. Other Federal agencies that are conducting relevant research, information management, and technical assistance activities would be invited to join as members. Members of the working group would contribute both financial and personnel support to the working group's activities, although each cooperating agency would be directly responsible for the management of its human and financial resources. The working group would develop and manage a coordinated research, information exchange, and technical assistance program. The working group would also collaborate and coordinate activities with other appropriate entities. The Working Group would be tasked to complete the three action items described above.

Strategic Issue #5 Encouraging Industry Leadership

Description

This Strategy intends to provide strong incentives for AFO owners and operators to develop and implement CNMPs. Other sections of the animal agriculture industry can also play a key role in helping to encourage adoption of these CNMPs and address water quality problems on individual AFOs. An example is the Comprehensive Environmental Framework for Pork Production Operations recommended by the National Environmental Dialogue on Pork Production. The Dialogue included representatives from State Agriculture and Environmental Agencies, USDA, EPA, and the pork industry. The National Pork Producers Council is recommending that the Framework would apply to all commercial pork production operations. The poultry industry is currently conducting a similar dialogue. These industry-led initiatives can significantly increase the voluntary adoption of CNMPs to protect water quality. In addition to the animal agriculture industry, other groups (i.e., co-ops, the Certified Crop Advisors, and the National Association of Independent Crop Consultants) can play a key role in helping AFOs protect water quality and public health.

USDA and EPA invite comments on how the agricultural and livestock industries can play an active role in ensuring that all AFOs have CNMPs.

Desired Outcomes

The animal agriculture industry will take the lead in promoting and ensuring the protection of water quality on individual AFOs though development and implementation of CNMPs on all AFOs.

Actions

The following are actions that USDA and EPA may take to promote industry involvement. USDA and EPA request comment on which of these actions or other actions would benefit most from Federal involvement.

Industry-Led Initiatives—USDA and EPA will work with industry, in particular integrators, to identify opportunities for greater industry involvement in pollution prevention. This could include the integrators providing technical, educational, and financial assistance to producers and/or requiring CNMPs in contracts with producers. This could also include industry use of climate, soil, and crop information supplied by USDA and EPA to locate future operations. USDA and EPA will promote industry-led dialogues in different AFO sectors such as the recently concluded pork dialogue and the ongoing poultry dialogue.

Manure Brokering Networks—USDA and EPA will investigate with the industry the potential for manure brokering networks to make sure excess manure is available to the cropland which needs it.

AFO Owner/Operator Peer Network—USDA and EPA will promote with the industry a peer network of AFO owners and operators willing to assist other producers in their area with questions or assistance on CNMPs.

AFO Awards Program—USDA and EPA will work with AFO Industry groups to develop an awards program to promote innovative and effective water quality management of AFOs.

Disseminate Information—USDA and EPA will work with industry (associations, integrators, etc.) to disseminate information on the revised NPDES regulations and effluent guidelines, beginning in 2001.

Locally-Led Watershed Efforts—USDA and EPA will work with the AFO industry to promote locally led watershed efforts.

Industry-Developed Planning Tools—USDA and EPA will encourage and support industry efforts to develop and distribute planning tools to members to enable them to develop and implement CNMPs.

Environmental Reviews—USDA and EPA will promote industry efforts to conduct environmental reviews of members' AFOs to evaluate environmental performance and assist in enhancing environmental protection.

Manure/Fertilizer/Biosolids Dialogue—USDA and EPA will encourage dialogue on how to maximize the benefits of using manure, fertilizer, and biosolids.

Marketing and Promotion Orders—The 1996 Farm Bill authorized conservation as a purpose for marketing and promotion orders. Marketing and promotion orders allow an agriculture industry (e.g., livestock) to assess a charge on the product to be used for conservation and environmental activities. These marketing and promotion orders generate needed funds for an activity and can provide financial support for all its producers (e.g., growers). In implementing a marketing and promotion order (i.e., check-off program) through the Secretary of Agriculture, additional revenue can be generated to support, while maintaining a level playing field throughout the industry, needed nutrient management practices.

Strategic Issue #6 Data Coordination

Description

Several kinds of data are useful in assessing and managing the water quality impacts of AFOs. Ambient water quality information allows the identification of water quality impacts that may be attributable to AFOs. Aggregate information about multiple

AFOs can be used to target both regulatory and voluntary activities, including watershed-level planning. Finally, information about individual AFOs is helpful for those assisting owners and operators in developing CNMPs, identifying facilities that may be subject to the regulatory program, and for the development and implementation of watershed-level plans. These three kinds of data are available from multiple sources, including USDA, EPA, USGS, Army Corps of Engineers, and State agencies.

Recently, questions have been raised regarding the public availability of some types of information related to AFOs- in particular, data related to individual AFOs used by USDA to assist in conservation planning. USDA and EPA affirm the need to protect the trust relationship that exists between farmers and USDA and as characterized by Secretary of Agriculture Dan Glickman's call to ''maintain a firewall between voluntary and regulatory programs.'' On May 22, 1998, NRCS issued a policy statement that prohibits the release of AFO-specific information in conservation plans and case files that has been developed through voluntary technical and financial assistance programs. In accordance with EPA regulations most information on individual facilities, collected or generated as part of the NPDES program, is publicly available.

Desired Outcomes

USDA/EPA coordination on data sharing that protects the trust relationship between USDA and farmers and provides regulatory authorities with information that is useful in protecting water quality.

Actions

Joint Policy Statement on Data Coordination—EPA and USDA will develop a joint policy statement on information coordination. Both agencies agree to review existing policies and guidance based on the joint policy statement.

Water Quality Inventory Enhancements—EPA will improve the 305(b) Water Quality Inventory to better report the water quality impacts caused by AFOs.

Cost-Benefit Methodology—EPA and USDA will develop a joint evaluation of the costs and benefits of this Strategy and options considered in developing revised CAFO regulations. USDA and EPA will convene an interagency economic analysis work group to develop the economic analysis methodology and data that may be used in the analysis.

CAFO Inventory—To ensure a program that is consistent with NPDES program activities, EPA will develop an inventory of facilities subject to regulatory activities.

Strategic Issue #7—Performance Measures and Accountability

Description

USDA and EPA believe that it is critical to establish performance measures to gauge our success in implementing this Strategy and meeting relevant goals in each agency's strategic plan established under the Government Performance and Results Act. Three types of performance measures are important. First, USDA and EPA are committed to completing each of the actions described under the strategic issues. Second, there are a number of programmatic activities (e.g., number of AFOs with CNMPs, number of CAFOs covered by NPDES permits) that we will evaluate to measure the level of activity being devoted to addressing water quality impacts from AFOs. Finally, and most importantly, USDA and EPA will develop appropriate environmental outcome measures to measure our progress in implementing this Strategy.

We recognize that measurement of AFO progress in addressing water quality issues will take time for two reasons: (1) it will take time to develop appropriate measures; and (2) it will take time for water quality progress to be achieved (maybe decades in some watersheds).

Desired Outcomes

An effective performance measurement system for AFOs that includes appropriate programmatic output and environmental outcomes that allows USDA, EPA and other stakeholders to determine the level of success and to improve AFO-related programs.

Actions

Performance Measurement—USDA, EPA, and other Federal agencies will establish a joint work group to develop a coordinated set of programmatic outputs and environmental outcome measures for this Strategy and identify a baseline against which to measure performance. The work group will seek input from States and SWCDs and will develop a performance measurement approach for AFOs by October 1999.

Watershed Nutrient Load Estimates—USDA and EPA will estimate by January 2000 a baseline of nutrient loads to watersheds with potential excess nutrients from animal waste using data from fertilizer sales, USGS/EPA nutrient loading analysis, Census of Agriculture, permit limits, and other estimates.

6.0 Roles

The successful implementation of this Strategy calls for a number of individuals and organizations to fulfill several key roles. These key roles are described in the following paragraphs.

- *Federal Government*—It is the Federal government's responsibility to establish minimum national expectations, technical standards, and regulatory requirements for AFOs, and to help provide the tools to achieve these expectations, standards, and requirements. EPA, through the CWA, Coastal Zone Act Reauthorization Amendments, and the Safe Drinking Water Act, is charged with the regulatory responsibilities, including permitting, compliance assurance, and enforcement, that relate to AFOs. USDA, through conservation, research, and education provisions of the Farm Bill and other legislation, is largely responsible for programs that help AFOs meet performance expectations through voluntary efforts. There are many ways that USDA, EPA, and other Federal agencies can work together to assist animal producers and the public including collaboration on research, education, technical assistance and financial assistance. USDA and EPA, in particular, will work closely and cooperatively, to ensure that the goals and expectations of this Strategy are met and its guiding principles are reflected in our combined and independent activities.
- *State/Local Government*—State and local governments often have the responsibility for implementing Federal programs. For example, 42 States and the Virgin Islands are authorized to implement the current CWA provisions that affect CAFOs. States also implement various nonpoint source control programs, including cost-share programs. States and SWCDs are key partners in implementing environmental and conservation programs. State Land Grant Universities are the primary mechanism to deliver agricultural research and extension programs. State, local, and Federal governments, and private sector partners work together to ensure that the actions taken on the ground are appropriate and cost effective. State and local governments also help determine where water quality and public health protection must be enhanced beyond the minimum performance expectations established through Federal programs, and often deal with local issues such as siting and odor.

• *Individual Producers*—No matter what size an operation or from what management activity, the release of pollutants to surface or groundwater from an AFO is to be avoided. It is the responsibility of individual owners and operators, and the companies and industries they are involved with, to minimize the release of pollutants from AFOs. Every operation should be implementing a CNMP that minimizes the risks of pollution.

• *Integrators*—Integrators should ensure that their contract growers are environmentally responsible. Feed mills and processing plants should incorporate the environmental impacts of the dissociated production operations into the siting and sizing of their plants. Integrators can also help develop alternatives for manure use and transport.

• *Livestock Industry*—The livestock industry as a whole has an obligation to educate its members and to provide leadership to ensure that its practices do not adversely impact society or the environment. Many sectors of the livestock industry have shown leadership by moving forward to establish new, industry-led efforts to improve the siting and management of AFOs, and to provide training to operators. This leadership must be enhanced and continue.

• *Other Private Sector*—The private sector can continue to contribute to new technologies and innovative strategies that capitalize on the nutrient and energy value of animal manure and related by-products of AFOs. This would include vendors and consultants of animal manure treatment and management systems. Various organizations, including livestock organizations and AFO-related companies provide educational programs to inform AFO owners and operators about Federal and State goals, standards, rules, and permitting processes, and to teach them how they can protect environmental quality and comply with regulatory provisions. The agricultural and environmental consulting community can also respond by helping to ensure that appropriate technical resources are available to assist with development of CNMPs for producers. Fertilizer producers and dealers can provide information on integrating use of manure and other nutrient sources to ensure appropriate nutrient use.

• *Research and Educational Institutions*—Public and private research organizations provide much of the knowledge and technology to better manage and utilize manure and related by-products of livestock production. USDA's and EPA's research, education, and technical assistance programs will provide leadership in developing new and innovative technologies for AFOs and analyzing their effectiveness.

• *Watershed or Community Responsibilities*—Every watershed where the concentration of AFOs is a potential source of pollution should have a watershed- or area-wide plan that helps AFO owners, operators, and others to work together to prevent pollution. Such planning is particularly important in areas where problems exist, such as where the quantity of manure and nutrients produced by AFOs exceeds what can be safely applied to land to meet crop needs. Locally led watershed efforts promote coordinated and integrated decision making to find sound, locally acceptable ways to achieve environmental quality.

• *Environmental Groups*—Environmental groups and grass-roots organizations play an important role in focusing public attention on environmental concerns with respect to animal production activities. Environmental groups can provide ''on-site'' reports about specific environmental quality concerns and can educate its members, the general public, the agricultural community and the media about important environmental concerns at the local, State, and national level.

Signed in Washington, D.C. on September 11, 1998.

James R. Lyons,

Under Secretary, Natural Resources and Environment, U.S. Department of Agriculture, Washington, D.C.

Dana D. Minerva,

Acting Assistant Administrator, Office of Water, U.S. Environmental Protection Agency, Washington, D.C.

[FR Doc. 98–25138 Filed 9–18–98; 8:45 am]

BILLING CODE 3410–16–p

DEPARTMENT OF COMMERCE

Bureau of the Census

The 1998 Public Opinion Survey

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3 506(c)(2)(A)).

DATES: Written comments must be submitted on or before November 20, 1998.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) should be directed to Joanne Dickinson, Bureau of the Census, Room 3015–3, Washington, DC 20233, (301) 457–4081.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau's core business is large-scale surveys and censuses. This involves the full range of activities required to produce data, including survey and instrument design and data collection, processing, and dissemination. Research and data analysis activities directly support its capabilities to conduct large-scale surveys and censuses. Therefore, the Census Bureau plans to conduct the 1998 Public Opinion Survey (POS) to gather and benchmark useful and fundamental data about the public's perception of government information collection and its dissemination and use of the statistics it collects. Acknowledging steady declines in response rates to censuses and surveys, we would like to identify those barriers that inhibit responsiveness. As the preeminent collector and provider of timely, relevant, and quality data about the people and economy of the United States, we need also to better understand the public's values for its information and the public's awareness, exposure to, and use of statistical information that it disseminates to be more responsive to customers needs and preferences. Next, the Census Bureau needs to better inform and educate its staff about the public's opinions of this agency and its practices to help them better target communications and to more effectively converse with them. Finally, the Census Bureau would like to use this input to redefine its strategic goals and activities in the post-2000 period.

The Census Bureau wants to endow all its employees with the findings from this research to help them to individually and to collectively implement the timely findings and recommendations from this research. It is essential that the Census Bureau

improve the focus and effectiveness of communications about census 2000 and other programs. With response rates sliding downward in general and the Census Bureau's need to maintain and/or improve response rates to its various censuses and surveys, most especially the census 2000, it is imperative that we identify and develop effective mechanisms and communications that will help identify and to remove barriers to response. Equally significant to the Census Bureau's current plans for effective outreach and targeted promotions is the need for early identification and removal of barriers that limit or prohibit effective communications with the public. We also need to share these findings and recommendations about the public's mind set with Census Bureau management as they prepare to redefine customer-focused strategic goals and activities for the post-2000 era.

This research would complement and extend earlier research sponsored by the Census Bureau. These studies focused on the public's knowledge, attitudes, and perceptions about the Census Bureau and its practices. The 1998 POS will bridge the gap of information collected earlier about the specific public perceptions. This research will further define/refine for the Census Bureau the public's image of it in general, as a Federal Government agency, and as a statistics' collector and provider. To more effectively inform, educate, and reach the public with its communications, the Census Bureau needs to know how the public sees, hears, reads, gets, or uses statistics and how it can more effectively inform, educate, reach and/or involve them in forthcoming activities.

II. Method of Collection

A contractor will conduct the national survey with telephone interviewing using an automated survey instrument and a list-assisted random digit dialing (RDD) sampling design. The RDD methodology will incorporate a number of peripheral survey techniques that have been shown to raise response rates. By applying results and recommendations from earlier research, the Census Bureau will collect accurate and reliable data with a maximal response rate and minimal bias.

III. Data

OMB Number: Not available.

Form Numbers: The automated survey instrument will not have a form number.

Type of Review: Regular review.

Affected Public: Individuals or households.

Estimated Number of Respondents: 1,200.

Estimated Time Per Response: 15 minutes.

Estimated Total Annual Burden Hours: 300.

Estimated Total Annual Cost: The only cost to the respondents in participating is that of their time.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 United States Code, Section 193.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for 0MB approval of this information collection; they also will become a matter of public record.

Dated: September 15, 1998.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 98–25153 Filed 9–18–98; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of the Census

Census Advisory Committee of Professional Associations

AGENCY: Bureau of the Census, Commerce.

ACTION: Notice of Public Meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (Pub. L. 92–463 as amended by Pub. L. 94–409), we are giving notice of a meeting of the Census Advisory Committee of Professional Associations.

The Committee is composed of 36 members appointed by the Presidents of the American Economic Association, the American Statistical Association, the Population Association of America, and the Chairperson of the Board of the American Marketing Association. The Committee advises the Director of the Bureau of the Census on the full range of Census Bureau programs and activities in relation to their areas of expertise.

DATES: The meeting will convene on October 22–23, 1998. On October 22, the meeting will begin at 9:00 a.m. and adjourn at 5:00 p.m. On October 23, the meeting will begin at 9:00 a.m. and adjourn at 12:30 p.m.

ADDRESSES: The meeting will take place at the Francis Amasa Walker Conference Center, Bureau of the Census, 4700 Silver Hill Road, Suitland, MD 20746.

FOR FURTHER INFORMATION CONTACT: Census Bureau Committee Liaison Officer, Ms. Maxine Anderson-Brown, Room 1647, Federal Building 3, Washington, DC 20233. Her phone number is 301–457–2308, TDD 301–457–2540.

SUPPLEMENTARY INFORMATION: The agenda for the meeting on October 22, which will begin at 9:00 a.m. and adjourn at 5:00 p.m., is the following:

- Introductory Remarks by the Acting Director, Bureau of the Census.
- Census Bureau Responses to Committee Recommendations.
- Census 2000 Updates.
- How Do We Provide Maximum Access to Census 2000 Data While Maintaining the Perception as Well as the Reality of Confidentiality?
- What are the implications of implementing the North American Industry Classification System (NAICS) in Census Bureau Programs?
- Evaluation of Communications/Marketing Plans for Geographic Products, NAICS, and Foreign Trade Statistics.
- The Census Bureau's Role in Improving the Quality of the GDP Estimates.
- Update on Census 2000 Research and Experimentation Program.
- Customer Services for a Post-2000 Internet Environment.
- Developing NAICS Time Series for Back Years.
- Factors to Consider in the Shift from Products to Reimbursable Services (Post-2000).
- Linking Economic and Demographic Data Sets at Census.
- How Do We Redesign the Census Bureau Website to Better Meet Census and User Needs?
- The agenda for the meeting on October 23, which will begin at 9:00 a.m. and adjourn at 12:30 p.m., is the following:
- Census 2000 Data Products and Dissemination.
- Applying Cognitive Survey Methods to the Study of Statistical

Reporting by Large Multiunit Establishments.

- Activities of the Office of Chief Economist.
- Develop Recommendations and Special Interest Activities.
- Closing Session.

The meeting is open to the public, and a brief period is set aside, during the closing session, for public comment and questions. Those persons with extensive questions or statements must submit them in writing to the Census Bureau Committee Liaison Officer. Individuals wishing additional information or minutes regarding this meeting may contact the Officer as well. Her address and phone number are identified above.

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should also be directed to the Committee Liaison Officer.

Dated: September 15, 1998.

James F. Holmes,

Acting Director, Bureau of the Census.

[FR Doc. 98–25168 Filed 9–18–98; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

Cornell University; Notice of Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Room 4211, U.S. Department of Commerce, 14th and Constitution Avenue, N.W., Washington, D.C.

Docket Number: 98–035. *Applicant:* Cornell University, Ithaca, NY 14853. *Instrument:* Scanning Tunneling Microscope, Model JAFM–4500XT. *Manufacturer:* JEOL Ltd., Japan. *Intended Use:* See notice at 63 FR 40473, July 29, 1998.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States. Reasons: The foreign instrument provides: (1) operation at temperatures to 500°C and (2) measurement of the motion of the cantilever tip in the plane of the sample (frictional interaction). A domestic manufacturer of similar equipment advised August 28, 1998 that (1) these capabilities are pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

Gerald A. Zerdy,

Program Manager, Statutory Import Programs Staff.

[FR Doc. 98–25114 Filed 9–18–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Applications for Duty-Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, Department of Commerce, Washington, D.C. 20230. Applications may be examined between 8:30 A.M. and 5:00 P.M. in Room 4211, Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C.

Docket Number: 98–043. *Applicant:* University of Pennsylvania, Electron Microscopy Core Laboratory, B–110 Richards Building, 36th and Hamilton, Philadelphia, PA 19104–6085. *Instrument:* Electron Microscope, Model JEM–1010. Manufacturer: JEOL, Ltd., Japan. *Intended Use:* The instrument will be used to study the effects of various agents or disease conditions on cellular morphology determined by routine ultrastructural analysis. In addition, the instrument will be used to teach the techniques of electron microscopy and ultrastructural analysis to graduate students, postdoctoral fellows and faculty members. *Application accepted by Commissioner of Customs:* August 28, 1998.

Docket Number: 98–044. *Applicant:* University of North Dakota School of Medicine & Health Sciences, Department of Anatomy & Cell Biology, 501 North Columbia Road, Box 9037, Grand Forks, ND 58202. *Instrument:* Electron Microscope, Model H–7500. *Manufacturer:* Hitachi, Japan. *Intended Use:* The instrument will be used for biological studies including observations of normal and diabetic human eye and kidney tissues, laboratory animal central nervous system tissues and scleral tissues from the posterior portion of the eye globe in newborn chicks. In addition, the instrument will be used in the training of undergraduate, graduate and postgraduate students in the use of transmission electron microscopy for biological research. *Application accepted by Commissioner of Customs:* August 28, 1998.

Gerald A. Zerdy,

Program Manager, Statutory Import Programs Staff.

[FR Doc. 98–25115 Filed 9–18–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 081398A]

Endangered and Threatened Species; Retention of Species on Candidate Species List Under the Endangered Species Act (ESA)

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

ACTION: Notice of retention of Atlantic sturgeon on list of candidate species.

SUMMARY: NMFS retains Atlantic sturgeon (*Acipenser oxyrinchus oxyrinchus*) on its list of candidate species. In a notice published today in the **Federal Register**, NMFS and the U.S. Fish and Wildlife Service (Services) found that listing Atlantic sturgeon under the ESA is not warranted at this time. The finding summarizes the Services' concerns regarding the species. NMFS encourages Federal agencies and other appropriate parties to take Atlantic sturgeon into account in project planning.

DATES: September 15, 1998.

FOR FURTHER INFORMATION CONTACT: Marta Nammack or Terri Jordan at (301) 713–1401.

SUPPLEMENTARY INFORMATION: In a separate **Federal Register** document published today, the Services find that listing Atlantic sturgeon in the United States as a threatened or endangered species is not warranted at this time. The finding also summarizes the

Services' concerns regarding the species. NMFS will retain Atlantic sturgeon on its list of candidate species in order to continue to monitor the species' status.

The candidate species list serves to notify the public that NMFS has concerns regarding these species/vertebrate populations that may warrant listing it as a threatened or endangered species in the future, and it facilitates voluntary conservation efforts. NMFS believes it is important to highlight candidate species so that Federal and state agencies, Native American tribes, and the private sector are aware of which species could benefit from proactive conservation efforts and to take these species into account in project planning.

Dated: September 15, 1998.

Patricia A. Montanio,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 98–25104 Filed 9–15–98; 4:48 pm]

BILLING CODE 3510–22–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 081998D]

Marine Mammals

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

ACTION: Issuance of permit.

SUMMARY: Notice is hereby given that LGL Limited, environmental research associates, 22 Fisher Street, P.O. Box 280, King City, Ontario, Canada L7B 1A6, has been issued a permit to take bowhead whales (*Balaena mysticetus*), ringed seals (*Phoca hispida*), bearded seals (*Erignathus barbatus*) and beluga whales (*Delphinapterus leucas*) for purposes of scientific research.

ADDRESSES: The permit 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); and

Regional Administrator, Alaska Region, NMFS, 709 W. 9th Street, Federal Building, P.O. Box 21668, Juneau, Alaska 99802 (907/586–7012).

FOR FURTHER INFORMATION CONTACT: Jeannie Drevenak, 301/713–2289.

SUPPLEMENTARY INFORMATION: On July 17, 1998, notice was published in the **Federal Register** (63 FR 38557) that a request for a scientific research permit to take bowhead whales, ringed seals, bearded seals, and beluga whales had been submitted by the above-named individual. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR Part 216), the Endangered Species Act (ESA) of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Regulations Governing the Taking, Importing, and Exporting of Endangered Fish and Wildlife (50 CFR part 222).

Issuance of this amendment, as required by the ESA, was based on a finding that such permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of the endangered species which is the subject of this permit; and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: August 24,1998.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 98–25189 Filed 9–18–98; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 98–52]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Assistance Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of P.L. 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSAA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 98–52, with attached transmittal and policy justification.

Dated: September 15, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5000–01–M

DEFENSE SECURITY ASSISTANCE AGENCY

WASHINGTON, DC 20301-2800

9 SEP 1998
In reply refer to:
I-71147/98

Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 98-52, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance (LOA) to Egypt for defense articles and services estimated to cost $200 million. Soon after this letter is delivered to your office, we plan to notify the news media.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Same ltr to: House Committee on International Relations
Senate Committee on Appropriations
Senate Committee on Foreign Relations
House Committee on National Security
Senate Committee on Armed Services
House Committee on Appropriations

Transmittal No. 98-52

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

(i) **Prospective Purchaser:** Egypt

(ii) **Total Estimated Value:**

Major Defense Equipment*	$ 0 million
Other	$ 200 million
TOTAL	$ 200 million

(iii) **Description of Articles or Services Offered:** F-16 Depot Level Maintenance Program including depot level repair capability for landing gear, hydraulics, pneumatics, fuel, electrical; instrument and environmental/oxygen components; construction; training and training equipment; support equipment; publications and technical data; U.S. Government and contractor representatives; spare and repair parts; and other related elements of program support.

(iv) **Military Department:** Air Force (QDL, Amendment 2)

(v) **Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:** none

(vi) **Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:** none

(vii) **Date Report Delivered to Congress:** 9 SEP 1998

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Egypt - Depot Level Maintenance Program

The Government of Egypt has requested a possible sale for F-16 Depot Level Maintenance Program including depot level repair capability for landing gear, hydraulics, pneumatics, fuel, electrical; instrument and environmental/oxygen components; construction; training and training equipment; support equipment; publications and technical data; U.S. Government and contractor representatives; spare and repair parts; and other related elements of program support. The estimated cost is $200 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country which has been and continues to be an important force for political stability and economic progress in the Middle East.

This proposed sale will provide the Egyptian Air Force an initial F-16 depot level maintenance capability and will allow them to be self-sufficient in performing their own maintenance.

This proposed sale of this program will not affect the basic military balance in the region.

Several individual contractors will be involved with small portions of the program after source selection. There are no offset agreements proposed to be entered into in connection with this potential sale.

The number of U.S. Government personnel and contractor representatives required in-country to support the program for up to five years will be determined as the program proceeds.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 98–25127 Filed 9–18–98; 8:45 am]
BILLING CODE 5000–04–C

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the Advisory Council on Dependents' Education

AGENCY: Office of the Secretary, Department of Defense Education Activity (DoDEA).

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given of a forthcoming semiannual public meeting of the Advisory Council on Dependents' Education (ACDE).

DATES: October 8–9, 1998.

ADDRESSES: The meeting will be preceded by visits to DoD overseas schools in Germany, from October 5–7. The formal meeting will be held October 8, at the Wings Hotel in Raunheim, Germany.

FOR FURTHER INFORMATION CONTACT: Ms. Polly Purser, Department of Defense Education Activity, 4040 North Fairfax Drive, Arlington, Virginia, 22203–1635. Ms. Purser can be reached at 703–696–4235, extension 1911.

SUPPLEMENTARY INFORMATION: The Advisory Council on Dependents' Education is established under title XIV, section 1411, of Pub. L. 95–561, Defense Dependents' Education Act of 1978, as amended (20 U.S.C. section 929). The purpose of the council is to recommend to the Director, Department of Defense Dependents Schools (DoDDS), general policies for the operation of the DoDDS; to provide the Director, DoDDS, with information about effective educational programs and practices that should be considered by DoDDS; and to perform other tasks as may be required by the Secretary of Defense.

Dated: September 15, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98–25159 Filed 9–18–98; 8:45 am]
BILLING CODE 5000–14–M

DEPARTMENT OF DEFENSE

Office of the Secretary

U.S. Strategic Command Strategic Advisory Group

AGENCY: Office of the Secretary, USSTRATCOM, Department of Defense.

ACTION: .Notice.

SUMMARY: The Strategic Advisory Group (SAG) will meet in closed session on November 19 and 20, 1998. The mission of the SAG is to provide timely advise on scientific, technical, and policy-related issues to the Commander in Chief, U.S. Strategic Command, during the development of the nation's strategic war plans. At this meeting, the SAG will discuss strategic issues that relate to the development of the Single Operational Plan (SIOP). Full development of the topics will require discussion of information classified TOP SECRET in accordance with Executive Order 12958, April 17, 1995. Access to this information must be strictly limited to personnel having requisite security clearances and specific need-to know. Unauthorized disclosure of the information to be discussed at the SAG meeting could have exceptionally grave impact upon national defense.

In accordance with section 10(d) of the Federal Advisory Committee Act, (5 U.S.C. App 2), it has been determined that this SAG meeting concerns matters listed in 5 U.S.C. 552b(c) and that, accordingly, this meeting will be closed to the public.

Dated: September 15, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98–25158 Filed 9–18–98; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Department of the Navy

Record of Decision for the Transfer and Reuse of Naval Weapons Industrial Reserve Plant, Calverton, New York

AGENCY: Department of the Navy, DOD.

ACTION: Notice of Record of Decision.

SUMMARY: The Department of the Navy, after carefully weighing the environmental implications of transferring Naval Weapons Industrial Reserve Plant (NWIRP) Calverton out of Navy ownership, announces its decision to transfer the property to the Town of Riverhead, NY; the New York State Department of Environmental Conservation (NYSDEC); and the Department of Veterans Affairs.

FOR FURTHER INFORMATION CONTACT: Mr. Bob Ostermueller, Northern Division Naval Facilities Engineering Command (Code 202.2), Mail Stop 82, 10 Industrial Highway, Lester, PA 19113, telephone (610) 595–0759.

SUPPLEMENTARY INFORMATION: The text of the entire Record of Decision is provided as follows:

Pursuant to Public Law (PL) 103–C337 and 104–106, Section 102(2)C of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4331 *et seq.*) and the Council on Environmental Quality Regulations for implementing NEPA procedures (40 CFR 1500–1508), the Department of the Navy (Navy) announces its decision to transfer the Naval Weapons Industrial Reserve Plant Calverton (NWIRP Calverton) to the Town of Riverhead, NY; the New York State Department of Environmental Conservation (NYSDEC); and the U.S. Department of Veterans Affairs (VA). The transfer and subsequent reuse of these properties will be consistent with the preferred alternative as described in the Final Environmental Impact Statement (FEIS) prepared for this action.

Background

The transfer of this property has been authorized by two acts of legislation. Under PL 130–C–337, ''the Secretary of the Navy may convey, without consideration, to the Community Development Agency of the Town of Riverhead, all right, title, and interest of the United States in and to a parcel of land, and improvements thereon, consisting of approximately 2,900 (2,923) acres and comprising a portion of the Naval Weapons Industrial Reserve Plant, Calverton, New York''. Also, the legislation allows for the transfer of the remaining 3,137 acres, consisting of flight operations buffer zones, to the NYSDEC. Under PL 104–106, ''the Secretary of the Navy may transfer, without reimbursement, to the administrative jurisdiction of the Secretary of Veterans Affairs a parcel of real property consisting of approximately 150 acres located adjacent to the Calverton National Cemetery, Calverton New York, and comprising a portion of the buffer zone of the Naval Weapons Industrial Reserve Plant, Calverton NY''.

Alternatives Considered

The Navy considered three alternatives for reuse of the 2,923 acres of NWIRP Calverton and a no action alternative where the 2,923 acres would be retained as federal property. The transfer of 3,137 acres to the NYSDEC and the transfer of 150 acres to the VA are components of each of the three reuse alternatives. The transfer of 3,137 acres is not a component of the no action alternative and transfer of this property to the NYSDEC and the transfer of 150 acres to the VA are independent of the decision to transfer the 2,923 acre parcel to the Town of Riverhead.

Transfer of the property to Riverhead, and its subsequent implementation of the Calverton Enterprise Park Reuse Plan, the preferred reuse alternative, would result in the development of a multi-use enterprise park with a core industrial complex and a limited industrial air park, with other uses including a theme park and attractions; commercial recreation; family entertainment center; stadium; golf course; and open space. The 3,137-acre flight operation buffer zones would remain in their natural (undeveloped) state and would be transferred to the NYSDEC.

The second reuse alternative is the Calverton Enterprise Park/Raceway Alternative. This alternative would retain many of the land uses of the preferred alternative with the most significant difference being that an automobile raceway complex of approximately 808 acres would replace the airport (835 acres). The automobile raceway would occupy much of the terrain as the airport proposed in the reuse plan. This alternative retains the industrial business park use and the existing 10,000 ft runway.

The third reuse alternative is the Peconic Village Alternative and, although this alternative includes some of the land use features of the other two alternatives (the industrial business park, hotel conference center, golf courses and open space), the site would be developed primarily as an age-restricted residential community containing an estimated 688 units of assisted living and 1,350 units of senior housing to accommodate a total of 2,889 residents. Approximately 260 acres of new buildings and paved areas would be expected. Combined with existing development, it is estimated that a total of 690 acres would be developed as buildings and/or paved areas.

Navy also evaluated a no action alternative that would leave the property in caretaker status with the Navy maintaining the physical condition of the property, providing a security force, and making repairs essential to safety.

Environmental Impacts of the Preferred Alternative

There are no direct environmental impacts related to the transfer of the property. This ROD focuses on the indirect environmental impacts that would likely result from the Town of Riverhead implementing the preferred alternative plan. The development of the Enterprise Park which has been estimated to occur over a 20-year period, will result in significant new vehicular traffic in the region. Over 42,000 daily vehicular trips are expected, a significant increase over the amount of daily traffic generated at NWIRP Calverton prior to its closure in 1994 (2,820 daily trips). Roadway improvements will be necessary to accommodate this increase in traffic and are expected to be undertaken by the local and state governments as the need arises.

Similarly, the increase in traffic following development of the Enterprise Park will result in higher noise levels, particularly in the late evening hours. The higher noise levels will exceed Federal Highway Administration standards for certain locations. Expected noise levels from aviation uses at the Park will not be significant because the level of aviation activity will be low.

Construction of a new sewage treatment facility and extension of a potable water supply will be required to meet the utility demands of the Enterprise Park development. There will be a loss of vegetation and habitat as new development is added to the Enterprise Park. Wetlands are located on the site and may be impacted by new development. However, any new construction that may impact wetlands must comply with appropriate federal and state regulations governing development in or near wetlands.

There are three eligible historic buildings and several sites of archeologically sensitive land at NWIRP Calverton. The Navy, the New York State Historic Preservation Office (SHPO), and the Advisory Council on Historic Preservation (ACHP) have signed a Programmatic Agreement (PA) that will protect these resources.

The expected fiscal impact, after the 20-year development period, will result in estimated annual employee earnings of approximately $140 million. Over 6,200 direct and indirect jobs will be created and local tax revenues are predicted to be about $19 million annually.

In accordance with Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, the indirect effects of the proposed transfer and reuse are not expected to cause disproportionate adverse environmental or economic impacts specific to any groups or individuals from minority or low-income populations residing in the region. All populations will be affected equally and in the same manner by the proposed action.

Mitigation

Implementation of the decision to transfer Navy property does not require Navy to perform any mitigation measures, beyond those discussed here. As appropriate, the Navy will incorporate notices in the conveyance documents indicating that wetlands or threatened/endangered species occur on the parcel. The Navy will also fulfill its responsibilities in the Programmatic Agreement, and include a restrictive covenant in the conveyance documents to protect archeological resources. Redevelopment of NWIRP Calverton in accordance with the preferred alternative will result in impacts to the environment that can be mitigated or lessened by various mitigation measures. The measures would be the responsibility of the Town of Riverhead or an applicant proposing redevelopment at NWIRP Calverton.

Reuse will cause significant traffic impacts at various intersections in the study area surrounding the NWIRP Calverton. Potential mitigation measures may include changing of traffic signal timing, geometric improvements, and regulatory measures. These measures could be implemented by the State, the Town of Riverhead or an applicant proposing redevelopment at NWIRP Calverton.

Most of the on-site ponds are associated with wetlands and would not be adversely affected by future development because the developer must comply with strong state and federal laws protecting wetlands. Local planning review procedures ensure that sediment control measures would be included in construction design plans to mitigate the potential for adverse effects on surface waters.

The Town of Riverhead or its developers will have to consult with the NYSDEC before development can occur in the sections of the parcel designated as Compatible Growth Area of the Pine Barrens.

Three state-listed species are in an area where commercial and recreational development is proposed. The Town of Riverhead or its developers must consult with NYSDEC, and mitigate as appropriate.

Comments Received on the Final EIS

The Navy received comment letters from the US Environmental Protection Agency (EPA), the Department of Veterans Affairs (VA), a real estate and development company, a commentor on behalf of the Montaukett Indian Tribe, and the local descendants of a former property owner. Several comments were editorial in nature. Substantive comments are categorized as follows:

Wetlands and State-Listed Threatened/ Endangered Species

EPA requested that the Navy consider the use of conservation easements to ensure the protection of wetlands that may be impacted during the redevelopment of the site. EPA also recommended that the property deed transfers be conditioned to require mitigation for protection of state-listed threatened/endangered species. The Navy will provide notification of the existence of these natural features in the transfer documents, and identify the regulatory agencies that have jurisdiction over these natural resources.

Hazardous Materials and Installation Restoration

Two commentors requested that Navy commit to completing all sampling, studies, and remedial actions necessary to implement the planned reuses in a manner consistent with protection of human health and the environment including lead-based paint in soils. The Navy will follow procedures mandated in the Comprehensive, Environmental Response, Compensation and Liability Act (CERCLA) to identify the extent of contaminants and apply the appropriate remediation to protect human health and the environment consistent with the preferred land use for the site. Only after the remedial action is completed or after installation of the selected remedy which has been demonstrated to be operating properly and successfully, will the retained federal lands be transferred. With regard to the treatment of lead-based paint in soils, the Navy believes that the normal use and maintenance of lead-based paint does not constitute evidence of a release of a hazardous substance as defined by CERCLA that requires a response.

Native American Concerns

Comments were received on behalf of the Montaukett Tribe of Long Island concerning the ''official status'' (federal recognition) of the Tribe and suggested that the FEIS is defective in ways that pose risk of severe harm to the Montaukett Tribe. Of primary concern to the Tribe was the archeological

investigations conducted by the Navy for this project. The commentor was concerned that the North American Graves Protection and Repatriation Act (NAGPRA) was not considered. This law provides Indian Tribes, recognized by the Bureau of Indian Affairs (BIA), certain rights concerning the treatment of ancestral burial. Another commentor noted that it appeared that no tribal representatives had been contacted during the preparation of the environmental impact statement, and that the archeological survey conducted for this project appears to have not been adequately completed. In response to these concerns, the Navy solicited the identification of interested persons and/or issues that should be addressed in the EIS through the scoping process, the notice of which was published in the **Federal Register** and local area newspapers. Additionally, the Navy consulted with the BIA, state and local governments and other interested agencies during the preparation of the EIS. Regarding the protection of ancestral burials, the Navy, in conjunction with the SHPO, developed a Phase IA archeological survey which identified approximately 300 acres of NWIRP Calverton that may contain artifacts that may be eligible for listing on the National Register of Historic Places. A follow-on study, also developed with the SHPO, was conducted to complete further archeological investigations on the lands most likely to be developed through the reuse of the site. Results of these surveys and the Programmatic Agreement prepared for the treatment of cultural resources at NWIRP Calverton, which requires that future development on archeologically sensitive portions of NWIRP Calverton be preceded by appropriate archeological studies, will ensure archeological resources, including burial sites in accordance with NAGPRA, are protected. The Programmatic Agreement covers the entire NWIRP Calverton site and requires future development to be preceded by consultation with and approval by the SHPO.

Cultural Resources

A number of commentors were concerned about the protection of cultural and archeological resources. EPA requested that Navy incorporate provisions of the Programmatic Agreement, developed in compliance with National Historic Preservation Act, into this ROD. The Navy will fulfill its responsibilities designated in the Programmatic Agreement.

Environmental Justice

EPA requested information concerning how the Navy satisfied its responsibilities under Executive Order (EO) 12898 for Environmental Justice particularly with regard to the concerns of the Montaukett Tribe. The Tribe notified EPA that the Tribe would be disproportionately affected by the reuse of NWIRP Calverton by the loss of Tribal burial grounds that may be disturbed during redevelopment of the site. The FEIS states that the proposed transfer and reuse of the site are not expected to cause disproportionate adverse environmental impacts specific to any groups or individuals from minority or low income populations residing in the study area. The concern noted by the Montaukett Tribe with regard to the requirements of this EO on the future development of the site potentially impacting ancestral burial areas has been considered and is provided for in the Programmatic Agreement and attached archeology covenant that will be included in the deed.

Calverton National Cemetery

The VA commented that increased traffic will affect public access to the Calverton National Cemetery. The Navy acknowledges that the planned redevelopment of the NWIRP facility will result in additional vehicular traffic in the area. The FEIS identified traffic improvements that may be implemented by the state and local governments that will improve traffic conditions.

Conclusion

The Calverton Enterprise Park Reuse Plan has been identified by the Town of Riverhead as its preferred alternative reuse plan. In the development of this plan, the Town of Riverhead Planning Commission established the following goals for the reuse of the NWIRP site: maximize job creation; increase tax bases; and enhance regional quality of life. The Calverton Enterprise Park Reuse Plan responds to local and regional economic conditions and promotes economic recovery from the closure of the NWIRP Calverton. The resultant environmental impacts can be mitigated by the acquiring entity under the direction of federal, state and local requirements.

The transfer of property to NYSDEC will allow undeveloped, wooded land to remain in its natural state. The transfer of property to VA for use as a federal cemetery will ensure a land use consistent with the adjoining VA property, and will allow the continued service that VA provides to the community.

Although the ''no action'' alternative has less potential for causing adverse environmental impacts, this alternative would not promote local economic redevelopment of the NWIRP site and would not create new jobs. Additionally it would not take advantage of the property's physical characteristics and infrastructure.

Based on the analysis contained in the FEIS and support provided in the administrative record, I have decided, on behalf of the Department of Navy, to direct transfer of portions of NWIRP Calverton to the Town of Riverhead to be redeveloped consistent with the Calverton Enterprise Plan; to the New York State Department of Environmental Conservation; and to the Department of Veterans Affairs.

Dated: September 9, 1998.

Duncan Holaday,

Deputy Assistant Secretary of the Navy, (Installations and Facilities).

[FR Doc. 98–25179 Filed 9–18–98; 8:45 am]

BILLING CODE 3810–FF–M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Acting Deputy Chief Information Officer, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before November 20, 1998.

ADDRESSES: Written comments and requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651, or should be electronically mailed to the internet address *Pat Sherrill@ed.gov,* or should be faxed to 202–708–9346.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early

opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Deputy Chief Information Officer, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

The Department of Education is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: September 16, 1998.

Hazel Fiers,

Acting Deputy Chief Information Officer, Office of the Chief Information Officer.

Office of Postsecondary Education

Type of Review: Extension.

Title: Student Assistance General Provisions—Subpart I—Immigration Status Confirmation.

Frequency: On occasion.

Affected Public: Businesses or other for-profits; Not-for-profit institutions.

Reporting and Recordkeeping Burden:

Responses: 7,310.

Burden Hours: 23,026.

Abstract: Collection of this information used for immigration status confirmation reduces the potential of fraud and abuse caused by ineligible aliens receiving Federally subsidized student financial assistance under Title IV of the Higher Education Act (HEA) of 1965, as amended. The respondent population is comprised of 7,310 postsecondary institutions who participate in administration of the Title IV, HEA programs.

[FR Doc. 98–25169 Filed 9–18–98; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

ACTION: Submission for OMB review; comment request.

SUMMARY: The Acting Deputy Chief Information Officer, Office of the Chief Information Officer, invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before October 21, 1998.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Danny Werfel, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503 or should be electronically mailed to the internet address Werfel__d@a1.eop.gov. Requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651, or should be electronically mailed to the internet address Pat__Sherrill@ed.gov, or should be faxed to 202–708–9346.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Deputy Chief Information Officer, Office of the Chief Information Officer, publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

Dated: September 16, 1998.

Hazel Fiers,

Acting Deputy Chief Information Officer, Office of the Chief Information Officer.

Office of Educational Research and Improvement

Type of Review: New.

Title: Third International Mathematics and Science Study Video—Repeat (TIMSS–R).

Frequency: On Occasion.

Affected Public: Individuals or households; Not-for-profit institutions.

Reporting and Recordkeeping Hour Burden:

Responses: 6,200.

Burden Hours: 1,400.

Abstract: Videotape study of 8th grade math and science classrooms in the United States, the Czech Republic, France, Japan, the Netherlands, and One Asian Nation during the 1998–1999 school year. Designed and conducted by the U.S., this study supplements the Main TIMSS–R academic assessment data collection in which 45 to 50 countries are expected to participate. This study is based on and extends the work of the previous TIMSS video study. That study included only mathematics and compared the U.S. data with two other countries—Japan and Germany. This study will include science in addition to mathematics lessons, will be conducted in five high-achieving nations, and will collect and produce video tapes that will be useful for improving teaching practices.

Office of Postsecondary Education

Type of Review: Revision.

Title: William D. Ford Federal Direct Loan Program Electronic Debit Account Brochure and Authorization Form.

Frequency: On occasion.

Affected Public: Individuals or households.

Reporting and Recordkeeping Hour Burden:

Responses: 102,000.

Burden Hours: 3,400.

Abstract: This form will be the means by which a Direct Loan borrower authorizes establishment of an Electronic Debit Account.

Office of the Under Secretary

Type of Review: Reinstatement.

Title: Safe and Drug-Free Schools and Communities Act: Request for Clearance of the State Education Agency and Governor's Reporting Forms.

Frequency: Annually.

Affected Public: State, local or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 109.

Burden Hours: 4,360.

Abstract: Section 4117 of the Safe and Drug-Free Schools and Communities Act (SDFSCA) requires state chief executive officers, and state educational agencies (SEAs) to submit to the Secretary on a triennial basis a report on the implementation and outcomes of state, local and Governor's SDFSCA programs. ED must report to the President and Congress on a biennial basis regarding the national impact of SDFSCA programs. The two instruments, one for SEAs and one for Governor's programs, included with this Paperwork Reduction Act submission will be used by states to submit the required data to ED.

Office of Postsecondary Education

Type of Review: Revision.

Title: Guaranty Agency Quarterly/Annual Report.

Frequency: Annually.

Affected Public: Businesses or other for-profits; State, local or Tribal Gov't; SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 37.

Burden Hours: 9,250.

Abstract: The Guaranty Agency Quarterly/Annual Report is submitted by 37 agencies operating a student loan Insurance Program under agreement with the Department of Education. These reports are used to evaluate agency operations, make payments to agencies as authorized by law, and to make reports to Congress.

[FR Doc. 98–25170 Filed 9–18–98; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: Department of Energy.

ACTION: Notice. Comment request.

SUMMARY: The Department of Energy (DOE) intends to renew an information collection package with the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

The Information Management collection package, OMB Control No. 1910–0100, collects information from DOE's Management and Operating (M&O) Contractors concerning the management and administration of their information resources. The collection of this data is critical to the Department. It is used to ensure that the Department's information resources are managed properly. The data collected involves telecommunications, hardware and software, and printing management.

DATES AND ADDRESSES: Comments regarding this information collection package should be submitted to the OMB Desk Officer at the following address no later than October 21, 1998: OMB Desk Officer, Office of Management and Budget (OIRA), Room 3001, New Executive Office Building, Washington, DC 20503.

If you wish to submit comments, but find it difficult to do so within the time period allowed, please notify the OMB Desk Officer of your intent as soon as possible. The Desk Officer may be reached at (202) 395–3084. In addition, please notify the DOE contact listed in this notice.

FOR FURTHER INFORMATION AND COPIES OF RELEVANT MATERIALS CONTACT: Mary Ann Wallace, Director, Information, Records & Resource Management (HR–41), Department of Energy, Washington, DC 20585, (301) 903–4353.

SUPPLEMENTARY INFORMATION: This package contains the following information: (1) Title of the information collection package; (2) current OMB control number; (3) type of respondents; (4) estimated number of respondents; (5) estimated total number of burden hours; (6) purpose; and (7) the number of collections contained in the package.

Package Title: Information Management.

Current OMB No.: 1910–0100.

Type of Respondents: DOE Management and Operating Contractors (M&O).

Estimated Number of Respondents: 22,295.

Estimated Total Burden Hours: 22,190.

Purpose: This information is required for management oversight of DOE M&O Contracts/Contractors and to ensure that the administrative and information management requirements of the contract are managed efficiently and effectively.

Number of collections: This package contains 17 collections of information and/or record-keeping requirements.

Statutory Authority: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (Pub. L. No. 104–13).

Issued in Washington, D.C. on August 27, 1998.

Mary Ann Wallace,

Director, Information, Records & Resource Management Group (HR–41).

[FR Doc. 98–25171 Filed 9–18–98; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Docket No. EA–193]

Application to Export Electric Energy; Energy Atlantic, LLC

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: Energy Atlantic, LLC (Energy Atlantic) has applied for authority to transmit electric energy from the United States to Canada pursuant to section 202(e) of the Federal Power Act.

DATES: Comments, protests or requests to intervene must be submitted on or before October 21, 1998.

ADDRESSES: Comments, protests or requests to intervene should be addressed as follows: Office of Coal & Power Im/Ex (FE–27), Office of Fossil Energy, U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585–0350 (FAX 202–287–5736).

FOR FURTHER INFORMATION CONTACT: Ellen Russell (Program Office) 202–586-9624 or Michael Skinker (Program Attorney) 202–586–6667.

SUPPLEMENTARY INFORMATION: Exports of electricity from the United States to a foreign country are regulated and require authorization under section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)).

On September 9, 1998, the Office of Fossil Energy (FE) of the Department of Energy (DOE) received an application from Energy Atlantic to transmit electric energy from the United States to Canada. Energy Atlantic is a power marketer and wholly-owned subsidiary of Maine Public Service Company. Energy Atlantic proposes to transmit to Canada electric energy purchased from

electric utilities and other suppliers within the U.S.

Energy Atlantic proposes to arrange for the delivery of electric energy to Canada over transmission facilities owned by the Joint Owners of the Highgate Project, Maine Electric Power Company, Maine Public Service Company and Vermont Electric Transmission Company. The construction of each of the international transmission facilities to be utilized by Energy Atlantic, as more fully described in the application, has previously been authorized by a Presidential permit issued pursuant to Executive Order 10485, as amended.

Procedural Matters

Any person desiring to become a party to this proceeding or to be heard by filing comments or protest to this application should file a petition to intervene, comment or protest at the address provided above in accordance with §§ 385.211 or 385.214 of the FERC's Rules of Practice and Procedures (18 CFR 385.211, 385.214). Fifteen copies of each petition and protest should be filed with the DOE on or before the date listed above.

Comments on the Energy Atlantic application to export electric energy to Canada should be clearly marked with Docket EA–193. Additional copies are to be filed directly with Michael E. Small, Wendy N. Reed, Wright & Talisman, P.C., 1200 G Street, NW, Suite 600, Washington, DC 20005 *and* Paul Cariani, President, Maine Public Service Company, P. O. Box 1204, Presque Isle, Maine 04769–1209.

A final decision will be made on this application after the environmental impacts have been evaluated pursuant to the National Environmental Policy Act of 1969 (NEPA), and a determination is made by the DOE that the proposed action will not adversely impact on the reliability of the U.S. electric power supply system.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above or by accessing the Fossil Energy Home Page at http://www.fe.doe.gov. Upon reaching the Fossil Energy Home page, select ''Regulatory'' and then ''Electricity'' from the options menus.

Issued in Washington, D.C., on September 15, 1998.

Anthony J. Como,

Manager, Electric Power Regulation, Office of Coal & Power Im/Ex, Office of Coal & Power Systems, Office of Fossil Energy.

[FR Doc. 98–25174 Filed 9–18–98; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Notice of Solicitation for Financial Assistance Number DE–SC07–99ID13658; Environmental Monitoring and Ecological Research for the Idaho National Engineering and Environmental Laboratory (INEEL)

SUMMARY: The U.S. Department of Energy, Idaho Operations Office intends to issue a solicitation in anticipation of making one financial assistance award for environmental monitoring and ecological research of geographical areas peripheral to and on the Idaho National Engineering and Environmental Laboratory (INEEL). The services required include: (1) Wildlife, habitat and vegetation surveys, studies and research; (2) offsite surveillance including sample collection and analysis of air, water, soil, milk, wheat, lettuce, and meat (domestic and wildlife) for radionuclides including the analysis and reporting of data obtained; (3) sitewide research about endangered wildlife species, pollutants in the environment, and revegetation, and; (4) diverse, but program specific research projects, including a demonstration of a biobarrier for environmental restoration or waste management areas, assessment of iodine—129 levels in the environment and impact of effluent disposal in lined ponds. Estimated cost for the services is approximately 1.67M to 1.9M per year over a five-year cooperative agreement.

FOR FURTHER INFORMATION CONTACT: T. Wade Hillebrant, Contract Specialist; Procurement Services Division; U.S. DOE, Idaho Operations Office, 850 Energy Drive, MS 1221, Idaho Falls, ID 83401–1563; telephone (208) 526–0547.

SUPPLEMENTARY INFORMATION: The statutory authority for the program is Section 102 of the DOE Organization Act, as amended, P.L. 95–91. The Catalog of Federal Domestic Assistance (CFDA) Number for this program is 81.502. The solicitation text is expected to be posted on the ID Procurement Services Division home page on or about October 7, 1998, and may be accessed using Universal Resource Locator address http://www.id.doe.gov/doeid/solicit.html. Application package forms are available at http://www.id.doe.gov/doeid/application.html or may be requested from the contract specialist. Requests for application packages must be written. Those intending to propose must notify Mr. Hillebrant via fax, letter or e-mail. Include company name, mailing address, point of contact, telephone number, e-mail address and fax number. Contact the contract specialist at the address above, via fax number (208) 526–5548, or via email to hillebtw@id.doe.gov.

Issued in Idaho Falls, Idaho, on September 11, 1998.

R. Jeffrey Hoyles,

Director, Procurement Services Division.

[FR Doc. 98–25172 Filed 9–18–98; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[FE Docket Nos. 98–56–NG, 97–74–NG, 96–76–NG, 94–55–NG, 98–58–LNG, 98–57–NG, 93–96–NG, 91–39–NG, 98–59–NG]

Office of Fossil Energy; Orders Granting, Amending and Vacating Authorizations to Import and/or Export Natural Gas, Including Liquefied Natural Gas

Union Gas Limited, Centra Gas Ontario, Inc., Union Gas Limited, Union Gas Limited (Formerly Centra Gas Ontario Inc.), Distrigas Corporation, Upstate Energy Inc., The Montana Power Gas Company, The Montana Power Gas Company, Southern Company Energy Marketing L.P.

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of orders.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that it has issued Orders granting, amending and vacating various natural gas, including liquefied natural gas, import and export authorizations. These Orders are summarized in the attached appendix.

These Orders may be found on the FE web site at http://www.fe.doe.gov., or on the electronic bulletin board at (202) 586–7853.

They are also available for inspection and copying in the Office of Natural Gas & Petroleum Import and Export Activities, Docket Room 3E–033, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, (202) 586–9478. The Docket Room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, D.C., on September 14, 1998.

John W. Glynn,

Manager, Natural Gas Regulation Office of Natural Gas & Petroleum Import and Export Activities, Office of Fossil Energy.

ORDERS GRANTING, AMENDING AND VACATING IMPORT/EXPORT AUTHORIZATION

[DOE/FE Authority]

Order No.	Date issued	Importer/Exporter FE Docket No.	Two-Year maximum		Comments
			Import volume	Export volume	
1404	08/12/98	Union Gas Limited, 98–56–NG.	216 Bcf		Import and export combined total from and to Canada beginning August 15, 1998, and ending August 14, 2000.
1311–A	08/12/98	Centra Gas Ontario, Inc., 97–74–NG.			Blanket authority vacated.
1214–A	08/12/98	Union Gas Limited, 96–76–NG.			Blanket authority vacated.
968–A	08/13/98	Union Gas Limited (Formerly Centra Gas Ontario Inc.) 94–55–NG.			Name change.
1405	08/13/98	Distrigas Corporation, 98–58–LNG.	100 Bcf		Import of LNG from any foreign supplier beginning on the date of first import delivery after September 8, 1998.
1407	08/18/98	Upstate Energy Inc., 98–57–NG.	73 Bcf		Import and export combined total from and to Canada and Mexico beginning on the date of first import or export delivery.
865–A	08/20/98	The Montana Power Gas Company, 93–96–NG.			Long-term authority vacated.
538–B	08/20/98	The Montana Power Gas Company, 91–39–NG.			Long-term authority vacated.
1408	08/27/98	Southern Company Energy Marketing L.P., 98–59–NG.	7.3 Tcf		Import and export combined total from and to Canada beginning on the date of first import or export delivery.

[FR Doc. 98–25173 Filed 9–18–98; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–767–000]

Great Lakes Gas Transmission Limited Partnership; Notice of Application

September 15, 1998.

Take notice that on September 4, 1998, Great Lakes Gas Transmission Corporation Limited Partnership (Great Lakes), One Woodward Avenue, suite 1600, Detroit, Michigan 48226, filed a request with the Commission in Docket No. CP98–767–000 pursuant to Sections 7(b) and 7(c) of the Natural Gas Act (NGA) for (1) permission and approval to abandon up to 12.6 miles of pipeline looping over a three-year period, and (2) for temporary and permanent authorization to construct and operate an approximately equivalent amount of replacement pipeline, over the same three-year period, in Itasca, Aitkin, and St. Louis Counties, Minnesota, all as more fully set forth in the application which is open to the public for inspection.[1]

Great Lakes requests permission and approval to abandon, over a period ending March 31, 2001, up to 12.6 miles of 36-inch diameter pipe between Great Lakes' mainline valves 4–3 and 4–4. Great Lakes also proposes to construct and operate, over a period also ending March 31, 2001, an approximately equivalent length of 36-inch diameter pipe to replace segments of mainline pipe abandoned between mainline valves 4–3 and 4–4. Great Lakes also requests temporary authority to engage in certain preconstruction activities such as using an offsite contractor, storage yards, and preparing ice access roads. Great Lakes states that it would spend approximately $250,000 to remove old pipeline segments and approximately $12,237,000 to construct the new pipeline facilities.

Any person desiring to be heard or to make any protest with reference to said application should on or before October 6, 1998, file with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the NGA and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Great Lakes to appear or be represented at the hearing.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 98–25136 Filed 9–18–98; 8:45 am]

BILLING CODE 6717–01–M

[1] Great Lakes states that this filing may also be reviewed on its website at: http://www.greatlakesgas.com/transport/floodwood.htm

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–761–000]

Viking Gas Transmission Company; Notice of Application

September 15, 1998.

Take notice that on September 3, 1998, Viking Gas Transmission Company (Viking) 825 Rice Street, St. Paul Minnesota 55117, filed in Docket No. CP98–761–000 an application, pursuant to Section 7(c) of the Natural Gas Act, for a certificate of public convenience and necessity authorizing it to construct and operate approximately 45 miles of 24-inch diameter looping along with related tie-in piping and metering facilities, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Viking proposes to construct a 1999 Expansion Project to provide additional firm forward haul transportation capacity to serve new loads off Viking and to increase system reliability and flexibility for existing Viking shippers. Viking asserts the project is necessary to enable Viking to meet Project Shipper demands for 28,200 Dekatherms per day (Dthd) of additional winter firm transportation service between Emerson and various delivery points and 22,200 Dthd of additional summer firm transportation service. The proposed project is a response to long-term transportation service requests and subsequent precedent agreements received from shippers following Viking's open season announcement in May 1998.

Viking proposes the following specific facilities:

(1) Five separate segments of 24-inch mainline looping totaling 45 miles as follows:

- 8.2 miles of looping in Kittson and Marshall Counties, commencing 19.6 miles downstream of the discharge side of Viking's Hallock Compressor Station;
- 8.3 miles of looping in Polk County, Minnesota commencing 11.8 miles downstream of Viking's Angus Compressor Station;
- 10.1 miles of looping in Clay County, Minnesota commencing 19.6 miles downstream of Viking's Ada Compressor Station;
- 7.4 miles of looping in Ottertail County, Minnesota commencing on the discharge side of Viking's Frazee Compressor Station; and
- 11.0 miles of looping in Morrison County, Minnesota commencing 9.9 miles downstream of Viking's Staples Compressor Station

(2) Tie-in piping with mainline suction and discharge isolation valves within the boundaries of the Frazee Compressor Station, new crossover assemblies at the ends of 4 of the new loops segments, three mainline isolation valves with crossover assemblies, new taps with valves for emergency tie-over to the existing Hawley, Randall, and Camp Ripley meter station, and two mainline drip assemblies.

(3) A new meter station within the boundaries of Viking's Frazee Compressor Station to provide a new delivery point to serve the City of Perham municipal gas utility, which would include a 2-inch hot tap fitting, piping, valves, measurement, and data acquisition equipment.

Viking proposes to place the project facilities in operation by November 1, 1999, and requests a certificate no later than March 1, 1999.

Viking states that it announced an open season for the proposed capacity in May 1988. As an alternative to constructing new capacity, Viking also canvassed existing shippers to determine whether any shippers would permanently release existing Emerson capacity. No shippers offered to release capacity.

Viking asserts that substantially all of the capacity to be constructed is subscribed under binding precedent agreements which contemplate 15-year contracts for firm capacity. The 28,200 Dthd of firm design winter capacity is fully subscribed and approximately 22,000 Dthd of the 30,000 Dthd of firm summer capacity is subscribed. Viking notes that nearly 89 percent of the total billing determinants are thus subscribed. Viking states it will continue to market the unsubscribed capacity under the Rate Schedule FT–D rate structure. Viking asserts that an ''at risk'' condition should not be imposed since most of the project capacity is subscribed and since other customers on Viking's system will not have to subsidize the cost of the expansion facilities.

Viking proposes to charge initial demand rates calculated on an incremental basis based on the actual cost of the 1999 Expansion. Viking states that the precedent agreements between Viking and the project shippers contemplate that approximately 30 days prior to the in-service date of the project, Viking will make a limited Section 4 tariff filing to establish rate schedule sheets for the transportation service to be provided through the 1999 Expansion facilities. The precedent agreements also obligate Viking to make a subsequent limited Section 4 ''true-up'' filing following a final accounting of the project's costs. The precedent agreements further provide that the trued-up rates will be effective retroactive to the in-service date of the project, and that Viking will refund any differences between the project initial rates and the trued-up rates finally approved by the Commission. It is stated that the trued-up rates will be based on actual billing determinants and actual costs. Viking notes that in no event, will the limited Section 4 ''trued-up'' demand rates for Zone 1–1 capacity exceed $10.65 per Dth per month. For Zone 1–2 capacity, Viking proposes a Zone 1–2 demand rate of $13.69. None of the currently subscribed capacity is Zone 1–2, however, the unsubscribed summer capacity may be sold as Zone 1–2. Viking indicates that the Zone 1–2 rate would be ''trued-up'' on a pro rata basis with the Zone 1–1 upon determination of actual costs. Thus, Viking requests that the Commission in an effort to induce customer cooperation in minimizing the required facilities, Viking also offered to reduce the expansion rate for customers with existing primary delivery points downstream of Emerson who wished to acquire a primary firm transportation path between their existing primary delivery point and a downstream primary delivery point. Because such customers would require expansion capacity only from their existing primary delivery point to a downstream primary delivery point, and not from Emerson to that downstream point, Viking offered to reduce their expansion rate by an amount equal to one-half the rate for the customer's current firm transportation service from Emerson to the existing primary delivery point. NSP Minnesota was the only customer to accept this offer, by signing up for firm summer capacity from its existing East Grand Forks, Grand Forks, Moorhead, and Fargo primary delivery point to Chicago. Consequently, the rate to be paid by NSP-Minnesota for service between these existing primary delivery points and Chicago will be reduced by one-half the amount of NSP-Minnesota's effective rate for firm transportation from Emerson to the existing primary delivery points. In summary, Viking requests the Commission to establish initial demand rates of $10.65 Dth per month for Zone 1–1 and $13.69 Dth per month for Zone 1–2, subject to true-up in a later Section 4 filing.

Viking proposes to set the initial commodity and fuel rates for the Project shippers equal to Viking's existing commodity and fuel rates for firm

shippers under Rate Schedule FT–A, FT–B, and FT–C. Viking does not expect the 1999 Expansion Project to materially affect Viking's variable costs or fuel requirements.

Viking does not seek as part of the subject filing an initial determination allowing roll-in of the 1999 Expansion Project costs at the time of its next general rate case. However, Viking explicitly reserves the right to seek such a roll-in at the time of the next Viking Section 4 rate case.

Viking asserts that it currently has not unsubscribed forward haul capacity from Emerson to Chicago. Viking anticipates that the proposed facilities will benefit existing and project shippers in that the project will be used to serve the new firm forward haul requirements of the Project Shippers and to provide greater reliability and additional operating flexibility.

The Project Shippers and their requested service levels are as follows:

Shipper	(Dth/d) Requested service level
(1) Cardinal FG	3,700
(2) City of Perham	1,500
(3) NSP—Minnesota	10,000 (Nov–Mar) 15,000 (Apr–Oct)
(4) NSP—Wisconsin	11,000 (Oct–Apr)
(5) UtiliCorp United ...	2,000
Unsubscribed	8,000 (May–Sept)
Capacity (subscribed and unsubscribed).	28,200 (Winter) 33,200 (Apr & Oct) 30,200 (Summer)

Any person desiring to participate in the hearing process or to make any protest with reference to said application should on or before October 6, 1998, file with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

A person obtaining intervenor status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by every one of the intervenors. An intervenor can file for rehearing of any Commission order and can petition for court review of any such order. However, an intervenor must submit copies of comments or any other filing it makes with the Commission to every other intervenor in the proceeding, as well as 14 copies with the Commission.

A person does not have to intervene, however, in order to have comments considered. A person, instead, may submit two copies of comments to the Secretary of the Commission. Commenters will be placed on the Commission's environmental mailing list, will receive copies of environmental documents and will be able to participate in meetings associated with the Commission's environmental review process. Commenters will not be required to serve copies of filed documents on all other parties. However, commenters will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek rehearing or appeal the Commission's final order to a federal court.

The Commission will consider all comments and concerns equally, whether filed by commenter or those requesting intervenor status.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Section 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the item required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Viking to appear or be represented at the hearing.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 98–25135 Filed 9–18–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1991–009; Idaho]

City of Bonners Ferry; Notice of Availability of Draft Environmental Assessment

September 15, 1998.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR Part 380 (order No. 486, 52 FR 47897), the Office of Hydropower Licensing has reviewed the application for a new license for the existing Moyie River Hydroelectric Project and has prepared a Draft Environmental Assessment (DEA) for the project. The project is located near Moyie Springs, in Boundary County, Idaho. The Commission staff has prepared a Draft Environmental Assessment (DEA) on the project. The DEA contains the staff's analysis of the potential environmental impacts of the project and has concluded that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

Copies of the DEA are available for review in the Public Reference Room, Room 2A, of the Commission's offices at 888 First Street, N.E., Washington, D.C. 20426.

Any comments should be filed within 30 days from the date of this notice and should be addressed to David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426. For further information, contact Tim Looney, Environmental Coordinator, at (202) 219–2852.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 98–25137 Filed 9–18–98; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6163–7]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Verification of Test Parameters and Parts Lists for Light-Duty Vehicles and Light-Duty Trucks

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: Verification of Test Parameters and Parts Lists for Light-Duty Vehicles and Light-Duty Trucks, OMB Control Number 2060–0094, expiration date 12/31/98. The ICR describes the nature of the information collection and its expected burden and cost; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before October 21, 1998.

FOR FURTHER INFORMATION: For a copy of the ICR, call Sandy Farmer at EPA, by phone at (202) 260–2740, by E-Mail at Farmer.Sandy@epamail.epa.gov or download off the Internet at http://www.epa.gov/icr/icr.htm, and refer to EPA ICR No. 0167.06.

SUPPLEMENTARY INFORMATION:

Title: Verification of Test Parameters and Parts Lists for Light-Duty Vehicles and Light-Duty Trucks, OMB Control Number 2060–0094, EPA ICR Number 0167.06, expiration date 12/31/98. This is a request for extension of a currently approved collection.

Abstract: The EPA tests in-use vehicles in order to enforce compliance with light-duty vehicle and light-duty truck emission standards. The Federal Test Procedure (FTP), which is used for determining compliance, requires test parameters and procedures that are necessary to conduct a valid test. Therefore, after EPA has selected these parameters and procedures from previously submitted manufacturer data, EPA gives the motor vehicle manufacturer the opportunity to review and verify that EPA has selected the correct parameters and procedures for vehicle emission testing. Providing part numbers gives the manufacturer the opportunity to help ensure that defective or incorrect parts will be replaced by those which the manufacturer feels are necessary to correctly evaluate the emissions performance of the vehicles tested. Though this information request is voluntary, EPA uses the manufacturers' input as part of the verification of EPA's work. If this information is not reviewed and provided by the manufacturers, EPA and the manufacturers may waste resources on tests that were performed improperly and the manufacturers may not have as much opportunity to participate in a compliance program that has the potential to adversely affect them.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15. The **Federal Register** Notice required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on May 8, 1998; no comments were received.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 2 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Manufacturers of light-duty vehicles and light-duty trucks.

Estimated Number of Respondents: 15.

Frequency of Response: On occasion.

Estimated Total Annual Hour Burden: 150.

Estimated Total Annualized Cost Burden: 0.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the following addresses. Please refer to EPA ICR No. 0167.06 and OMB Control No. 2060–0094 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, Office of Policy, Regulatory Information Division (2137), 401 M Street, SW, Washington, DC 20460

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503

Dated: September 16, 1998.

Joseph Retzer,

Director, Regulatory Information Division.

[FR Doc. 98–25196 Filed 9–18–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6163–6]

Retrofit/Rebuild Requirements for 1993 and Earlier Model Year Urban Buses; Approval of a Notification of Intent To Certify Equipment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Agency approval of an application for equipment certification.

SUMMARY: The Agency received an application dated October 21, 1997 from the Engelhard Corporation (Engelhard) with principal place of business at 101 Wood Avenue, Iselin, New Jersey for certification of urban bus retrofit/rebuild equipment pursuant to 40 CFR 85.1404–85.1415. The equipment is applicable to Detroit Diesel Corporation's (DDC's) petroleum-fueled 6V92TA model engines having electronically controlled fuel injection (DDEC) of model years 1988 through 1993. On April 9, 1998 EPA published a notice in the **Federal Register** (63 FR 17411) that the notification had been received and made the notification available for public review and comment for a period of 45 days. EPA has completed its review and the Director of the Vehicle Programs and Compliance Division has determined that it meets the requirements for certification, conditioned on the terms discussed below in section IV. The effective date of certification is discussed below under **DATES**.

The certified equipment complies with the 0.10 gram per brake horsepower-hour (g/bhp-hr) particulate matter (PM) standard for the engines for which it is certified (see below). In addition, the equipment will be offered to all parties for $7,940 or less (in 1992 dollars) incremental to the cost of a standard rebuild. Certification of the ETX equipment, as it applies to engines of model years 1988 through 1990, is conditioned upon Engelhard complying with the terms discussed below in section IV.

The certification of this equipment triggers requirements for all transit operators using compliance Program 1 (including engines certified to meet California emissions standards) that have engines in their fleet covered by this certification.

ADDRESSES: The Engelhard application, as well as other materials specifically relevant to it, are contained in Public Docket A–93–42, Category XXII–A, entitled ''Certification of Urban Bus Retrofit/Rebuild Equipment''. Docket items may be inspected from 8 a.m. until 5:30 p.m., Monday through Friday. As provided in 40 CFR part 2, a reasonable fee may be charged by the Agency for copying docket materials.

DATES: Today's **Federal Register** notice announces the Agency's decision to certify the ETX equipment, as described below. The effective date of certification was established in a letter dated July 1, 1998, from the Director of the Vehicle Programs and Compliance Division to Engelhard Corporation. (A copy of the letter is in the public docket, which is located at the address noted above.) This certified equipment may be used immediately by urban bus operators, subject to the condition in Section IV. Transit operators having affected engines and using compliance program 1 are required to use equipment certified to the 0.10 g/bhp-hr PM standard when rebuilding or replacing applicable engines six months or more after September 21, 1998. For determining compliance with the requirements of program compliance option 1, the effective date of certification is September 21, 1998.

FOR FURTHER INFORMATION CONTACT: William Rutledge, Engine Programs and Compliance Division (6403J), U.S. Environmental Protection Agency, 401 M St. SW, Washington, D.C. 20460. Telephone: (202) 564–9297.

SUPPLEMENTARY INFORMATION:

I. Background and Equipment Identification

In a notification of intent to certify signed October 21, 1997, Engelhard Corporation (Engelhard) applied for certification of equipment under the urban bus program. The notification is clarified in letters from Engelhard dated February 9, 1998, June 4, 1998, June 15, 1998, July 1, and August 6, 1998. The equipment is referred to as the ETX rebuild kit, and is applicable to 1988 through 1993 model year Detroit Diesel Corporation 6V92TA diesel engines equipped with Detroit Diesel Electronic Control (DDEC).

The notification states that the ETX rebuild kit is designed to update all electronically controlled DDC 6V92TA DDEC II engines to either 253 or 277 horsepower (hp). The ETX kit incorporates engine components (cylinder head fire deck, valve faces and piston crowns) that are coated with Engelhard's proprietary GPX technology, a CMX catalytic muffler, and an improved turbocharger. The GPX® and CMX™ technologies are identical to the technologies of the kit certified to the 0.10 g/bhp-hr standard for DDC 6V92TA model engines that use mechanical unit injectors (MUI). That certification is described in the **Federal Register** on March 14, 1997 (62 FR 12166).

The basis for the kit is a 6V92TA DDEC II engine that is rebuilt to a standard 1991 to 1993 DDC specification. However, when the engine is rebuilt it will utilize ETX-specific coated cylinder heads, coated valves, cylinder kits incorporating coated piston domes, an improved turbocharger, and a CMX–5 catalytic muffler. The 1988 to 1990 model year engines also receive an upgraded control program for the electronic control module. The ETX parts list is provided in the letter to EPA dated August 6, 1998, which can be found in the public docket at the address listed above.

Engelhard indicates that the coated engine components utilize unique properties to improve the combustion efficiency of the engine to reduce the engine-out emissions of particulate matter (PM). The improved turbocharger operates like a typical turbocharger but with improved efficiency and airflow. The improved airflow improves combustion efficiency which reduces engine-out PM. The CMX–5 catalytic muffler incorporates Engelhard's oxidation catalyst technology to reduce PM emissions in the exhaust.

The specific catalytic converter part to be used depends on the type of coach as well as the type of engine. Engelhard's notification provides a table listing the various catalytic converter kits available for different engine/coach combinations. Therefore, transit operators cannot use the previously certified converter in place of the new converter in the candidate kit.

Using engine dynamometer testing conducted in accordance with the Federal Test Procedure (FTP) for heavy-duty diesel engines, Engelhard documented in its October 21, 1997 notification, PM emissions below the 0.10 g/bhp-hr level. This test data is shown in Table 1.

Engelhard presents emissions data from testing two baseline engines, one rebuilt to a 1988 California (50-state) configuration, and the other rebuilt to a 1991 through 1993 model year DDC DDEC II standard configuration (using a DDC DDEC II upgrade kit). A certification test was performed on the engine after being rebuilt with the ETX Rebuild Kit. Lists of parts used in the rebuilds are provided in a letter dated February 9, 1998, from Engelhard. This letter can be found in the public docket at the address listed above. Transient testing was performed in accordance with the federal test procedure of 40 CFR part 86, subparts N and I.

The certification testing document a PM emissions level of 0.09 g/bhp-hr, and also show that emissions of hydrocarbon (HC), carbon monoxide (CO), oxides of nitrogen (NO_X), and smoke are within the applicable standards.

The emissions data of the notification are summarized below in Table 1. Based on this testing demonstration, EPA believes that all ETX-equipped engines will meet the 0.10 g/bhp-hr PM standard because installation of the kit upon engine rebuild results in the replacement of all emissions related parts with a specific set of parts, the combination of which results in a documented PM level of 0.09 g/bhp-hr.

The fuel consumption impact of the ETX kit is discussed below as it relates to the life cycle cost analysis.

TABLE 1.—SUMMARY OF ENGELHARD TESTING

Gaseous and particulate test	g/bhp-hr					
	HDDE standards			1988 Calif 6V92TA DDEC II baseline [1]	1991–1993 6V92TA DDEC II baseline [2]	6V92TA DDEC II with ETX kit
	1988	1990	1991			
HC	1.3	1.3	1.3	0.8	0.5	0.2
CO	15.5	15.5	15.5	1.4	1.9	0.6
NO_X	10.7	6.0	5.0	5.5	4.7	5.0
PM	0.60	0.60	0.25	0.43	0.28	0.094
BSFC [3]				0.481	0.498	0.503

TABLE 1.—SUMMARY OF ENGELHARD TESTING—Continued

Gaseous and particulate test	g/bhp-hr					
	HDDE standards			1988 Calif 6V92TA DDEC II baseline [1]	1991–1993 6V92TA DDEC II baseline [2]	6V92TA DDEC II with ETX kit
	1988	1990	1991			
Hp (R/O) [4]				277/273 ...	277/281 ...	277/266
Smoke Test	Standards (percent)					
ACCEL	20			.....	.....	3.6
LUG	15			.....	.....	0.6
PEAK	50			.....	.....	8.1

[1] All 6V92TA testing was performed on engine identification number 6VF–118287.
[2] The DDC upgrade kit (25% reduction) configures an engine to the 1991 model year.
[3] Brake Specific Fuel Consumption (BSFC) is measured in units of lb/bhp-hr.
[4] Horsepower (Rated/Observed during testing).

Today's certification extends certification of equipment to engines originally certified, or rebuilt, to meet emissions standards of California (also referred to as 50-state configurations). The impact of this decision on transit operators is discussed in more detail in the ''Transit Operator Requirements'' section below.

The ETX kit is intended to be installed at the time of a standard engine rebuild. The contents of the ETX kit will vary depending upon the model year of the engine to be rebuilt. All ETX kits will include coated cylinder heads, coated cylinder kits, improved turbocharger, and CMX–5 catalytic muffler. Additionally, the kit for applicable 1988 through 1990 model year engines will include fuel injectors, engine camshafts, and ECM upgrade. To complete a rebuild of 1988 through 1990 model year engines, an operator must acquire on its own, the other required (specified) standard engine rebuild parts: Blower and engine gasket kit. To complete a rebuild of 1991 through 1993 model year engines, an operator must acquire the specified standard blower, fuel injectors, engine camshafts, and gasket kit. The emissions defect warranty will cover the parts which Engelhard supplies in the ETX kit.

Engelhard is required to provide a 100,000 mile defect warranty and 150,000 mile emissions performance warranty for the components of ETX kit.

The ETX equipment is certified to a PM emission level of 0.10 g/bhp-hr for all 1988 through 1993 DDC 6V92TA DDEC II urban bus engines using either diesel fuel #1 or #2 (including engines originally certified, or rebuilt, to meet California emissions standards). Table 2 lists the applicable engine models and certification levels associated with the certification announced in today's **Federal Register**.

TABLE 2.—CERTIFICATION LEVELS

Applicable models [1]	Engine code	Certified PM level
1988–1993 Detroit Diesel 6V92TA DDEC II	ALL (including those certified or rebuilt to meet California or 50-state emissions standards).	0.10 g/bhp-hr.

[1] Conditional certification applies to 1988 through 1990 model year engines. See discussion in section IV.

II. Summary and Analysis of Comments

Comments were received from four parties in response to the **Federal Register** notice (63 FR 17411, April 9, 1998): Detroit Diesel Corporation (DDC), Johnson Matthey, Incorporated (JMI), New York City Transit (NYCT), and Chicago Transit Authority (CTA). DDC is the original manufacturer of the engines to which the ETX kit applies, and both DDC and JMI have applied for certification of equipment to meet the 0.10 g/bhp-hr standard under the urban bus program for these engines. NYCT and CTA are both operators of urban bus fleets in areas to which the Urban Bus Rebuild Requirements apply.

Comments and issues generally fell into the following categories: (a) Equipment identification; (b) engine power rating; (c) emissions testing; (d) durability and in-service concerns; (e) installation and maintenance instructions; (f) exhaust back pressure; (g) components of the kit; (h) life cycle cost; and, (i) California Engines. These are discussed in the sections below.

Copies of the complete comments and other documentation are available in the public docket, which is located at the address stated above.

a. Equipment Identification

The Engelhard notification of October 21, 1997, proposed upgrading all engines to one standard 277 hp configuration. Both DDC and JMI comment that Engelhard should provide the programming for the electronic control module (ECM) for each applicable engine and fuel combination (left-hand rotation, right-hand rotation, diesel fuel #1, and diesel fuel #2). DDC also notes that two different sets of engine camshafts are necessary, depending upon engine rotation direction.

In response, Engelhard provides the ECM program numbers in its June 4 and 15, 1998 letters to EPA, as well as the camshaft part numbers for left-and right-hand rotating engines.

b. Engine Power Rating

Both DDC and JMI comment that the ETX kit would update all applicable engines, generally 253 and 277 horsepower, to only one standard 277 horsepower (hp) configuration. JMI questions whether there are additional costs or ramifications for transit operators who operate 253 hp engines, and states that Engelhard should justify

the upgrading of the 253 hp engines. DDC states that requiring conversion from 253 hp to 277 hp would unfairly penalize operators who presumably originally selected the 253 hp rating because it best met their operating requirements, would create hardship if vehicle cooling systems or drive lines needed to be upgraded to accommodate the higher power level. DDC states that, if the ETX kit is approved as a trigger of program requirements, then the trigger requirement should be restricted to the 277 hp rating.

In response, in letters to EPA dated June 15 and August 6, 1998, Engelhard states that it will offer 253 hp (high and low torque) configurations of the ETX kit. EPA notes that today's certification will trigger the 0.10 g/bhp-hr standard for both 253 hp and 277 hp engines. EPA notes that the only difference between either the 253 hp and 277 hp configurations is the ECM programming. Engelhard notes that DDC's own DDEC 25% upgrade kit, converts both 253 hp and 277 hp engines to one standard 277 hp. Engelhard states that the ETX 277 hp conversion does not require an upgrade of the cooling system—both the 253 hp and 277 hp engine ratings use the same cooling system. Further, the ceramic coated parts in the ETX kit reduce the load on the cooling system.

EPA notes that DDC's 25 percent upgrade kit for the DDEC engines converts applicable engines to one standard 277 hp configuration. However, this DDC kit is not required to be used by any operator, because the kit did not trigger any program requirements. Instead, the certified DDC 25 percent kit was an available option to operators that were required to meet the program requirement of reducing PM emissions by at least 25 percent.

c. Emissions Testing

NYCT comments that, although the ETX kit functioned adequately under the Federal Test Procedure (FTP), further emissions testing is required to prove that the ETX will perform to the same level of emission reduction when subjected to a bus's operational cycle. NYCT recommends using the Federal Transit Administration's Advanced Design Bus Urban Driving Cycle to provide assurance that the projected reductions are being achieved and that the full value of the investment in the technology can be achieved.

Engelhard notes that the testing required by the regulation was conducted, and that alternative cycle testing was not conducted.

EPA notes that to comply with the 0.10 g/bhp-hr PM standard of the Urban Bus Rebuild Requirements, manufacturers must show compliance using the FTP described at 40 CFR part 86 subpart N. This requirement is consistent with EPA's new engine certification program, which requires the engine FTP. Chassis cycle testing, as NYCT suggests, generally determines emission rates on a grams per mile basis, which is difficult to directly correlate to the grams per brake-horsepower-hour (g/bhp-hr) determined by the engine FTP. While the level of emissions reductions achieved by the ETX kit under the Advanced Design Bus Urban Driving Cycle would be interesting, emission reductions determined by chassis cycle testing may vary depending upon the specific driving cycle and the specific coach used, and these reductions may not be equivalent to the reductions predicted by the FTP. Chassis testing would be of no use towards determining compliance with the 0.10 g/bhp-hr standard because compliance with this absolute standard does not necessarily correlate with a specific reduction, and it would be a significant additional testing burden. The program regulation also requires that candidate equipment must not cause an engine to fail to meet applicable federal emission requirements (other than PM) under part 86, which also requires testing using the engine FTP. EPA believes that the FTP is the appropriate test cycle for determining compliance with the 0.10 g/bhp-hr standard, and that it is not appropriate to require Engelhard to conduct chassis testing to prove compliance with that standard.

d. Equipment Durability and In-service Concerns

DDC provided several comments regarding durability. First, DDC states that the performance and durability of the ETX kit has not been demonstrated and that there is insufficient information in the Engelhard notification. DDC acknowledges that the urban bus retrofit/rebuild regulations do not require such testing as a condition of certification, but expresses the concerns because trigger technology places requirements on transit operators. DDC notes that the ETX turbocharger is new, and without additional information, the effects of the turbocharger on the operational characteristics can't be assessed. DDC states concerns that the cylinder kits utilize DDC 15-to-1 nominal compression ratio piston domes modified to accept the GPX coating. The effective compression ratio of this cylinder kit is roughly 12.96 compared to roughly 13.96 with the standard DDC piston dome. The reduction in compression ratio can have substantial effects on cold starting, cold smoke, and noise. Experience with the ETX kit for the MUI engine should not be taken as evidence of satisfactory cold starting and noise performance because injection timing and spray characteristics are different between the DDEC and MUI systems.

JMI also provided several comments regarding durability. JMI notes that this ETX kit includes a new turbocharger, and that Engelhard should be required to provide durability data or history for the use of this part. Also, JMI states that Engelhard should be required to state which piston dome is used in the ETX kit, because of recent changes that DDC has made in certain design parameters in the piston dome, piston rings, and piston skirt of its 25 percent upgrade kit. JMI indicates that if the previous piston dome is used in the ETX kit, then transits should expect to incur problems related to the rings, and that Engelhard should modify its kit components and retest to confirm emissions data.

Both NYCT and CTA comment about durability and reliability. CTA asks whether Engelhard has performed thorough and long term in-service reliability testing to ensure that the coated parts will last as long as standard, non-coated parts. CTA notes durability problems that they experienced with CMX converter model 0060, requiring replacement of over 200 units in their fleet, and asks how much testing was performed on the CMX–5 to ensure that problems will not be duplicated. Maintenance, testing and reusability of used converts is a concern. CTA also asks how a transit operator judges whether a converter is still functioning correctly, and whether the engine coatings will affect oil analysis and other maintenance programs.

NYCT comments that there is virtually no in-service operation experience with the ETX kit, and states that such information is essential to show that the technology can function reliably on a large scale in daily operation. NYCT also states that it has experienced extraordinary costs using a previously certified Engelhard converter. NYCT has discovered that in certain circumstances the converter becomes plugged, which drastically reduces the service life of the units. The reduction in service life must affect the life cycle cost calculations. NYCT states that it has installed more than 1,500 Engelhard catalytic converters, and in-service back pressure checks have been very inconsistent and in some case are increasing. Two catalyst units are known to have plugged and have had to

be disassembled for repair. Increased back pressure results in greater fuel consumption, which should be included in the life cycle cost analysis.

In response to the DDC comments, Engelhard states that the improved Engelhard turbocharger of the kit operates on the same principal as DDC's certified MUI kit utilizing the Turbodyne Turbopac—increased air flow and improved turbocharger response and that Engelhard has had urban bus DDEC engines operating with GPX for nearly 7 years, turbochargers in operation for over 100,000 miles, and diesel oxidation catalysts in operation for over 300,000 miles. A turbocharger has been in operation since December 1997 on a revenue-service DDC 6V92 DDEC II bus with no durability, performance or operational problems. Engelhard says that the transit operator is happy with the improved fuel economy and performance due to the installation of the turbocharger. A similar turbocharger has accumulated over 100,000 miles of normal operation on a Class 8 tractor trailer utilized by Engelhard.

EPA notes that DDC does not specifically state what additional information on the Engelhard's turbocharger that it needs, and that Engelhard requests that information on the turbocharger remain confidential. Regarding the comment that the cylinder kit will reduce the compression ratio of the engine, Engelhard states that the statement is false and the combination of the coated cylinder head and coated piston is designed to maintain a compression ratio nearly identical to that of a standard cylinder head and piston.

In response to the JMI comments, Engelhard states that it supplies the cylinder kits of the ETX kit, which it assembles from standard DDC parts, and Engelhard wishes that the specific part descriptions remain confidential. In its May 30, 1997 letter to EPA, DDC describes the changes that it made to its cylinder kits in order to improve cylinder kit life, and states that the design changes have no effect on engine performance or emissions. DDC also notes that the previous parts are to be discontinued. Based on the available information, EPA has no reason to believe that the parts of the ETX kit will negatively affect emissions. Also, EPA notes that the components, as part of the certified kit, are required to be covered by the program warranties.

In response to the NYCT comments, Engelhard states that DDEC engines have been operating with GPX for nearly 7 years, turbochargers in operation for over 100,000 miles, and diesel oxidation catalysts in operation for over 300,000 miles. Over 500 buses (with MUI engines) have installed ETX kits with some in operation for over 18 months with no complaints about the coated components. The issue of coating durability was addressed during the certification process of the ETX kit for the MUI engines. If a coated component fails under warranty it will be replaced by Engelhard free of charge as specified in the emissions warranty. If one part of an ETX kit fails outside of the warranty, a transit will be able to purchase specific components having a standard Engelhard product warranty.

Engelhard states that it has worked closely with CTA to resolve the early problems experienced with the CMX model 0060, which were caused by inherent design defects of the bus and engine installation. The engine in this bus model vibrates excessively and has continually destroyed engine mounts, OEM mufflers, and catalytic mufflers regardless of the supplier. The CMX 0060 has been redesigned to overcome the problems. Due to the bus design, correct muffler installation is critical for the muffler durability. Engelhard worked with CTA to ensure proper installation to prevent future failures. All units have been replaced at Engelhard's expense, including those that failed due to incorrect installation, vibration failure, and muffler design failures. Engelhard states that the problems experienced are caused by the original bus design and limited to this one particular bus and CMX combination. The particular bus model is essentially limited to CTA, and is therefore not a widespread problem. Engelhard solved all of the durability issues associated with this CMX unit with the Engelhard re-design, which includes strengthening the inlet and outlet pipe mounting points to the CMX body, upgrading the muffler material from aluminized steel to stainless steel, and revising the catalyst sleeving. This redesign will be incorporated in the CMX–5 provided with the ETX kit.

Regarding NYCT's catalyst comments, Engelhard states that NYCT's problematic units were supplied by DDC and Donaldson as trap replacement converter mufflers, and do not have an Engelhard warranty. As a result, Engelhard does not know the history of the units. Engelhard and its distributor have been working very hard with NYCT to resolve their problems. Engelhard strongly suspects that the problem is caused by engine malfunctions and engine failures, because the catalysts have been installed for several years at this point in time, and the engines were probably not rebuilt prior to catalyst installation (since the catalysts were trap replacement units). Certified catalysts, which began to be installed since the end of 1995, are generally installed at the time an engine is rebuilt. When an engine begins to fail it starts to use excessive oil and emit particulate that have a very high soluble organic fraction, which can result in plugging. The 2 catalyst units that NYCT references as being plugged are Donaldson units in-use for 4 to 5 years (possibly beyond the 100,000-mile warranty period that would have been applicable to a certified catalyst), and the engines were not rebuilt prior to installation of the catalysts. Engelhard has offered to reclaim some of these Donaldson units for no cost to NYCT, but is under no warranty to provide the service.

Regarding the in-service back pressure checks conducted by NYCT, Engelhard has told EPA in a telephone conversation, that back pressure can vary due to several factors, including the amount of prior idling, and ambient pressure.

EPA notes that the NYCT comments reference several problems with catalysts. For several reasons, however, EPA does not believe that there is clear evidence that it is appropriate to apply additional costs, either in terms of additional fuel consumption or maintenance, to the life cycle cost analysis. First, catalysts used to replace exhaust traps are not certified under the urban bus program, and it is not clear that all in-service experience with such catalysts are relevant to certified catalysts. (Pursuant to an agreement between DDC and EPA, Donaldson traps were removed, because of severe durability concerns, and replaced with catalytic converter-mufflers.) As Engelhard notes, the problems NYCT has experienced occurred with uncertified trap-replacement catalysts, not those certified under the urban bus program, and the units were installed on engines that were not rebuilt prior to installation. Second, NYCT does not present any data for quantifying additional costs. NYCT does not indicate how much fuel economy is affected by any in-use increases in back pressure, or how often catalyst cleaning is necessary and how much time and material are required for cleaning. NYCT comments do not substantiate that a reduction in service life is due to catalyst plugging, or that additional maintenance for cleaning the catalyst is necessary. EPA notes that, from the information provided in NYCT's comments, 2 units plugged out of 1500, and that these were trap-replacement

units. Engelhard's service procedure for the CMX notes that ''catalytic converter mufflers are susceptible to plugging if the engine is operated under low load conditions for extended periods of time while (a) the engine is improperly maintained; or (b) the engine is not properly calibrated for the specific fuel type and use of the catalytic muffler.'' At this time, EPA does not have adequate basis to either confirm that additional maintenance or fuel consumption occurs with properly installed certified catalysts, or to quantify additional costs.

Regarding CTA's concern about re-use of catalytic converters, Engelhard states that it understands that operators would like to re-use catalytic mufflers, but a used catalyst is an unknown quantity. A method for accurately testing PM performance of a catalyst in the field does not exist. Therefore, Engelhard requires that a complete kit be installed for warranty purposes.

Engelhard states that the ETX kit does not need or require any additional maintenance above the recommended DDC maintenance and, in general, CMX converter mufflers do not require preventative maintenance if the engines are operating properly. All analysis and maintenance programs conducted by transit operators should continue as they are now.

EPA has previously certified an Engelhard equipment package utilizing GPX coatings (60 FR 47170, September 11, 1995). From the standpoint of physical durability of the coating, EPA is not aware of any premature wear or failure of this certified equipment. As mentioned previously, in response to concerns about the physical durability of the new GPX–5m coating, in a May 23, 1996 letter to EPA, Engelhard provided data from three in-use buses using previous generation GPX–4 coatings. Coating thickness measurements were made on piston crowns and cylinder head combustion chambers, and were found to be within nominal design specifications at an average of 123,000 miles. In addition, deposit formations on the combustion surfaces were nearly non-existent. Engelhard indicates that design advances in the current GPX–5m coatings are intended to further reduce deposit formation and increase coating durability beyond that of the GPX–4 coating.

EPA appreciates that transit operators are concerned with the durability of retrofit/rebuild equipment, and subsequent additional costs or engine damage that potentially could result from premature equipment failure. However, EPA notes that the urban bus retrofit/rebuild regulations do not require an in-service durability demonstration as a condition of certification. Rather, equipment certifiers, including Engelhard, are required pursuant to 40 CFR 85.1409 to provide a 100,000 mile equipment defect warranty and a 150,000 mile emissions performance warranty.

EPA believes that equipment suppliers will evaluate the durability of their equipment in order to minimize their liability resulting from the emissions defect and performance warranties. EPA believes that the available information does not indicate a durability concern with the equipment certified in today's notice, and therefore, does not provide sufficient basis to deny certification on these grounds. EPA will continue to monitor problems with this, and other certified equipment, and encourages transit operators to provide specific detailed information regarding in-service problems with certified equipment.

The equipment certifier is responsible for the emissions performance of the engine through the 150,000 mile emissions performance warranty period, if the transit properly installs and maintains equipment in accordance with the equipment manufacturer's instructions. The transit operator is responsible for proper installation and use of certified equipment, and is responsible for the emissions performance of equipment operated beyond the 150,000 miles emissions warranty period. Also, the retrofit/rebuild program does not obviate compliance with any state or local emission requirements, such as inspection/maintenance (I/M) or smoke testing programs.

e. Installation Instructions

DDC comments on several items of Engelhard's ETX ''Installation Instructions'' for the ETX kit that were unclear, contain errors, and/or lack appropriate instructions or information.

Engelhard agrees with DDC's comments, admits that these items are not necessary for installation of the ETX, and Engelhard will remove the requirements from the guidelines. Engelhard notes that the guidelines were originally developed for installation of GPX in any engine, and provided rebuild suggestions intended to prevent incorrect engine assembly.

EPA appreciates DDC's in-depth review of the instructions, but does not believe a detailed review of each item is necessary in today's **Federal Register** notice. Details of these comments are in DDC's letter to EPA dated May 22, 1998, which is available to interested parties in the public docket referenced above.

f. Catalyst Checking Procedure

Both JMI and DDC provided comments expressing opposition to the procedure recommended by Engelhard for determining whether the catalyst unit requires cleaning. JMI comments that Engelhard, in its procedure to determine whether the CMX–5 is operating properly, should be required to change its procedure to match DDC's, which states that exhaust back pressure measurements should be taken at wide open throttle and full load.

CTA asks whether the issue of back pressure exceeding DDC's limits has been addressed and resolved.

Engelhard's instructions involve operating the engine in a rated speed, no load condition (high idle) and recording the pressure drop across the CMX–5 unit. This is the same procedure recommended by Engelhard for determining back pressure across the original CMX catalytic muffler, and was derived from DDC Service Information Bulletin 7-D–95. DDC, however, contends that this service procedure was only intended for a limited population of 6V92TA engines that were originally equipped with particulate traps. (Pursuant to an agreement with EPA, these traps were removed because of durability concerns, and replaced with catalytic converter-mufflers.) DDC's states that its back pressure limits apply at all engine operating conditions, including the point of maximum exhaust flow which occurs at rated engine speed, full load. An exhaust system which just meets DDC's specified back pressure limit at WOT, no load (which is how the Engelhard procedure is conducted) will exceed the DDC limit over a large portion of the engine speed/load operating map and thus would be in violation of DDC's guidelines. Excessive back pressure results in fuel economy and power losses, and raises cylinder temperatures and increases soot build-up in the lubricating oil. These effects can reduce engine life.

Engelhard states that there is no difference between the specific 1993 engine models for which the DDC procedure applies, and the other standard DDEC II engines. EPA notes that DDC has provided no explanation of the difference, in terms of susceptibility to back pressure impacts, between the engines for which Service Information Bulletin 7-D–95 was intended, and those which are covered by this, and other, retrofit certifications utilizing catalytic mufflers.

Regarding back pressure of the CMX units on the CTA buses discussed above, Engelhard states that in testing done by Donaldson, the OEM muffler had a back pressure of 3.7 inches Hg at full load. The CMX actually has a back pressure equal to or lower than the OEM muffler. In all cases the CMX–5 converter mufflers meet the back pressure limitations of the OEM muffler designs and DDC specifications.

EPA is not requiring Engelhard to revise the screening procedure, for several reasons. First, and in general, the program regulations do not require any specific check procedures for any components of certified kits. Second, EPA notes that the maximum exhaust back pressure specification for several engine calibrations (codes) of the 6V92TA DDEC II engines is 4.0 inches of mercury (as specified in DDC's application for certification of 1991 and 1992 6V92TA DDEC engines under EPA's new engine certification program), and that the back pressure specification for the Engelhard procedure is 3.0 inches of mercury. Third, the Engelhard procedure is intended as a ''screen'' to determine whether a catalyst muffler needs cleaning, not to measure exhaust back pressure for comparison with DDC's maximum specifications. For additional discussion of the issue, refer to page 12177 of the **Federal Register** notice describing certification of the ETX kit for 6V92TA MUI engines (62 FR 12166, March 14, 1997.

Any future information provided by interested parties regarding the impacts of certified equipment on exhaust back pressure would be taken under consideration. EPA appreciates that there may room for improvement in maintenance procedures of equipment certified under this program. Such concerns, in general, can also occur with procedures relating to new engines. EPA encourages all equipment certifiers to issue revised check procedures when appropriate. If Engelhard determines that another check is appropriate, or if EPA becomes aware that back pressure is exceeding manufacturer limits on in-use buses, then Engelhard should revise such procedures. Pursuant to 40 CFR 85.1413, EPA has authority to decertify equipment that does not comply with the requirements of the regulations.

g. Components of the Kit

Engelhard has proposed to exclude certain parts from the ETX kit, which are typically replaced during a standard rebuild. JMI comments that Engelhard should include the fuel injectors, camshafts, and blower in the ETX kit, and provide program warranty coverage for the parts. JMI feels these parts should be included in the kit because the parts are emissions related.

Engelhard will make available two ETX kits—one for the 1988 through 1990 model year engines, and the other for 1991 through 1993 model year engines. The particular kit required for any specific engine will be determined by the DDC parts list requirement for the engine, which will be determined by engine serial number. The kits differ as described below. Applying the kit upon engine rebuild will result in engines configured to one general (physical) ETX configuration. A difference will be the ECM programming, which is related to power rating, fuel type, and engine rotation direction.

The ETX kit for the 1988—1990 model year engines will include fuel injectors and engine camshafts. The kit for the 1991—1993 will not include the fuel injectors or engine camshafts. Neither kit will include the blower assembly. The injectors and camshafts that must be used with the ETX kit are common, non-unique, rebuild components for the 1991—1993 model year engines, and therefore, not required to be in the certified kit for 1991—1993 model year engines. A transit operator would typically acquire the same parts for a ''standard'' engine rebuild of a 1991 through 1993 model year engine, and the operator is responsible for doing so when using the ETX kit. These parts (fuel injectors, engine camshafts, and blower assembly) are required to be the specified DDC-supplied components, because the DDC components were used for the certification testing. In a letter from DDC to EPA dated June 12, 1996, DDC states that there were no emission related design changes made to the blower between 1988 and 1991. Therefore, EPA does not require the blower to be included with the ETX kit because it is not unique for the applicable engines. Engelhard is required to provide program warranty coverage only for parts included with the kit.

The ETX kit includes a list of the specific engine rebuild parts that are required to be used upon engine rebuild with the ETX kit. EPA notes that in accordance with 85.1404, operators are required to maintain records of all parts used in rebuilds. Using incorrect components with the ETX kit at the time of kit installation can be considered as failure to install a certified kit under the urban bus rebuild requirements, and subject the operator to the significant penalties provided by the regulation.

h. Life Cycle Cost

EPA requested comments on the life cycle cost analysis in the **Federal Register** notice of April 9, 1998 (63 FR 17411) which summarized the Engelhard notification and made it available for public comment. Section 1403(b) of the program regulations describe those items which must be considered when analyzing life cycle cost of equipment, including equipment purchase price, incremental fuel cost/savings, installation costs, maintenance costs, and other costs specific to fuel additives and fuel conversions. All commenters provided input on at least one cost-sensitive topic area. The comments received are described below, and are grouped by general item or topic.

JMI comments that Engelhard should substantiate the validity of the $6,966 that Engelhard uses (in their October 21 notification) for the cost of a standard rebuild, and that EPA should scrutinize that figure and subject it to the ''weighted rebuild'' cost analysis that was completed for the Engelhard 0.10 g/bhp-hr MUI certification. EPA's determination of life cycle costs is presented below in this section. EPA's position on comments or issues, and scrutiny and analysis of life cycle costs, are discussed below.

1. Comments on Purchase Price

Both DDC and JMI comment that Engelhard should include the cost of reprogramming in the life cycle cost.

In response, Engelhard states that it will include the necessary ECM reprogramming as part of the cost of the ETX kit.

2. Comments on Maintenance Cost

NYCT comments that it does not know the details of maintenance required for the ETX kit, but it is confident that there is some maintenance required, and the cost of such maintenance should be included in the life cycle cost calculations.

Engelhard states that the ETX kit does not need or require any additional maintenance above the recommended DDC maintenance. Engelhard notes that, as with any engine there is a certain amount of up-keep required. In the ETX application, Engelhard has stated that no additional maintenance is required above and beyond the standard maintenance specified by DDC for the 6V92 DDEC engine. Because the maintenance requirement is identical to a standard engine, a cost of maintenance is not necessary for the life cycle cost calculation. Additionally, Engelhard maintains that the CMX–5 catalyst unit

is maintenance-free over the emissions performance warranty period of 150,000 miles, and notes that the currently certified CMX has been in operation for over a year.

EPA believes that the engine upgrade portion of this equipment requires no additional maintenance incremental to that required on a standard rebuild. In addition, the coated component portion of the kit cannot be serviced because the coated parts are internal to the engine. Therefore, no additional maintenance is expected related to the coated components. Regarding the catalyst unit, EPA has not seen any clear and convincing information that it requires periodic maintenance during its warranted lifetime, on properly operating engines. Therefore, in the life cycle cost analysis presented below, EPA assumes that the ETX kit does not require any additional maintenance above the recommended DDC maintenance.

3. Comments on Fuel Consumption

NYCT comments that the ETX kit will have a fuel penalty, when based on bus operating profiles, that is greater than the $1,315 determined by Engelhard based on the FTP certification engine test cycle.

Both DDC and JMI comment that the test data indicate one percent increase in fuel consumption between the ETX (0.503 lb/bhp-hr) and the 1991 DDEC engine test (0.498 lb/bhp-hr), and that this cost impact should be included in the life cycle cost analysis. JMI states that Engelhard's standard rebuild engine (a California configuration) is not an appropriate baseline for fuel consumption impact because the California standard for NO_X (6.0 g/bhp-hr) is lower than the 49-state standard (10.7 g/bhp-hr), and an engine operating with lower NO_X emissions has higher fuel consumption. Also, it is improper to use the DDC DDEC II 25% upgrade kit fuel penalty, because the ETX kit uses a different turbocharger, and calls for Engelhard to conduct a baseline test on a 1988 federal engine. JMI has accumulated test data from a 1988 federal engine, and has made this data available to EPA. The data show a brake-specific fuel consumption (BSFC) for a 1988 federal configuration 6V92TA DDEC II engine of 0.460 lb/bhp-hr. JMI presents this data solely to illustrate that there is a difference between 1988 federal and California engines, and not to suggest that Engelhard should use JMI's baseline data.

With regard to NYCT's comment about fuel consumption, Engelhard responds that the fuel consumption data was generated during the Federal Test Procedure (FTP) as specified by the urban bus rebuild regulations. Therefore, Engelhard must use it as the basis for the life cycle cost.

EPA notes that 40 CFR 85.1407 (a)(3) states, in part, that certifiers must include in their notification of intent to certify ''(t)he percent change in fuel economy * * * based on testing performed over the heavy-duty engine Federal test procedure or an approved alternative test procedure''. Engelhard complied with this requirement by providing the percent change in fuel economy resulting from use of the ETX kit as measured over the heavy-duty engine Federal test procedure (FTP) described at 40 CFR Part 86 Subpart N. In addition, in order to demonstrate compliance with the 0.10 g/bhp-hr PM, and other regulated exhaust emissions standard, testing must be conducted using the engine-based FTP. Therefore, the procedure used by Engelhard is in compliance with program requirements, and EPA is not requiring Engelhard to perform testing beyond the program requirements.

Regarding the JMI and DDC comments that the data show a one percent fuel consumption penalty when the ETX kit is applied to 1991 model year engines, Engelhard has submitted, in one of its letters dated June 15, 1998, data from one additional test of the ETX configuration and two additional tests of the original DDC 1991–1993 model year configuration. The fuel consumption data, referred to as brake specific fuel consumption (BSFC), is measured in units of pounds of fuel per unit of engine work, or brake-horsepower-hour (lb/bhp-hour). The totality of fuel consumption data provided by Engelhard is summarized below in Table 3. All of this testing was conducted in the same test cell using the same basic engine (and power rating).

TABLE 3.—ENGELHARD BASELINE AND ETX TEST DATA

Test description	BSFC [1]	Average
ETX Kit (277 hp)	0.503	
ETX Kit (277 hp)	0.513	0.508
1991 50-s (277 hp)	0.498	
1991 50-s (277 hp)	0.519	
1991 50-s (277 hp)	0.511	0.509
1988 50-s (277 hp)	0.481	0.481

[1] Brake-specific fuel consumption measured in units of pounds of fuel per brake horsepower-hour.

The average fuel consumption of the two ETX tests (0.508 lb/bhp-hr) indicate that the ETX kit will present no fuel consumption penalty when compared to the average of three tests in the 1991 model year configuration (0.509 lb/bhp-hr). Also, the data indicate that installing the ETX kit on 1988 through 1990 50-state (California) engines will result in 5.6 percent increase in fuel consumption (comparing 0.508 to 0.481).

With regard to JMI's comment that Engelhard should conduct baseline testing using a 1988 model year 49-state (federal) engine, this data is not available (Engelhard has not conducted testing on a 1988 model year configuration). With regard to Engelhard's use of DDC data (supplied by DDC during the certification process for its 25-percent DDEC upgrade kit) for Engelhard's life cycle cost analysis, EPA believes that it is not the most accurate way to determine fuel consumption impact because of variables such as engines of different power ratings, in different test cells, and being conducted two years apart. Additionally, because different test cells were used, EPA agrees with JMI that it is not appropriate to use JMI's 1988 federal engine data as a baseline to compare data from ETX testing conducted for Engelhard. Instead, EPA believes that other data, as discussed below, is adequate to determine the impact of the ETX kit on 1988 through 1990 model year 49-state (federal) engines.

In a telefax to EPA dated June 5, 1998, JMI provided documentation of testing the 1988 model year federal 6V92TA that is referenced in its above-mentioned comments. Additionally, JMI provided documentation from testing a

1992 model year 6V92TA, in its notification of intent to certify equipment dated March 6, 1998. EPA believes that these test data, performed on 277 hp engines in the same test cell, can be used to compare a 1991 configuration (the 1992 model year is considered equivalent to the 1991) with a 1988 configuration. EPA believes that the difference predicted by these data will be equivalent to the impact on 1988–1990 engines resulting from installation of the ETX kit, because the above-mentioned ETX testing indicates that the ETX kit will result in no increased consumption compared to 1991 model year engines. The JMI test documentation show a measured fuel consumption of 0.483 lb/bhp-hr for the 1992 engine, which is 5.2 percent greater than the 0.459 lb/bhp-hr measured for the 1988 engine. These data predict that 1988 through 1990 model year configurations will experience 5.2 percent increased fuel consumption when equipped with the ETX kit. This level of impact is generally supported by the above-mentioned DDC data. That DDC data, as noted by Engelhard in its October 21, 1997 notification, shows an impact of 4.7 percent. The 5.2 percent impact predicted using the JMI data is greater than originally proposed by Engelhard (based on the DDC data) in its notification of October 21. Also, EPA believes use of the JMI data is more accurate because it was conducted using two configurations (1992 and 1988 model years) of the same power rating in the same test cell. The testing conducted by JMI can be found in the public docket located at the above address.

EPA recognizes that the available data is limited, but believes it adequate for the purpose of determining the life cycle cost analysis. In summary, the installation of the ETX kit on 1991–1993 model year engines is determined to result in no additional fuel consumption, on 1988–1990 50-state (California) engines is determined to result in 5.6 percent increased fuel consumption, and on 1988–1990 49-state (federal) engines is determined to result in 5.2 percent increased in fuel consumption. The impact of increased fuel consumption on life cycle costs is determined below.

4. EPA Determination of Life Cycle Cost

Section 1403(b)(1)(ii) describes those items which must be considered when analyzing life cycle cost of equipment, including equipment purchase price, incremental fuel cost, installation costs, maintenance costs, and costs of any fuel additives required. To trigger the 0.10 g/bhp-hr standard, the life cycle cost of equipment can be no more than $7,940 (in 1992 dollars), incremental to the cost of a standard rebuild.

In this section, EPA analyzes the life cycle costs using a methodology similar to that described in the **Federal Register** notice of March 14, 1997, which describes the certification of Engelhard's ETX kit applicable to DDC's 6V92TA engines with mechanical unit injectors (MUI). The analysis first determines the cost of a ''weighted'' rebuild, which reflects operators' use of non-original equipment parts and rebuilding certain components in-house. The weighted rebuild ''corrects'' all cost information to a 1992 base, which is the time period for which the life cycle cost limit of $7,940 is based. EPA uses the cost of a weighted rebuild to represent the cost of a standard rebuild, which is then used to determine a maximum allowable purchase price such that the life cycle cost of the equipment meets the life cycle cost limit. The maximum purchase price, when added to the incremental fuel penalty and installation cost, and offset by the value of displaced standard rebuild parts, must be no more than $7,940 (in 1992 dollars), incremental to the cost of a standard rebuild.

i. Cost of a standard rebuild. Engelhard presented a life cycle cost analysis in its notification signed October 21, 1997, and made changes to the analysis in subsequent letters to EPA. The Engelhard analyses rely on DDC suggested list prices to determine the cost of a ''standard'' rebuild. Engelhard, in one of its letters dated June 15, 1998, provides a letter from Atlantic Detroit Diesel-Allison with current suggested list prices for DDC parts. Table 4 below presents OE list prices presented by Engelhard for the standard rebuild parts affected by the ETX kit. In the table, EPA has corrected the information to a 1992 time period, using a multiplicative ratio of Consumer Price Indices (CPI). The average CPI for 1992 is 140.3, as specified by the program regulation. The April 1998 CPI, for all items and all urban consumers, is 162.5. These values are available from the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 4.—ORIGINAL EQUIPMENT (OE) PARTS PRICES

Item in kit (quantity)	OE suggested list price	Normally replaced at overhaul ?	Price corrected to 1992 (based on CPIs)
Cylinder Kits (6)	$2,394	Yes	$2,067
Gasket Kit (1)	207	Yes	179
Fuel Injectors (6)	1,688	Yes	1,457
LB Camshaft (1)	854	Yes	738
RB Camshaft (1)	731	Yes	631
Blower Ass'y (1)	575	Yes	496
Turbo Ass'y (1)	890	Yes	768
Heads Ass'y (2)	1,166	Yes	1,007
ECM Program (1)	(1)	No	
Totals	$8,505		$7,343

[1] Not required.

Engelhard, in one of its letters dated June 15, 1998, states that it is their experience that almost all major transits in major metropolitan areas use 100 percent DDC parts. Therefore, non-OE parts do not affect the life cycle cost. Also, Engelhard states that, although at one time a common practice, today virtually no large urban transit companies re-manufacture their own components (such as turbochargers, blowers, and heads). Engelhard further notes that in-house engine rebuilding refers to the process of disassembling and reassembling the engine, and that this is different from re-manufacturing engine components.

In response to Engelhard's comments about the current practice of (not) re-manufacturing components in-house, EPA believes that the current practice is not relevant. Instead, the relevant practice is the amount of in-house re-manufacturing at the point in time when the life cycle cost ceiling was established (that is, in the 1992–1993 time frame). EPA acknowledges that industry practice may have changed since 1993, for various reasons, such as general industry trends, or perhaps the urban bus program certification of kits that include most emissions related parts. However, at the relevant point in time (1993 or earlier), EPA believes that a significant number of transits re-manufactured parts in-house. EPA understands Engelhard's comment concerning the difference between in-house engine rebuilding and component re-manufacturing, but the practice of in-house re-manufacturing is supported by Engelhard's comments (''at one time this was a common practice . . .'') and EPA telephone conversations with transit operators. Therefore, for the determination of the cost of a weighted rebuild, EPA assumes that some parts used in the rebuild of engines are non-OE parts, and that most transits re-manufacture certain components in-house.

In comments related to certification of its ETX kit for 6V92TA MUI engines, Engelhard stated that the weighted cost approach should be adjusted to reflect an additional cost to transit operators who rebuild in-house, because parts are occasionally not rebuildable due to catastrophic failure. EPA is retaining this methodology for determining the cost of a weighted rebuild for DDEC engines. Engelhard stated that 10 percent of turbochargers and blowers are not rebuildable, and that 50 percent of cylinder heads are not rebuildable. When parts are non-rebuildable, a transit operator would typically purchase a new component at fleet cost. The nominal cost of these components assumes the exchange of a rebuildable core. If the core is not rebuildable, then the operator pays a core charge plus the nominal cost of the component. The sum of the component fleet price plus the core charge represent additional costs to fleets that rebuild in-house, due to non-rebuildable parts. When weighted based on the frequency at which the part is non-rebuildable, it yields an additional cost on a per-component basis. Consistent with the past cost analysis, EPA assumes in-house rebuild of three components: the turbocharger, the blower, and the cylinder heads. Table 5 below summarizes estimates of the additional costs related to the in-house rebuild of these parts.

Also, EPA has included injectors in Table 5 below, based on new information presented by Engelhard in one of its letters dated June 15, 1998. Engelhard stated that injectors should be included in this table because operators normally purchase rebuilt injectors that have a core charge. The 1998 core charge is $200 per injector and approximately 10 percent fail, but since the list price of a new injector is $604, an operator will pay the core charge and still purchase a rebuilt injector.

TABLE 5.—CORE COST IMPACT OF NON-REBUILDABLE PARTS

[1992 Dollars]

Item	OE suggested price	OE fleet price	In-house rebuild cost	Fraction damaged	Core charge (1)	Total cost to transit
A	B	C	D	E	F	G
1 Injector	$243	$224	NA	0.10	$173	$242
Blower	496	459	$223	0.10	474	294
Turbo	768	710	346	0.10	288	411
1 Head	503	465	227	0.50	395	543

The OE Fleet Prices for the blower, turbocharger, and cylinder heads are estimated by EPA, using the same ratio of the prices for these parts set forth during the certification process of the ETX kit for 6V92TA MUI engines. Core charges for the blower, turbocharger, and cylinder head are estimated by EPA based on the fractions (of OE suggested prices) as the values EPA used in the methodology of the analysis of weighted rebuild in the ETX 0.10 MUI kit. The core charge for the injectors is provided by Engelhard in one of its letters dated June 15, 1998. In-House Rebuild Costs are 45% of OE suggested prices, based on JMI comment relating to certification of the DDC MUI 25% upgrade kit (60 FR 51472, October 2, 1995).

For the blower, turbocharger, and heads, Table 5 above makes a correction to the calculation described in the July 19, 1996 **Federal Register** (61 FR 37738). Table 5 determines a weighted Total Cost to Transit, based on the fraction of parts damaged. Total Cost to Transit = (1–E)(D)+(E)(C+F) for the blower and turbocharger. For the cylinder heads, the Total Cost = (D)/2 + (C+F)/2, which is an average cost for one head. For fuel injectors, the Total Cost = (1–E)(C)+(E)(C+F) per injector.

Table 6 below summarizes the cost of a weighted rebuild (in 1992 dollars) including adjustments to the above components.

TABLE 6.—COST OF A WEIGHTED REBUILD

[1992 Dollars]

Item in kit	OE list price	Non-OE cost	OE fleet price	Weighted rebuild
1 Cylinder Kit	$2,067	$1,049	$1,777	$1,540
2 Gasket Kit	179	134	153	147
3 Fuel Injectors	1,457	NA	1,346	1,450
4 LB Camshaft	738	553	632	606
5 RB Camshaft	631	473	541	519
6 Blower Ass'y	496	294	459	302
7 Turbo Ass'y	768	411	710	424
8 Heads Ass'y	1,007	1,087	930	1,079

TABLE 6.—COST OF A WEIGHTED REBUILD—Continued

[1992 Dollars]

Item in kit	OE list price	Non-OE cost	OE fleet price	Weighted rebuild
9 ECM Program	(1)	(1)	(1)	(1)
Totals	7,343			6,067

1 Not required.

The non-OE cylinder kit cost is based on an Engelhard comment dated July 19, 1995, that the aftermarket cylinder kit costs 1,139.94, corrected to 1992 dollars (the CPI for June 1995 is 152.5). The prices of non-OE gasket kit and camshafts are 75% of the 1992 corrected OE prices, based on 25 percent discount from OE list prices, as discussed in the March 14, 1997 **Federal Register** notice (62 FR 12177). The OE Fleet Prices are estimated by EPA, as the same fractions (of OE suggested prices) as the values EPA used in the analysis of the Engelhard 0.10 MUI kit.

As was done in the analyses of a MUI weighted rebuild, EPA makes two adjustments to its analysis of the cost of a weighted rebuild. First, all costs are corrected to 1992 dollars. Second, the weighted rebuild is modified to reflect non-OE parts costs that are 25 percent less than OE cost.

For the cylinder kits, gasket kit, and both camshafts, a weighted cost is determined as the sum of the non-OE cost, weighted 32.6 percent, plus the DDC suggested cost of parts, weighted 67.4 percent. This weighting is based on the APTA survey showing the relative split in operators' parts business between OE and non-OE parts suppliers. The APTA survey (American Public Transit Association Transit Bus Diesel Engine Rebuilding Survey by Michael J. Meloche, January 1991) indicates that 67.4% of operators parts business is with OE parts suppliers, and 32.6% is with non-OE suppliers. The APTA survey can be found in the public docket at the above address. The cost of the fuel injectors are determined above in Table 5. Based on the APTA survey, 95.5 % of the blower, turbochargers, and heads are assumed to be re-manufactured in-house at the Non-OE Costs, and the balance purchased at OE fleet prices. The ECM is not reprogrammed during a standard rebuild.

EPA recognizes that there are a number of uncertainties and assumptions involved with this ''weighted'' approach, but believes, based on the available information, that the cost of a standard rebuild of a DDC 6V92TA DDEC engine is best approximated by the weighted rebuild costs shown above in Table 6, for the purposes of determining the maximum allowable purchase price for the Engelhard ETX kit.

ii. Incremental fuel cost. The percentage fuel consumption impacts, as discussed in above Section 3, are shown below in Table 7 along with the impact due to increased life-time fuel costs pursuant to the calculations of 40 CFR 85.1403(b)(1).

TABLE 7.—FUEL CONSUMPTION IMPACT OF ETX KIT

[1992 dollars]

Applicable engine	Percent BSFC impact	Fuel penalty per 40 CFR 85.1403(b)(1)
1988–1990 49-s	−5.2	($1,473)
1991–1993 49-s	0.2	0
1988–1990 50-s	−5.6	(1,581)

iii. Installation costs. As defined in 40 CFR 85.1403 (b)(1)(ii)(B), the installation cost of certified equipment is ''the labor cost of installing the equipment on an urban bus engine, incremental to a standard rebuild, based on a labor rate of $35 per hour'' (in 1992 dollars). Engelhard states that the labor required to rebuild an engine will be the same for a standard rebuild and the ETX kit, with the exception of the additional labor required for installation of the CMX catalytic muffler. The urban bus engines for which this equipment is intended were not originally equipped with catalytic convertors. Therefore, the muffler unit must be removed from the engine, and the CMX–5 unit installed in its place. Engelhard states that installation of the CMX–5 catalyst unit requires a maximum time of six hours to install on an urban bus engine. Using the labor rate of $35.00 per hour, as specified in the regulation (40 CFR 85.1403), the six hours is valued at $210 (in 1992 dollars). The $210 is incremental to the cost of a standard rebuild.

iv. Maintenance costs. Engelhard states that after installation of the ETX kit, an engine will require no maintenance above the standard rebuild. EPA has no information to conclude that any additional maintenance is necessary for the CMX–5 catalyst muffler, or would increase life cycle costs. Therefore, no additional maintenance costs are listed for the ETX kit.

v. Costs of fuel additives. No fuel additives are required for the ETX kit.

vi. Total life cycle cost calculation. The regulation at 40 CFR 85.1403 requires that the life cycle cost, for equipment that triggers the 0.10 g/bhp-hr standard, be no more than $7,940 (in 1992 dollars) incremental to the cost of a standard rebuild. Table 8 below summarizes the life cycle costs for the ETX kit for each of the three groups of applicable engines: 1988 to 1990 model year 49-state engines, 1988 through 1990 model year 50-state engines, and 1991 through 1993 model year 50-state engines. Separate summaries are presented because of the differing kits, and the different fuel penalty determined for each group.

TABLE 8.—LIFE CYCLE COSTS

[1992 dollars]

	Applicable engines		
	1988–1990 49-State	1991–1993 49-State	1988–1990 50-State
Maximum Allowable Purchase Price	$11,876	$10,774	$11,768
Offset for kit parts normally replaced during a standard rebuild	(5,619)	(3,044)	(5,619)
Installation Cost	210	210	210
Fuel Penalty	1,473	0	1,581
Total Incremental Life Cycle Cost	7,940	7,940	7,940

The table displays the maximum allowable purchase prices for the ETX kits, in 1992 dollars. The total incremental life cycle cost is the sum of the listed items. An ''offset'' is provided to the life cycle cost because certain components provided in the ETX kits offset costs for parts which otherwise are replaced during a standard engine rebuild. The values, for the individual rebuild parts that are offset by the kit parts, are discussed above in conjunction with the determination of a weighted rebuild and itemized in Table 6. To determine the incremental life cycle cost, these ''offset'' costs are subtracted, as shown in Table 8. As shown in the table, the total incremental life cycle cost is no more than the ceiling specified in the program regulations, $7,940 in 1992 dollars. Engelhard, in its letter to EPA dated July 1, 1998, guarantees to make ETX kits available to all affected urban bus operators for no more than the maximum allowable purchase price. Current values of the maximum purchase prices are discussed below.

vii. Current Maximum Allowable ETX Purchase Price. Table 9 below shows the maximum allowable purchase price (in 1992 dollars) as determined above. The current (April 1998) maximum allowable purchase prices, calculated using a multiplicative ratio of CPI's, are also shown in the table. The average CPI for 1992 is 140.3, as specified by the program regulation. The April 1998 CPI, for all items and all urban consumers, is 162.5. These CPI values are provided by the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 9.—CURRENT MAXIMUM ETX KIT PURCHASE PRICE

Applicable model year	1992 maximum purchase price	April 1998 maximum purchase price
1988–1990 49-State	$11,876	$13,755
1991–1993 50-State	10,774	12,479
1988–1990 50-State (California)	11,768	13,630

III. California Engines

The NO_x emission standard for new engine certification applicable to 1988 through 1990 model year engines sold in the State of California is 6.0 g/bhp-hr. For 1991 through 1993, the standard is 5.0 g/bhp-hr. The emissions testing presented by Engelhard demonstrate a NO_x emissions level that complies with the 5.0 g/bhp-hr standard. Therefore, today's certification of the ETX kit for DDEC II engines applies to DDEC II engines certified to meet California emissions standards, subject to the conditions discussed below.

The equipment certified today may require additional review by the California Air Resources Board (CARB) before use in the State of California. EPA recognizes that special situations may exist in California that are reflected in the unique emissions standards, engine calibrations, and fuel specifications of the State. While requirements of the federal urban bus program apply to several metropolitan areas in California, EPA understands the view of CARB that equipment certified under the urban bus program, to be used in California, must be provided with an executive order exempting it from the anti-tampering prohibitions of that State. Parties interested in additional information should contact the Aftermarket Part Section of CARB, at (818) 575–6848.

IV. Certification and Conditional Certification

EPA has reviewed this notification, along with comments received from interested parties, and finds the equipment described in this notification of intent to certify:

(1) Complies with a particulate matter emissions standard of 0.10 g/bhp-hr, without causing the applicable engine families to exceed other applicable emission requirements, subject to the conditions discussed below;

(2) Will not cause an unreasonable risk to the public health, welfare or safety;

(3) Will not result in any additional range of parameter adjustability; and

(4) Meets other requirements necessary for certification under the Urban Bus Rebuild Requirements (40 CFR Sections 85.1401 through 85.1415).

With the following conditions, EPA hereby certifies this equipment for use in the Urban Bus Retrofit/Rebuild Program. As noted above, the equipment being certified today includes, for 1988–1990 model year engines, an upgraded control program for the electronic control module. EPA has recently become concerned that many electronically controlled engines may have been equipped by the original manufacturers with strategies designed to decrease fuel consumption during certain driving modes not substantially included in the federal test procedure, with the effect of substantially increasing NO_x during these modes. Such electronic control strategies have the potential to be ''defeat devices'' as defined at 40 CFR 86.094–22, and thus may violate 40 CFR 85.1406 and 85.1408 if included in an urban bus retrofit application. The upgraded control program used for the 1988–1990 model year upgrade must therefore be reviewed for such violations.

As a result, certification of the ETX kit, as it applies to 1988 through 1990 model year engines, is conditioned upon Engelhard demonstrating by January 1, 1999 that any replacement engine control module (ECM) or ECM program used in conjunction with the certified kit will not adversely impact the emissions of NO_X in comparison to the ECM or ECM program that is being replaced under conditions which may reasonably be expected to be encountered in normal vehicle operation and use unless such conditions are substantially included in the Federal emission test procedure. The equipment, the ETX–2002™ Emissions Rebuild Kit, may be used immediately by transit operators in compliance with requirements of this program, subject to the above condition.

V. Transit Operator Responsibilities

Today's **Federal Register** notice announces certification of the above-described Engelhard equipment, when properly applied, as meeting the 0.10 g/bhp-hr particulate matter standard of the Urban Bus Rebuild Program for urban bus engines certified as meeting both federal and California emissions standards. Affected urban bus operators who choose to comply with compliance program 1 are required to use this, or other equipment that is certified to meet the 0.10 g/bhp-hr particulate matter standard, for any engines listed in Table 2 which are rebuilt or replaced on or after March 22, 1999, subject to the condition of Section IV.

Urban bus operators who choose to comply with compliance program 2 may use the certified Engelhard equipment, and those who use this equipment may claim the respective particulate matter certification level from Table 2 when calculating their Fleet Level Attained (FLA), subject to the condition of Section IV.

Urban bus operators must be aware of their responsibility for maintenance of records pursuant to 40 CFR 85.1403 through 85.1404. The ETX kit may not include, depending upon model year of the applicable engine, fuel injectors, engine camshafts, and blower assembly. As stated in the program regulations (40 CFR 85.1401 through 85.1415), operators should maintain records for each engine in their fleet to demonstrate that they are in compliance with the Urban Bus Rebuild Requirements beginning on January 1, 1995. These records include purchase records, receipts, and part numbers for the parts and components used in the rebuilding of urban bus engines. Urban bus operators must be able to demonstrate that all parts used in the rebuilding of engines are in compliance with program requirements. In other words, urban bus operators must be able to demonstrate that all required components of the kit certified in today's **Federal Register** notice are installed on applicable engines.

Dated: September 11, 1998.

Robert Perciasepe,

Assistant Administrator for Air and Radiation.

[FR Doc. 98–25198 Filed 9–18–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6164–3]

Clean Air Act Advisory Committee: Accident Prevention Subcommittee's RMP Implementation Workgroup; Series of Conference Call Meetings September–December, 1998

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Section 112(r) of the Clean Air Act (CAA) requires covered facilities to develop risk management programs to prevent accidental releases of dangerous chemicals. Facilities are to submit risk management plans (RMPs) to a central location by June 1999. The RMPs will be electronically available to State and local governments and citizens to help them understand local chemical hazards and take steps to prevent accidents.

The Accident Prevention Subcommittee of the CAA Advisory Committee was established in September 1996 to provide EPA with advice and counsel on scientific and technical aspects of CAA section 112(r). In October 1996, the Accident Prevention Subcommittee established the Electronic Submission Workgroup which submitted its final recommendations report on June 18, 1997. At its May 9th meeting, the Accident Prevention Subcommittee established a second workgroup, the RMP Implementation Workgroup, to ensure that all stakeholders have the tools they need to implement a risk management program under CAA § 112(r).

The RMP Implementation Workgroup identifies activities that must be undertaken and products that must be developed. Additionally, the Workgroup makes recommendations to EPA and the Accident Prevention Subcommittee about the best methods for carrying out these activities. The Workgroup works with EPA to ensure that products are developed and issues are addressed within appropriate time frames.

The Workgroup addresses the following:

1. Risk Communication
2. Guidance for Implementing Agencies
3. Guidance for Industry
4. Audit protocol and guidance
5. RMP*Info, RMP*Submit
6. Outreach, Training, and Program Evaluation
7. Guidance for LEPCs

The Workgroup includes 30–35 members, with balanced membership from the following organizations: States, local government and LEPCs, industry, environmentalists, non-profits, EPA CEPPO (HQ and Regions), other EPA offices, and other groups.

DATES: Pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. 2, notice is hereby given that the next four meetings of the RMP Implementation Workgroup will be held at the following times (all Eastern time).

(1) September 16, 1998—2:00 p.m. to 4:00 p.m.

(2) October 21, 1998—2:00 p.m. to 4:00 p.m.

(3) November 18, 1998—2:00 p.m. to 4:00 p.m.

(4) December 16, 1998—2:00 p.m. to 4:00 p.m.

On September 9, 1998, the Accident Prevention Subcommittee voted for continuation of the RMP Implementation Workgroup through calendar year 1999. Meetings after December of this year will be scheduled and announced at least four weeks in advance. All meetings are open to the public.

ADDRESSES: The Workgroup meetings held in September, October and November will be located at EPA Headquarters in Washington, D.C., in Washington Information Center (WIC) conference room #13 North. The address is 401 M St., SW, Washington, D.C. 20460. The location of the final meeting in December will be announced at least two weeks prior to the meeting date. Members of the public are welcome to attend in person.

FOR FURTHER INFORMATION: Members of the public desiring additional information about these meetings should contact Kate Narburgh, US EPA (5104), 401 M. St., SW, Washington, DC 20460, via the Internet at: *narburgh.kate@epamail.epa.gov*, by telephone at (202) 260–8247 or FAX at (202) 401–3448.

Additional information on the RMP Implementation Workgroup is available on the Internet at: *http://www.epa.gov/swercepp/rmp-imp.html.* Information on

the Accident Prevention Subcommittee is available at: *http://www.epa.gov/swercepp/acc-pre.html.*

If you would like to automatically receive future information on the Accident Prevention Subcommittee and its Workgroups by e-mail, you can subscribe to the EPA–RMP Listserve by sending the following message to *listserver@unixmail.rtpnc.epa.gov:*

SUBSCRIBE EPA–RMP <Your firstname> <Your lastname>

Example: SUBSCRIBE EPA–RMP John Smith

Dated: September 15, 1998.

Karen Shanahan,

Designated Federal Official.

[FR Doc. 98–25197 Filed 9–18–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6143–9]

ACTION: Notice of Management Committee Meeting

SUMMARY: The Gulf of Mexico Program will hold it's Management Committee Meeting October 13 & 14, 1998 at the Magnolia Plantation Hotel in Gulfport, Mississippi.

DATES: The meeting will be held on October 13 & 14, 1998.

ADDRESSES: The meeting will be held at the Magnolia Plantation Hotel, 16391 Robinson Road, Gulfport, Mississippi. (601) 832–8400.

FOR FURTHER INFORMATION CONTACT: James D. Giattina, Director, Gulf of Mexico Program Office, Building 1103, Room 202, Stennis Space Center, MS 39529–6000 at (228) 688–1172.

SUPPLEMENTARY INFORMATION: The Gulf of Mexico Program will hold its Management Committee Meeting on October 13 & 14, 1998 at the Magnolia Plantation Hotel in Gulfport, MS. The meeting is from 1:00 p.m. until 5:00 p.m. on the 13th and from 8:30 a.m. until 2:00 p.m. on the 14th. Agenda items will include: Gulfwide Priorities & Watershed/Estuary Targets and Updates for Public Health, Nonindigenous Species, Nutrient Enrichment & Habitat Focus Teams; National Fish & Wildlife Foundation Gulf Habitat Restoration Fund presentation; Mississippi River/Gulf of Mexico Nutrient Task Force Update; and Coastal Sewage Issue Characterization report.

The meeting is open to the public.

James D. Giattina,

Director, Gulf of Mexico Program Office.

[FR Doc. 98–25199 Filed 9–18–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6163–3]

Notice of Proposed Prospective Purchaser Agreement Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as Amended by the Superfund Amendments and Reauthorization Act, Industrial Hard Chrome Plating Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: Notification is hereby given that a Proposed Prospective Purchaser agreement (PPA) associated with the Industrial Hard Chrome Plating Superfund Site located in Denver, Colorado was executed by the United States Department of Justice on August 18, 1998. This Agreement is subject to final approval after the comment period. The Prospective Purchaser Agreement would resolve certain potential EPA claims under sections 106 and 107 of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended by the Superfund Amendments and Reauthorization Act of 1986 (CERCLA), against 919 Santa Fe Properties, LLC, the prospective purchaser (the purchaser).

The settlement would require the purchaser to pay the U.S. Environmental Protection Agency $2,500. The purchaser intends to use the purchased property for a parking and office building. The purchaser agreed to provide EPA with an irrevocable right of access to the Site, to conduct all business in compliance with all applicable local, State, and federal laws and regulations, and to exercise due care at the Site. The purchaser will record a certified copy of the PPA with the local Recorder's Office, and thereafter, each deed, title, or other instrument conveying an interest in the Property shall contain a notice stating that the Property is subject to the Agreement.

For thirty (30) days following the date of publication of this document, the Agency will receive written comments relating to the proposed settlement. The Agency's response to any comments received will be available for public inspection at the Superfund Records Center at the U.S. Environmental Protection Agency, Region VIII, 999 18th Street, Denver, Colorado 80202.

Availability: The proposed settlement is available for public inspection at the U.S. Environmental Protection Agency, Region VIII, 999 18th Street, Denver, Colorado, 80202. A copy of the proposed Agreement may be obtained from Mia Wood, Enforcement Attorney, U.S. Environmental Protection Agency, Region VIII, 999 18th Street, Denver, Colorado 80202. Comments should reference the ''Industrial Hard Chrome Plating Superfund Site Prospective Purchaser Agreement'' and should be forwarded to Veronica Jacobson, Enforcement Specialist, at the U.S. Environmental Protection Agency, Region VIII, 999 18th Street, Denver, Colorado 80202.

FOR FURTHER INFORMATION CONTACT: Mia Wood, Enforcement Attorney, U.S. Environmental Protection Agency, Region VIII, 999 18th Street, Denver, Colorado 80202. (303) 312–6554.

William P. Yellowtail.

Regional Administrator, Region VIII.

[FR Doc. 98–25194 Filed 9–18–98; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

[Report No. IN 98–48; DA 98–1703]

International Mobile Telecommunications—2000 (IMT–2000)

AGENCY: Federal Communications Commission.

ACTION: Notice; seeking comment.

SUMMARY: Commission staff seeks comment on spectrum issues related to third generation wireless telecommunications systems.

DATES: Comments are due on or before September 30, 1998.

ADDRESSES: Parties should file an original and one copy of comments with Richard B. Engelman, Chief, Planning & Negotiations Division, International Bureau, Federal Communications Commission, 2000 M St., N.W., Suite 800, Washington, D.C. 20554. Comments will be available for public inspection during regular business hours in the International Reference Center, 2000 M St., N.W., Room 102, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Maureen C. McLaughlin, International Bureau at (202) 418–2404.

SUPPLEMENTARY INFORMATION: This public notice was released August 26, 1998 and is available in its entirety for inspection and copying during normal business hours in the FCC International Reference Center, 2000 M St., N.W., Room 102, Washington, D.C. 20554 and may also be purchased from the

Commission's copy contractor, International Transcription Services, (202) 857–3800, fax (202) 857–3805, 1231 20th Street, N.W., Washington, D.C. 20036.

Synopsis of the Public Notice

The International Telecommunication Union (ITU) is in the process of identifying the long-term spectrum requirements for future ''third generation'' mobile wireless telecommunications systems, referred to as International Mobile Telecommunications—2000 (IMT–2000). In 1992, the ITU identified 230 megahertz of spectrum near 2 GHz that could be used by administrations wishing to implement IMT–2000 systems. Based on concerns that 230 megahertz might be insufficient in the long term, the ITU is now considering whether additional spectrum should be identified for IMT–2000 systems. In conjunction with the ITU's efforts, Commission staff are participating in domestic and international efforts to determine whether additional spectrum is required for IMT–2000 systems and, if so, how much. This determination, along with the possible identification of frequency bands that could be made available for use by IMT–2000 systems, must include consideration of numerous factors, including: other wireless services that have already been authorized; compatibility with current spectrum uses; interference potential; and sharing issues. To refine our analysis of potential IMT–2000 spectrum needs, Commission staff seeks comment on a series of questions regarding the types of wireless services expected in the future, bandwidth and overall spectrum requirements, spectrum location, technological advancements, and spectrum efficiency. We also seek comment regarding the potential impact on the existing services and the potential for IMT–2000 sharing with those services.

Richard B. Engelman,

Chief, Planning & Negotiations Division, International Bureau.

[FR Doc. 98–25165 Filed 9–18–98; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1241–DR]

Florida; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Florida (FEMA–1241–DR), dated September 4, 1998, and related determinations.

EFFECTIVE DATE: September 4, 1998.

FOR FURTHER INFORMATION CONTACT: Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 4, 1998, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), as follows:

I have determined that the damage in certain areas of the State of Florida, resulting from Hurricane Earl on September 3, 1998 is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, P.L. 93–288, as amended (''the Stafford Act''). I, therefore, declare that such a major disaster exists in the State of Florida.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and Hazard Mitigation in the designated areas. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Paul Fay of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Florida to have been affected adversely by this declared major disaster:

Bay, Dixie, Franklin, Gulf, and Wakulla Counties for Individual Assistance.

All counties within the State of Florida are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program)

James L. Witt,

Director.

[FR Doc. 98–25187 Filed 9–18–98; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1244–DR]

New York; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of New York (FEMA–1244–DR), dated September 11, 1998, and related determinations.

EFFECTIVE DATE: September 11, 1998.

FOR FURTHER INFORMATION CONTACT: Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of New York, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of September 11, 1998.

Monroe, Oneida, and Wayne Counties for Categories A and B (debris removal and emergency protective measures) under the Public Assistance Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program)

Lacy E. Suiter,

Executive Associate Director, Response and Recovery Directorate.

[FR Doc. 98–25184 Filed 9–18–98; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1243–DR]

South Carolina; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of South Carolina (FEMA–1243–DR), dated September 4, 1998, and related determinations.

EFFECTIVE DATE: September 4, 1998.

FOR FURTHER INFORMATION CONTACT: Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 4, 1998, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), as follows:

I have determined that the damage in certain areas of the State of South Carolina, resulting from Hurricane Bonnie on August 25, 1998, through and including September 1, 1998 is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, Pub.L. 93–288, as amended (''the Stafford Act''). I, therefore, declare that such a major disaster exists in the State of South Carolina.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation in the designated areas. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance or Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Glenn Woodard of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of South Carolina to have been affected adversely by this declared major disaster:

Horry County for Public Assistance.

All counties within the State of South Carolina are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program)

James L. Witt,

Director.

[FR Doc. 98–25185 Filed 9–18–98; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1239–DR]

Texas; Amendment No. 7 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Texas, (FEMA–1239–DR), dated August 26, 1998, and related determinations.

EFFECTIVE DATE: September 11, 1998.

FOR FURTHER INFORMATION CONTACT: Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of Texas, is hereby amended to include the following areas among those area determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of August 26, 1998.

Edwards County for Individual Assistance (already designated for Public Assistance).

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program)

Dennis H. Kwiatkowski,

Deputy Associate Director, Response and Recovery Directorate.

[FR Doc. 98–25188 Filed 9–18–98; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1242–DR]

Commonwealth of Virginia; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Commonwealth of Virginia (FEMA–1242–DR), dated September 4, 1998, and related determinations.

EFFECTIVE DATE: September 4, 1998.

FOR FURTHER INFORMATION CONTACT: Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 4, 1998, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), as follows:

I have determined that the damage in certain areas of the Commonwealth of Virginia, resulting from Hurricane Bonnie on August 25, 1998, through and including September 1, 1998, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, Pub.L. 93–288, as amended (''the Stafford Act''). I, therefore, declare that such a major disaster exists in the Commonwealth of Virginia.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and Hazard Mitigation in the designated areas. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Robert J. Gunter of the Federal Emergency Management Agency

to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the Commonwealth of Virginia to have been affected adversely by this declared major disaster:

The independent cities of Chesapeake, Norfolk, Portsmouth, Suffolk, and Virginia Beach for Individual Assistance.

All counties within the Commonwealth of Virginia are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program)

James L. Witt,

Director.

[FR Doc. 98–25186 Filed 9–18–98; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL HOUSING FINANCE BOARD

Sunshine Act Meeting; Announcing an Open Meeting of the Board

TIME AND DATE: 10:00 A.M., Wednesday, September 23, 1998.

PLACE: Board Room, Second Floor, Federal Housing Finance Board, 1777 F Street, N.W., Washington, D.C. 20006.

STATUS: The entire meeting will be open to the public.

MATTERS TO BE CONSIDERED DURING PORTIONS OPEN TO THE PUBLIC:

- Mortgage Partnership Finance Program: Terms and Conditions.
- Office of Finance—Board Appointments.

CONTACT PERSON FOR MORE INFORMATION: Elaine L. Baker, Secretary to the Board, (202) 408–2837.

William W. Ginsberg,

Managing Director.

[FR Doc. 98–25246 Filed 9–17–98; 10:45 am]

BILLING CODE 6725–01–P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

TIME AND DATE: 10:00 A.M.—September 21, 1998.

PLACE: 800 North Capitol Street, N.W.—Room 904, Washington, D.C.

STATUS: Closed.

MATTER(S) TO BE CONSIDERED: 1. Carrier Pricing Practices in the Transpacific Trades.

CONTACT PERSON FOR MORE INFORMATION: Joseph C. Polking, Secretary, (202) 523–5725.

Joseph C. Polking,

Secretary.

[FR Doc. 98–25316 Filed 9–17–98; 2:55 pm]

BILLING CODE 6730–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0304]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Application for FDA Approval to Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by October 21, 1998.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Application for FDA Approval to Market a New Drug—21 CFR Part 314—(OMB Control Number 0910–0001—Reinstatement)

Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States, imported, or exported from the United States, unless an approval of an application filed with FDA under section 505(b) or (j) of the act is effective with respect to such drug. Section 505(b) and (j) of the act requires a sponsor to submit to FDA a new drug application (NDA) containing, among other things, full reports of investigations that show whether or not the drug is safe and effective for use, a full list of articles used as components in the drug, a full description of manufacturing methods, samples of the drugs required, specimens of the labeling proposed to be used, and certain patent information as applicable. Under the act, it is the sponsor's responsibility to provide the information needed by FDA to make a scientific and technical determination that the product is safe and effective.

This information collection approval request is for all information requirements imposed on sponsors by the regulations under part 314 (21 CFR part 314), who apply for approval of a NDA in order to market or to continue to market a drug.

The following sections in part 314 set forth the specific format and content requirements for NDA's.

Section 314.50(a) requires that an application form (Form FDA 356h) includes basic introductory information about the drug as well as a checklist of enclosures. (Section 314.50(a) is already approved by OMB under 0910–0338 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.50(b) requires that an index be submitted with the archival copy of the application and that it reference certain sections of the application.

Section 314.50(c) requires that a summary of the application be submitted that presents a good general synopsis of all the technical sections and other information in the application.

Section 314.50(d) requires that the NDA contain the following technical sections about the new drug: Chemistry, manufacturing, and controls; nonclinical pharmacology and toxicology; human pharmacokinetics and bioavailability; microbiology; clinical data; and statistical section.

Section 314.50(e) requires the applicant to submit samples of the drug if requested by FDA. In addition, the archival copy of the application must include copies of the label and all labeling for the drug.

Section 314.50(f) requires that case report forms and tabulations be submitted with the archival copy.

Section 314.50(h) requires that patent information as described under § 314.53 be submitted with the application. (Section 314.50(h) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.50(i) requires that patent certification information be submitted in 505(b)(2) applications for patents claiming the drug, drug product, method of use, or method of manufacturing. (Section 314.50(i) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.50(j) requires that applicants that request a period of marketing exclusivity submit certain information with the application. (Section 314.50(j) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.50(k) requires that an archival, review, and field copy of the application be submitted.

Section 314.52 requires that notice of certification of invalidity or noninfringement of a patent to patent holders and NDA holders be sent by 505(b)(2) applicants and that certain content and notification procedures be followed. (Section 314.52 is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.54 sets forth the content requirements for applications filed under section 505(b)(2) of the act.

Section 314.60 sets forth reporting requirements for sponsors who amend an unapproved application.

Section 314.65 states that the sponsor must notify FDA when withdrawing an unapproved application.

Sections 314.70 and 314.71 require that supplements be submitted to FDA for certain changes to an approved application.

Section 314.72 requires sponsors to report to FDA any transfer of ownership of an application.

Section 314.80(c)(1) and (c)(2) sets forth requirements for expedited adverse drug experience postmarketing reports and followup reports, as well as for periodic adverse drug experience postmarketing reports (Form FDA 3500A). (Section 314.80(c)(1) and (c)(2) is already approved by OMB under 0910–0230 and 0910–0291 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.80(c)(1)(i) and (c)(1)(iii) establish recordkeeping requirements for reports of postmarketing adverse drug experiences. (Sections 314.80(c)(1)(i) and (c)(1)(iii) is already approved by OMB under 0910–0230 and 0910–0291 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.81(b)(1) requires that field alert reports be submitted to FDA (Form FDA 3331).

Section 314.81(b)(2) requires that annual reports be submitted to FDA (Form FDA 2252).

Section 314.81(b)(3)(i) requires that drug advertisements and promotional labeling be submitted to FDA (Form FDA 2253). (Section 314.81(b)(3)(i) is already approved by OMB in ''Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics For Human Use,'' which published in the **Federal Register** of October 24, 1997 (62 FR 55408), and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.81(b)(3)(iii) sets forth reporting requirements for sponsors who withdraw an approved drug product from sale. (Section 314.81(b)(3)(iii) is already approved by OMB under 0910–0045 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.90 sets forth requirements for sponsors who request waivers from FDA for compliance with §§ 314.50 through 314.81. (The information collection hour burden estimate for NDA waiver requests is included in Table 1 of this document under estimates for §§ 314.50, 314.60, 314.70, and 314.71.)

Section 314.93 sets forth requirements for submitting a suitability petition in accordance with 21 CFR 10.20 and 10.30. (Section 314.93 is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document.)

The following sections in part 314 set forth requirements when submitting an abbreviated new drug application (ANDA).

Section 314.94(a) and (d) requires that an ANDA contain the following and information: Application form; table of contents; basis for ANDA submission; conditions of use; active ingredients; route of administration, dosage form, and strength; bioequivalence; labeling; chemistry, manufacturing, and controls; samples; and patent certification.

Section 314.95 requires that notice of certification of invalidity or noninfringement of a patent to patent holders and NDA holders be sent by ANDA applicants. (Section 314.95 is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.96 sets forth requirements for amendments to an unapproved application.

Section 314.97 sets forth requirements for submitting supplements to an approved ANDA for changes that require FDA's approval.

Section 314.98(a) sets forth postmarketing adverse drug experience reporting and recordkeeping requirements. (Section 314.98(a) is already approved by OMB under 0910–0230 and 0910–0291 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.98(c) requires other postmarketing reports: Field alert reports (Form FDA 3331), annual reports (Form FDA 2252), and advertisements and promotional labeling (Form FDA 2253). (The information collection hour burden estimate for field alert reports is included in Table 1 of this document under § 314.81(b)(1); the estimate for advertisements and promotional labeling is included under § 314.81(b)(3)(i).)

Section 314.99(a) requires that sponsors comply with certain reporting requirements for withdrawing an unapproved ANDA and for a change in ownership of an ANDA.

Section 314.99(b) sets forth requirements for sponsors who request waivers from FDA for compliance with §§ 314.92 through 314.99. (The information collection hour burden estimate for ANDA waiver requests is included in Table 1 of this document under estimates for §§ 314.94(a) and (d), 314.96, and 314.97.)

Section 314.101(a)(3) states that, if FDA refuses to file an application, the applicant may request an informal conference with FDA and request that the application be filed over protest.

Section 314.107(c)(4) requires notice to FDA by ANDA or 505(b)(2) application holders of any legal action concerning patent infringement. (Section 314.107(c)(4) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.107(e)(2)(iv) requires that an applicant submit a copy of the entry of the order or judgement to FDA within 10 working days of a final judgement. (Section 314.107(e)(2)(iv) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.107(f) requires that an ANDA or 505(b)(2) applicants notify FDA of the filing of any legal action filed within 45 days of receipt of the notice of certification. A patent owner may also notify FDA of the filing of any

legal action for patent infringement. The patent owner or approved application holder who is an exclusive patent licensee must submit to FDA a waiver that waives the opportunity to file a legal action for patent infringement. (Section 314.107(f) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.110(a)(3) and (a)(4) requires after receipt of an FDA approvable letter, an applicant request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (Section 314.110(a)(3) and (a)(4) is included under the parts 10 through 16 (21 CFR part 10 through 16) hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.110(a)(5) requires that, after receipt of an approvable letter, an applicant notify FDA that it agrees to an extension of the review period so that it can determine whether to respond further.

Section 314.110(b) provides that, after receipt of an approvable letter, an ANDA applicant may request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (Section 314.110(b) is included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.120(a)(3) requires that an applicant request within 10 days after receipt of a not approvable letter, an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (Section 314.120(a)(3) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.120, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.120(a)(5) requires that an applicant notify FDA within 10 days after receipt of a not approvable letter, that it agrees to an extension of the review period so that it can determine whether to respond further.

Section 314.122(a) states that an ANDA or a suitability petition that relies on a listed drug that has been voluntarily withdrawn from sale must be accompanied by a petition seeking a determination whether the drug was withdrawn for safety or effectiveness reasons. (Section 314.122(a) is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.122(d) sets forth requirements for relisting petitions for unlisted discontinued products. (Section 314.122(d) is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.126(c) sets forth requirements for a petition to waive criteria for adequate and well-controlled studies. (Section 314.126(c) is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.151(a) and (b) set forth requirements for the withdrawal of and approval of an ANDA and the applicant's opportunity for a hearing and submission of comments. (Section 314.151(a) and (b) is included under the parts 10 through 16 hearing regulation, in accordance with § 314.201, and it is not included in the hour burden estimates in Table 1 of this document.)

Section 314.151(c) sets forth the requirements for withdrawal of approval of an ANDA and the applicant's opportunity to submit written objections and participate in a limited oral hearing. (Section 314.151(c) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.152(b) sets forth the requirements for suspension of an ANDA when the listed drug is voluntarily withdrawn for safety and effectiveness reasons, and the applicant's opportunity to present comments and participate in a limited oral hearing. (Section 314.152(b) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.161(b) and (e) set forth the requirements for submitting a petition to determine whether a listed drug was voluntarily withdrawn from sale for safety or effectiveness reasons. (Section 314.161(b) and (e) is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.200(c), (d), and (e) requires that applicants or others subject to a notice of opportunity for a hearing who wish to participate in a hearing file a written notice of participation and request for a hearing as well as the studies, data, and so forth, relied on. Other interested persons may also submit comments on the notice. This section also sets forth the content and format requirements for the applicants' submission in response to notice of opportunity for hearing. (Section 314.200(c), (d), and (e) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.200(f) requires that participants in a hearing may make a motion to the presiding officer for the inclusion of certain issues in the hearing. (Section 314.200(f) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.200(g), requires that a person who responds to a proposed order from FDA denying a request for a hearing provide sufficient data, information, and analysis to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing. (Section 314.200(g) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.420 states that an applicant may submit to FDA a drug master file in support of an application, in accordance with certain content and format requirements.

Section 314.430 states that data and information in an application are disclosable under certain conditions, unless the applicant shows that extraordinary circumstances exist. (Section 314.430 is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.530(c) and (e) requires that, if FDA withdraws approval of a drug approved under the accelerated approval procedures, the applicant has the opportunity to request a hearing and submit data and information. (Section 314.530(c) and (e) is included under the parts 10 through 16 hearing regulation, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.530(f) requires that an applicant first submit a petition for stay of action before requesting an order from a court for a stay of action pending review. (Section 314.530(f) is already approved by OMB under 0910–0194 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.550 requires that applicants submit all promotional materials to FDA for consideration during the preapproval review period. (The burden hours required for

§§ 314.550 are reported and approved under OMB control number 0910–0376, which published in the **Federal Register** at 62 FR 55408 and is not included in the hour burden estimates in Table 1 of this document.)

Respondents to this collection of information are all persons who submit an application or abbreviated application or an amendment or supplement to FDA under part 314, to obtain approval of a new drug or antibiotic drug, and any person who owns an approved application or abbreviated application.

In the **Federal Register** of May 28, 1998 (63 FR 29229), the agency requested comments on the proposed collection of information. No comments were received.

Elsewhere in this issue of the **Federal Register**, the agency has published a Notice of Availability of a Draft Guidance for Industry on Submission of Abbreviated Reports and Synopses in Support of Marketing Applications in accordance with section 118 of the FDA Modernization Act. The goal of the draft guidance is to reduce the submission burden of applicants where appropriate. The estimated PRA reporting burden for § 314.50 reflects an anticipated reduction of 300 hours in burden.

Based on the information provided by the pharmaceutical industry for the number of hours per response, on FDA's estimate of the reduction in reporting resulting from the draft guidance for submitting abbreviated reports and synopses for marketing applications, and on FDA's prior experience with respondents, the number of responses per respondent, and the number of total annual responses, FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section [Form Number]	No. of Respondents	No. of Responses per Respondents	Total Annual Responses	Hours per Response	Total Hours
314.50 (b), (c), (d), (e), (f), and (k)	83	1.49	124	1,300	161,200
314.54	4	1.25	5	300	1,500
314.60	144	16.89	2,432	80	194,560
314.65	18	1.28	23	2	46
314.70 and 314.71	418	5.33	2,229	300	668,700
314.72	59	2.17	128	2	256
314.81(b)(1) [3331]	140	5	700	48	33,600
314.81(b)(2) [2252]	269	9.06	2,438	40	97,520
314.94(a) and (d)	117	3.96	464	480	222,720
314.96	315	12.43	3,915	80	313,200
314.97	152	19.74	3,000	80	240,000
314.98(c) [2252]	265	17.17	4,551	40	182,040
314.99(a)	46	13.04	600	2	1,200
314.110(a)(5)	55	1.13	62	8	496
314.120(a)(5)	26	1.12	29	8	232
314.420	450	1.11	500	8	4,000
Total					2,121,270

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–25142 Filed 9–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0159]

International Conference on Harmonisation; Guidance on Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guidance entitled ''Q5D Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The document provides broad guidance on appropriate standards for the derivation and characterization of cell substrates used in the production of biotechnological/biological products and recommends information in these areas that should be presented in marketing applications.

DATES: Effective September 21, 1998. Submit written comments at any time.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the guidance are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Single copies of the guidance may be obtained by mail from the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), or by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Copies may be obtained from CBER's FAX Information System at 1–888–CBER–FAX or 301–827–3844.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Neil D. Goldman, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0377.

Regarding ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory

authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In the **Federal Register** of May 2, 1997 (62 FR 24312), FDA published a draft tripartite guideline entitled ''Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products.'' The notice gave interested persons an opportunity to submit comments by June 16, 1997.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies on July 17, 1997.

In accordance with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997), this document has been designated a guidance, rather than a guideline.

The document provides broad guidance on appropriate standards for the derivation of human and animal cell lines and microbial cells to be used to prepare biotechnological/biological products and for the preparation and characterization of cell banks to be used for production. The guidance recommends information in these areas that should be presented in marketing applications for these products.

This guidance represents the agency's current thinking on standards for the derivation and characterization of cell substrates used for production of biotechnological/biological products. It does not create or confer any rights for, or on, any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. The comments in the docket will be periodically reviewed, and, where appropriate, the guidance will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this guidance is available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/publications.htm''.

The text of the guidance follows:

Q5D Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products [1]

1.0 Introduction

1.1 Objective

The objective of this guidance is to provide broad guidance on appropriate standards for the derivation of human and animal cell lines and microbial cells to be used to prepare biotechnological/biological products defined in section 1.3, Scope, and for the preparation and characterization of cell banks to be used for production. The document, therefore, provides recommendations on the information in these areas that should be presented in marketing applications for these products.

1.2 Rationale

Historically, some quality concerns for cell-derived biological products have originated from the presence of adventitious contaminants or from the properties of the cells used to prepare the product. Recombinant DNA (rDNA)-derived products also carry quality concerns regarding the expression construct contained in the cell substrate. Thus, it is well established that the properties of the cell substrate and events linked to the cell substrate can affect resultant product quality and safety and, further, that effective quality control of these products requires appropriate controls on all aspects of handling the cell substrate.

This document complements other guidances to provide a comprehensive approach to quality issues arising from biological aspects of processing products from metazoan and microbial cell culture.

1.3 Scope

This guidance covers cell substrates having a cell banking system. In this document, ''cell substrate'' refers to microbial cells or cell lines derived from human or animal sources that possess the full potential for generation of the desired biotechnological/biological products for human in vivo or ex vivo use. Reagents for in vitro diagnostic use are outside the scope of this document. Animal sources of cell lines include all those of metazoan origin. Both continuous cell lines of indefinite in vitro lifespan and diploid cells of finite in vitro lifespan are included. Microbial sources include bacteria, fungi, yeast, and other unicellular life forms.

''Biotechnological/biological products'' refers to any products prepared from cells cultivated from cell banks with the exception of microbial metabolites such as, for example, antibiotics, amino acids, carbohydrates, and other low molecular weight substances. Cell banks used to prepare gene therapy products or vaccines should follow the recommendations presented in this document. Some biological products, such as certain viral vaccines, are prepared in primary cell cultures derived directly from animal tissues or organs. Primary cells are not banked and therefore are not addressed by this document. However, other considerations which may apply to primary cells are discussed further in Appendix 1 of this document.

2.0 Guidelines

2.1.0 Source, History, and Generation of the Cell Substrate

2.1.1 Introduction

It is important to provide supportive documentation which describes the history of the cell substrate that is used in the manufacture of a biotechnological/biological product, as well as any parental cell line

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from which it was totally or partially derived. Events during the research and development phases of the cell substrate may contribute significantly to assessment of the risks associated with the use of that particular cell substrate for production. The information supplied in this regard is meant to facilitate an overall evaluation that will ensure the quality and safety of the product.

Careful records of the manipulation of the cell substrate should be maintained throughout its development. Description of cell history is only one tool of many used for cell substrate characterization. In general, deficiencies in documented history may not, by themselves, be an impediment to product approval, but extensive deficiencies will result in increased reliance on other methods to characterize the cell substrate.

2.1.2 Origin, Source, and History of Cells

The source of cells (laboratory or culture collection) from which the cell substrate was derived should be stated, and relevant references from the scientific literature should be cited. Information obtained directly from the source laboratory is preferred. When this is not available, literature references may be utilized.

For human cell lines, it is relevant to describe the following characteristics of the original donor: Tissue or organ of origin, ethnic and geographical origin, age, sex, and general physiological condition. If known, the state of health or medical history of the donor should be reported along with the results of any tests of the donor for pathogenic agents. Specifically for human diploid fibroblasts, the age of the donor may influence the in vitro lifespan of the cell line and this information should be provided if available. For animal cell lines, relevant descriptions of the source include species, strains, breeding conditions, tissue or organ of origin, geographical origin, age and sex, the results of tests for pathogenic agents, and general physiological condition of the original donor.

For microbes, manufacturers should describe the species, strain, and known genotypic and phenotypic characteristics of the organism from which the cell substrate was derived. Manufacturers should also describe the pathogenicity, toxin production, and other biohazard information, if any.

The cultivation history of the cells should be documented. The method originally used for the isolation of the cells should be described as well as the procedures used in the culturing of the cells in vitro and any procedures used to establish cell lines (for example, use of any physical, chemical, or biological procedure, or added nucleotide sequences). A description of any genetic manipulation or selection should be provided. All available information regarding the identification, characteristics, and results of testing of these cells for endogenous and adventitious agents should be provided.

For continuous cell lines of metazoan origin, it is usually adequate to quantitate culture duration by estimation of either number of population doublings, or number of subcultivations at defined dilution ratio, or time in days. For diploid cell lines possessing finite in vitro lifespan, accurate estimation of the number of population doublings during all stages of research, development, and manufacturing is important. For microbial cells, documentation of subcultivation frequency after cell substrate generation is considered adequate.

Regarding the generation of cell substrates, applicants should provide a thorough discussion of procedures that would provide exposure to infectious agents. Constituents of the culture medium should be described, in particular, information regarding exposure of the cells to materials of human or animal origin such as serum, enzymes, hydrolysates, or other living cells. The description should include the source, method of preparation and control, test results, and quality assurance. Relevant literature on these points may be referenced when available. This information will allow a detailed analysis of potential entry routes for adventitious agents from these sources, and would be part of the risk-benefit analysis of the product.

2.1.3 Generation of the CelpaSubstrate

A crucial step is the choice of a suitable parental cell line. For recombinant products, a parental cell line is typically the untransfected recipient cell line. The use of characterized parental cell banks is suggested, but is not considered essential. A characterized parental cell bank may be of benefit, especially when multiple cell substrates are generated from the same parental cell type, by providing a set of information on which the quality assessment of the Master Cell Bank (MCB) can be based. For example, the myeloma cell line may be banked as a parental cell line for hybridomas.

During the generation of the cell substrate, one or more specific procedures may be utilized in the ultimate development of the desired characteristics. These may include, for example, cell fusion, transfection, selection, colony isolation, cloning, gene amplification, and adaptation to specific culture conditions or media. Information regarding the methodologies utilized in developing the cell substrate can help to provide a clear understanding of the history of the cell substrate. Some cell substrates, such as human diploid fibroblasts, may not need extensive manipulation or cloning prior to cell banking.

For recombinant products, the cell substrate is the transfected cell containing the desired sequences, which has been cloned from a single cell progenitor. For further information on generation of rDNA-modified cell substrates, consult other relevant (e.g., regional or international) guidances. For nonrecombinant products or nonrecombinant vaccines, the cell substrate is the cell from the parental cell line chosen for preparation of the MCB without further modification. For products derived from hybridomas, the cell substrate is the hybridoma cell line derived by fusion of the parental myeloma cell line with other parental cells, e.g., immune spleen cells.

2.2.0 Cell Banking

One of the most important advantages of using serially subcultivated cells to produce biotechnological/biological products is the ability to have a characterized common starting source for each production lot, i.e., the preserved bank of cells. Manufacturers may prepare their own cell banks or may obtain them from external sources. Manufacturers are responsible for ensuring the quality of each cell bank and of the testing performed on each bank.

2.2.1 Cell Banking System

The concept of a two-tiered cell bank, in which the MCB is used to generate Working Cell Banks (WCB's), is generally accepted as the most practical approach to providing a supply of cell substrate for continued manufacture of the product. Manufacturers should describe their strategy for providing a continued supply of cells from their cell bank(s), including the anticipated utilization rate of the cell bank(s) for production, the expected intervals between generation of new cell bank(s), and the criteria for qualification of cell bank(s).

Generally, the MCB is made first, usually directly from an initial clone or from a preliminary cell bank derived from an initial clone. It is not considered necessary to prepare cell banks from clones for certain types of cells (e.g., diploid cells, where limited in vitro life span or other technical factors make cell cloning impractical) or where the uncloned cell population is already adequately homogeneous for the intended use.

A WCB is derived from one or more containers of the MCB. It is the WCB that is typically used to directly provide cells for the manufacturing process. Additional WCB's are generated from the MCB as needed. A newly prepared WCB should be appropriately qualified by characterization and testing.

It should be noted that the MCB and WCB may differ from each other in certain respects, e.g., culture components and culture conditions. Similarly, the culture conditions used to prepare the MCB and WCB may differ from those used for the production process. If changes in cell culture process do not affect product quality, it is not considered necessary to reclone the cells or to rebank the MCB or WCB. It is important that a characterized bank provides a consistent product.

A single-tiered banking system consisting only of the MCB but no WCB's could be used in principle, for example, if relatively few containers were needed each year to produce the desired product.

In some microbial expression systems, a new transformation is performed for each new cell substrate container lot, based upon using aliquots of thoroughly tested host cell banks and plasmid banks for each new transformation and on testing of each transformed cell substrate bank. This transformed cell substrate bank is considered the MCB, and it is used as the source of cell substrate for production. Host cell banks, plasmid banks, and MCB's are maintained by appropriate preservation methods. This alternative system is considered adequate because the transformation of bacteria and yeast is generally a very reproducible and easily performed process, unlike the events needed for transfection of metazoan cells. Manufacturers should provide information on the host cells, rDNA molecules (such as plasmids), method of transformation and of

cell banking, and the results of characterization studies.

2.2.2 Cell Banking Procedures

It is important to prevent a contaminated cell substrate (or bank) from being used in production and to avoid a loss of product availability or development time resulting from the need to recreate a cell bank found to be unusable due to contamination. It is recognized that no cell bank testing regimen is able to detect all potential contaminants; therefore, use of these preventive principles during cell banking is important to provide reasonable assurance of the absence of contamination and to provide a reliable source of the cell substrate.

Manufacturers should describe the type of banking system used, the size of the cell bank(s), the container (vials, ampules, or other appropriate vessels) and closure system used, the methods used for preparation of the cell bank(s) including the cryoprotectants and media used, and the conditions employed for cryopreservation and storage.

Manufacturers should describe the procedures used to avoid microbial contamination and cross-contamination by other cell types present in the laboratory and the procedures that allow the cell bank containers to be traced. This should include a description of the documentation system as well as that of a labeling system that can withstand the process of preservation, storage, and recovery from storage without loss of labeling information on the container.

Manufacturers should describe their cell banking procedures. Cells are generally prepared for banking by expanding cultures in a progressively greater number or larger size of vessel until a pool of cells can be obtained that is sufficient to generate enough containers for the bank. To ensure the uniform composition of the contents of each container, a single pool of cells for banking should be prepared by combining the cells from all of the culture vessels, if more than one vessel is used.

Cells suspended in preservation medium are aliquoted from the single pool into sterilized containers which are then sealed and stored under appropriate conditions. For example, animal cells in media containing a cryoprotectant are frozen in the sealed containers under defined and controlled conditions and then transferred to storage in the vapor or liquid phase of liquid nitrogen or at equivalent ultra low temperatures. Other methods of preservation and storage may be adequate depending on the organism used, but they should be capable of maintaining a level of cell viability upon reconstitution that is both consistent and adequate for production use.

To ensure continuous, uninterrupted production of pharmaceuticals, manufacturers should carefully consider the steps that can be taken to provide for protection from catastrophic events that could render the cell bank unusable. Examples of these events include fires, power outages, and human error. Manufacturers should describe their plans for such precautions; for example, these may include redundancy in the storage of bank containers in multiple freezers, use of back-up power, use of automatic liquid nitrogen fill systems for storage units, storage of a portion of the MCB and WCB at remote sites, or regeneration of the MCB.

The starting point of reference for estimates of in vitro cell age during manufacturing should be the thawing of one or more containers of the MCB. For diploid cell lines, in vitro lifespan should be estimated in terms of population doubling levels. The population doubling level at which senescence occurs should be determined for diploid cells.

2.3.0 General Principles of Characterization and Testing of Cell Banks

The characterization and testing of banked cell substrates is a critical component of the control of biotechnological and biological products. Characterization of the MCB allows the manufacturer to assess this source with regard to presence of cells from other lines, adventitious agents, endogenous agents and molecular contaminants (e.g., toxins or antibiotics from the host organism). The objective of this testing is to confirm the identity, purity, and suitability of the cell substrate for manufacturing use. In some cases, additional testing such as tumorigenicity or karyology may be useful. The testing program chosen for a given cell substrate will vary according to the biological properties of the cells (for example, growth requirements), its cultivation history (including use of human-derived and animal-derived biological reagents), and available testing procedures. The extent of characterization of a cell substrate may influence the type or level of routine testing needed at later stages of manufacturing. Manufacturers should perform tests for identity and purity once for each MCB and tests of stability during cell cultivation once for each product to be registered. In addition, tests of purity and limited tests of identity should be performed once on each WCB. Also, applicants should consult the ICH guidance on viral safety. Relevant tests among those described below should be performed and described in the marketing application, along with the results of the testing.

For cell lines containing exogenously assembled expression constructs, the relevant ICH guidance on rDNA expression constructs should be consulted for guidance on the characterization of nucleotide and amino acid sequences. It may also be useful to examine, by similar methods, the coding sequences in some nonrecombinant DNA-derived cell lines where the gene sequences have been characterized and are well understood. However, it is not considered necessary to carry out investigations of the sequences encoding complex natural products, for example, families of related gene products, microbial vaccine antigens, or monoclonal antibodies from hybridomas.

Manufacturers are also encouraged to employ ''state-of-the-art'' methods and technological improvements in cell substrate characterization and testing as they become available, as long as the specificity, sensitivity, and precision of the newer methods are at least equivalent to those of existing methods.

The manufacturer may choose to characterize the WCB instead of the MCB, if justified.

2.3.1.0 Tests of Identity

Appropriate tests should be performed to determine that the banked cell is what it is represented to be. Either phenotypic or genotypic characteristics may be used in identity testing. It is not considered necessary to do all the possible tests. Tests of identity are generally performed on the MCB. In addition, limited identity testing is generally performed on each WCB.

2.3.1.1 Metazoan Cells

For human or animal cells that grow attached to a substratum, morphological analysis may be a useful tool in conjunction with other tests. In most cases, isoenzyme analysis is sufficient to confirm the species of origin for cell lines derived from human or animal sources; other tests may be appropriate depending on the history of the cell line. Other technologies may be substituted to confirm species of origin, including, for example, banding cytogenetics or use of species-specific antisera. An alternative strategy would be to demonstrate the presence of unique markers, for example, by using banding cytogenetics to detect a unique marker chromosome, or DNA analysis to detect a genomic polymorphism pattern (for example, restriction fragment length polymorphism, variable number of tandem repeats, or genomic dinucleotide repeats). Either confirmation of species of origin or presence of known unique cell line markers is considered an adequate test of identity. Expression of the desired product may represent a complementary approach to confirmation of identity.

2.3.1.2 Microbial Cells

For most microbial cells, analysis of growth on selective media is usually adequate to confirm host cell identity at the species level for the host cell bank and the transformed cell bank. For *E. coli*, where a variety of strains may be used, biological characterization methods such as phage typing should be considered as supplementary tests of identity. For plasmid banks, identity assessment can be accomplished as described by the ICH document on analysis of the expression construct. Expression of the desired product is also considered adequate to confirm the identity of the microbial expression system.

2.3.2.0 Tests of Purity

A critical aspect of cell development and banking is the assessment that the MCB and WCB are biologically pure, i.e., are free from adventitious microbial agents and adventitious cellular contaminants. The impact of selective agents and antibiotics on the detection of adventitious microbial contaminants should be considered when planning and performing these tests.

2.3.2.1 Metazoan Cells

Tests for the presence of bioburden (bacteria and fungi) should be performed on individual containers (1 percent of the total number but not less than two containers) of the MCB and WCB. In all other aspects, the current methodologies described in either the

European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP), or the U.S. Pharmacopoeia (U.S.P.) for testing microbial limits or microbial sterility may be considered adequate.

Tests for the presence of mycoplasma should be performed on the MCB and WCB. Current procedures considered adequate include both the agar and broth media procedures as well as the indicator cell culture procedure. Current methods for mycoplasma testing are described in Ph. Eur., JP, and ''Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals'' (FDA, CBER, 1993). Testing cells derived from a single container is generally considered adequate. For nonmammalian animal cell lines, alternative controls and/or assay conditions may be appropriate; manufacturers should consult with the national/regional regulatory authority for appropriate methodology.

If future efforts to harmonize bioburden and mycoplasma assays are fruitful, then the scientifically appropriate harmonized assay should be used.

Virus testing of cell substrates should be designed to detect a wide spectrum of viruses by using appropriate screening tests and relevant specific tests, based on the cultivation history of the cell line, to detect possible contaminating viruses. Applicants should consult the ICH guidance on viral safety. For product classes not covered by the viral safety guidance, the current World Health Organization (WHO) documents for use of animal cells may be consulted.

The purity of cell substrates can be compromised through contamination by cell lines of the same or different species of origin. The choice of tests to be performed depends upon whether opportunities have existed for cross-contamination by other cell lines. In some cases, it may be necessary to maintain growing cultures of different cell lines in the same laboratory. During procedures in cell banking where open manipulations are performed, care should be taken to ensure that simultaneous open manipulations of other cell lines are avoided to prevent cross-contamination. Whenever another cell line was present in the cell banking room at the same time that open cell banking procedures were being performed (such as cell expansion, pooling, or aliquoting of the chosen cell line), the cell banks should be tested for the presence of cells from (or products derived from) the second cell line. In general, the methods described in section 2.3.1.0 to assess cell identity are also considered adequate tests to detect cross-contamination by other cell lines. Additional assurance of lack of cross-contamination can be provided by successful preparation of the intended product from the cell substrate.

2.3.2.2 Microbial Cells

The design and performance of specific tests for adventitious microbial agents and adventitious cellular contaminants in microbial cell banks should take into account the properties of the banked cell, the likely contaminants based upon scientific literature, source, methods and materials used for cultivation, and other organisms present in the banking laboratory. For example, visual examination of the characteristics of well-isolated colonies is suggested, using several microbiological media, of which some do and some do not support growth of the cell substrate. However, it is not intended that manufacturers necessarily characterize resistant mutants of the cell substrate arising from such studies, or other artifacts of such assays. Rather, the purpose of such assays is to detect existing contaminants.

2.3.3 Cell Substrate Stability

Another dimension to cell characterization is appropriateness for intended use in production. There are two concerns for cell substrate stability: Consistent production of the intended product and retention of production capacity during storage under defined conditions.

For the evaluation of stability during cultivation for production, at least two time points should be examined, one using cells that have received a minimal number of subcultivations, and another using cells at or beyond the limit of in vitro cell age for production use described in the marketing application. The limit of in vitro cell age for production use should be based on data derived from production cells expanded under pilot plant scale or commercial scale conditions to the proposed limit of in vitro cell age for production use or beyond. Generally, the production cells are obtained by expansion of cells from the WCB; cells from the MCB could be used with appropriate justification. This demonstration of cell substrate stability is commonly performed once for each product marketing application.

Evaluation of the cell substrate with respect to the consistent production of the intended product of interest should be the primary subject of concern. The type of testing and test article(s) used for such assessments will depend on the nature of the cell substrate, the cultivation methods, and the product. For cell lines containing recombinant DNA expression constructs, consistency of the coding sequence of the expression construct should be verified in cells cultivated to the limit of in vitro cell age for production use or beyond by either nucleic acid testing or product analysis, as described in the relevant ICH guidance. For nonrecombinant cell lines in which the coding sequence for the desired product has already been analyzed at the MCB or WCB level, invariability of the protein coding sequence during production should be verified in the production cells cultivated to the proposed limit of in vitro cell age for production use or beyond by either nucleic acid testing or analysis of the purified protein product.

Where the product cannot be analyzed as described above, other specific traits, which may include, for example, morphological characteristics, growth characteristics, biochemical markers, immunological markers, productivity of the desired product, or other relevant genotypic or phenotypic markers, may be useful for the assessment of cell substrate stability. In some cases, where direct comparison of the characteristics of the MCB with those of the production cells at or beyond the limit of in vitro cell age is difficult or impossible, one may compare the characteristics of cells at the initial stages of cultivation or production to those of cells at or beyond the limit of in vitro cell age for production use in order to assess cell stability during production. Indices such as, for example, oxygen or glucose consumption rates, ammonia or lactate production rates may be useful for such testing. Increases in the defined limit of in vitro cell age for production use should be supported by data from cells which have been expanded to the proposed new limit of in vitro cell age. For diploid cell lines, data should be presented that establish the finite in vitro lifespan of the cells from the WCB under conditions representative of those employed for manufacturing use.

Evidence for banked cell stability under defined storage conditions will usually be generated during production of clinical trial material from the banked cells. Data from the determination of cell viability when the preserved cells are reconstituted for production of clinical trial supplies will verify that the revived cells have survived the preservation process. Data from the preparation of clinical materials will demonstrate that the revived cells can be used to prepare the desired product. Available data should be clearly documented in the application dossiers, plus a proposal for monitoring of banked cell stability should be provided. The proposed monitoring can be performed at the time that one or more containers of the cryopreserved bank is thawed for production use, when the product or production consistency is monitored in a relevant way, or when one or more containers of the cryopreserved MCB is thawed for preparation of a new WCB (and the new WCB is properly qualified), as appropriate. In the case when production does not take place for a long period of time, viability testing on the cell bank used as a source of the production substrate should be performed at an interval described in the marketing application. If the viability of the cell substrate is not significantly decreased, generally no further testing of the MCB or WCB is considered necessary.

2.3.4 Tests for Karyology and Tumorigenicity

Utilization of karyology and tumorigenicity testing for evaluating the safety of a diploid cell line or characterizing a new cell line may be useful depending on the cells, the nature of the product, and the manufacturing process. Extensive analysis to determine the relative abundance of aneuploid cells has not been found to be useful. Karyology need not be determined for rodent cell lines or new cell lines known to be nondiploid. However, cytogenetic analysis may be an adequate method to assess cell substrate identity or purity as described in sections 2.3.1.0 and 2.3.2.0. Repetition of tumorigenicity testing for cells with already documented evidence of tumorigenicity is not considered necessary.

For products that are highly purified and that contain no cells, karyology and tumorigenicity testing are generally not considered necessary, provided that appropriate limits for residual host cell DNA are shown to be consistently met by either

process validation studies or by lot release testing.

In general, products for which the presence of live cells cannot be excluded or which have little downstream purification (for example, some conventional live virus vaccines) will need such characterization of the cell substrate. The utility of tumorigenicity testing and chromosomal analysis for new cell substrates for unpurified products should be evaluated on a case-by-case basis. Use of cell lines known to be tumorigenic or to possess abnormal karyology should be evaluated in terms of risk-benefit for each product application when the product contains cells or when not highly purified.

Products that are manufactured in genetically unmodified MRC–5 or WI–38 cells do not need characterization of these cell substrates by karyology or tumorigenicity since extensive characterization has already been performed and published for these cell lines. However, for each MRC–5 and WI–38 WCB generated, manufacturers should confirm, once, that the cells grown in the manner to be used in production are diploid and have the expected lifespan.

For new or previously uncharacterized diploid cell substrates, confirmation of diploid karyology should be presented and tumorigenic potential should be established, using cells from the MCB.

3.0 Glossary

Cell bank—A cell bank is a collection of appropriate containers, whose contents are of uniform composition, stored under defined conditions. Each container represents an aliquot of a single pool of cells.

Cell line—Type of cell population that originates by serial subculture of a primary cell population, which can be banked.

Continuous cell line—A cell line having an infinite capacity for growth. Often referred to as ''immortal'' and previously referred to as ''established.''

Diploid cell line—A cell line having a finite in vitro lifespan in which the chromosomes are paired (euploid) and are structurally identical to those of the species from which they were derived.

Host cells—See parental cells.

In vitro cell age—Measure of time between thaw of the MCB vial(s) and harvest of the production vessel measured by elapsed chronological time, by population doubling level of the cells, or by passage level of the cells when subcultivated by a defined procedure for dilution of the culture.

Metazoan—Organism of multicellular animal nature.

MCB (Master Cell Bank)—An aliquot of a single pool of cells which generally has been prepared from the selected cell clone under defined conditions, dispensed into multiple containers, and stored under defined conditions. The MCB is used to derive all working cell banks. The testing performed on a new MCB (from a previous initial cell clone, MCB, or WCB) should be the same as for the original MCB unless justified.

Parental cells—Cells to be manipulated to give rise to a cell substrate or an intermediate cell line. For microbial expression systems, it is typical to also describe the parental cells as the host cells. For hybridomas, it is typical to also describe the parental cells as the cells to be fused.

WCB (Working Cell Bank)—The Working Cell Bank is prepared from aliquots of a homogeneous suspension of cells obtained from culturing the MCB under defined culture conditions.

Appendix 1

Primary Cell Substrates

I. Introduction

The principles contained in this document apply in general to biotechnological/biological products prepared from characterized banked cells. However, a number of biological products, in particular certain viral vaccines, are prepared using primary cells.

Because primary cell cultures are used within the first passage after establishment from the tissue of origin, it is not possible to carry out extensive characterization of the cells prior to their use as is done for banked cell substrates. In addition, biological products produced using primary cell substrates often do not undergo extensive processing (e.g., purification). Despite these differences, the approach taken to ensure the suitability and safety of primary cell substrates for production of biologicals is analogous, in many respects, to that outlined in this document and in other guidances.

This annex outlines cell substrate-related information that should be included in marketing applications for biological products prepared using primary cells. This information falls into three general categories: (1) Information concerning the source tissue (or organ) and other animal-derived raw materials used for the establishment of primary cell substrates, (2) information concerning the preparation of primary cell substrates, and (3) testing performed on primary cell substrates to ensure the safety of the product.

II. Source Tissue and Other Raw Materials

Information should be provided about the animals used as a source of tissue for the preparation of primary cell substrates. Tissue should be derived from healthy animals subjected to veterinary and laboratory monitoring to certify the absence of pathogenic agents. Whenever possible, donor animals should be obtained from closed, specific pathogen-free (when available) colonies or flocks. Animals used as tissue donors should not have been used previously for experimental studies. Animals should be adequately quarantined for an appropriate period of time prior to use for the preparation of cells. In some countries, animals may need to be quarantined in the country where the primary cells are prepared. Manufacturers should consult with national/regional authorities for specific requirements.

Information on materials and components used for the preparation of primary cell substrates should be provided, including the identity and source of all reagents of human or animal origin. A description of testing performed on components of animal origin to certify the absence of detectable contaminants and adventitious agents should be included.

III. Preparation of Primary Cell Substrates

Methods used for isolation of cells from tissue, establishment of primary cell cultures, and maintenance of cultures should be described.

IV. Testing of Primary Cell Substrates

Tests performed on primary cell substrates to qualify them for use in production should be described. As noted, the nature of primary cell substrates precludes extensive testing and characterization prior to use. Testing to demonstrate the absence of adventitious agents in these substrates is therefore conducted concurrently and may include: Observation of production or uninfected control cultures before, during, and beyond the period of production; inoculation of culture fluids from production and uninfected control cultures into various susceptible indicator cell cultures capable of detecting a wide range of relevant viruses, followed by examination for cytopathic changes and testing for the presence of hemadsorbing viruses; and other tests for specific agents (such as relevant retroviruses) as necessary. Additional information concerning specific viral tests may be found in the relevant national/regional/international guidances.

Appropriate testing regimens and test methods for cells used in the production of specific products will vary depending on the donor species used as a source of tissue, adventitious agents potentially present, the nature of the product, its intended clinical use, aspects of the manufacturing process, and the extent of testing performed on the final product. Applicants should explain and justify the approach taken with respect to their specific product.

Dated: August 28, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–25108 Filed 9–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Gas Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

The Food and Drug Administration (FDA) is announcing the following workshop: Medical Gas Workshop. The topics to be discussed are good manufacturing practices (GMP's) issues for the medical gas industry, including air liquefaction, both process and computer validation, transfilling of both liquid and high pressure cylinders, and hospital installations.

Date and Time: The workshop will be held on Tuesday, November 10, 1998, 8:30 a.m. to 4:30 p.m.

Location: The workshop will be held at the Century Center, Convention Hall

C–South, 120 South Saint Joseph St., South Bend, IN.

Contact: Keith J. Jasukaitis, Food and Drug Administration, 1560 East Jefferson Ave., Detroit, MI 48207, 313–226–6260, ext. 114, FAX 313–226–3076, or e-mail ''kjasukai@ora.fda.gov''.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number, and the number of people expected to attend) to the contact person by Friday, October 23, 1998.

If you need special accommodations due to a disability, please notify Keith J. Jasukaitis by October 23, 1998.

Dated: September 11, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–25109 Filed 9–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 22, 1998, 8:30 a.m. to 5 p.m.

Location: Advisory Committee conference room, rm. 1066, 5630 Fishers Lane, Rockville, MD 20852.

Contact Person: Kimberly L. Topper or Angie Whitacre, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857–1000, 301–827–7001, or e-mail ''Topperk@cder.fda.gov'', or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss: (1) Bioavailability/bioequivalence (BA/BE) issues related to solid oral dosage forms; (2) progress reports on guidances pertaining to the biopharmaceutical classification system, other BA/BE guidances; and (3) criteria (average, population, and individual) to allow comparison of BE measures/parameters.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 5, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 5, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 11, 1998.

Sharon Smith Holston,

Acting Commissioner of Food and Drugs.

[FR Doc. 98–25106 Filed 9–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Advisory Committee for Pharmaceutical Science and the Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Advisory Committee for Pharmaceutical Science and the Dermatologic and Ophthalmic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 23, 1998, 8:30 a.m. to 5 p.m.

Location: Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD 20852.

Contact Person: Kimberly L. Topper or Tracy Riley, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or e-mail ''Topperk@cder.fda.gov'', or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committees will discuss: (1) The draft guidance entitled ''Topical Dermatological Drug Product NDA's and ANDA's—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies;'' (2) public comments received on the draft guidance; and (3) additional information.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 5, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 5, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 11, 1998.

Sharon Smith Holston,

Acting Commissioner of Food and Drugs.

[FR Doc. 98–25107 Filed 9–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee); Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Department of Health and Human

Services. The meeting will be open to the public.

Name of Committee: Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee).

General Function of the Committee: To advise the Secretary and the Assistant Secretary for Health concerning its oversight of the conduct of the Ranch Hand Study by the Air Force and provide scientific oversight of the Department of Veterans Affairs (VA) Army Chemical Corps Vietnam Veterans Health Study, and other studies in which the Secretary or the Assistant Secretary for Health believes involvement by the Committee is desirable.

Date and Time: The meeting will be held on October 26, 1998, 1 p.m. to 5:30 p.m., and October 27, 1998, 8:30 a.m. to 5 p.m.

Location: Holiday Inn Riverwalk, 217 North St. Marys St., Tarantella Room, rm. 4, San Antonio, TX.

Contact Person: Ronald F. Coene, National Center for Toxicological Research (HFT–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6696, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12560. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 26, 1998, the VA will present an overview and data collection issues from the pilot study of the Army Chemical Corps Vietnam Veterans Health Study, and discuss considerations for the main health study. On October 27, 1998, the Air Force Health Study presentations will: (1) Provide Cycle 5 Health Exam information, summary, status, and proposed schedule for committee review; (2) report on the latest findings, as well as the status of special studies on half-life, adipose tissue analysis, glucose clamp, and multiple analyte; (3) present proposed measurements for the Cycle 6 Health Exam; (4) report the status of scanning and records maintenance; (5) present a summary of the biological archive; (6) discuss the release of the 1984 preliminary birth defects report; and (7) present the status of public release data.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 16, 1998. On October 26, 1998, oral presentations from the public will be scheduled between approximately 4:30 p.m. and 5:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 16, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

The Commissioner approves the scheduling of meetings at locations outside of the Washington, DC, area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 11, 1998.

Sharon Smith Holston,

Acting Commissioner of Food and Drugs.

[FR Doc. 98–25112 Filed 9–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0656]

Draft Guidance for Industry on Submission of Abbreviated Reports and Synopses in Support of Marketing Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Submission of Abbreviated Reports and Synopses in Support of Marketing Applications.'' This draft guidance, which implements section 118 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act), is intended to assist applicants who wish to submit abbreviated reports and synopses in lieu of full reports for certain clinical studies, both in marketing applications for new products and in supplements to approved applications. The draft guidance describes which studies may be submitted as abbreviated reports or synopses and describes a format for such submissions. In addition to seeking general comments on the draft guidance, FDA is soliciting comment on three specific issues related to certain types of study submissions and their formats.

DATES: Written comments may be submitted on the draft guidance by November 20, 1998. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or the Manufacturers Assistance and Communication Staff (HFM–42), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Debbie J. Henderson, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Submission of Abbreviated Reports and Synopses in Support of Marketing Applications.'' Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) provides that full reports of the investigations used to demonstrate a product's safety and effectiveness be submitted in a new drug application (NDA). Similarly, for biologics license applications (BLA's) FDA often requires that a manufacturer submit full reports to demonstrate that the biological product is safe, pure, and potent.

Section 118 of the Modernization Act, ''Data requirements for drugs and biologics,'' directs FDA to issue guidance on when abbreviated study reports may be submitted in NDA's and BLA's in lieu of full reports. This draft guidance is intended to fulfill the requirements of section 118 of the Modernization Act by providing guidance on the types of studies that may be submitted in abbreviated reports or synopses. This draft guidance also provides recommendations on the formats that should be used.

The NDA regulations at 21 CFR 314.50, which define what must be submitted in an application, do not explicitly define a ''full report,'' but require, among other things, submission of a ''description and analysis of each controlled clinical study pertinent to a proposed use of the drug'' and of ''any other data or information relevant to an evaluation of the safety and effectiveness of the drug product.''

In 1988, FDA issued ''Guidelines for the Format and Content of the Clinical and Statistical Sections of New Drug Applications'' (hereinafter referred to as the Clin/Stat Guideline), which described the contents of a full report of a study. This guidance called for full study reports for studies that contributed effectiveness data as well as safety information. For other studies, sponsors were advised to submit abbreviated reports of the effectiveness results.

In 1996, the International Conference on Harmonisation of the Technical Requirements for Registration of Pharmaceuticals (ICH) ''Guidelines for the Structure and Content of Clinical Study Reports'' (ICH E3) provided an updated description of the contents of a full study report and specific provisions for submitting less-than-full study reports.

Applicants have not used the provisions to submit less-thanfull study reports contained in both the Clin/Stat Guideline and ICH E3 as often as they could have because of difficulties experienced in deciding when a full study report is required by the reviewing body. For example, clinical drug and biologic product development programs often include numerous clinical studies and resulting data that are not intended to contribute to the evaluation of the effectiveness of a product for a particular use and are not needed to support information included in labeling. Accordingly, such studies may be submitted as abbreviated reports or synopses, and this guidance is intended to facilitate their submission.

In developing the guidance, FDA identified the following three issues on which it is specifically seeking public comment:

(1) In describing the format of an abbreviated study report, the draft guidance references selected sections of the study report format in ICH E3 and states that the abbreviated report should include these sections. An alternative approach considered by the agency was to recommend that all of the sections in the ICH E3 clinical study report format be included, but that some of them contain detailed information while others contain only minimal information. Which of these approaches is preferable, or is there another approach that the agency should consider?

(2) The draft guidance indicates that, in general, applicants should submit full reports of negative studies (studies adequately designed to evaluate efficacy that failed to demonstrate efficacy), but provides for the submission of abbreviated reports of such studies in some cases with agreement from the relevant review division. Should abbreviated reports of negative studies be recommended, and, if so, should more detailed information be provided on these trials than is contemplated by the proposed abbreviated report format?

(3) The draft guidance states that in the case of products that are the subject of very limited drug development programs (those with fewer than six studies from any phase of development designed to determine effectiveness including dose comparison trials), full reports of all studies ordinarily should be provided. The rationale for this provision is that, in such programs, even studies less central to the proposed application (e.g., related indication, different dosage form) often form a substantive proportion of the total clinical data base. The agency is seeking comment on whether the proposed definition of ''very limited drug development programs'' is appropriate. Should full reports of all studies be provided for drug development programs with fewer or more than six studies designed to determine effectiveness, or can commenters propose an alternative definition of ''very limited drug development programs?''

This draft guidance represents the agency's current thinking on submission of full study reports, abbreviated reports, and synopses of information related to effectiveness for new drugs and biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 11, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–25102 Filed 9–15–98; 4:19 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Receipt of Application for Endangered Species Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Receipt of Application for Endangered Species Permit.

SUMMARY: The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

DATES: Written data or comments on these applications must be received, at the address given below, by October 21, 1998.

FOR FURTHER INFORMATION CONTACT: Documents and other information submitted with these applications are available for review, *subject to the requirements of the Privacy Act and Freedom of Information Act*, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: David Dell, Permit Biologist). Telephone: 404/679–7313; Facsimile: 404/679–7081.

SUPPLEMENTARY INFORMATION:

Applicant: J. D. Wilhide, Arkansas State University, TE002413–0

The applicant requests authorization to take (capture, band, and harass during surveys) the endangered gray bat, *Myotis grisescens*, Indiana bat, *Myotis sodalis*, and Ozark big-eared bat, *Corynorhinus townsendii ingens*, throughout the species' range in Arkansas, for the purpose of enhancement of survival of the species.

Applicant: William Post, Miccosukee Tribe, Miami, Florida, TE002414–0.

The applicant requests authorization to take (harass during surveys) the endangered Cape Sable seaside sparrow, *Ammodramus maritimus mirabilis*, throughout the species range in Everglades National Park, for the purpose of enhancement of survival of the species.

Applicant: Cecil Lamar Comalander, Jr., Milliken Forestry Company, Inc., Columbia, South Carolina, TE002412–0.

The applicant requests authorization to take (capture, band, and harass during surveys) the endangered red-cockaded woodpecker, *Picoides borealis*, throughout the species range in South Carolina, for the purpose of enhancement of survival of the species.

Applicant: Stephen Hoffman, Hawkwatch International, Inc., Salt Lake City, Utah, TE002404–0.

The applicant requests authorization to take (capture, band, and collect feathers) the endangered peregrine falcon, *Falco peregrinus*, throughout the species range in the Florida Keys, Monroe County, Florida, for the purpose of enhancement of survival of the species.

Applicant: Andrea Christman, Withlacoochee Forestry Center, Brooksville, Florida, TE002507–0.

The applicant requests authorization to take (harass during installation of artificial cavities) the endangered red-cockaded woodpecker, *Picoides borealis*, throughout the species range in Florida, for the purpose of enhancement of survival of the species.

Dated: September 3, 1998.

Sam D. Hamilton,

Regional Director.

[FR Doc. 98–25125 Filed 9–18–98; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications.

The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*).

PRT–697830

Applicant: Assistant Regional Director for Ecological Services, Region 3, U.S. Fish and Wildlife Service, Ft. Snelling, Minnesota; William F. Hartwig, Regional Director.

The applicant requests an amendment to his permit for take activities of listed species in Region 3 to add the Illinois cave amphipod (*Gammarus acherondytes*), a recently listed species, for scientific purposes and the enhancement of propagation or survival of the species in the wild, in accordance with listing, recovery outlines, recovery plans, and/or other Service work for the species.

PRT–838055

Applicant: Ecological Specialists, St. Peters, Missouri; Heidi L. Dunn, President.

The applicant requests an amendment to her permit for take (capture and release; collect dead specimens) activities of listed freshwater mussels to add to the scope of permitted activities the states of Illinois, Missouri, Ohio, and West Virginia and the following species: fat pocketbook [*Potamilus* (=*Proptera*) *capax*], orange-foot pimple back pearlymussel (*Plethobasus cooperianus*), and pink mucket pearlymussel [*Lampsilis abrupta* (=*orbiculata*)]. Take activities are currently authorized in Iowa, Minnesota, and Wisconsin for Higgins' eye pearlymussel (*Lampsilis higginsi*) and winged mapleleaf mussel (*Quadrula fragosa*) for biological survey purposes. On September 2, 1998, a notice was published in the **Federal Register** seeking comments on an amendment request to add authorization for take activities in the state of Indiana for clubshell (*Pleurobema clava*), fanshell [(*Cyprogenia stegaria* (=*irrorata*)], and northern riffleshell (*Epioblasma torulosa rangiana*). Activities are proposed to document presence or absence of the species for the purpose of survival and enhancement of the species in the wild.

PRT–TE002722–0

Applicant: Voyageurs National Park, International Falls, Minnesota; Barbara West, Superintendent.

The applicant requests a permit to take (capture, radio-collar, and release) gray wolf (*Canis lupus*) in Voyageurs National Park, Minnesota. Activities are proposed for scientific research aimed at survival and enhancement of the species in the wild.

Written data or comments should be submitted to the Regional Director, U.S. Fish and Wildlife Service, Ecological Services Program, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056, and must be received within 30 days of the date of this publication.

Documents and other information submitted with these applications are available for review by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Ecological Services Program, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056. Telephone: (612/713–5332); FAX: (612/713–5292).

Dated: September 11, 1998.

Matthias A. Kerschbaum,

Acting Program Assistant Regional Director, Ecological Services, Region 3, Fort Snelling, Minnesota.

[FR Doc. 98–25126 Filed 9–18–98; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of a Technical/ Agency Draft Recovery Plan for Juglans Jamaicensis (West Indian Walnut or Nogal) for Review and Comment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: The Fish and Wildlife Service (Service) announces the availability for public review of a draft recovery plan for *Junglans jamaicensis* (West Indian walnut or nogal). In Puerto Rico this large tree is known from only 14 individuals at one locality near Adjuntas. The species is threatened by land-clearing for agriculture and rural development. The Service solicits review and comment from the public on this draft plan.

DATES: Comments on the draft recovery plan must be received on or before November 20, 1998 to receive consideration by the Service.

ADDRESSES: Persons wishing to review the recovery plan may obtain a copy by contacting the Field Supervisor, Boquerón Field Office, P.O. Box 491, Boquerón, Puerto Rico 00622 (Telephone 787/851–7297). Comments and materials are available on request for public inspection, by appointment, during normal business hours at the above-mentioned address.

FOR FURTHER INFORMATION CONTACT: Ms. Susan R. Silander at the address and telephone shown above.

SUPPLEMENTARY INFORMATION:

Background

Restoring an endangered or threatened animal or plant to the point where it is again a secure, self-sustaining member of its ecosystem is a primary goal of the U.S. Fish and Wildlife Service's endangered species program. To help guide the recovery effort, the Service is working to prepare recovery plans for most of the listed species native to the United States. Recovery plans describe actions considered necessary for the conservation of the species, establish criteria for the recovery levels for the

downlisting or delisting of them, and estimate time and cost for implementing the recovery measures needed.

The Endangered Species Act of 1973 (Act), as amended (16 U.S.C. 1531 *et seq.*) requires the development of recovery plans for listed species unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act, as amended in 1988, requires that public notice and an opportunity for public review and comments be provided during recovery plan development. The Service will consider all information presented during a public comment period prior to approval of each new or revised Recovery Plan. The Service and other Federal agencies will also take these comments into account in the course of implementing approved recovery plans.

This Recovery Plan is for *Juglans jamaicensis* (West Indian walnut or nogal). Nogal is a large tree which may reach up to 25 meters or 82 feet in height. Twigs, buds, and leaf axes have minute rusty hairs. Leaves are alternate and compound. The fruit, a drupe, is a walnut composed of a blackish husk and one large oily, edible seed. The tree may have once been more widespread in Puerto Rico in the past but much of the forested areas in the central mountain region were cut for the planting of coffee. Today it is known from 14 individuals at only one locality in Adjuntas, Puerto Rico. It is also known from the islands of Hispaniola and Cuba. In Puerto Rico it is threatened by land clearing for agriculture and rural development.

Public Comments Solicited

The Service solicits written comments on the recovery plan described. All comments received by the date specified above will be considered for inclusion in the Recovery Plan.

Authority

The authority for this action is Section 4(f) of the Endangered Species Act, 16 U.S.C. 1533(f).

Dated: September 10, 1998.

James P. Oland,

Field Supervisor.

[FR Doc. 98–25128 Filed 9–18–98; 8:45 am]

BILLING CODE 4310–55–P

DEPARTENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability; Addendum #2 to the Assessment Plan: Lower Fox River/Green Bay Natural Resource Damage Assessment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 30-day comment period.

SUMMARY: Notice is given that the document entitled: ''Lower Fox River/ Green Bay NRDA Initial Restoration and Compensation Determination Plan'' will be available for public review and comment on the date of publication in the **Federal Register**.

The assessment, including the activities addressed in this addendum, will be conducted in accordance with the guidance of the Natural Resource Damage Assessment Regulations found at 43 CFR Part 11, to the extent applicable. The public review of the Addendum announced by this Notice is provided for in 43 CFR 11.32(c).

Interested members of the public are invited to review and comment on the Addendum. Copies of the Addendum, and the ''Assessment Plan: Lower Fox River/Green Bay NRDA'' (''The Plan'') issued on August 23, 1996 (FR Doc. 96–21520), can be requested from the address listed below. All written comments will be considered and included in the Report of Assessment, at the conclusion of the assessment process.

DATES: Written comments on the Addendum must be submitted on or before October 21, 1998.

ADDRESSES: Requests for copies of the Addendum and/or the Plan may be made to: Frank Horvath, U.S. Fish and Wildlife Service, Region 3 (ATTN: ES/ EC–NRDA), B.H.W. Federal Building, 1 Federal Drive, Ft. Snelling, MN 55111–4096.

SUPPLEMENTARY INFORMATION: The purpose of this natural resource damage assessment is to confirm and quantify the suspected injuries to natural resources in the Lower Fox River, Green Bay, and Lake Michigan environment resulting from exposure to hazardous substances released by area paper mills and other potential sources. It is suspected that this exposure has caused injury and resultant damages to trustee resources. The injury and resultant damages will be assessed under the Comprehensive Environmental Response, Compensation, and Liability Act, as amended, and the Clean Water Act, as amended.

William F. Hartwig,

Regional Director, Region 3, U.S. Fish and Wildlife Service.

[FR Doc. 98–25144 Filed 9–18–98; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–020–5101–00–L012; FF091732]

Availability of the Record of Decision (ROD) for the Golden Valley Electric Association Northern Intertie Project (EIS #97–47); Alaska

AGENCY: Bureau of Land Management; Interior.

ACTION: Notice.

SUMMARY: Golden Valley Electric Association has applied to the Bureau of Land Management (BLM) for a Right-of-Way to construct, operate, and maintain a 230 kV transmission line from Healy, Alaska, to Fairbanks, Alaska. Pursuant to the Federal Land Policy and Management Act, as amended, the National Environmental Policy Act of 1969, as amended, and 40 CFR Parts 1500–1508, the BLM prepared an EIS. The public comment period on the Final EIS ended on July 20, 1998. Notice is hereby given on the availability of the Record of Decision (ROD) for this project. Copies of the ROD are available by mail or in person at the BLM Northern Field Office, 1150 University Avenue, Fairbanks, Alaska, 99709, or by calling (907) 474–2339.

DATES: The ROD may be appealed to the Interior Board of Land Appeals, Office of the Secretary, in accordance with the regulations contained in 43 CFR Part 4. If an appeal is taken, the notice of appeal must be filed in this office (at the above address) on or before October 21, 1998.

FOR FURTHER INFORMATION CONTACT: Gary Foreman, Project Manager, at 1–800–437–7021 or (907) 474–2339.

SUPPLEMENTARY INFORMATION: It is the decision of the Bureau of Land Management to issue a right-of-way grant to Golden Valley Electric Association pursuant to Title V of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1761). The route alternative selected in this decision is the Rex/South Route as identified in the Final EIS dated June 1998.

Tom Allen,

State Director, Alaska.

[FR Doc. 98–25152 Filed 9–18–98; 8:45 am]

BILLING CODE 4310–84–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–930–1430–01; N–62051]

Supplemental Notice of Realty Action; Nevada

AGENCY: Bureau of Land Management, DOI.

ACTION: Notice.

SUMMARY: A notice was published in the **Federal Register** on October 6, 1997, page 52148, listing the proponent of a direct sale as Elko General Hospital, a political subdivision of Elko County. The proponent is changed to read the City of Elko, Nevada. All other information regarding the notice remains the same. For a period of 45 days from the date of publication in the **Federal Register**, interested parties may submit comments to the Bureau of Land Management, Elko Field Office, 3900 E. Idaho Street, Elko, Nevada 89801. Any adverse comments will be evaluated by the State Director, who may sustain, vacate or modify this realty action and issue a final determination. In the absence of timely filed objections, this realty action will become a final determination of the Department of the Interior.

Dated: September 9, 1998.

Helen Hankins,

Field Manager.

[FR Doc. 98–25129 Filed 9–18–98; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF JUSTICE

Notice of Proposed Prospective Purchaser Agreement Under the Comprehensive Environmental Response, Compensation, and Liability Act

Notice is hereby given that a proposed Prospective Purchaser Agreement (''PPA'') was executed on August 12, 1998, by the U.S. Environmental Protection Agency (''EPA''), and is subject to final approval by the U.S. Department of Justice. The proposed PPA would resolve certain potential claims under Sections 106 and 107 of the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9606 and 9607, against P.O'B Libby, L.P. and Albertson's, Inc., as the prospective purchasers of approximately 13 acres of land (the ''Property'') within the boundaries of the Libby Groundwater Superfund Site located in Lincoln County, Montana. The PPA would require P.O'B Libby, L.P. and Albertson's, Inc. (the ''prospective purchasers'') to pay EPA $4,000 to defray EPA's administrative and oversight costs in connection with the PPA. The prospective purchasers would also be obligated to perform certain environmental work at the Property, including the proper abandonment of one of the groundwater monitoring wells in accordance with the requirements of the State of Montana, and the modification of four groundwater monitoring wells to protect them from traffic and pedestrian damage. The PPA would further require the prospective purchasers to provide access to the Property to the United States for the implementation of response actions by or at the direction of EPA at the Libby Groundwater Superfund Site.

EPA will receive for a period of thirty (30) days from the date of this publication comments relating to the PPA. Comments should be addressed to Jim Harris, Remedial Project Manager, U.S. Environmental Protection Agency, Region VIII, Montana Operations Office, Federal Building, 301 South Park, Drawer 10096, Helena, MT 59626–0096.

The proposed PPA may be examined at the U.S. Environmental Protection Agency, Region VIII, Montana Operations Office, Federal Building, 301 South Park, Drawer 10096, Helena, MT 59626–0096. A copy of the proposed Prospective Purchaser Agreement may be obtained in person, by mail from, or by calling Jim Harris, Remedial Project Manager, U.S. Environmental Protection Agency, Region VIII, Montana Operations Office, Federal Building, 301 South Park, Drawer 10096, Helena, MT 59626–0096, telephone number (406) 441–1150, extension 260.

Walker B. Smith,

Deputy Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 98–25284 Filed 9–18–98; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF LABOR

Office of the Secretary

Advisory Committee on Veterans' Employment and Training Notice of Renewal

In accordance with the provisions of the Federal Advisory Committee Act and Office of Management and Budget Circular A–63 of March 1974, and after consultation with GSA, the Secretary of Labor has determined that the renewal of the Advisory Committee on Veterans' Employment and Training is in the public interest in connection with the performance of duties imposed on the Department by section 4110 of title 38, United States Code.

The Advisory Committee on Veterans' Employment and Training shall: assess the employment and training needs of veterans; determine the extent to which the programs and activities of the Department of Labor are meeting such needs; carry out such other activities that are necessary to make the reports and recommendations required by law; and, not later than July 1 of each year, report to Secretary of Labor on the employment and training needs of veterans.

The Committee shall consist of at least 12, but not more than 18, individuals appointed by the Secretary of Labor to serve as members of the Advisory Committee, consisting of: representatives nominated by veterans' organizations that are chartered by Federal law and have a national employment program; and not more than 6 individuals who are recognized authorities in the fields of business, employment, training, rehabilitation, or labor and who are not employees of the Department of Labor.

The Advisory Committee will report to the Assistant Secretary for Veterans' Employment and Training. It will function solely as an advisory body and in compliance with the provisions of the Federal Advisory Committee Act, and its charter will be filed under the Act.

For further information contact Ms. Polin Cohanne, Chief of Staff, Office of the Assistant Secretary of Veterans' Employment and Training, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 219–9116.

Signed at Washington, DC, this 4th day of September 1998.

Alexis M. Herman,

Secretary of Labor.

[FR Doc. 98–25183 Filed 9–18–98; 8:45 am]

BILLING CODE 4510–79–M

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Business Research Advisory Council; Notice of Meetings and Agenda

The regular Fall meetings of the Business Research Advisory Council and its committees will be held on October 7 and 8, 1998. All of the meetings will be held in the Conference Center of the Postal Square Building, 2 Massachusetts Avenue, N.E., Washington, D.C.

The Business Research Advisory Council and its committees advise the

Bureau of Labor Statistics with respect to technical matters associated with the Bureau's programs. Membership consists of technical officials from American business an industry.

The schedule and agenda for the meetings are as follows:

Wednesday, October 7, 1998—Meeting Rooms 9 & 10, 10:00–11:30 a.m.—Committee on Employment Projections

1. Overview of the Office of Employment Projections program for Fiscal Year 1999 (Neal Rosenthal)
2. How technological change is accounted for in the development of employment projections
   a. Industry projections (Arthur Andreassen)
   b. Occupational projections (Neal Rosenthal)
3. Discussion of items for Spring 1999 meeting (Committee members)

1:00–3:00 p.m. Committee on Price Indexes

1. Consumer Price Index: Report on initiative to review our treatment of anti-pollution devices
2. Producer Price Index: Report on plans to develop new aggregate indexes encompassing goods and services

3:00–4:30 p.m. Committee on Employment an Unemployment Statistics

1. Election of chair and vice-chair
2. Updates on employment and unemployment statistics programs

Thursday, October 8, 1998—Meeting Rooms 9 & 10, 8:30–10:00 a.m.—Committee on Productivity and Foreign Labor Statistics

1. Election of vice-chair
2. Summary of new activities in Office of Productivity and Technology
3. Results from the expanded industry database
4. Recent developments in international labor markets
5. BLS international technical cooperation activities

10:30 a.m.—Council Meeting

1. Chairperson's opening remarks
2. Commissioner's address and discussion
3. Discussion of Year 2000 issues with BLS Director of Survey Processing

1:30–3:00 p.m.—Committee on Compensation and Working Conditions

1. Compensation inequality (Brooks Pierce)
2. Reducing the number of officially published ECI series (Phil Doyle)
3. Davis-Bacon benefits data tests (William Wiatrowski)
4. Other business

Thursday, October 8, 1998—Meeting Room 8, 1:30–3:00 p.m.—Committee on Occupational Safety and Health Statistics

1. Report on the 1997 Census of Fatal Occupational Injuries
2. Status of the 1997 Survey of Occupational Injuries and Illnesses
3. Status of the Fiscal Year 1999 budget

The meetings are open to the public. Persons with disabilities and those wishing to attend these meetings as an observer should contact Nancy Sullivan, Bureau of Labor Statistics, at (202) 606–5905, for appropriate accommodations.

Signed at Washington, D.C. the 14th day of September 1998.

Katharine G. Abraham,

Commissioner.

[FR Doc. 98–25182 Filed 9–18–98; 8:45 am]

BILLING CODE 4510–24–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 98–120]

NASA Advisory Council; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Advisory Council.

DATES: Tuesday, September 29, 1998, 9:00 a.m. to 3:00 p.m.; and Wednesday, September 30, 1998, 9:00 a.m. to 3:00 p.m.

ADDRESSES: National Aeronautics and Space Administration, Room 9H40, 300 E Street, SW, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Mr. Matthew Crouch, Code Z, National Aeronautics and Space Administration, Washington, DC 20546, 202/358–0808.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—Space Studies Board Overview
—Faster-Better-Cheaper Report
—Space Transportation Architecture Study
—Space Station Status Report
—NASA Safety
—Grants Management
—IFMP Update
—Committee/TaskForce/Working Group Reports
—Discussion of Findings and Recommendations

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitors register.

Dated: September 15, 1998.

Matthew M. Crouch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 98–25193 Filed 9–19–98; 8:45 am]

BILLING CODE 7510–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act Meetings

TIME AND DATE: 1:00 p.m., Wednesday, September 23, 1998.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, Virginia 22314–3428.

STATUS: Open

MATTERS TO BE CONSIDERED:

1. Requests from Two (2) Federal Credit Unions to Convert to Community Charters.
2. Request from a Credit Union to Convert Insurance.
3. Request from a Corporate Federal Credit Union for a Field of Membership (FOM) Amendment.
4. Request from a Corporate Credit Union to Merge with a Corporate Federal Credit Union.
5. Final Rule: Amendments to Parts 724 and 701, NCUA's Rules and Regulations, Trustees and Custodians of Pension Plans; FCU Employees Retirement Benefits.
6. Interim Final Rule: Amendments to Part 723, NCUA's Rules and Regulations, Member Business Loans.

RECESS: 2:30 p.m.

TIME AND DATE: 3:00 p.m., Wednesday, September 23, 1998

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, Virginia 22314–3428

STATUS: Closed

MATTERS TO BE CONSIDERED:

1. Administrative Action under Section 208 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A) (ii), and (9)(B).
2. Administrative Action under Part 704 of NCUA's Rules and Regulations. Closed pursuant to exemption (8).
3. Administrative Action under Part 745 of NCUA's Rules and regulations. Closed pursuant to exemption (8).
4. Administrative Action under Section 206 of the FCU Act. Closed pursuant to exemptions (7) and (8).

5. Two (2) Personnel Actions. Closed pursuant to exemptions (2) and (6).

FOR FURTHER INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone (703) 518–6304.

Becky Baker,

Secretary of the Board.

[FR Doc. 98–25243 Filed 9–16–98; 5:00 pm]

BILLING CODE 7535–01–M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–269, 50–270, and 50–287]

Duke Energy Corporation OCONEE Nuclear Station, Units 1, 2, and 3 Notice of Intent to Prepare an Environmental Impact Statement and Conduct Scoping Process

The Duke Energy Corporation (Duke Energy) has submitted an application for renewal of operating licenses DPR–38, DPR 47, and DPR–55 for an additional 20 years of operation at the Oconee Nuclear Station (Oconee), Units 1, 2, and 3, respectively. The plant is located in Oconee County, South Carolina. The application for renewal was submitted by letter dated July 6, 1998, pursuant to 10 CFR Part 54. A notice of receipt of application, including the environmental report (ER), was published in the **Federal Register** on July 14, 1998 (63 FR 37909). A notice of acceptance for docketing of the application for renewal of the facility operating licenses was published in the **Federal Register** on August 11, 1998 (63 FR 42885). The purpose of this notice is to inform the public that the U.S. Nuclear Regulatory Commission (NRC) will be preparing an environmental impact statement in support of the review of the license renewal application and to give the public an opportunity to participate in the environmental scoping process as defined in 10 CFR 51.29.

In accordance with 10 CFR 54.23 and 10 CFR 51.53(c), Duke Energy submitted the ER as part of the application. The ER was prepared pursuant to 10 CFR Part 51 and is available for public inspection at the Commission's Public Document Room in the Gelman Building, 2120 L Street, NW, Washington, D.C., and the Local Public Document Room located in the Oconee County Public Library, 501 West South Broad Street, Walhalla, SC 29691.

This notice advises the public that the NRC intends to gather the information necessary to prepare a plant-specific supplement to the Commission's ''Generic Environmental Impact Statement (GEIS) for License Renewal of Nuclear Plants'' (NUREG–1437) in support of the review of the application for renewal of the Oconee operating licenses for an additional 20 years. Possible alternatives to the proposed action (license renewal) include no action and reasonable alternative energy sources. 10 CFR 51.95 requires that the NRC prepare a supplement to the GEIS in connection with the renewal of an operating license. This notice is being published in accordance with the National Environmental Policy Act (NEPA) and the NRC's regulations found in 10 CFR Part 51.

The NRC will first conduct a scoping process for the supplement to the GEIS and, as soon as practicable thereafter, will prepare a draft supplement to the GEIS for public comment. Participation in this scoping process by members of the public and local, State, and Federal government agencies is encouraged. The draft supplement to the GEIS will be the subject of separate notices and a separate public meeting. Copies will be available for public inspection at the above-mentioned addresses, and one copy per request will be provided free of charge. After receipt and consideration of the comments, the NRC will prepare a final supplement to the GEIS, which will also be available for public inspection.

The scoping process for the supplement to the GEIS will be used to accomplish the following:

a. Define the proposed action, which is to be the subject of the supplement to the GEIS.

b. Determine the scope of the supplement to the GEIS and identify the significant issues to be analyzed in depth.

c. Identify, and eliminate from detailed study, those issues that are peripheral or that are not significant.

d. Identify any environmental assessments and other environmental impact statements (EISs) that are being or will be prepared that are related to but are not part of the scope of the supplement to the GEIS being considered.

e. Identify other environmental review and consultation requirements related to the proposed action.

f. Indicate the relationship between the timing of the preparation of environmental analyses and the Commission's tentative planning and decision making schedule.

g. Identify any cooperating agencies and, as appropriate, allocate assignments for preparation and schedules for completion of the supplement to the GEIS to the NRC and any cooperating agencies.

h. Describe how the supplement to the GEIS will be prepared, including any contractor assistance to be used.

The NRC invites the following entities to participate in the scoping process:

a. The applicant, Duke Energy Corporation.

b. Petitioners for leave to intervene in the proceeding, Norman (Buzz) Williams, William (Butch) Clay, W. S. Lesan, and the Chatooga River Watershed Coalition.

c. Any other Federal agency that has jurisdiction by law or special expertise with respect to any environmental impact involved or that is authorized to develop and enforce relevant environmental standards.

d. Affected State and local government agencies, including those authorized to develop and enforce relevant environmental standards.

e. Any affected Native American tribe.

f. Any person who requests or has requested an opportunity to participate in the scoping process.

Participation in the scoping process for the supplement to the GEIS does not, in itself, entitle participants to become parties to the proceeding to which the supplement to the GEIS relates. Notice of an opportunity for a hearing regarding the renewal application was the subject of the aforementioned **Federal Register** notice of acceptance of docketing (63 FR 42885). Matters related to participation in any hearing are outside the scope of matters to be discussed at this public meeting.

In accordance with 10 CFR 51.26, the scoping process for an EIS may include a public scoping meeting to help identify significant issues related to a proposed activity and to determine the scope of issues to be addressed in an EIS. The NRC has decided to hold a public meeting for the Oconee license renewal supplement to the GEIS. The scoping meeting will be held at the Ramada Inn, Clemson, South Carolina, on Monday, October 19, 1998. There will be two sessions to accommodate interested parties. The first session will convene at 2:00 p.m. and will continue until 5:00 p.m. The second session will convene at 7:00 p.m. with a repeat of the overview portions of the meeting and will continue until 10:00 p.m. Both meetings will be transcribed and will include (1) an overview by the NRC staff of the National Environmental Policy Act (NEPA) environmental review process, the proposed scope of the supplement to the GEIS, and the proposed review schedule; (2) an overview by Duke Energy of the proposed action, Oconee license renewal, and the environmental impacts as outlined in the ER; and (3) the

opportunity for interested Government agencies, organizations, and individuals to submit comments or suggestions on the environmental issues or the proposed scope of the supplement to the GEIS. Persons may pre-register to attend or to speak at the meeting on the NEPA scoping process by contacting Mr. James H. Wilson by telephone at 1–800–368–5642, Extension 1108, or by Internet to the NRC at oconeeis@nrc.gov no later than 12:00 noon on October 15, 1998. In addition, individuals may register to speak up until 15 minutes before the start of each session. Individual oral comments may be limited by the time available, depending on the number of persons who register. Members of the public who have not registered may also have an opportunity to speak, if time permits. Public comments will be considered in the scoping process for the supplement to the GEIS. If special equipment or accommodations are needed to attend or present information at the public meeting, the need should be brought to Mr. James H. Wilson's attention no later than October 13, 1998, so that the NRC staff can determine whether the request can be accommodated.

Members of the public may send written comments on the environmental scoping process for the supplement to the GEIS to: Chief, Rules and Directives Branch, Division of Administrative Services, Mailstop T–6 D 59, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Comments may be hand-delivered to the NRC at 11545 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. on Federal workdays. To be considered in the scoping process, written comments should be postmarked by November 19, 1998. Electronic comments may be sent by the Internet to the NRC at oconeeis@nrc.gov. Electronic submittals should be sent no later than November 19, 1998, to be considered in the scoping process and will be available for inspection at the NRC and Local Public Document Rooms.

At the conclusion of the scoping process, the NRC will prepare a concise summary of the determination and conclusions reached, including the significant issues identified, and will send a copy of the summary to each participant in the scoping process. The summary will also be available for inspection at the NRC and Local Public Document Rooms.

Information about the proposed action, the supplement to the GEIS, and the scoping process may be obtained from Mr. James H. Wilson at the aforementioned telephone number or e-mail address.

Dated at Rockville, Maryland, this 14th day of September 1998.

For the Nuclear Regulatory Commission.

Thomas H. Essig,

Acting Chief Generic Issues and Environmental Projects Branch, Division of Reactor Program Management, Office of Nuclear Reactor Regulation.

[FR Doc. 98–25175 Filed 9–18–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–8989; License No. SUA–1559]

Envirocare of Utah, Inc.; Issuance of Director's Decision Under 10 CFR 2.206

Notice is hearby given that the Director, Office of Nuclear Material Safety and Safeguards, has taken action with regard to a Petition for action under 10 CFR 2.206 received from Dr. Thomas B. Cochran, Director of Nuclear Programs, on behalf of the Petitioner, Natural Resources Defense Council (NRDC), dated December 12, 1997, as supplemented May 6, 1998, with regard to Envirocare of Utah, Inc. (Envirocare). Specifically, by letter dated December 12, 1997, the Petitioner requested that NRC (1) conduct an immediate investigation of issues raised in the Petition and immediately suspend Envirocare's NRC license; (2) conduct an investigation of possible criminal violations of section 223 of the Atomic Energy Act of 1954, as amended (the Act); (3) immediately suspend Envirocare's license with the State of Utah, under section 274j(2) of the Act; (4) investigate the adequacy of the State of Utah agreement state program to protect whistleblowers; (5) contact each current and former Envirocare employee personally, on a confidential basis, to advise them of their rights to inform the NRC of unsafe practices and violations, to inform them of the protections available to them, and to ask them if they have any information which they wish to disclose, on a confidential basis or otherwise; and (6) order a special independent review of Envirocare's relationships with its employees, along the lines of the review ordered by the NRC for the Millstone site.

Petitioner asserts, as a basis for the December 12, 1997, request, that Envirocare's employee-related practices and contractual provisions constitute a violation of 42 U.S.C. § 5851 (Section 211 (''Employee Protection'') of the Energy Reorganization Act of 1974(ERA)) and the NRC's whistleblower protection regulations under Parts 19 and 40 of Title 10 of the *Code of Federal Regulations* (i.e., 10 CFR 19.16, 19.20, and 40.7). Specifically, Petitioner states that current and former Envirocare employees who have provided to governmental authorities information adverse to Envirocare's interests fear for their lives and the lives of their families should their identities become known to Envirocare. Petitioner also states that certain provisions in Envirocare's standard employment contract prevent its employees from disclosing to the NRC information concerning unsafe practices and violations under the NRC license and threaten them with severe financial penalties in the event of a disclosure. By letter dated January 16, 1998, NRC acknowledged receipt of NRDC's December 12, 1997, Petition.

With respect to the May 6, 1998, Supplement, NRDC requested that (1) NRC suspend all licenses Envirocare has with the NRC; (2) NRC request the State of Utah to suspend all licenses that Envirocare holds with the State of Utah under the purview of the Utah Division of Radiation Control; (3) the license suspensions indicated in (1) and (2) above are to be enforced until such time as NRC and the State of Utah have completed the actions under (4) and (5) below; (4) NRC undertake a program, in cooperation with the State of Utah and the Environmental Protection Agency (EPA), to contact each and every current and past employee on an individual basis and obtain a sworn statement from each, indicating: (i) whether they were intimidated by the unlawful Envirocare Employee Agreement; (ii) whether they withheld or altered any health, safety, or environmental information in any Envirocare report, or in any written or oral communication with any official of the State of Utah, EPA or NRC; and, (iii) whether they failed to report any health, safety, or environmental information to appropriate authorities; and in cases where there was information withheld, altered, or not reported, identify fully what the information was; (5) NRC investigate the extent to which such information, revealed under (4) above, has affected existing and past licenses held by Envirocare issued by the NRC or the State of Utah, under the purview of the Utah Division of Radiation Control.

In support of Petitioner's May 6, 1998, request, NRDC asserted that NRC now has before it new information that it did not have at the time that NRDC's earlier Petition (dated January 8, 1997) requesting enforcement action against Envirocare was denied by NRC on

February 5, 1997. NRDC's Petition dated January 8, 1997, was addressed in Director's Decision (DD–97–02) which was issued on February 5, 1997. Petitioner further stated that this new information consists of NRC's letter of December 8, 1997, to Charles A. Judd, indicating that Envirocare's employee protection policies were in violation of NRC's Whistleblower Protection Regulations.

By letter dated June 9, 1998, NRC acknowledged receipt of the May 6, 1998, Petition and indicated that, because of the similarity of requested actions with those of the December 12, 1997, Petition that the May 6, 1998, Petition is being considered as a Supplement to the December 12, 1997, Petition.

The Director, Office of Nuclear Material Safety and Safeguards, has determined that the requests should be denied for the reasons stated in the ''Director's Decision Under 10 CFR 2.206'' (DD–98–09), the complete text of which follows this notice and which is available for public inspection in the Commission's Public Document Room, the Gelman Building, located at 2120 L Street, N.W., Washington D.C. 20555 and is also available on the NRC Electronic Bulletin Board at (800) 952–9676.

A copy of this Decision has been filed with the Secretary of the Commission for the Commission's review in accordance with 10 CFR 2.206(c) of the Commission's regulations. As provided by this regulation, this Decision will constitute the final action of the Commission 25 days after the date of issuance unless the Commission, on its own motion, institutes review of the Decision within that time.

Dated at Rockville, Maryland, this 14th day of September 1998.

For the Nuclear Regulatory Commission.

Carl J. Paperiello,

Director, Office of Nuclear Material Safety and Safeguards.

I. Introduction

On December 12, 1997, and May 6, 1998, Dr. Thomas B. Cochran, Director of Nuclear Programs, Natural Resources Defense Council (NRDC), filed Petitions with the U.S. Nuclear Regulatory Commission (NRC) pursuant to Title 10 of the *Code of Federal Regulations,* Section 2.206 (10 CFR 2.206). In these Petitions, NRDC requested that NRC take action to immediately suspend all licenses held by Envirocare of Utah, Inc. (Envirocare). Specifically, NRDC requested that NRC take the following actions.

Petition of December 12, 1997

(1) Conduct an immediate investigation of issues raised in the Petition and immediately suspend Envirocare's NRC license.

(2) Conduct an investigation of possible criminal violations of section 223 of the Atomic Energy Act of 1954, as amended (the Act).

(3) Immediately suspend Envirocare's license with the State of Utah, under section 274j(2) of the Act.

(4) Investigate the adequacy of the State of Utah agreement state program to protect whistleblowers.

(5) Contact each current and former Envirocare employee personally, on a confidential basis, to advise them of their rights to inform the NRC of unsafe practices and violations, to inform them of the protections available to them, and to ask them if they have any information which they wish to disclose, on a confidential basis or otherwise.

(6) Order a special independent review of Envirocare's relationships with its employees, along the lines of the review ordered by the NRC for the Millstone site.

NRDC asserts, as basis for the December 12, 1997, request, that Envirocare's employee-related practices and contractual provisions constitute a violation of 42 U.S.C. § 5851 (Section 211 (''Employee Protection'') of the Energy Reorganization Act of 1974 (ERA)) and the NRC's whistleblower protection regulations under Parts 19 and 40 of Title 10 of the *Code of Federal Regulations* (i.e., 10 CFR 19.16, 19.20, and 40.7). Specifically, NRDC asserts that current and former Envirocare employees, who have provided to governmental authorities information adverse to Envirocare's interests, fear for their lives and the lives of their families should their identities become known to Envirocare. NRDC also states that certain provisions in Envirocare's standard employment contract prevent its employees from disclosing to the NRC information concerning unsafe practices and violations under the NRC license and threaten them with severe financial penalties in the event of a disclosure. By letter dated January 16, 1998, I acknowledged receipt of NRDC's December 12, 1997, Petition.

Petition of May 6, 1998

(1) Suspend all licenses Envirocare has with the NRC.

(2) Request the State of Utah to suspend all licenses that Envirocare holds with the State of Utah under the purview of the Utah Division of Radiation Control.

(3) The license suspensions indicated in (1) and (2) above are to be enforced until such time as NRC and the State of Utah have completed the actions under (4) and (5) below.

(4) Undertake a program, in cooperation with the State of Utah and the Environmental Protection Agency (EPA), to contact each and every current and past employee on an individual basis and obtain a sworn statement from each, indicating: (i) whether they were intimidated by the unlawful Envirocare Employee Agreement; (ii) whether they withheld or altered any health, safety, or environmental information in any Envirocare report, or in any written or oral communication with any official of the State of Utah, EPA or NRC; and, (iii) whether they failed to report any health, safety, or environmental information to appropriate authorities; and in cases where there was information withheld, altered, or not reported, identify fully what the information was.

(5) Investigate the extent to which such information, revealed under (4) above, has affected existing and past licenses held by Envirocare issued by NRC or the State of Utah, under the purview of the Utah Division of Radiation Control.

In support of NRDC's request in this Petition, NRDC asserted that NRC now has before it new information that it did not have at the time that NRDC's earlier Petition, dated January 8, 1997, requesting enforcement action against Envirocare that was denied by NRC on February 5, 1997. NRDC's Petition dated January 8, 1997, was addressed in DD–97–02, issued February 5, 1997. NRDC stated that this new information consists of NRC's letter of December 8, 1997, to Charles A. Judd, indicating that Envirocare's employee protection policies were in violation of NRC's whistleblower protection regulations.

NRC's letter dated June 9, 1998, acknowledged receipt of the May 6, 1998, Petition and indicated that, because of the similarity of requested actions with those of the December 12, 1997, Petition, the May 6, 1998, Petition would be considered as a supplement to the December 12, 1997, Petition.

As was indicated in the NRC's acknowledgment letters dated January 16, 1998, and June 9, 1998, NRDC's requests for action concerning Envirocare's license with the State of Utah and the Utah Agreement State Programs concern matters that do not fall within the scope of matters ordinarily considered under 10 CFR 2.206. As indicated in the June 9, 1998, acknowledgment letter, these matters were addressed by Richard L. Bangart, Director of the Office of State Programs, in his February 18, 1998, letter to NRDC. Accordingly, this Director's Decision

will only address the NRDC requests for action that relate to the license to receive, store, and dispose of certain byproduct material issued to Envirocare by NRC, pursuant to Section 11e.(2) of the Act.[1] Allegations of possible criminal violations of section 223 of the Act have been referred to the Federal Bureau of Investigation (FBI). Although matters of federal criminal violation clearly fall under the jurisdiction of the FBI, the NRC staff has, in the course of its investigations into NRC-related matters, reviewed and examined documents bearing on these matters. NRC's evaluation of this information, which has been acquired either directly, or examined under condition of confidentiality, will be discussed briefly, to the extent possible, in Section III of this Decision.

II. Background

Envirocare operates a radioactive waste disposal facility in Clive, Utah, 128 kilometers (80 miles) west of Salt Lake City in western Tooele County. Radioactive wastes are disposed of by modified shallow land burial techniques. Envirocare submitted its license application to the NRC in November 1989 for commercial disposal of byproduct material, as defined in Section 11e.(2) of the Act (11e.(2) byproduct material). On November 19, 1993, NRC completed its licensing review and issued Envirocare an NRC license to receive, store, and dispose of uranium and thorium byproduct material. Envirocare began receiving 11e.(2) byproduct material in September 1994 and has been in continuous operation since.

To ensure that the facility is operated safely and in compliance with NRC requirements, the staff conducts routine, announced inspections of the site. Areas examined during the inspections include management organization and controls, operations review, radiation protection, radioactive waste management, transportation, construction work, groundwater activities, and environmental monitoring. The NRC has conducted ten inspections of the Envirocare facilities between April 14, 1994, and June 25, 1998, in conjunction with the 11e.(2) byproduct material license and has cited the licensee for ten violations. None of the violations are related to concerns raised in the NRDC Petitions. All violations were categorized in accordance with the guidance in NUREG–1600, ''General Statement of Policy and Procedures for NRC Enforcement Actions'' (Enforcement Policy) at a Severity Level IV.[2] The most recent inspection, conducted June 22–25, 1998, resulted in the issuance of two citations. The first violation relates to failure to follow procedures; the second violation results from failure to perform confirmatory ground-water sampling. The results of the June 1998 inspection are documented in Inspection Report 40–8989/98–01 which was issued on July 24, 1998.

In addition to the routine, announced site inspections described above, the staff has, since January 1997, conducted many investigations, interviews, and telephone conversations with numerous individuals into aspects of Envirocare's operations, including matters relating to concerns raised in NRDC's 10 CFR 2.206 Petitions. The staff's investigations included interviews with former Envirocare employees.

III. Discussion

NRDC asserts two bases in support of its requested actions: (1) Envirocare's employment contract non-disclosure covenant threatens the financial well being of employees who want to provide information regarding Envirocare operations, and (2) current and former Envirocare employees fear for their lives and lives of their families. NRDC states that it is apparent from sworn affidavits, compiled in the State of Utah Legislative Auditor General Investigation of Envirocare, that current and former employees of Envirocare fear for their lives and for the lives of their families. NRDC further states that Envirocare has required employees to enter into an employment agreement with onerous provisions that impose significant monetary penalties for disclosing safety-related information. NRDC, furthermore, asserts that such threatening practices constitute a violation of Section 211 of the ERA, 10 CFR §§ 19.16, 19.20, and 40.7. The NRC has evaluated these matters and found no basis to take the requested actions.

As an initial matter, NRDC requests that the NRC immediately suspend Envirocare's NRC licenses. The NRC's Enforcement Policy describes the various enforcement sanctions available to the Commission once it determines that a violation of its requirements has occurred. In accordance with the guidance of Section VI.C.2 of the Enforcement Policy, Suspension Orders may be used: (a) to remove a threat to the public health and safety, common defense and security, or the environment; (b) to stop facility construction when (i) further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component or (ii) the licensee's quality assurance program implementation is not adequate to provide confidence that construction activities are being properly carried out; (c) when the licensee has not responded adequately to other enforcement action; (d) when the licensee interferes with the conduct of an inspection or investigation; or (e) for any reason not mentioned above for which license revocation is legally authorized. Furthermore, in accordance with the guidance in Section VI.C.3. of the Enforcement Policy, Revocation Orders may be used: (a) when a licensee is unable or unwilling to comply with NRC requirements; (b) when a licensee refuses to correct a violation; (c) when a licensee does not respond to a Notice of Violation where a response was required; (d) when a licensee refuses to pay an application fee under the Commission's regulations; or (e) for any other reason for which revocation is authorized under Section 186 of the Act (e.g., any condition that would warrant refusal of a license on an original application). Pursuant to 10 CFR 2.202(a)(5), the Commission may issue an immediately effective order to modify, suspend, or revoke a license if the Commission finds that the public health, safety, or interest so requires or that the violation or conduct causing the violation was willful.

In this case the NRDC has not provided the NRC with substantiated information supporting the existence of circumstances that would provide a basis for immediate suspension of the Envirocare license. Furthermore, neither the investigations conducted by the NRC nor by the FBI have revealed evidence providing a basis for suspension of the license.

Assertion 1

Envirocare's Employment Contract Non-disclosure Covenant Threatens Financial Well Being of Employees Who Want to Provide Information Regarding Envirocare Operations

Prior to the filing of NRDC's Petition dated December 12, 1997, the NRC reviewed Envirocare's Whistleblower

[1] In its Petition of May 6, 1998, NRDC requests the NRC to suspend all licenses Envirocare has with NRC. The only license that has been issued to Envirocare by the NRC is the NRC license to receive, store, and dispose of uranium and thorium byproduct material, issued November 19, 1993, pursuant to Section 11e.(2) of the Act.

[2] As explained in Section IV. of the Enforcement Policy, violations are normally categorized in terms of four levels of severity (Severity Level I being the most significant). A Severity Level IV violation is defined as a violation of more than minor concern which, if left uncorrected, could lead to a more serious concern.

Protection Policy; its Environmental Compliance Program; and its Employment Agreement. By letter dated December 8, 1997 (the letter referenced by NRDC in support of its May 6, 1998, Petition), the NRC notified Envirocare that its written company policies were inconsistent with Section 211 of the ERA, 42 U.S.C. 5851, and 10 CFR 40.7. More specifically, the NRC staff found that while Envirocare's Whistleblower Protection Policy and Environmental Compliance Program encouraged employees to report suspected legal violations of state or federal environmental laws and violations of the ERA and the Act, they did not incorporate all of the protections afforded in Section 211 of the ERA and 10 CFR 40.7. Further, the policies established an incorrect standard with respect to the nature of safety hazards that would trigger employees' reports to appropriate governmental authorities. In addition, the NRC notified Envirocare that its Employment Agreement could be interpreted to preclude the disclosure to the NRC or another government agency of data in support of a nuclear safety concern.

As a result of its review, the NRC requested Envirocare to modify its Whistleblower Protection Policy, Environmental Compliance Program, and Employment Agreement to ensure compliance with NRC requirements. By correspondence dated January 21, 1998, Envirocare responded to the NRC's December 8, 1997, letter. Among other things, Envirocare amended its Whistleblower Protection Policy, Environmental Compliance Program, and Employment Agreement in an effort to bring those documents into compliance with NRC requirements. NRC reviewed Envirocare's modifications to its corporate policies and employment agreement and concluded that they satisfied NRC requirements. By letter dated February 9, 1998, the NRC staff informed Envirocare that it found the modifications acceptable.

Moreover, by letter dated December 31, 1997, the NRC required Envirocare to respond to the allegations raised in the December 12, 1997, Petition. That letter requested Envirocare to indicate whether it intended to enforce its Employment Agreement against current and former employees who have engaged, or do engage, in protected activities cognizable under Section 211 of the ERA and 10 CFR 40.7. It also requested that Envirocare indicate what actions it would take to notify current and former employees that the Employment Agreement will not be applied to protected activities. In its January 21, 1998, response, Envirocare asserted that it has not in the past, nor does it intend to claim or assert in the future, that any current or former employee who has engaged in protected activities is in violation of Envirocare's Employment Agreement. Additionally, Envirocare has made reasonable efforts to notify by letter all current and former employees that the Employment Agreement in effect at the time of their employment does not prevent them from raising nuclear safety concerns or otherwise discourage them from engaging in protected activities.

With respect to asserted violations by Envirocare of Section 211 of the ERA and 10 CFR 40.7 against its employees, the NRC has investigated these and other Envirocare-related matters extensively over a period of approximately 19 months (January 1997 through August 1998). These investigations included: (1) conversations and interviews (both in person and telephonically), (2) acquisition of and evaluation of many documents acquired from several sources during the course of the investigation, and (3) frequent contact with the FBI. The conversations and interviews were conducted with many individuals, including many present and former employees of Envirocare as well as present employees of the State of Utah.

Additionally, NRC's investigations included interviews and meetings with individuals including representatives of the organizations (law firms and the State of Utah, Office of Legislative Research and General Counsel) identified in NRDC's letter of January 21, 1998.[3] It was suggested by NRDC that the individuals identified in its January 21, 1998, letter may possess information relating to the asserted violations of NRC's whistleblower regulations by Envirocare. The FBI, although focusing on alleged criminal activities (bribery and extortion) associated with Envirocare's then-President Khosrow Semnani, did, in the course of these investigations, also acquire information bearing on the above NRC-related matters. This information was investigated by the NRC and revealed no evidence that any current or former Envirocare employee has received threats of financial harm or has felt threatened by Envirocare's employment non-disclosure covenant.

Assertion 2

Current and Former Envirocare Employees Fear For Their Lives and Lives of Their Families

Allegations of possible criminal violations of the Act had been referred to the FBI as indicated in my letter of January 16, 1998. Nonetheless, in the course of its various investigations, the NRC staff acquired information bearing on the matter of death threats. The scope of NRC's investigations conducted for Assertion 2 was identical to that conducted for Assertion 1 and is described above.

In addition, the Utah Attorney General's Office had initiated a criminal investigation in early 1997 into the matter of the relationship (alleged bribery/extortion) between Mr. Larry F. Anderson, former Director of the Utah Division of Radiation Control and Mr. Khosrow B. Semnami, former President of Envirocare. This alleged bribery/extortion investigation was later assumed by the FBI. The FBI's investigation into this matter has resulted in a July 22, 1998, filing of a Cooperation Agreement between Mr. Semnani and the U.S. Attorney's Office. No information surfaced during the FBI investigation indicating that death threats had been made against either present or former employees by Mr. Semnani or other officers of Envirocare.

Based on the investigations of Envirocare that have been conducted by the NRC and the FBI, there has been no evidence uncovered indicating that any current or former Envirocare employee: (1) has received threats of financial harm or has felt threatened by Envirocare's employment contract non-disclosure covenant, or (2) fears for his/her life or the lives of his/her family as a result of threats received, either directly or indirectly, from any officer of Envirocare.

IV. Conclusion

On the basis of the above assessment, I have concluded that no substantial health and safety issues have been raised regarding Envirocare that would require initiation of the action requested by the NRDC. As explained above, the NRDC has not provided any specific information that would provide a basis, for suspension of the Envirocare license. Furthermore, neither the investigations conducted independently by the NRC nor by the FBI have revealed the existence of circumstances that would warrant immediate suspension of the

[3] In its acknowledgment letter dated January 16, 1998, the NRC requested the NRDC to provide the NRC the names of ''unidentified individuals (and attendant background information) referenced in the Petition,'' indicating that confidentiality consistent with the NRC allegation program would be provided. The NRDC's letter of January 21, 1998, responded to that request.

Envirocare license. Accordingly, the Petitioner's request for action is denied.

Dated at Rockville, Maryland this 14th day of September 1998.

For the Nuclear Regulatory Commission.

Carl J. Paperiello,

Director, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 98–25177 Filed 9–18–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 070–00133 (terminated)]

Notice of Removal from the Site Decommissioning Management Plan for the former Clevite Corporation site (Clevite)

This notice is to inform the public that the Nuclear Regulatory Commission (NRC) is removing the former Clevite Corporation (Clevite) site in Cleveland, Ohio from the Site Decommissioning Management Plan (SDMP). Clevite manufactured nuclear fuel for the Atomic Energy Commission (AEC), including high-enriched uranium fuel for the U.S. Navy and AEC research reactors, as well as thorium products. The AEC issued several licenses to Clevite in the late 1950s. Licensed activities at the site ceased in 1962.

NRC surveys conducted in 1993 showed uranium contamination at several locations in the facility. Gould, Electronics, Inc. (formerly Gould, Inc.), which merged with the Clevite Corporation in 1969, accepted responsibility for remediation of the site. Gould, Electronics, Inc. began the remediation process in 1993 and completed remediation in May 1998. Based on: (1) remedial actions taken by Gould, Electronics, Inc. and documented in the Final Status Survey Report, and (2) the results of NRC's confirmatory surveys, NRC concludes that the facility has been adequately remediated and is suitable for unrestricted use. Removal from the SDMP will be reopened only if additional contamination, or noncompliance with remediation commitments is found indicating a significant threat to public health and safety.

For further information, contact John Buckley, Office of Nuclear Material Safety and Safeguards, Washington, DC 20555, telephone: (301) 415–6607.

Dated at Rockville, Maryland, this day of September, 1998.

For the Nuclear Regulatory Commission

John W. N. Hickey,

Chief, LLW and Projects Decommissioning Projects Branch, Division of Waste Management, Office of Nuclear Materials Safety and Safeguards.

[FR Doc. 98–25178 Filed 9–18–98; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 23435; 812–11300]

Crabbe Huson Funds, et al.; Notice of Application

September 14, 1998.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of application for exemption under section 6(c) of the Investment Company Act of 1940 (the ''Act'') from section 15(a) of the Act.

SUMMARY OF APPLICATION: The requested order would permit the implementation, without prior shareholder approval, of new investment advisory agreements (''New Agreements'') for a period of up to 120 days following the later of the date of the acquisition of the assets of The Crabbe Huson Group, Inc. (the ''Advisor'') by LFC Acquisition Corp. (the ''New Advisor'') or the date on which the requested order is issued (but in no event later than February 28, 1999) (the ''Interim Period''). The order also would permit the New Advisor to receive all fees earned under the New Agreements during the Interim Period following shareholder approval.

APPLICANTS: Crabbe Huson Funds (the ''Trust''), The Crabbe Huson Special Fund, Inc. (the ''Special Fund''), Advisor, and New Advisor.

FILING DATES: The application was filed on September 11, 1998.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on October 8, 1998, and should be accompanied by proof of service on applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants: Mr. Charlie Davidson, c/o The Crabbe Huson Group, 121 S.W. Morrison, Suite 1425, Portland, OR 92704, and Ms. Lindsay Cook, c/o Liberty Financial Companies, Inc., 600 Atlantic Ave., Boston, MA 02210.

FOR FURTHER INFORMATION CONTACT: John K. Forst, Attorney Advisor, at (202) 942–0569, or Mary Kay Frech, Branch Chief, at (202) 942–0564 (Office of Investment Company Regulation, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch, 450 Fifth Street, N.W., Washington, D.C. 20549 (tel. 202–942–8090).

Applicants' Representations

1. The Trust, a Delaware business trust, and the Special Fund, an Oregon corporation, are registered under the Act as open-end management investment companies. The Trust currently offers eight portfolios [1] and the Special Fund constitutes a single portfolio (each portfolio and the Special Fund are a ''Fund''). The Advisor, an investment adviser registered under the Investment Advisers Act of 1940 (the ''Advisers Act''), serves as investment adviser for the Funds pursuant to existing investment advisory agreements (the ''Existing Agreements''). The New Advisor is a subsidiary of Liberty Financial Companies, Inc. (''Liberty''). The New Advisor will be registered as an investment adviser under the Advisers Act by the closing date of the Acquisition, as defined below, and will serve as investment adviser for the Funds pursuant to new investment advisory agreements (the ''New Agreements'').

2. On June 10, 1998, the Advisor, the New Advisor, Liberty, and certain shareholders of the Advisor entered into an agreement under which the New Advisor will purchase substantially all of the assets of the Advisor (the ''Acquisition''). Applicants state that the Acquisition may be deemed to result in an indirect transfer of the Existing Agreements to the New Advisor. Applicants expect closing of the Acquisition (the ''Closing Date'') to occur on September 30, 1998.

3. Applicants believe that the Acquisition will result in an assignment

[1] The Trust is comprised of six portfolios for purposes of this application: Crabbe Huson Income Fund, Crabbe Huson Asset Allocation Fund, Crabbe Huson Small Cap Fund, Crabbe Huson Equity Fund, Crabbe Huson Oregon Tax-Free Fund and Crabbe Huson Real Estate Investment Fund.

and thus the automatic termination of the Existing Agreements. Applicants request an exemption to permit (i) the implementation during the Interim Period, prior to obtaining shareholder approval, of the New Agreements, and (ii) the New Advisor to receive from each Fund, upon approval of that Fund's shareholders of the relevant New Agreement, any and all fees earned (plus interest thereon) under the New Agreement during the applicable Interim Period. The requested exemption would cover the Interim Period of not more than 120 days which would begin on the later of the Closing Date or the date on which the requested order is issued and will continue through the date on which the applicable New Agreement is approved or disapproved by the shareholders of each Fund, but in no event later than February 28, 1999.[2] Applicants represent that each New Agreement will have substantially the same terms and conditions as the respective Existing Agreement, except in each case for the effective date, termination date, and escrow provisions. Applicants state that the Funds should receive, during the Interim Period, the same advisory services, provided in the same manner and at the same fee levels, by substantially the same personnel, as they received prior to the Acquisition.

4. On July 17, 1998, the board of trustees of the Trust and the board of directors of Special Fund (collectively, the ''Boards''), including a majority of the members who are not ''interested persons,'' as that term is defined in section 2(a)(19) of the Act (the ''Independent Board Members''), voted in accordance with section 15(c) of the Act to approve the New Agreements and to submit the New Agreements to the shareholders of each of the Funds at a meeting to be held on September 30, 1998 (the ''Meeting''). Applicants state that proxy materials were mailed to the Funds' shareholders on or about August 18, 1998.

5. Applicants propose to enter into an escrow arrangement with an unaffiliated financial institution. The fees payable to the New Advisor during the Interim Period under the New Agreements will be paid into an interest-bearing escrow account maintained by the escrow agent. The escrow agent will release the amounts held in the escrow account (including any interest earned): (a) To the New Advisor only upon approval of the relevant New Agreement by the shareholders of the relevant Fund; or (b) to the relevant Fund if the Interim Period has ended and its New Agreement has not received the requisite shareholder approval. Before any such release is made, the Independent Board Members will be notified.

Applicants' Legal Analysis

1. Section 15(a) of the Act provides, in pertinent part, that it is unlawful for any person to serve as an investment adviser to a registered investment company, except pursuant to a written contract that has been approved by the vote of a majority of the outstanding voting securities of the investment company. Section 15(a) further requires the written contract to provide for its automatic termination in the event of its ''assignment.'' Section 2(a)(4) of the Act defines ''assignment'' to include any direct or indirect transfer of a contract by the assignor.

2. Applicants state that, following the Acquisition, the New Advisor will own substantially all of the assets of the Advisor. Applicants believe, therefore, that the Acquisition will result in an assignment of the Existing Agreements, and that the Existing Agreements will terminate according to their terms.

3. Rule 15a–4 provides, in pertinent part, that if an investment advisory contract with a registered investment company is terminated by an assignment, the adviser may continue to serve for 120 days under a written contract that has not been approved by the company's shareholders, provided that: (a) the new contract is approved by that company's board of directors (including a majority of the non-interested directors); (b) the compensation to be paid under the new contract does not exceed the compensation that would have been paid under the contract most recently approved by the company's shareholders; and (c) neither the adviser nor any controlling person of the adviser ''directly or indirectly receives money or other benefit'' in connection with the assignment. Applicants state that the Advisor may be deemed to receive a benefit in connection with the Acquisition, thus applicants may not be entitled to rely on rule 15a–4.

4. Section 6(c) provides that the SEC may exempt any person, security, or transaction from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants believe that the requested relief meets this standard.

5. Applicants note that the terms and timing of the Acquisition were determined by Liberty and the Advisor in response to a number of factors beyond the scope of the Act and unrelated to the Funds. Applicants believe that allowing the New Advisor to provide investment advisory services to the Funds during the Interim Period, thereby avoiding any interruption in services to the Funds, is in the best interests of the Funds and their shareholders and is in keeping with the spirit of the provisions of rule 15a–4 and with the purposes of section 15 of the Act.

6. Applications submit that the scope and quality of services provided to the Funds during the Interim Period will not be diminished. During the Interim Period, the New Advisor would operate under the New Agreements, which would be substantially the same as the Existing Agreements, except for their effective dates, termination dates, and escrow provisions. The Advisor and New Advisor have advised the Boards that they are not aware of any material changes in the personnel who will provide investment management services during the Interim Period. Accordingly, the Funds should receive, during the Interim Period, the same advisory services, provided in the same manner, at the same fee levels, and by substantially the same personnel as they received before the Acquisition.

Applicants' Conditions

Applicants agree as conditions to the issuance of the exemptive order requested by the application that:

1. Each New Agreement will have substantially the same terms and conditions as the respective Existing Agreement, except for the effective date, termination date, and escrow provisions.

2. Advisory fees earned by the New Advisor during the Interim Period will be maintained in an interest-bearing escrow account, and amounts in the account (including interest earned on such amounts) will be paid (a) to the New Advisor, in accordance with the relevant New Agreement, after the requisite shareholder approval is obtained, or (b) to the relevant Fund, in the absence of such approval with respect to such Fund.

[2] If the Closing Date of the Acquisition precedes the issuance of the order, the New Advisor will serve as investment adviser after the Closing Date and prior to the issuance of the order in a manner consistent with its fiduciary duty to provide investment advisory services to the Funds even though approval of the New Agreements has not yet been secured from the Fund's respective shareholders. Applicants submit that in such event the New Advisor will be entitled to receive from the Funds, with respect to the period from the Closing Date until the receipt of the order, no more than the actual out-of-pocket cost to the New Advisor for providing investment advisory services to the Funds.

3. Each of the Funds will hold a meeting of shareholders to vote on approval of the New Agreements for the Funds on September 30, 1998, or within the 120 day period following the commencement of the Interim Period (but in no event later than February 28, 1999).

4. Liberty and the Advisor will bear the costs of preparing and filing the application, and Liberty will bear any costs relating to the solicitation of shareholder approval necessitated by the Acquisition.

5. The New Advisor will take all appropriate actions to ensure that the scope and quality of advisory and other services provided to the Funds during the interim Period will be at least equivalent, in the judgment of the Boards, including a majority of the Independent Board Members, to the scope and quality of services previously provided. In the event of any material change in personnel providing services pursuant to the New Agreements caused by the Acquisition, the New Advisor will apprise and consult with the Boards to assure that the Boards, including a majority of the Independent Board Members, are satisfied that the services provided will not be diminished in scope or quality.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–25132 Filed 9–18–98; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 23437; 812–10744]

Z-Seven Fund, Inc.; Notice of Application

September 15, 1998.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application under section 23(c)(3) of the Investment Company Act of 1940 (the ''Act'') for an exemption from section 23(c) of the Act.

SUMMARY OF THE APPLICATION: The requested order would permit the Z-Seven Fund, Inc. (the ''Company'') to repurchase 698,210 of its common shares from Agape Co., S.A. (''Agape'') in exchange for cash.

FILING DATES: The application was filed on August 7, 1997, and amended on September 14, 1998.

HEARING OF NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on October 8, 1998, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicant, 1819 South Dobson Road, Suite 109, Mesa, Arizona 85202–5656.

FOR FURTHER INFORMATION CONTACT: Kathleen L. Knisely, Staff Attorney, at (202) 942–0517, or Mary Kay Frech, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Commission's Public Reference Branch, 450 Fifth Street, N.W., Washington, D.C. 20549 (tel. 202–942–8090).

Applicant's Representations

1. The Company, a Maryland corporation, is registered under the Act as a closed-end management investment company. The Company has one class of common shares which are traded on The NASDAQ Stock Market and the Pacific Exchange.

2. Agape, a Panamanian corporation, owns approximately 27% or 698,210 of the Company's issued and outstanding shares (''Shares''). Agape purchased the Shares in December 1992 pursuant to a purchase agreement (''Purchase Agreement'') between Agape and the Company. The Purchase Agreement gave Agape the right, after the first anniversary of Agape's purchase, to require the Company to register, at the Company's expense, the Shares for resale to the public (''Registration Rights''). On November 27, 1996, Agape informed the Company of its desire to liquidate its interest in the Company and requested that the Company consider a repurchase of the Shares at their net asset value (''NAV'') in exchange for Agape waiving its Registration Rights.

3. At special meetings of the board of directors of the Company (''Board'') on January 8, 1997, June 5, 1997, and July 29, 1998, the Board discussed the advantages and disadvantages associated with: (a) the sale of the Shares with a help of a broker/dealer; (b) the repurchase by the Company of the Shares at a negotiated price (''Repurchase''); and (c) the registration of the Shares for sale in brokerage or other open market transactions. The Board considered, among other things, the likely effect of each alternative on: (a) the market price of the Company's common shares; (b) Company's expense ratio; (c) the trading market for the Company's common shares; (d) the Company's total assets; and (e) the Company's expenses. The Board also considered the amount of time it would take to sell the Shares.

4. The Board approved the Repurchase on the following terms: (a) the Repurchase would be effected in four different transactions over a period of eighteen months; (b) the purchase price for the Shares would be one-half of one percent below the NAV of the Shares as determined at the time of each Repurchase transaction, provided that no Repurchase transaction would occur unless the Company's shares are trading at or above NAV; and (c) Agape and the Company would issue joint press releases announcing each Repurchase transaction.

5. The first Repurchase transaction will be for 200,000 shares and will occur two months after the order requested in the application is granted. The three subsequent Repurchase transaction will be for 150,000 shares, 150,000 shares, and 198,210 shares, respectively, and will occur at six-month intervals thereafter. The specific timing of each Repurchase transaction will be determined by the Company, provided the shares are trading at or above NAV. If a Repurchase transaction cannot be completed because the shares are trading at a discount from NAV, the Repurchase period will be extended and the Repurchase will be completed as soon as the discount disappears.[1]

6. The Company intends to raise cash for the Repurchase through the orderly liquidation of its portfolio securities as is necessary as of the time of each Repurchase transaction. The Company

[1] The Company has disclosed to shareholders, in its most recent annual report, that it was seeking an order from the Commission to repurchase the Shares from Agape over an 18-month period following receipt of the order, at a price of one-half of one percent below NAV at the time of each Repurchase transaction.

does not believe that the liquidation would disrupt the Company's portfolio for the remaining shareholders and states that the planned and longer term nature of the Repurchase would allow the Company appropriate time to plan for the necessary sale of portfolio securities.

Applicant's Legal Analysis

1. Section 23(c) of the Act prohibits a registered closed-end investment company from purchasing its own securities other than on a securities exchange or pursuant to a tender offer. Section 23(c)(3) also allows purchases to be made under such other circumstances as the Commission may permit by order for ''the protection of investors to insure that such purchases are made in a manner or on a basis which does not unfairly discriminate against any holders of the class or classes of securities to be purchased.''

2. Applicant states that the Repurchase permits the Company to satisfy its contractual obligation to Agape and will have less of an effect on the market value of the common shares than registering the Shares for resale on the open market. Applicant also asserts that their terms of the Repurchase were developed in response to Agape's Registration Rights under the Purchase Agreement and were not influenced by Agape's status as an affiliated person of the Company.[2] Applicant also states that the Repurchase price will be one-half of one percent lower than NAV; thus there will be no dilution of the other shareholders' net interest in the Company. Applicant also states that because there will be no Repurchase transaction if the NAV per share exceeds market value per share, the price received by Agape will be no higher than the market price (the price that may be obtained by other shareholders that wish to sell their shares.) Applicant thus asserts that the Repurchase does not unfairly discriminate against the shareholders of the Company. Applicant also asserts that for the reasons discussed above, the Repurchase is in the best interests of the Company and its shareholders.

[2] Agape is an affiliated person of the Company because it owns more than 5% of the Company's voting securities. *See* section 2(a)(3) of the Act. Agape is presumed to control the Company by virtue of owning 25% or more of the Company's voting securities. *See* section 2(a)(9) of the Act. The Company states that Agape represented in the Purchase Agreement that it was not investing in the Company for the purpose of exercising or obtaining control of the Company and that it was not the intention of Agape to directly or indirectly exercise a controlling influence over the management or policies of the Company. Agape does not have a representative on the Company's Board.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–25131 Filed 9–18–98; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40440; File No. SR–CBOE–98–22]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change and Amendment Nos. 1, 2 and 3 by Chicago Board Options Exchange, Inc. Relating to Floor Official Fining Authority

September 14, 1998.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 28, 1998, the Chicago Board Options Exchange, Inc. (''CBOE'') or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change. The proposed rule change, as amended, is described in Items I, II, and III below, which Items have been prepared by the Exchange. The CBOE filed Amendment No. 1 to its proposal with the Commission on July 8, 1998,[3] Amendment No. 2 on August 27, 1998 [4] and Amendment No. 3 on September 9, 1998.[5] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the CBOE made the following changes to its proposal: (1) amended Exchange Rule 6.61 to consolidate summary fine authority under Exchange Rule 17.50; (2) clarified the meaning of the term ''service personnel'' as used in the proposal; (3) clarified that greater fines may be applicable for more serious behavior; (4) conformed the amount of the fines payable for failing to supervise a visitor and failing to abide by floor official determination or floor official request for information as stated in the text of the proposal with the amount of the fines identified in the proposed Regulatory Circular to Exchange members; (5) made minor technical changes to the language of the amended rules; and (6) clarified the Exchange's deletion of its use of the term ''member organization'' in the Exchange Rules. *See* Letter from Debora E. Barnes, Senior Attorney, CBOE, to Gail Marshall-Smith, Special Counsel, Division of Market Regulation (''Division''), Commission, dated July 7, 1998 (''Amendment No. 1'').

[4] In Amendment No. 2, the CBOE made technical changes to the language of the amended rules. *See* Letter from Debora E. Barnes, Senior Attorney, CBOE, to Terri L. Evans, Attorney, Division, Commission, dated August 26, 1998 (''Amendment No. 2'').

[5] In Amendment No. 3, the CBOE made technical changes to the Exchange's proposed rule language and concurred with the recommendations made by the Commission regarding the expansion of the discussion on the proposed rule change. *See* Letter from Debora E. Barnes, Senior Attorney, CBOE, to Terri L. Evans, Attorney, Division, Commission, dated September 8, 1998.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify certain Exchange rules and a related regulatory circular to consolidate most Floor Official fining authority governed by Exchange Rule 17.50, Imposition of Fines for Minor Rule Violations (''Summary Fine Rule''), under one regulatory circular. The text of the proposed rule change and regulatory circular follows: new text is italicized; deleted text is bracketed.

CHAPTER I—Definitions

Definitions

RULE 1.1. When used in these Rules, unless the context otherwise requires:

(a) through (jj) No Change.

Joint Venture Participant

(kk) The term ''joint venture participant'' means a member or non-member of the Exchange who is qualified to execute in person transactions in joint venture contracts in a trading crowd on the floor of the Exchange. A non-member joint venture participant shall be treated as a member for purposes of Rules 6.7 and 6.20(a), (b), [and] (c), *and (d)* and *Rule 6.20* Interpretation*s* and Policies .01 and .04 (iv), (v), and (vi) unless otherwise specified.

(ll) through (ww) No Change.

. . . Interpretations and Policies

.01 No Change.

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CHAPTER VI—Doing Business on the Exchange Floor

* * * * *

Section B: Member Activities on the Floor

* * * * *

Admission to and Conduct on the Trading Floor; Member Education

RULE 6.20. (a) Admission to *Trading* Floor. Unless otherwise provided in the Rules, no one but a member or an Order Book Official designated by the Exchange pursuant to Rule 7.3 shall make any transaction on the floor of the Exchange. Admission to the *floor* [Floor] shall be limited to members, employees of the Exchange, clerks employed by members and registered with the

Exchange, *service personnel and Exchange visitors authorized admission to the floor pursuant to Exchange policy,* and such other persons *permitted admission to the floor by the President of the Exchange* [as may be provided by resolution of the Board].

(b) Conduct on the Exchange. Members and persons employed by or associated with any member, while on any premises of the Exchange, including the trading floor of the Exchange, shall not engage in conduct (i) inconsistent with the maintenance of a fair and orderly market; (ii) apt to impair public confidence in the operations of the Exchange; (iii) inconsistent with the ordinary and efficient conduct of business; or (iv) detrimental to the safety or welfare of any other person.

(c) Fines Imposed by Floor Officials. The Exchange shall periodically issue fine schedules setting forth which violations of the Exchange's trading conduct and decorum policies are subject to fines pursuant to Rule 17.50 and the specific dollar amounts of such fines. Floor Officials may *(i)* fine members and persons employed by or associated with members *pursuant to Rule 17.50* for *trading conduct and decorum violations which are subject to fine under such fine schedules,* [violations of this rule and/or may] *(ii)* direct members and [such other] persons *employed by or associated with members* to act or cease to act in a manner to ensure compliance with Exchange *Rules* [rules] and accepted and established standards of trading conduct and decorum *and/or (iii) refer violations of the foregoing to the Business Conduct Committee for disciplinary action pursuant to Chapter XVII of the Rules.* [A member or person employed by or associated with a member who is adversely affected by a determination made under this rule may obtain a review thereof in accordance with the provisions of Chapter XIX, except as otherwise provided in Rule 17.50.] Any action taken by Floor Officials *under this paragraph (c)* [hereunder] shall not preclude *additional* [further] disciplinary action by the Business Conduct Committee under Chapter XVII of the Rules [, except as otherwise provided in Rule 17.50]. Any application or interpretation of Rules, and any decision to impose a fine *under this paragraph (c)* [hereunder], shall be agreed upon by at least two Floor Officials. Floor Officials shall file with the Exchange a written report of any action taken pursuant to authority specifically granted them by the Rules and of any interpretation of the Rules.

(d)[(c)] Clerks of Members. While on the trading floor, clerks shall display at all times the badge(s) supplied to them by the Exchange. Any Market-Maker clerk who writes up an option or stock order must give his employer a copy of that order before it is delivered; the employer must retain the copy on his person until it is executed. A clerk receiving a phone order must initial, must mark as opening or closing, and must time-stamp the order. A clerk shall remain at a booth assigned to his employer or assigned to his employer's clearing firm unless he is *(i)*[(1)] entering or leaving the trading floor, *(ii)*[(2)] transmitting or checking the status of an order or reporting a fill, *(iii)*[(3)] standing in the same crowd as his employer who is a Market-Maker or Floor Broker, *(iv)*[(4)] supervising his firm's clerks if he is a floor manager or *(v)*[(5)] acting as a clerk for an order service firm. Only order service firm clerks and Market-Maker or Floor-Broker clerks may stand in or near a trading crowd; in the latter case, the Market-Maker or Floor Broker must be present in the same trading crowd. Quote terminals on the trading floor (except those located in booths) may not be used by a clerk unless his employer is a Market-Maker or Floor Broker who is standing near the quote terminal.

(e)[(d)] Educational Classes. Members and persons associated with members are required to attend such educational classes as the Exchange may require from time to time. Failure to attend Exchange mandated continuing educational classes may subject members and persons associated with members to sanctions pursuant to the Exchange's Minor Rule Violation *Plan* provided in Exchange Rule 17.50. Any action taken by Floor Officials hereunder shall not preclude further disciplinary action by the Business Conduct Committee under Chapter XVII of the Rules[, except as otherwise provided in Rule 17.50].

. . . Interpretations and Policies:

.01 Only those members who have been approved to perform a floor function are authorized to enter into transactions on the floor. Such members include Floor Brokers who are registered pursuant to Rule 6.71, Board Brokers who are registered pursuant to Rules 7.2 and 7.3, and Market-Makers registered pursuant to Rules 8.2 and 8.3. While on the floor such floor members shall at all times display a floor member's badge.

.02 Order Book Officials may effect transactions on the floor only in the classes of option contracts to which they have been assigned and only in their capacity as Order Book Officials.

.03 Rule 3.21 provides that a Government securities options permit holder is entitled to enter into principal transactions as a Market-Maker and agency transactions as a Floor Broker in Government securities options settled by physical delivery on the floor of the Exchange until his permit expires.

.04 Activities which may violate the provisions of Rule 6.20(b) include, but are not limited to, the following:

(i) Effecting or attempting to effect a transaction with no public outcry in violation of Rule 6.43 or 6.74;

(ii) Failure of a Market-Maker to respond to a request for a market by an Order Book Official pursuant to Rule 7.5;

(iii) Failure of a Market-Maker to bid or offer within the ranges specified by Rule 8.7(b);

(iv) Failure of a member or *an associated person of a member in a supervisory capacity* [member organization] to adequately supervise a person employed by or associated with such member [or member organization] to ensure that person's compliance with the provisions of Exchange Rules 6.20(a), (b), [and] (c), *and (d)*;

(v) Failure to abide by a determination of Floor Officials;

(vi) Refusal to provide information requested by a Floor Official acting in his official capacity; and

(vii) Failure to abide by the provisions of Rule 8.51.

.05 Two Floor Officials may nullify a transaction or adjust its terms if they determine the transaction to have been in violation of any of the following: (i) Rule 6.43 (manner of bidding and offering), (ii) Rule 6.45 (priority of bids and offers), (iii) Rule 6.46 (transactions outside the book's last quoted range), (iv) Rule 6.47 (priority on split price transactions), or (v) Rule 8.51 (trading crowd firm disseminated market quotes).

.06 Deleted February 5, 1986.

.07 Non-member joint venture participants are subject to the provisions of Rule 6.20(a),(b),[and] (c), *and (d)* and *Rule 6.20 Interpretation and Policy* [Interpretations and Policies] .01 and *are subject to fines under Rule 17.50 pursuant to Rule 6.20(c) for violations of Rule 6.20, and Rule 6.20 Interpretations and Policies* .04(iv),(v), and (vi). *A non-member joint venture participant against whom a fine is imposed under Rule 17.50 may contest the fine in accordance with the appeal provisions of Rule 17.50.*

.08 Deleted December 2, 1997.

.09 Members of the appropriate Market Performance Committee may

perform the functions of a Floor Official for the purpose of enforcing trading conduct policies, including but not limited to, enforcing policies and acting pursuant to rules related to the Retail Automatic Execution System, fast markets, and the firm quote requirement of Rule 8.51(a).

* * * * *

Section C: Trading Practices and Procedures

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Reporting Duties

RULE 6.51.
(a) through (d) No Change.

. . . Interpretations and Policies:

.01 The Exchange has established the following procedure for reporting transactions pursuant to Rule 6.51(a) and (b).

For each transaction on the Exchange both the buyer and seller shall immediately record on a card or ticket, or enter in an electronic data storage medium acceptable to the Exchange, his assigned broker initial code and his clearing firm (if a Market-Maker), the symbol of the underlying security, the type, expiration month and exercise price of the option contract, the transaction price, the number of contract units comprising the transactions, the time of the transaction obtained from a source designated by the Exchange, the name of the contra clearing firm member and the assigned broker initial code of the contra member. Such a record shall constitute the ''transaction record.'' The transaction record for any agency order shall also include the account origin code, as set forth in Interpretation .02 below. The seller in each transaction, or the buyer if designated by the Exchange, shall also immediately place a paper form copy of the transaction record in the price reporting belt provided at the station or, alternatively shall provide the information required for price reporting through an electronic data transmission link approved by the Exchange. Then, the buyer and seller in each transaction shall, within the established time frames, provide the transaction record to the member for whom the transaction was executed and/or the clearing member that will clear the transaction. A member receiving a report of execution from another member shall immediately forward the report to the clearing member that will clear the transaction.

Before submitting the transaction record information for price reporting purposes in the manner prescribed above, the member shall use his best efforts to make sure that the Order Book Official acting in option contracts of the class involved, or the Order Book Official's clerk, is aware of the transaction and its price. A member shall also submit the transaction record information for price reporting purposes in the manner prescribed above whenever the transaction represents the partial execution of a larger order.

Any floor member failing to report a transaction in accordance with Rule 6.51(a) or (b) and this interpretation shall be subject to *discipline* [being fined by the appropriate Floor Procedure Committee or disciplined] by the Business Conduct Committee.

.02 No Change.

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Reconciliation and Resolution of Unmatched Trades

Rule 6.61
No Change.

*** * * Interpretations and Policies:**

.01–.04 No Change.

.05 With regard to transactions in index options and in any class of options which will trade ex-dividend or ex-distribution the following day:

(a)–(c) No Change.

(d) Any member of member firm who fails to observe the above procedures will be responsible for any liability resulting from an unmatched transaction which should have matched prior to Second Pass processing. [The Exchange may establish a schedule of fines. In addition, repeated or aggravated failure to comply with Interpretation and Policy .05 will be referred to the Business Conduct Committee.]

.06–.07 No Change.

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CHAPTER VIII—Market-makers, Trading Crowds and Modified Trading Systems

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Section B: Trading Crowds

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Trading Crowd Firm Disseminated Market Quotes

RULES 8.51.
(a) through (b) No Change.

. . . Interpretations and Policies:

.01–.04 No Change.

.05 *Floor Officials may, as provided for under Rules 6.20(c) and 17.50(g)(6),* [Pursuant to Rule 6.20(b) and Interpretation and Policies .04 thereunder, Floor Officials of the appropriate Market Performance Committee and the appropriate Floor Procedure Committee, may] impose a fine on members of the trading crowd for violations of this Rule and its Interpretations and Policies.

.06–.08 No Change.

* * * * *

CHAPTER XVII—Discipline

Imposition of Fines for Minor Rule Violations

RULE 17.50.
(a) through (g)(5) No Change.

(g)(6) Violations of Trading Conduct and Decorum Policies. (Rule 6.20)

The Exchange's trading conduct and decorum policies shall be distributed to the membership periodically and shall set forth the specific dollar amounts that may be imposed as a fine hereunder with respect to any violations of those policies. *If warranted under the circumstances in the view of two floor officials, the fine authorized under those policies for a second or third offense may be imposed for a first offense and the fine authorized for a third offense may be imposed for a second offense.* [The maximum fine authorized under those policies—this is, for violations subsequent to second offense—may be imposed for a first or second offense if warranted under the circumstances in the view of the Floor Officials Committee.]

(g)(7) No Change.

*** * * Interpretation and Policies:**

.01–.05 No Change.

* * * * *

CHAPTER XIX—Hearings and Review

Scope of Chapter

RULE 19.1. No Change.

*** * * Interpretations and Policies:**

.01 No Change.

.02 For the purposes of this Chapter ''persons aggrieved by Exchange action'' may include non-member joint venture participants only *as provided pursuant to Rule 6.20, Interpretation and Policy .07 and Rule 17.50(d)* [in connection with Exchange taken pursuant to Rule 6.20].

* * * * *

Regulatory Circular *RG98–* (RG92–14, Revised) (RG95–37, Revised)

Date: *, 1998* [April 11, 1995]
To: All Exchange Members and Personnel
From: Floor Officials Committee
Re: Violations of Trading Conduct and Decorum Policies

The purpose of this circular is to advise members and their personnel of the provisions of Exchange Rule 17.50, Imposition of Fines for Minor Rule

Violations, as they related to violations of the Exchange's trading conduct and decorum policies under Exchange Rule 6.20, Admission to and Conduct on the Trading Floor.

(1) The Rule. Rule 17.50(g)(6) provides for the imposition of fines for violations of the Exchange's trading conduct and decorum policies under Rule 6.20. The following schedule identifies certain conduct deemed *to violate* [violative of] those policies and lists the applicable fines that may be imposed for such violations by the Exchange under Rule 17.50(g)(6). *Please be advised that Rule 17.50(g)(6) enables the Exchange, if warranted under the circumstances, to impose for a first offense the fine authorized for a second or third offense and to impose for a second offense the fine authorized for a third offense.* [Please be advised that Rule 17.50(g)(6) enables the Exchange to impose the maximum fine authorized under those policies—that is, the fine authorized for subsequent offenses—in connection with a first or second offense, if warranted under the circumstances.]

FINE SCHEDULE FOR TRADING CONDUCT AND DECORUM VIOLATIONS

Number of Violations in Any Twelve Month Period [Violation Within One Calendar Year]	lst Offense	2nd Offense	Subsequent offenses
Abusive language	$100	$250	$500
Abusing Exchange Property:			
—No property damage	100	250	500
—Property damage (plus repair or replacement costs)	500	[750] *1,000*	[1,000] *2,000*
Book Priority Violation	400	800	1,200
Disruptive Announcement of Stock Print	200	400	500
Dress Code *Violation*	*$*50	*$*250	*$*500
Failure to Display ID	50	250	500
Food or Drink on Floor	250	500	1,000
Enabling/Assisting Non-Member *or Barred/Suspended Member* to Gain Improper Access to Floor	500	1,000	2,000
Enabling/Assisting Member or Associated Person to Gain Improper Access to Floor	*100*	*250*	*500*
Gaining Improper Access to Floor	*100*	*250*	*500*
Improper Use of Runners' Aisle	25	50	100
Smoking in Unauthorized Areas	50	250	500
Trading in Aisle	250	500	1,000
Physical Violence:			
—Shoving	500	1,500	2,500
—Fighting	1,500	3,000	5,000
Running	100	250	500
Unbusinesslike Conduct	[$]250	[$]500	[$]1,000
Impermissible Use of [Using] Member Phones	50	150	300
Visitor Badge *Returned* Late or Not Returned	(1)	25	[25] *50*
Failure to Attend Exchange Mandated Education Training	500	750	1000
Failure to Supervise a Visitor	*50*	*100*	*250*
Effecting or Attempting to Effect Transaction with No Public Outcry	*500*	*1,000*	*2,000*
Failure of Market-Maker to Respond to Request for Market by Order Book Official	*500*	*1,000*	*2,000*
Failure to Bid or Offer within Ranges Specified by Rule 8.7(b)	*500*	*1,000*	*2,000*
Failure to Abide by Floor Official Determination or Floor Official Request for Information	*1,000*	*2,500*	*5,000*
Violation of Rule 8.51 in an Option Class Other than OEX or DJX	(2)	(2)	(2)

1 Warning.
2 *Any amount up to 5,000.*

(2) Floor Officials. Fines under Rule 17.50(g)(6) may be imposed upon the determination of two Floor Officials that the person fined has *committed any of the trading conduct and decorum violations enumerated in the schedule above* [violated Rule 6.20]. Any application or interpretation of the Rules relating to conduct on Exchange premises shall be agreed upon by at least two Floor Officials. Floor Officials shall file with the Exchange a written report of any action taken pursuant to authority specifically granted them by the Rules and of any interpretation of the Rules.

(3) Persons Subject to Fine. The Exchange may impose the preceding fines against either or both of the following: (a) the individual responsible for the subject violation and/or (b) if such individual is employed by or associated with a member [or member organization], the member *and*/or *any supervisory personnel of the member* [member organization] that failed to adequately supervise such individual to ensure compliance with Exchange rules. Any member or *supervisory person* [member organization] who is fined more than one (1) time in any *twelve month period* [calendar year] for failure to supervise shall be subject to the fines specified above for second offenses and subsequent offenses, regardless of the number of offenses committed by the individual subject to fine for the underlying violation.

(4) Right to Contest *Fines.* Any person against whom a fine is imposed pursuant to Rule 17.50(g)(6) may contest that fine. Specifically, fines imposed under Rule 17.50(g)(6) that do not exceed $2,500 may be contested before the Appeals Committee in accordance with the provisions of Rule 17.50(d), and fines imposed under Rule 17.50(g)(6) that exceed $2,500 may be contested before the Business Conduct Committee in accordance with the provisions of Rule 71.50(c). *Persons* [Please be advised that persons] wishing to contest such fines must comply with the deadlines and all other requirements set forth in Rule 17.50(d) or Rule 17.50(c), as applicable. *Please be advised that if a fine imposed under Rule 17.50(g)(6) is contested and the reviewing body finds that the person fined committed the rule violation(s)*

alleged, the reviewing body may impose any one or more of the disciplinary sanctions authorized by the Exchange's Constitution and Rules, including but not limited to a higher fine than the fine imposed pursuant to Rule 17.50(g)(6). In addition, if a person contests a fine imposed under Rule 17.50(g)(6) and the fine is upheld by the reviewing body, the reviewing body will impose a forum fee against the person in the amount of $100 if the reviewing body's determination was reached without a hearing, or in the amount of $300 if a hearing was conducted.

(5) Additional Floor Official Action. In addition to, or instead of, issuing a fine pursuant to Rule 17.50(g)(6), Rule 6.20(c) provides that Floor Officials may direct members and their associated persons to act or cease to act in a manner to ensure compliance with Exchange Rules and accepted and established standards of trading conduct and decorum and/or refer violations of the foregoing to the Business Conduct Committee for disciplinary action pursuant to Chapter XVII of the Rules. Furthermore, any action taken by Floor Officials under Rules 17.50(g)(6) and 6.20(c) does not preclude additional disciplinary action by the Business Conduct Committee under Chapter XVII.

Any questions in connection with this circular should be directed to Andrew Spiwak *of the Legal Department* at (312) 786–7483 [, Legal Department] *or to Gregory Rich of the Trading Floor Liaison Group at (312) 786–7847.*

(RG92–14 and RG95–37, Revised)

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 CBOE included statements concerning the purpose of, and statutory 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 CBOE 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 modify Exchange Rule 6.20, Admission to and conduct on the Trading floor, and certain other Exchange rules to consolidate most Floor Official fining authority governed by the Summary Fine Rule under one regulatory circular.[6] The CBOE also proposes to modify its regulatory circular pertaining to the administration and enforcement of paragraph (g)(6) of the Summary fine Rule, as it relates to minor rule violations applicable to trading conduct and decorum policies (''Trading Conduct and Decorum Circular'').

The purpose of the CBOE's summary fine plan is to provide a mechanism whereby certain minor violations of Exchange rules can be resolved fairly, effectively and expeditiously. Because the minor rule violations subject to summary fines are easily ascertainable by floor officials, they are suitable for summary fine treatment. The proposed changes are meant to clarify the categories of behavior subject to summary fines and clarify the authority of floor officials to summarily fine under the Summary Fine Rule.

Currently, rule 6.20 provides that admission to the Exchange's trading floor is limited to members, employees of the Exchange, clerks employed by members and registered with the Exchange, and such other persons as may be provided by resolution of the Board. The Exchange is proposing to amend Rule 6.20 to clarify that Exchange visitors and service personnel, including but not limited to, electricians, building maintenance engineers, and computer repair support staff, are authorized admission to the trading floor pursuant to and in accordance with Exchange policy concerning admission to the trading floor.[7] In addition, the amendment to Rule 6.20 grants the President, rather than the Board, the authority to allow other people admission to the floor, because admission to the floor is primarily an administrative issue and the President is generally able to act more expeditiously than the Board which generally must convene a meeting to take action.

The summary fines for Rule 6.20 violations are set forth in the Trading Conduct and Decorum Circular. Currently, if a member is fined for a Rule 6.20 violation more than once in a calendar year, that individual will then be subject to increased summary fines for second or subsequent offenses of that kind in that calendar year. The Exchange proposes to amend the Trading Conduct and Decorum Circular to provide that summary fines for second or subsequent offenses will be assessed on a twelve-month rolling period, rather than on a calendar year basis. This Circular is also being amended to allow for the fining of any supervisory personnel of an associated person of a member who failed to adequately supervise the associated person. The Circular and Rule 17.50 also are being amended to clarify that the Exchange, if warranted under the circumstances, may impose a fine for a first offense equal to the fine authorized for a second or third offense and to impose for a second offense the fine authorized for a third offense. This permits the Exchange to impose greater fines for more serious behavior. Currently, floor officials only have the ability to impose a fine authorized for a third offense for a first or second offense, which has restricted the ability of floor officials to fine in a manner corresponding to the circumstances.[8]

The Exchange is also amending the Trading Conduct and Decorum Circular to add the following summary fine categories: Enabling a barred or suspended member to gain improper access to the floor, with fines of $500 for a first violation, $1000 for a second violation, and $2000 for a third violation; Enabling or assisting a member or associated person to gain improper access to the floor, with fines of $100 for a first violation, $250 for a second violation, and $500 for a third violation; Gaining improper access to the floor, with fines of $100 for a first violation, $250 for a second violation, and $500 for a third violation; Impermissible use of member phones, with fines of $50 for a first violation, $150 for a second violation, and $300 for a third violation; Visitor badge returned late, with a warning for the first violation, a $25 fine for a second violation, and a $50 fine for a third violation; and Failure to supervise a visitor, with fines of $50 for a first violation, $100 for a second violation, and $250 for a third violation.

Additionally, the Exchange is amending the Trading Conduct and Decorum Circular to specify fine amounts for the following conduct: Effecting or attempting to effect transactions with no public outcry, with fines of $500 for a first violation, $1000 for a second violation, and $2000 for a third violation; Failure of a market-maker to respond to a request for the

[6] The Exchange has issued separate circulars setting forth fine schedules for violations of Rule 8.51 with respect to OEX and DJX options. These circulars were approved by the Commission in SR–CBOE 96–31 and SR–CBOE 97–45

[7] *See* Amendment No. 1, *supra* note 3.

[8] Telephone conversation between Arthur Reinstein, Associate General Counsel, CBOE, Debora Barnes, Senior Attorney, CBOE, and Terri Evans, Attorney, Division, Commission, on September 1, 1998. *See* Amendment No. 3, *supra* note 5.

market by order book official, with fines of $500 for a first violation, $1000 for a second violation, and $2000 for a third violation; Failure to bid or offer within ranges specified by Rule 8.7(b), with fines of $500 for a first violation, $1000 for a second violation, and $2000 for a third violation; Failure to abide by floor official determination or floor official request for information, with fines of $1000 for a first violation, $2500 for a second violation, and $5000 for a third violation; and Violation of Rule 8.51 in an option class other than OEX or DJX, with fines of any amount up to $5000 for first, second and third violations. Floor Officials currently have fining authority for this conduct under Rule 6.20.04, but specific fine amounts for the conduct are not set forth in the Trading Conduct and Decorum Circular. Including this conduct in the Circular will clarify that floor official fines for this conduct are imposed under the Summary Fine Rule.

The Exchange is also proposing to change some of the summary fine amounts in the Trading Conduct and Decorum Circular. The current fine for property damage is $500 for the first violation, $750 for the second violation and $1000 for the third violation. The Exchange is proposing to increase the latter two fines to $1000 for a second violation and $2000 for a third violation.

The Exchange also is proposing to amend Rule 6.20(c) to clarify that the Exchange has the authority to direct members and persons employed by or associated with members to act or cease to act in a manner to ensure compliance with Exchange Rules.[9] In addition, because the Exchange is consolidating all summary fine procedures under the Summary Fine Rule, the Exchange is proposing to amend Rule 6.20(c) by deleting the reference to Chapter XIX and its appeal procedures because the appeal procedures for summary fines are set forth in the Summary Fine Rule.

The Exchange also proposes to amend Exchange Rule 6.51, Interpretation and Policy .01, by amending the final paragraph to delete the reference to the Floor Procedure Committee. This change is being proposed to conform the Exchange's rule language with the Exchange's current practice. The Floor Procedure Committee is no longer involved in fining floor members who violate Rule 6.51(a) or (b); instead members are fined pursuant to the Summary Fine Rule.[10]

The proposed rule change also amends Rule 6.61, Interpretation and Policy .05(d) by deleting the last two sentences. The Exchange is deleting this language because it is attempting to consolidate summary fine authority under Exchange Rule 17.50. In addition, a member's failure to observe the procedures referenced in Interpretation and Policy .05 is subject to the disciplinary authority of the Business Conduct Committee under Chapter XVII of the Exchange's Rules, therefore making the cross-reference in Interpretation and Policy .05 unnecessary.[11]

The Exchange is proposing that Rule 8.51 (''Firm Quote Rule'') be revised as well, to provide that Floor Officials may fine members of trading crowds under the Summary Fine Rule for violations of the Firm Quote Rule.[12] This change is being proposed to consolidate all of the minor rule violation authority of Floor Officials under the Summary Fine Rule, rather than having the Firm Quote Rule refer to Rule 6.20, which then refers back to the Summary Fine Rule. This proposed rule change also makes certain changes to clarify and incorporate Rule 6.20, the Summary Fine Rule, and the Trading Conduct and Decorum Circular into other Exchange Rules.[13]

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)(5) of the Act[14] in that it is designed to clarify and enhance the Exchange's summary fine plan as applied to trading conduct and decorum policies, thereby promoting just and equitable principles of trade and protecting investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room in Washington D.C. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to file number SR–CBOE–98–22 and should be submitted by October 13, 1998.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[15]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–25164 Filed 9–18–98; 8:45 am]

BILLING CODE 8010–01–M

[9] Telephone conversation between Arthur Reinstein, Associate General Counsel, CBOE, Debora Barnes, Senior Attorney, CBOE, and Terri Evans, Attorney, Division, Commission, on September 1, 1998. *See* Amendment No. 3, *supra* note 5.

[10] *Id.*

[11] *See* Amendment No. 1, *supra* note 3.

[12] The Exchange has issued separate circulars setting forth fine schedules for violations of Rule 8.51 with respect to OEX and DJX options. These circulars were approved by the Commission in SR–CBOE 96–31 and SR–CBOE–97–45

[12] For example, in Amendment No. 1, the Exchange notes that it has deleted the reference to member organizations in certain of the rules proposed to be amended by the rule filing that also refer to members, because Section 1.1 of the Exchange Constitution defines the term ''member'' to include either an individual member or a member organization.

[14] 15 U.S.C. 78f(b)(5).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40433; File No. SR–EMCC–98–08]

Self-Regulatory Organizations; Emerging Markets Clearing Corporation; Notice of Filing of a Proposed Rule Change Relating to the Offering of Shares of Common Stock

September 11, 1998.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on August 17, 1998, Emerging Markets Clearing Corporation (''EMCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which items have been prepared primarily by EMCC. The Commission is publishing this notice to solicit comments from interested persons on the proposed rule change.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Under the proposed rule change, EMCC will reclassify 2,000 shares of previously authorized EMCC common stock as Class A common stock (''Class A stock'') and will create a second class of common stock. In addition, EMCC will amend its shareholder agreement to reflect the changes to its common stock.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, EMCC 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. EMCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

On March 2, 1998, the Commission authorized EMCC to issue 2,000 shares of common stock (''original stock'').[3] On July 31, 1998, EMCC filed an amendment to its certificate of incorporation to reclassify the original stock as Class A stock and to authorize the issuance of non-voting Class B stock. The creation and offering of the Class B stock will permit EMCC to raise additional capital which EMCC will use in part to fund the development of EMCC projects.

EMCC will offer shares of Class B stock to the same entities that were offered the opportunity to purchase the original stock.[4] The purchase price of Class B stock is $1,000 per share with a minimum purchase requirement of $25,000. EMCC will offer the Class B shares to prospective buyers through an offering letter.[5]

The Class B stock is non-voting and is subject to repurchase upon the determination of EMCC's Board. However, EMCC has no obligation to repurchase Class B shares owned by a member that terminates its EMCC membership prior to the repurchase of all Class B shares. All purchasers of Class A and Class B stock will be required to enter into an amended version of EMCC's shareholder agreement. No dividends will be paid on either the Class A or Class B stock and shareholders may sell or transfer their shares only in compliance with EMCC's shareholder agreement.

EMCC's amended shareholder agreement will replace the shareholder agreement written for the original offering.[6] The changes to the shareholder agreement will reflect (i) the creation and offering of the Class B stock, (ii) the conditions under which EMCC may repurchase the Class B stock, and (iii) the fact that EMTA has not yet been issued any shares of EMCC stock. In addition, the amended shareholder agreement will permit EMCC to issue EMTA 300 Class A shares prior to, concurrent with, or after the closing of the issuance of Class A stock to all other persons. A further modification will reflect that the issuance of the original stock did not occur prior to the previously established deadline of June 30, 1998, and that the issuance and sale of Class A stock must be completed by December 31, 1998.

EMCC contemplates issuing the Class A and Class B stock on September 25, 1998. Each purchaser of Class A or Class B shares will be obligated to enter into the amended shareholder agreement.

After the Class A stock has been issued, EMCC will amend its articles of incorporation to permit the following actions to be taken upon a two-thirds vote of the shareholders instead of the current requirement of unanimity: (i) any amendment or change to EMCC's certificate of incorporation; (ii) any adoption, amendment or repeal by the shareholders of by-laws of the corporation; (iii) any repurchase of any securities issued by the corporation; and (iv) any issuance of any securities by the corporation.

EMCC believes the proposed rule change is consistent with the requirements of Section 17A of the Act[7] and the rules and regulations thereunder because the additional capital raised by the Class B offering will further EMCC's ability to provide for the prompt and accurate clearance and settlement of emerging markets securities.

(B) Self-Regulatory Organization's Statement on Burden on Competition

EMCC does not believe that the proposed rule change will have an impact on or impose a burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments relating to the proposed rule change have been solicited or received. EMCC will notify the Commission of any written comments received by EMCC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which EMCC consents, the Commission will:

(A) by order approve such proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

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[1] 15 U.S.C. 78s(b)(1).

[2] The Commission has modified the text of the summaries prepared by EMCC.

[3] Securities Exchange Act Release No. 39694 (March 2, 1998), 63 FR 10251 [File No. SR–EMCC–98–01].

[4] The original stock was offered to the entities that contributed to the development fund for the organization and initial operation of EMCC.

[5] Each prospective purchase of the original stock was provided with a copy of EMCC's Form CA–1 (excluding the confidential documents). EMCC will provide the prospective purchasers of the Class B stock with updates to the Form CA–1 as appropriate.

[6] The signatories of the amended shareholder agreement are the National Securities Clearing Corporation (''NSCC''), the International Securities Markets Association (''ISMA''), and the Emerging Markets Traders Association (''EMTA'').

[7] 15 U.S.C. 78q–1.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of EMCC.

All submissions should refer to File No. SR–EMCC–98–08 and should be submitted by October 13, 1998.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–25133 Filed 9–18–98; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40365A; File No. SR–NASD–98–29]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Approving Proposed Rule Change and Amendment No. 1 Thereto and Notice of Filing and Order Granting Accelerated Approval to Amendment No. 2 to Proposed Rule Change Relating to Standards for Individual Correspondence

September 15, 1998.

Correction

In FR Document No. 98–23769, beginning on page 47062 for Thursday, September 3, 1998, make the following correction. On page 47063, second column, the first full paragraph, revise the first sentence to read:

The NASDR proposes to define the word ''correspondence'' in new subparagraph (a)(3) to NASD Rule 2210 as ''* * * [a]ny written or electronic communication prepared for delivery to a single current or prospective customer, and not for dissemination to multiple customers or the general public.''

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[1]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–25130 Filed 9–18–98; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40437; File No. SR–NASD–98–60]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to Nasdaq's Automated Confirmation Transaction Service

September 14, 1998.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 12, 1998, the National Association of Securities Dealers, Inc. (''NASD'' or ''Association), through its wholly-owned subsidiary, The Nasdaq Stock Market, Inc. (''Nasdaq''), filed with the Securities and Exchange Commission (''SEC'' or Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by Nasdaq. The Commission is publishing this notice and order to solicit comments on the proposed rule change from interested persons and to grant accelerated approval to the proposed rule change.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change is designed to integrate Nasdaq's Automated Confirmation Transaction Service (''ACT'') trade reporting system with the recently approved Order Audit Trail System (''OATS''). The text of the proposed rule change is available at the Office of the Secretary, Nasdaq, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. Nasdaq has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq is proposing to amend its ACT trade-reporting rules to integrate them with the OATS rules, which were recently approved by the Commission.[3] OATS is designed to provide the NASD's regulatory subsidiary, NASD Regulation, Inc. (''NASDR''), with the ability to reconstruct markets promptly, conduct efficient surveillance, and enforce NASD and SEC rules. The Commission has directed that OATS must provide an accurate, time-sequenced record of orders and transactions from the receipt of an order through its execution.[4] To accomplish this goal, NASDR will combine information submitted to OATS with transaction data reported by members through ACT, as well as quotation information disseminated by Nasdaq. These proposed rules provide for the submission of data to ACT sufficient to allow for effective analysis and comparison of trading activity.

Under the proposal, all trade reports for OATS-eligible securities entered into Nasdaq's ACT system will be required to have a time of execution expressed in hours, minutes, and seconds. Such trade reports also will be required to have an order identifier, to be prescribed by the Association, sufficient to allow a comparison of the information contained in the trade report with data submitted to NASDR via OATS. In addition, Nasdaq is proposing to codify the requirement that all ACT participants, including those who have trade report information submitted to

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[8] 17 CFR 200.30–3(a)(12).

[1] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 39729 (March 6, 1998) 63 FR 12559 (March 13, 1998) (order approving OATS rules); NASD Notice to Members 98–33 (March 1998).

[4] *See* In the Matter of National Association of Securities Dealers, Inc., Securities Exchange Act Release No. 37538, August 8, 1996; Administrative Proceeding File No. 3–905, at 7–8.

Nasdaq through third parties, obtain and use a unique Market Participant Symbol (''MPID'') or ''MMID'') for trade reporting and audit trail purposes.

Nasdaq proposes that the rule changes requested here be implemented in tandem with the OATS testing and effectiveness dates, already approved by the Commission.[5] NASD Rule 6957 establishes the following schedule for implementation of OATS reporting requirements: (1) March 1, 1999—electronic orders received by market makers or ECNs; (2) August 1, 1999—all electronic orders; (3) July 31, 2000—all non-electronic (manual) orders. Nasdaq believes that coordinating effective dates with the OATS schedule will help ensure that any new member obligations under the rule changes proposed here will not take effect materially in advance of the corresponding OATS mandates. Such coordination also will assist in a smooth migration of systems in conformity with OATS timetables. In addition, these limited changes to ACT's trade-reporting rules will allow Nasdaq to meet its OATS obligations to provide audit trail information to NASDR while protecting the current functionality and capacity of the ACT system.

2. Statutory Basis

Based on the foregoing, Nasdaq believes the proposed rule change is consistent with Section 15A(b)(6) of the Act[6] in that the proposal is designed to prevent fraudulent and manipulative acts and practices and to promote just and equitable principles of trade.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will impose a 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

Written comments were neither solicited nor received

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, N.W., Washington D.C. Copies of such filing also will be available for inspection and copying at the NASD. All submissions should refer to File No. SR–NASD–98–60 and should be submitted by October 13, 1998.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

Nasdaq has requested that the Commission approve the proposal prior to the thirtieth day after publication in the **Federal Register**. The Commission finds the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association.[7] Specifically, the Commission believes the proposal is consistent with the requirements of Section 15A(b)(6) of the Act[8] in that it is designed to prevent fraudulent and manipulative acts and practices and to protect investors and the public interest. The Commission believes that the proposal, which integrates ACT with OATS, is designed to prevent fraudulent and manipulative acts and practices by providing the Association with sufficient information to effectively surveil transactions in Nasdaq securities.

Nasdaq's proposal requires all trade reports for OATS-eligible securities, as defined by NASD Rule 6952(c), to identify the time of execution in hours, minutes, and seconds. The Commission believes that this requirement is reasonable, given that the NASD's OATS rules require that level of specificity for all ''reportable events.''[9] Similarly, Nasdaq proposes to require a unique order identifier that satisfies such parameters as established by the Association, as required by the OATS rules. In addition, Nasdaq proposes to codify the requirement that all ACT participants obtain and use a unique Market Participant Symbol, regardless of whether third parties transmit trade report information on their behalf. The Commission believes that Nasdaq's proposal, with respect the specificity of time of execution, the unique order identifier, and the unique Market Participant Symbol, is designed to achieve uniformity between the NASD's rules governing OATS and ACT. The proposed uniformity between the NASD's rules governing ACT and OATS should assist the Association's efforts to more easily scrutinize transactions in Nasdaq securities. As a result, the Commission believes that the proposal is consistent with the Act.

Nasdaq also proposes to establish an implementation schedule for the proposed changes to the ACT rules that mirrors the schedule previously approved by the Commission for the OATS rules. The Commission believes that establishing a single implementation schedule may ease the compliance burdens on both member firms and Nasdaq.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after publication of the proposed rule change in the **Federal Register.** The Commission notes that the proposed rule change merely incorporates the changes to ACT necessitated by the Commission's approval of the OATS rules, for which the Commission has previously solicited comments. As a result, the Commission believes that the proposal raises no new issues of regulatory concern. For the foregoing reasons, the Commission believes that good cause exists, pursuant to Section 19(b)(2) of the Act,[10] to approve the proposed rule change on an accelerated basis.

It is Therefore ordered, pursuant to Section 19(b)(2) of the Act,[11] that the proposed rule change (SR–NASD–98–60) is hereby approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–25134 Filed 9–18–98; 8:45 am]

BILLING CODE 8010–01–M

[5] *See* Release No. 39729, *supra* note 3.

[6] 15 U.S.C. 78o–3(b)(6).

[7] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78o–3(b)(6).

[9] Such ''reportable events'' include the origination, receipt, transmission, modification, cancellation, or execution of orders by NASD members relating to equity securities traded on Nasdaq. *See* Release No. 39729, *supra* note 3.

[10] 15 U.S.C. 78s(b)(2).

[11] 15 U.S.C. 78s(b)(2).

[12] 17 CFR 200.30–3(a)(12).

TENNESSEE VALLEY AUTHORITY

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Tennessee Valley Authority (Meeting No, 1508).

TIME AND DATE: 9 a.m. (CDT), September 23, 1998.

PLACE: Carroll County Civic Center, 201 Mustang Drive, Huntingdon, Tennessee.

STATUS: Open.

Agenda

Approval of minutes of meeting held on August 19, 1998.

Discussion Item

Rate Review

New Business

A—Budget and Financing

A1. Approval of short-term borrowing from the Treasury.

B—Purchase Awards

B1. Contract with Nations Bank for a TVA travel card system.

B2. Supplements to contracts with BTG, Inc. (97BYC–142392–001), and Tennessee Computer Specialist, Inc. (97BYC–142392–002), for an indefinite quantity of personal computers, software, peripherals, accessories, and integration services.

B3. Supplements to contracts with Sylvest Management Systems Corporation (97BYQ–216424–001); BTG, Inc. (97BYQ–216424–002); Vista Information Systems (97BYQ–216424–003); and Government Micro Resources, Inc. (97BYQ–216424–004), for an indefinite quantity of UNIX-based workstations and servers.

C—Energy

C1. Increase in prices under Dispersed Power Price Schedule—CSPP (October 1, 1998).

E—Real Property Transactions

E1. Sale of a permanent industrial easement to Mead Containerboard, Inc. (Tract No. XGR–7461E), affecting approximately 21 acres of land on Guntersville Lake in Jackson County, Alabama, and amendment of the Guntersville Reservoir Land Management Plan to change the allocated use for a portion of Tract No. XGR–129PT from agriculture and wildlife management to barge terminal and industrial access.

E2. Public auction sale of approximately 2.89 acres of TVA land on Guntersville Lake in Marshall County, Alabama (Tract No. XGR–700).

E3. Abandonment of certain easement rights and modification of certain restrictive covenants affecting approximately 0.33 acre of land on Kentucky Lake in Perry County, Tennessee (Tract No. GIR–6449E).

E4. Sale of permanent easement to Zachary M. Walden affecting approximately 0.01 acre of land located on Blue Ridge Lake in Fannin County, Georgia (Tract No. XBRR–13E).

E5. Sale of a permanent easement of John Clabough affecting approximately 0.02 acre of land on Norris Lake in Union County, Tennessee (Tract No. XNR–905E).

E6. Deed modification affecting approximately 0.04 acre of former TVA land on Norris Lake in Union County, Tennessee (Tract No. XNR–232).

E7. Deed modification affecting approximately 0.08 acre of former TVA land on Chickamauga Lake in Hamilton County, Tennessee (Tract No. XCR–515).

Information Items

1. Modification of Contract No. P–97P01–200076 with Arch Coal Sales Company, resulting from renegotiation under a reopener provision.

2. Permanent easement to Tennessee Department of Transportation affecting 4.55 acres of land on Douglas Lake in Jefferson County, Tennessee (Tract No. XTDR–33H.

3. Delegation of authority to the Senior Vice President, Economic Development, to compromise a debt owed to TVA by Mid-America Plastics, Inc.

4. Approval for the Executive Vice President, Resource Group, to enter into a contract with the Ministry of Interior, Republic of Argentina, under which TVA would provide floodplain management consulting services.

5. Modification of Contract No. P–93P07–115641 with U.S. Coal, Inc., resulting from renegotiation under a reopener provision.

6. Modification of Contract No. P–91P08–116119 with Midwest Coal Sales Company, resulting from renegotiation under a reopener provision.

7. Approval of new investment manager and proposed new Investment Management Agreement between TVA Retirement System and WRH Partners Global Securities, L.P.

8. Authorization to conduct a Financial Trading Pilot Program under which TVA would trade the Chicago Board of Trade's TVA electricity futures and options on futures contracts and enter into electricity-related swap and option on swap transactions within certain specified parameters and delegation of authority to the Chief Financial Officer to carry out said Pilot Program.

9. Approval for the sale of Tennessee Valley Authority Power Bonds.

For more information: Please call TVA Public Relations at (423) 632–6000, Knoxville, Tennessee. Information is also available at TVA's Washington Office (202) 898–2999.

Dated: September 16, 1998.

William L. Osteen,

Associate General Counsel and Assistant Secretary.

[FR Doc. 98–25245 Filed 9–17–98; 10:51 am]

BILLING CODE 8120–08–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Reports, Forms and Recordkeeping Requirements

AGENCY: Office of the Secretary, DOT.

ACTION: Notice.

SUMMARY: This notice lists those forms, reports, and recordkeeping requirements imposed upon the public which were transmitted by the Department of Transportation to the Office of Management and Budget (OMB) for its approval in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). Section 3507 of Title 44 of the United States Code, requires that agencies prepare a notice for publication in the **Federal Register**, listing information collection request submitted to OMB for approval or renewal under that Act. OMB reviews and approves agency submissions in accordance with criteria set forth in that Act. In carrying out its responsibilities, OMB also considers public comments on the proposed forms and the reporting and recordkeeping requirements. The **Federal Register** Notice soliciting comments on this information collection was published on June 23, 1998 (63 FR 34211–34212).

DATES: Comments on this notice must be received on or before October 21, 1998.

FOR FURTHER INFORMATION CONTACT: Copies of the DOT information collection requests submitted to OMB may be obtained from Ms. Judith Street, Federal Aviation Administration, Corporate Information Division, ABC–100, 800 Independence Ave., SW.,Washington, DC 20591. Telephone (202) 267–9895.

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: Inflight Medical Incident Report.

OMB Control Number: 2120–0629.

Form(s): N/A.

Type of Request: Extension of a currently approved collection.

Affected Public: Approximately 30 air carriers.

Abstract: The Aviation Medical Assistance Act of 1998 directs the Administrator of the Federal Aviation Administration to reevaluate the equipment in medical kits and emergency training requirements for flight attendants, and to determine whether automatic external defibrillators should be required equipment on air carriers and possibly at airports. To make this determination, the Act directs, in part, that a major air carrier shall make a good faith effort to obtain, and submit quarterly reports to the Federal Aviation Administration on in-flight medical emergencies that result in death or the threat of death.

Estimated Burden: The estimated total annual burden is 274 hours.

Addresses: Written comments on the DOT information collection request should be forwarded, within 30 days of publication, to Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, Washington, DC 20503, ATTN: FAA Desk Officer. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. If you anticipate submitting substantive comments, but find that more than 10 days from the date of publication are needed to prepare them, please notify the OMB official of your intent immediately.

Comments are invited on: Whether the proposed collections of information are necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collections; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on September 14, 1998.

Phillip A. Leach,

Clearance Officer, United States Department of Transportation.

[FR Doc. 98–25204 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice Of Document Availability; Draft Environmental Assessment for Jackson Hole Airport, Jackson, Wyoming

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) has released for public and agency review and comment, a Draft Environmental Assessment for proposed runway safety improvements at Jackson Hole Airport, Jackson, Wyoming.

Description of Existing Safety Issue

The alarming number of runway excursions at the Jackson Hole Airport is the major motivation for the runway modification proposed by the Jackson Hole Airport Board and the Federal Aviation Administration. Between 1985 and 1998, there were 15 aircraft runway excursions at the airport. A ''runway excursion'' occurs when, during a landing or aborted take off, the pilot is unable to stop the aircraft on the available runway length and the aircraft comes to rest in the unpaved area beyond the runway end or off the side of the runway. Eight of the 15 runway excursions at this airport involved commercial aircraft loaded with passengers. The number of runway excursions experienced at this airport exceeds that of any other commercial service airport in the United States during the same period.

Purpose of the Environmental Assessment

The purpose of the FAA Environmental Assessment is to document the evaluation of potential environmental impacts associated with providing standard Runway Safety Areas and Runway Object Free Areas at both ends of the runway, construction and operation of an airport traffic control tower, implementation of a voluntary preferential runway use program, reconstruction of the existing runway length, and installation of runway end identifier lights and other navigational aids at the Jackson Hole Airport, Jackson, Wyoming.

DATES: Comments should be submitted no later than October 30, 1998, to Mr. Dennis Ossenkop, Airports Division, Federal Aviation Administration, Northwest Mountain Region, 1601 Lind Avenue, S.W., Renton, WA 98055–4056.

Any person desiring to review the Draft Environmental Assessment may do so during normal business hours at the following locations:

Federal Aviation Administration, Airports Division, Room 315, 1601 Lind Avenue, S.W., Renton, Washington

Federal Aviation Administration, Airports District Office, 26805 E. 68th Ave., Suite 224, Denver, CO

Jackson Hole Airport, 1250 East Airport Road, Jackson, WY

Teton County Library, 125 Virginian Lane, Jackson, WY

Issued in Renton, Washington on September 11, 1998.

Lowell H. Johnson,

Manager, Airports Division, Federal Aviation Administration, Northwest Mountain Region, Renton, Washington.

[FR Doc. 98–25207 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

RTCA Special Committee 188; Minimum Aviation System Performance Standards for High Frequency Data Link

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for Special Committee 188 meeting to be held October 6–9, 1998, starting at 9:00 a.m. each day. The meeting will be held at RTCA, 1140 Connecticut Avenue, NW., Suite 1020, Washington, DC 20036.

The agenda will include: October 6–7, (1) Working Group 2, Minimum Operational Performance Standards; October 7–8 (starting at 1:00 p.m. on October 7), (2) WG–1, Minimum Aviation System Performance Standards; October 9, Plenary Session: (3) Chairman's Opening Remarks; (4) Introductions; (5) Review of Agenda; (6) Review and Approval of Minutes of the Previous Meeting; (7) Review of WG–1 Status; (8) Review of WG–2 Status; (9) Review Activities of Other Standards Groups; (10) Open Discussion; (11) Confirm Dates for Future Meetings; (12) Closing.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue, NW., Suite 1020, Washington, DC 20036; (202) 833–9339 (phone); (202) 833–9434 (fax); or http://www.rtca.org (web stie). Members of the public may

present a written statement to the committee at any time.

Issued in Washington, DC, on September 15, 1998.

Janice L. Peters,

Designated Official.

[FR Doc. 98–25205 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

RTCA; Joint RTCA Special Committee 181/EUROCAE Working Group 13 Standards of Navigation Performance

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for a joint Special Committee 181/EUROCAE Working Group 13 meeting to be held October 5–9, 1998, starting at 9:00 a.m. The meeting will be held at the Hotel Sofitel Toulouse Centre, Allees Jean Jaures, 31000 France (phone 33 5 61 10 23 20, fax 33 5 61 10 23 51). The host, Gilles de Cevins, Aerospatiale, may be reached at 33 5 61 93 98 13 (phone), 33 5 61 93 80 06 (fax), gilles.decevins@avions.aerospatiale.fr (electronic mail).

The agenda will be as follows: Monday, October 5—Wednesday, October 7, 9:00 a.m.–5:00 p.m. (1) Working Groups 1 and 2 to meet separately; Thursday, October 8, 9:00 a.m.–5:00 p.m. Opening Plenary Session: (2) Presentation of DO–201A; Friday, October 9, 8:30–11:30 a.m., (3) Presentation of DO–201A, continued; 12:30–2:00 p.m. Closing Plenary Session: (4) Reports from Working Groups 1, 2, and 4; (5) Chairman's Remarks; (6) Dates and Locations of Future Meetings; (7) New Business; (8) Adjourn.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue, NW, Suite 1020, Washington, DC 20036; (202) 833–9339 (phone); (202) 833–9434 (fax); or http://www.rtca.org (web site). Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on September 15, 1998.

Janice L. Peters,

Designated Official.

[FR Doc. 98–25206 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–13–M

UNITED STATES INFORMATION AGENCY

Culturally Significant Objects Imported for Exhibition Determination: ''Edgar Degas, Photographer''

ACTION: Notice.

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978 (43 FR 13359, March 29, 1978), and Delegation Order No. 85–5 of June 27, 1985 (50 FR 27393, July 2, 1985). I hereby determine that the objects to be included in the exhibit, ''Edgar Degas, Photographer,'' (see list), imported from abroad for the temporary exhibition without profit, within the United States, are of cultural significance. These objects are imported pursuant to a loan agreement with a foreign lender. I also determine that the exhibition or display of the listed objects at The Metropolitan Museum of Art from on or about October 13, 1998 to on or about January 3, 1999 and at the J. Paul Getty Museum, Los Angeles, California from on or about February 2, 1999 to on or about march 28, 1999 is in the national interest.

Public Notice of these Determinations is ordered to be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Neila Sheahan, Assistant General Counsel, Office of the General Counsel, 202/619–5030, and the address if Room 700, U.S. Information Agency, 301 4th Street, S.W., Washington, D.C. 20547–0001.

Dated: September 15, 1998.

Les Jin,

General Counsel.

[FR Doc. 98–25154 Filed 9–18–98; 8:45 am]

BILLING CODE 8230–01–M

UNITED STATES INFORMATION AGENCY

Culturally Significant Objects Imported for Exhibition Determinations

AGENCY: United Information Agency.

ACTION: Notice.

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978 (43 FR 13359, March 29, 1978), and Delegation Order No. 85–5 of June 27, 1985 (50 FR 27393, July 2, 1985). I hereby determine that the objects to be included in the exhibit *''Jackson Pollock: A Retrospective''* (see list), imported from various foreign lenders for the temporary exhibition without profit within the United States, are of cultural significance. These objects are imported pursuant to loan agreements with the foreign lenders. I also determine that the exhibition or display of the listed exhibit objects at The Museum of Modern Art, New York, New York on or about October 28, 1998, to on or about February 4–22, 1999, is in the national interest. Public Notice of these determinations is ordered to be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Carol B. Epstein, Assistant General Counsel, 202/619–6981, and the address is Room 700, U.S. Information Agency, 301 4th Street, SW, Washington, DC 20547–0001.

Dated: September 15, 1998.

Les Jin,

General Counsel.

[FR Doc. 98–25156 Filed 9–18–98; 8:45 am]

BILLING CODE 8320–01–M

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0404]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to file a claim for increased VA disability compensation based on unemployability.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before November 20, 1998.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20S52), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420. Please refer to ''OMB Control No. 2900–0404'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Public Law 104–13; 44 U.S.C., 3501 '' 3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Veteran's Application for Increased Compensation Based on Individual Unemployability, VA Form 21–8940.

OMB Control Number: 2900–0404.

Type of Review: Extension of a currently approved.

Abstract: VA Form 21–8940 is used by veterans for the purpose of making a claim for increased VA disability compensation based unemployability. Without the information, entitlement to the unemployability benefits could not be determined.

Affected Public: Individuals or households.

Estimated Annual Burden: 18,000 hours.

Estimated Average Burden Per Respondent: 45 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 24,000.

Dated: May 15, 1998.

By direction of the Secretary.

Sandra S. McIntyre,

Management Analyst, Information Management Service.

[FR Doc. 98–25140 Filed 9–18–98; 8:45 am]

BILLING CODE 8320–01–P

Corrections

Federal Register

Vol. 63, No. 182

day, September 21, 1998

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Proposed Collection; Comment Request

Correction

In notice document 98–24553, beginning on page 49122, in the issue of Monday, September 14, 1998, make the following correction:

On page 49122, in the third column, in the **DATES:** section, in the second line, ''[insert date 60 days from publication in the Federal Register]'' should read ''November 13, 1998''.

BILLING CODE 1505-01-D

Federal Register

Monday
September 21, 1998

Part II

Environmental Protection Agency

40 CFR Parts 9 and 63

National Emission Standards for Hazardous Air Pollutants for Source Categories: Pharmaceuticals Production; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 63

[AD–FRL–6135–6]

RIN–2060–AE83

National Emission Standards for Hazardous Air Pollutants for Source Categories: Pharmaceuticals Production

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action promulgates national emission standards for hazardous air pollutants (NESHAP) to reduce air emissions of hazardous air pollutants (HAP) from existing and new facilities that manufacture pharmaceutical products. The Agency intends that this promulgated rule will have a common technology basis with a rule promulgated this date under the Clean Water Act (CWA) and published elsewhere in this issue of the **Federal Register**; this will allow coordinated and cost effective compliance planning by the industry. The standards implement section 112 of the Clean Air Act (CAA) as amended in 1990. The standards apply to major source facilities which produce pharmaceutical products.

The major HAP emitted by facilities covered by this final rule include methylene chloride, methanol, toluene, and hydrogen chloride. Methylene chloride is considered to be a probable human carcinogen and the other pollutants can cause noncancer health effects in humans. The promulgated rule is estimated to reduce HAP emissions from existing facilities by 22,000 megagrams per year (Mg/yr) (24,000 tons per year [tons/yr]). It also reduces volatile organic compound (VOC) emissions.

DATES: This regulation is effective on September 21, 1998. The incorporation by reference of certain publications listed in the regulation is approved by the Director of the Office of the Federal Register as of September 21, 1998. See the **SUPPLEMENTARY INFORMATION** section concerning judicial review.

ADDRESSES: *Docket.* Docket No. A–96–03, containing supporting information used in developing the standards, is available for public inspection and copying between 8:30 a.m. and 3:30 p.m., Monday through Friday, at EPA's Air Docket Section, Waterside Mall, Room 1500, 1st Floor, 401 M Street SW., Washington, DC 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: For information concerning the final CAA standard, contact Mr. Randy McDonald at (919) 541–5402, Organic Chemicals Group, Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. For further information concerning the CWA effluent limitation guidelines pretreatment standards and new source performance standards, contact Dr. Frank H. Hund, at (202) 260–7786, Engineering and Analysis Division (4303), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. For information concerning applicability and rule determinations, contact your State or local representative or the appropriate EPA regional representatives. For a listing of EPA regional contacts, see the following **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION: An electronic version of documents from the Office of Air and Radiation (OAR) are available through EPA's OAR Technology Transfer Network Web site (TTNWeb). The TTNWeb is a collection of related Web sites containing information about many areas of air pollution science, technology, regulation, measurement, and prevention. The TTNWeb is directly accessible from the Internet via the World Wide Web at the following address, ''http://www.epa.gov/ttn''. Electronic versions of this preamble and rule are located under the OAR Policy and Guidance Information Web site, ''http://www.epa.gov/ttn/oarpg/'', under the **Federal Register** Notices section. If more information on the TTNWeb is needed, contact the Systems Operator at (919) 541–5384.

Regulated entities. Entities potentially regulated are those which produce pharmaceutical products and intermediates and are located at facilities that are major sources as defined in section 112 of the CAA. Regulated categories and entities include:

Category	Regulated entities
Industry	• Facilities described by the SIC codes 2833 and 2834 and NAICS codes 32541 and 325412. • Producers of finaished dosage forms of drugs, for example, tablets, capsules, solutions, that contain an active ingredient generally, but not necessarily, in association with inactive ingredients. • Producers of components whose intended primary use is to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility, company, business, organization, etc., is regulated by this action, you should carefully examine the applicability criteria in § 63.1250 of the rule. If you have questions regarding the applicability of this action to a particular entity, contact the appropriate Regional representative:

Region I

NESHAP (MACT) Coordinator, U.S. EPA Region I, John F. Kennedy Federal Building, One Congress Street, Boston, MA 02203–001, (617) 565–3438

Region II

Umesh Dholakia, U.S. EPA Region II, 290 Broadway Street, New York, NY 10007–1866, (212) 637–4023 (Umesh), (212) 637–4065 (Yue-On)

Region III

Bernard Turlinski, U.S. EPA Region III, 841 Chestnut Building, Philadelphia, PA 19107, (215) 566–2150

Region IV

Lee Page, U.S. EPA Region IV, Atlanta Federal Center, 61 Forsyth Street SW, Atlanta, GA 30303–3104, (404) 562–9131

Region V

Bruce Varner, U.S. EPA Region V, 77 West Jackson Boulevard, Chicago, IL 60604–3507, (312) 886–6793

Region VI

Robert Todd, U.S. EPA Region VI, First Interstate Bank Tower @ Fountain Place, 1445 Ross Avenue, 12th Floor, Suite 1200, Dallas, TX 75202–2733, (214) 665–2156

Region VII

Richard Tripp, U.S. EPA Region VII, Air Toxics Coordinator, 726 Minnesota Avenue, Kansas City, KS 66101, (913) 551–7566

Region VIII

Ann Marie Patrie, U.S. EPA Region VIII, Air Toxics Coordinator, 999 18th Street, Suite 500, Denver, CO 80202–2466, (303) 312–6524

Region IX

Nahid Zoueshtiagh, U.S. EPA Region IX, Air Division-6, 75 Hawthorne Street, San Francisco, CA 94105, (415) 744–1261

Region X

Andrea Wullenweber, U.S. EPA Region X, Air Toxics Coordinator, 1200 Sixth Avenue, Seattle, WA 98101, (206) 553–8760

Judicial review. Under section 307(b)(1) of the Act, judicial review of NESHAP is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit within 60 days of today's publication of this final rule. Under section 307(b)(2) of the Act, the requirements that are the subject of today's notice may not be challenged later in civil or criminal proceedings brought by the EPA to enforce these requirements. The information presented in this preamble is organized as follows:

I. List of Source Categories

Section 112 of the amended Act requires that EPA evaluate and control emissions of HAP. The control of HAP is achieved through promulgation of emission standards under sections 112(d) and 112(f) and work practice and equipment standards under section 112(h) for categories of sources that emit HAP. On July 16, 1992, EPA published an initial list of major and area source categories to be regulated (57 FR 31576). Included on that list were major sources emitting HAP from pharmaceuticals production.

Production methods used in the manufacture of pharmaceutical products include both batch and continuous operations, although batch operations make up a majority of the processes. The sizes of the facilities range from those that make one product at the rate of several hundred kilograms per year (kg/yr) to those that produce numerous pharmaceutical products on the scale of thousands of kilograms (megagrams [Mg]) per year. Air emissions of HAP compounds originate from breathing and withdrawal losses from storage tanks, venting of process vessels, leaks from piping and equipment used to transfer HAP compounds (equipment leaks), and volatilization of HAP from wastewater streams. Pollutants emitted from the production processes include a range of organic compounds, including VOC and several specific HAP. Among the most prevalent are methylene chloride and methanol, which account for nearly 70 percent of all HAP emissions from this industry. Detailed information describing manufacturing processes and emissions can be found in the basis and purpose document located in Docket A–96–03, Item No. III–B–01.

As of 1992, over 80 U.S. companies at 270 facilities were producing pharmaceutical products. Manufacturing operations covered by this NESHAP include chemical synthesis, formulation, fermentation, and extraction processes and are generally classified under standard industrial classification 283. An estimated 101 facilities are considered to be major sources according to the CAA criterion of having the potential to emit 10 tons/yr of any one HAP or 25 tons/yr of combined HAP, based on 1992 emissions data. Today's final standard applies to all major sources that produce pharmaceutical products. Area sources are not subject to this standard.

II. Background

A. Summary of Considerations Made in Developing These Standards

This regulation reduces emissions of many of the HAP listed in section 112(b)(1) of the CAAA. The alternatives considered in the development of this regulation, including those alternatives selected as standards for new and existing sources, are based on process and emissions data received from the existing facilities known by the EPA to be in operation.

Regulatory alternatives more stringent than the maximum achievable control technology (MACT) floor (minimum control level) were selected when they were judged to be reasonable, considering cost, nonair impacts, and energy requirements.

Today's final rule gives existing affected sources 3 years from the date of promulgation to comply. This is the maximum amount of time allowed by the Act. New affected sources are required to comply with the standard upon startup.

Included in today's final rule are methods for determining initial compliance as well as monitoring, recordkeeping, and reporting requirements. All of these components are necessary to ensure that affected sources comply with the standards both initially and over time. However, the

EPA has made every effort to simplify the requirements in the final rule. In addition, EPA has significantly reduced the amount of cross-referencing to other rules included in today's final standards at the request of facilities affected by these standards.

In addition, this rule contains an important and innovative pollution prevention alternative for the pharmaceutical industry that provides an option to reduce HAP emissions through reductions in HAP solvent consumption as opposed to installing end-of-pipe controls. The EPA has developed a regulation that provides a pollution prevention compliance alternative to the traditional control requirements, and the EPA encourages the pharmaceutical industry to meet the CAA requirements through its use. This alternative demonstrates EPA's commitment to developing regulations that are cost effective and flexible, and that reduce monitoring, recordkeeping, and reporting burdens.

Representatives from other interested EPA offices and programs, including State and regional environmental agency personnel, and representatives from industry participated in the regulatory development process as MACT partnership members. For example, Region II, acting as the lead, worked closely with the States of New York and New Jersey as well as the pharmaceutical industry in developing the pollution prevention alternative. The partnership members were given opportunities to review and comment on the regulation prior to proposal and had the opportunity to comment on the proposed standards and to provide additional information during the public comment period that followed proposal.

The standards were proposed in the **Federal Register** on April 2, 1997 [62 FR 15754]. The preamble to the proposed standards and the basis and purpose document (Docket Item III–B–01) described the rationale for the proposed standards. Public comments were solicited at the time of proposal. To provide interested persons the opportunity for oral presentation of data, views, or arguments concerning the proposed standards, a public hearing was offered at proposal. However, the public did not request a hearing and, therefore, one was not held. The public comment period was from April 2, 1997 to July 2, 1997. More than 40 letters were received during the comment period. Commenters included industry representatives and State agencies. The comments were carefully considered, and changes were made in the proposed standards when determined by the EPA to be appropriate. A detailed discussion of these comments and responses can be found in the promulgation background information document (BID) which is located in Docket No. A–96–03, Item V–B–01, which is referenced in the ADDRESSES section of this preamble. The promulgation BID (summary of comments and responses document) serves as the basis for the revisions that have been made to the standards between proposal and promulgation. Section VI of this preamble discusses these major changes.

B. Regulatory Background

Today's final rule implements section 112(d) of the Clean Air Act (CAA) amendments of 1990, which require the Administrator to regulate emissions of HAP listed in section 112(b) of the CAA. The intent of this rule is to protect the public health by requiring new and existing major sources to reduce generation of emissions by using pollution prevention strategies or to control emissions to the level achievable by the maximum achievable control technology (MACT), taking into consideration the cost of achieving such emission reductions, any nonair quality and other air quality related health and environmental impacts, and energy requirements.

In 1978, EPA published a control techniques document entitled ''Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products,'' EPA–450/2–78–029. The control technique guidelines document (CTG) contains a presumptive norm for reasonably available control technology (RACT) for the manufacturing operations covered under SIC Codes 2833 and 2834. Today's final rule does not affect the presumptive RACT guidelines, although a portion of emissions sources are covered by both today's final regulation and the CTG document.

In 1994, EPA promulgated National Emission Standards for Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks. Pharmaceutical processes, defined as processes that synthesize pharmaceutical intermediates or final products using carbon tetrachloride or methylene chloride as a reactant or process solvent, are subject to this rule. Today's final rule requires control of leaking components that are currently not subject to the Negotiated Regulation for Equipment Leaks, but that contain and/or transport HAP and are associated with processes in this source category. Today's rule also allows sources subject to the Negotiated Regulation to comply with the LDAR provisions of this rule.

C. Regulation of the Pharmaceutical Manufacturing Industry Under the Clean Water Act

The Clean Water Act (CWA) and a recent settlement agreement (see 59 FR 25869) require EPA to develop effluent limitations guidelines and standards regulations for the pharmaceutical manufacturing industry.

On May 2, 1995 at 60 FR 21592, the EPA proposed best available technology (BAT) economically achievable and new source performance standards (NSPS) regulations for 53 volatile and semivolatile organic pollutants of which 17 are HAP. The Agency also proposed pretreatment standards for existing sources (PSES) and performance standards for new sources (PSNS) for 45 volatile organic pollutants of which 16 are HAP. The technology basis for the volatile organic limitations were based on steam stripping and advanced biological treatment. The proposed NSPS and PSNS differed from BAT and PSES, respectively, in that they were based on steam stripping plus distillation.

In the April 2, 1997 proposal EPA indicated that it was considering changing the BAT technology basis to advanced biological treatment only. The EPA also described three options under consideration for setting PSES and PSNS to address HAP and non-HAP wastewater pollutant discharges not controlled by the MACT standards. Under the first option compliance with the MACT standards would constitute compliance with PSES and PSNS. Option 2 involved compliance with the MACT standards plus additional PSES based on the performance data base for the 1995 proposed PSES for all volatile organic pollutants except alcohols and related pollutants, and Option 3 was the same as Option 2 except the additional pollutants included alcohols and related pollutants.

On August 8, 1997, at 62 FR 42720, the EPA published a Notice of Availability (NOA) to allow public comment on the data received since the May 2, 1995 CWA proposal and to further develop and revise options for the control of volatile organic pollutant discharges presented in the April 2, 1997 MACT proposal. The EPA provided the results of an EPA sampling study designed to provide information concerning the pass-through analysis for water soluble organic pollutants such as methanol and provided a discussion thereafter of the final pass-through analysis that EPA would be performing with respect to these and other

pollutants. The EPA also presented revisions to the pretreatment options (Options 2 and 3) which were first suggested in the CWA section of the April 2, 1997 MACT proposal.

Elsewhere in today's **Federal Register** EPA is publishing final effluent limitation guideline and standards under the Clean Water Act for the pharmaceutical manufacturing point source category.

III. Authority for National Emission Standards for Hazardous Air Pollutants (NESHAP) Decision Process

A. Source of Authority for NESHAP Development

Section 112 of the Clean Air Act gives the EPA the authority to establish national standards to reduce air emissions from sources that emit one or more HAP. Section 112(b) contains a list of HAP to be regulated by NESHAP. Section 112(c) directs the Agency to use this pollutant list to develop and publish a list of source categories for which NESHAP will be developed; this list was published in the **Federal Register** on July 16, 1992 (57 FR 31576). The Agency must list all known categories and subcategories of ''major sources'' that emit one or more of the listed HAP. A major source is defined in section 112(a) as 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 in the aggregate, considering controls, 10 tons/yr or more of any one HAP or 25 tons/yr or more of any combination of HAP.

B. Criteria for Development of NESHAP

The NESHAP are to be developed to control HAP emissions from both new and existing sources according to the statutory directives set out in section 112(d) of the Act. The statute requires the standards to reflect the maximum degree of reduction in emissions of HAP that is achievable for new or existing sources. This control level is referred to as the ''maximum achievable control technology'' (MACT). The selection of MACT must reflect consideration of the cost of achieving the emission reduction, any nonair quality health and environmental impacts, and energy requirements for control levels more stringent than the floor (described below).

The MACT floor is the least stringent level for MACT standards. For new sources, the standards for a source category or subcategory ''shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source, as determined by the Administrator'' [section 112(d)(3)]. Existing source standards should be no less stringent than the average emission limitation achieved by the best performing 12 percent of the existing sources for categories and subcategories with 30 or more sources or the average emission limitation achieved by the best performing 5 sources for categories or subcategories with fewer than 30 sources [section 112(d)(3)]. The determination of the MACT floor for existing sources under today's rule is that the average emission limitation achieved by the best performing sources is based on a measure of central tendency, such as the arithmetic mean, median, or mode. The determination of percentage reduction in the production-indexed consumption factors used in the pollution prevention alternative is based on the criteria that the alternative must achieve emissions reductions equivalent to what would have been achieved by complying with the MACT.

IV. Summary of Promulgated Standards

A. Source Categories to be Regulated

Today's final rule regulates HAP emissions from pharmaceutical production facilities that are determined to be major sources. These standards apply to existing sources as well as new sources. The final standards for existing and new source are summarized in Table 1.

BILLING CODE 6560–50–P

TABLE 1.—STANDARDS FOR NEW AND EXISTING SOURCES

Emission point	New or existing?	Applicability		Requirement
		Applicability Level	Cutoff	
Process vents ...	New	Processes	>400 lb HAP/yr uncontrolled.	98 percent control or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit.
	Existing	Processes	≥2,000 lb HAP/yr controlled.	93 percent control or 2,000 lb HAP/yr or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit (if there are any vents in a process not manifolded to the control device, process must still meet 93 percent control); and 98 percent* for individual vents (within a process) meeting cutoff based on flow and emissions or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit.
Storage tanks ...	New and existing.	≥10,000 gal and <20,000 gal.	≥1.9 psia vapor pressure of liquid stored.	90 percent control or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit.
		≥20,000 gal	≥1.9 psia vapor pressure of liquid stored.	95 percent control or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit**
Wastewater	New and existing.	>Mg/yr total HAP load from all POD from PMPU.	≥1,300 ppm at POD of Table 2 HAP.	99 percent reduction of Table 2 HAP.
			≥5,200 ppmw at POD of total HAP load.	99 percent reduction of Table 2 HAP. 90 percent reduction of Table 3 HAP. 95 percent reduction of total HAP using biotreatment.
		>1 Mg/yr total HAP load from facility.	≥10,000 ppmw at POD of total HAP load.	99 percent reduction of Table 2 HAP. 90 percent reduction of Table 3 HAP. 95 percent reduction of total HAP using biotreatment.
	New	>1 Mg/yr total HAP load from all POD from PMPU.	≥110,000 ppmw at POD of Table 3 HAP.	99 percent reduction of Table 3 HAP and existing source requirements.

TABLE 1.—STANDARDS FOR NEW AND EXISTING SOURCES—Continued

Emission point	New or existing?	Applicability		Requirement
		Applicability Level	Cutoff	
Equipment leaks	New and existing.	All components in HAP service.		LDAR program.

*For process vents controlled to 93 percent prior to April 2, 1997, no additional control is required.
**For tanks controlled to 90 percent prior to April 2, 1997, no additional control is required.

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B. Pollutants to be Regulated and Associated Environmental and Health Benefits

Pharmaceutical production facilities emit an estimated 34,000 Mg/yr of organic and inorganic HAP. Organic HAP include methylene chloride, methanol, toluene, dimethylformamide, and hexane as well as other HAP. Hydrogen chloride is an inorganic HAP emitted by this industry. Today's final rule reduces HAP emissions from pharmaceutical facilities by 65 percent. Some of these pollutants are considered to be carcinogenic, and all can cause toxic health effects following exposure, including nausea, headaches, and possible reproductive effects. The EPA does recognize that the degree of adverse effects to human health can range from mild to severe. The extent and degree to which the human health effects may be experienced is dependent upon (1) the ambient concentration observed in the area (e.g., as influenced by emission rates, meteorological conditions, and terrain); (2) the frequency of and duration of exposures; (3) characteristics of exposed individuals (e.g., genetics, age, pre-existing health conditions, and lifestyle) which vary significantly with the population; and (4) pollutant specific characteristics (toxicity, half-life in the environment, bioaccumulation, and persistence).

Most of the organic HAP emitted from this industry are classified as VOC. The emission controls for HAP will reduce non-HAP VOC emissions as well. Emissions of VOC have been associated with a variety of health and welfare impacts. Volatile organic compound emissions, together with nitrogen oxides, are precursors to the formation of tropospheric ozone. Exposure to ambient ozone is responsible for a series of public health impacts, such as alterations in lung capacity; eye, nose, and throat irritation; nausea; and aggravation of existing respiratory disease. The welfare impacts from exposure to ambient ozone include damage to selected commercial timber species and economic losses for commercially valuable crops such as soybeans and cotton.

Hydrogen chloride is listed under section 112(r) of the CAA. The intent of section 112(r), Prevention of Accidental Releases, is to focus on chemicals that would pose a significant hazard to the community in the event of an accident, to prevent their accidental release, and to minimize consequences should a release occur. Hydrogen chloride, along with the other substances listed under section 112(r)(3), is listed because it is known to cause, or may be reasonably anticipated to cause death, injury, or serious adverse effects to human health or the environment (see 59 FR 4478, January 31, 1994). Sources that handle hydrogen chloride in greater quantities than the established threshold quantity under section 112(r)(5) are subject to the risk management program requirements under section 112(r)(7) (see 58 FR 54190, October 20, 1993).

In essence, the MACT standards mandated by the CAA will ensure that all major sources of air toxic emissions achieve the level of control already being achieved by the better controlled and lower emitting sources in each category. This approach provides assurance to citizens that each major source of toxic air pollution will be required to effectively control its emissions. In addition, the emission reductions achieved by today's final standards, when combined with the reductions achieved by other MACT standards, will contribute to achieving the primary goal of the CAA, which is to ''protect and enhance the quality of the Nations's air resources so as to promote the public health and welfare and the productive capacity of its population'' (the CAA, section 101(b)(1)).

C. Affected Sources

Emission points identified from pharmaceuticals production include process vents, equipment leaks, storage tanks, wastewater collection and treatment systems, and heat exchange systems. The affected source subject to this subpart is any pharmaceutical manufacturing operation, as defined in § 63.1251 of today's final rule, that meets the following criteria: (1) it manufactures a pharmaceutical product, as defined in § 63.1251; (2) it is located at a plant site that is a major source as defined in section 112(a) of the Act; and (3) it processes, uses, or produces HAP. Based on this definition of affected source, new sources are created by reconstructing existing sources, constructing new ''greenfield'' facilities, or constructing an addition to an existing source which is a dedicated pharmaceutical manufacturing process unit (PMPU) and exceeds 10 tons/yr of an individual HAP or 25 tons/yr of combined HAP. Reconfigurations of existing equipment do not constitute ''construction'' and therefore NSM would not be triggered under this circumstance. Therefore, a new affected source subject to this subpart is any affected source for which construction or reconstruction commenced after April 2, 1997, and the standard was applicable at the time of construction or reconstruction, or any PMPU that is dedicated to manufacturing a single product that has the potential to emit 10 tons per year of any one HAP or 25 tons per year of combined HAP, for which construction commenced after April 2, 1997.

The PMPU is defined according to the equipment used to make a pharmaceutical product. The PMPU also includes storage tanks that are associated with the process.

D. Storage Tank Provisions

Today's final standards require existing and new sources to control emissions from storage tanks having volumes greater than or equal to 38 cubic meters (m^3) (10,000 gallons), and storing material with a vapor pressure of greater than or equal to 13.1 kPa (1.9 psi). The final standards require that emissions from storage tanks with capacities greater than or equal to 38 m^3 (10,000 gallons) and less than 75 m^3 (20,000 gallons) be reduced by 90 percent. Emissions from storage tanks greater than or equal to 75 m^3 (20,000 gallons) must be reduced by 95 percent.

One of the following control systems can be applied to meet these requirements:

1. An internal floating roof with specified seals and fittings;
2. An external floating roof with specified seals and fittings;
3. An external floating roof converted to an internal floating roof with specified seals and fittings; or
4. A closed vent system with the appropriate 90 or 95 percent efficient control device.

The final rule also includes an alternative standard for any storage tank vents that are routed to an add-on control device. Under the alternative standard, an owner or operator may choose to comply with a total organic compound (TOC) and hydrogen halide and halogen limit of 20 ppmv or less, measured prior to dilution and at the outlet of the control device. The alternative standard is discussed in more detail in sections IV.K and VI.G of this preamble and is included in § 63.1253(d) of the final rule. Today's final rule does not provide for vapor balancing systems to be used as an alternative means of control for storage tanks.

E. Process Vent Provisions

The MACT standard for most existing process vents was set at the floor level of control, which was determined to be 93 percent control. The final standards require existing sources to reduce emissions from the sum of all vents within a process to 900 kg/yr (2,000 pounds per year [lb/yr]), considering control, or meet an overall process control level of 93 percent. The 2,000 lb/yr compliance option is limited to seven processes per year per facility. Additionally, a regulatory alternative beyond the floor was selected that requires 98 percent control of some large emission vents. Individual process vents (manifolded or nonmanifolded) meeting the annual emissions and flow rate criteria are required to achieve 98 percent control, independent of the overall 93 percent requirement. (Those process vents achieving 93 percent control prior to April 2, 1997 are not required to meet the 98 percent control requirement.) The MACT standard for process vents at new sources was set at the floor level of control. The MACT floor was determined from the best controlled similar source and is based on the most stringent control level achieved for both chemical synthesis and formulation type processes. Today's final standards for new sources require 98 percent control of vents in a process that has uncontrolled emissions greater than 182 kg/yr (400 lb/yr).

An alternative standard for process vents was added to the final rule [see § 63.1254(c)]. Under the alternative standard, an owner or operator may choose to comply with a TOC and hydrogen halide and halogen limit of 20 ppmv or less, measured prior to dilution and at the outlet of the control device. If only a portion of the process vents associated with a process comply with the alternative standard, then the remaining process vents must be controlled to the levels required by the standards (e.g., 93 percent for the sum of remaining vents and/or 98 percent control of some individual vents for existing sources and 98 percent control of the sum of remaining vents for new sources).

The process vent and storage tank standards also contain provisions for complying in essentially the same manner as is described by the alternative standard—by routing streams to control devices achieving an outlet concentration of TOC and hydrogen halide and halogen limit of 20 ppmv or less, measured prior to dilution. These provisions differ from those described under the Alternative standard only in the monitoring options available.

F. Wastewater Provisions

The MACT floor for wastewater at existing sources was determined to be 54 percent control of HAP emissions from wastewater. The EPA calculated HAP concentration cutoffs for wastewater streams, above which steam stripping of wastewater streams would result in a level of control as stringent as the floor. This approach is similar to the hazardous organic NESHAP (HON) and allows for the control of those wastewater streams containing the most significant amount of HAP. The final standards require existing sources to control wastewater with the following characteristics at the point of determination (POD):

1. Streams having partially soluble HAP compound concentrations of 1,300 ppmw or greater and a total PMPU HAP load of 1 Mg/yr or greater;
2. Streams having a combined total HAP concentration of 5,200 ppmw or greater and a total PMPU load of 1 Mg/yr or greater;
3. Streams having a total HAP concentration of 10,000 ppmw with a total facility HAP load of 1 Mg/yr or greater; or

The final standards require that air emissions from wastewater collection systems be suppressed and that wastewater is treated. Compliance is demonstrated by one of the following methods:

1. Using an enhanced biotreatment system for soluble HAP;
2. Demonstrating removals achieving 99 percent by weight of partially soluble HAP compounds, and 90 percent by weight of soluble HAP compounds, from treatment systems; or
3. Demonstrating a removal of 95 percent by weight of total organic HAP from treatment systems.

For new sources, the MACT floor for wastewater is based on a facility that currently incinerates a significant percentage of wastewater containing HAP in an incinerator combusting a mixture of wastes. The final standards require the same applicability and control requirements described above for existing sources and an increased removal of solubles (from 90 to 99 percent) for streams having a soluble HAP concentration of 110,000 ppmw at any of the load criteria (1 Mg/yr total HAP from the PMPU, or facility).

A de minimis HAP concentration and flow rate exemption was added to today's final rule. Streams containing less than 5 ppmw of partially soluble and/or soluble HAP and a total yearly load of 0.05 kg/yr of partially soluble and/or soluble HAP are not considered wastewater, and thus, are exempted from the wastewater provisions in today's final rule.

G. Equipment Leaks

Today's final rule contains revisions to the proposed equipment leak requirements that were originally based on subpart H (of the HON rule). The final rule primarily contains changes to the standards for valves and connectors in gas/vapor service and light liquid service. The standards for valves in gas/vapor service and in light liquid service were changed as follows: the requirement to implement a quality improvement program and all references to § 63.175 have been removed; an allowance for monitoring every 2 years for those processes with less than 0.25 percent leaking valves has been added; an allowance for valve subgrouping was also added; the equation used to determine the percent of leaking valves in a process was changed to eliminate the optional credit for valves removed, Vc; and the rolling average of leaking valves was revised so that it is calculated as an average of the last 3 monitoring periods for annual or biannual monitoring programs. The monitoring schedule for connectors in gas/vapor service and light liquid service was revised to allow for decreased monitoring for those components with the lowest leak rates. For leak rates less than 0.25, the monitoring frequency for connectors is

now once every 8 years. Finally, the equipment leak provisions were removed from appendix GGGA to Section 63.1255.

H. Pollution Prevention Alternative

Today's final standards include a pollution prevention (P2) alternative standard that meets the MACT floor for existing sources and can be implemented in lieu of meeting the requirements for existing process vents, storage tanks, wastewater streams and equipment leaks. The P2 alternative only applies to existing sources and includes two options which are shown in Table 2. Under option 1, owners or operators can satisfy the requirements for all emission source types associated with each pharmaceutical manufacturing process unit (PMPU) by demonstrating that the production-indexed consumption of HAP has decreased by at least 75 percent from a baseline set no earlier than the 1987 calendar year. The production indexed HAP consumption factor is expressed as kg HAP consumed/kg product produced. Under the second P2 option, owners or operators must demonstrate at least a 50 percent reduction in the production indexed HAP consumption factor, plus an additional amount of reduction in HAP emissions through the use of add-on controls, such that the overall reduction in HAP emissions is at least 75 percent from the baseline period.

TABLE 2.—ALTERNATIVE P2 STANDARD

Option	Description of P2 option
1	Demonstrate at least a 75 percent reduction in the kg consumption/kg production factor from a baseline period.
2	Demonstrate at least a 50 percent reduction in the kg/kg factor, plus an additional reduction from add-on control equivalent to at least a 75 percent overall reduction in the kg/kg factor from baseline.

The following restrictions also apply to the pollution prevention standards in today's final rule. For any reduction in the production-indexed HAP consumption factor that is achieved by reducing a HAP that is also a VOC, an equivalent reduction in the production-indexed VOC consumption factor is required. For any reduction in the production-indexed HAP consumption factor that is achieved by reducing a HAP that is not a VOC, the production-indexed VOC consumption factor may not be increased. Also, the final rule allows owners or operators of PMPU's that generate HAP emissions to qualify for the pollution prevention alternative, provided that the HAP emissions generated in the PMPU are reduced to the required levels for process vents, storage tanks, wastewater streams and equipment leaks specified in §§ 63.1252 through 63.1256 of today's final standards. The baseline production-indexed HAP and VOC consumption factors must be based on consumption and production values averaged over the time period from startup of the process until the present time (assuming the process has been in operation at least 1 full year), or the first 3 years of operation (beginning no earlier than 1987), whichever is the lesser time period. Processes that began operation after April 2, 1997 are not eligible for the P2 alternative.

Today's final standards also require owners and operators complying with the P2 standard to submit a P2 Demonstration Summary as part of the Precompliance Notification Report that describes how the P2 alternative will be applied at their facilities. The minimum data requirements for the P2 Demonstration Summary are listed in § 63.1257(f) of today's final rule.

I. Heat Exchange Provisions

Today's final standards for heat exchange systems are unchanged from proposal. Owners or operators must comply with the heat exchange provisions listed in the HON at § 63.104 with two exceptions: (1) the monitoring frequency shall be no less than quarterly, and (2) owners or operators of heat exchange systems that meet current good manufacturing practice (CGMP) requirements at 21 CFR part 211 may elect to use the physical integrity of the reactor as the surrogate indicator of heat exchange system around reactors.

J. Emissions Averaging Provisions

The emissions averaging provisions in today's final rule are unchanged from proposal. The final rule allows emissions averaging among process vents and among storage tanks at existing sources. Restrictions on the use of emissions averaging are listed in § 63.1252(d) of today's final rule and are essentially the same as those contained in the HON. The alternative standard (see following section K) is not to be included in the emissions averaging provisions and/or calculations.

K. Alternative Standard

For owners or operators of affected sources that treat emissions with an add-on control device, an alternative standard has been added under §§ 63.1253(d) (storage tanks) and 63.1254(c) (process vents). To comply with today's alternative standard(s), the control device must achieve an outlet, undiluted TOC concentration, as calibrated based on methane or the predominant HAP, of 20 ppmv or less and a hydrogen halide and halogen concentration of 20 ppmv or less, as demonstrated through the test methods and procedures in § 63.1257 and monitoring provisions in § 63.1258. The applicability level is the control unit and all sources vented to the control unit which is considered one regulated entity. Because the applicability of this standard is focused on the control device, this scenario is considered one regulated entity with regard to the number of violations that would apply if there is an exceedance of the 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet concentration limit(s). The remaining process vents within a process not controlled by the alternative standard must be controlled to the percent reduction required by the standards.

L. Test Methods and Compliance Procedures

To determine compliance with the percent reduction requirement for pharmaceutical process vents, uncontrolled and controlled emissions from all process vents within the process shall be quantified to demonstrate the appropriate overall reduction requirements (93 percent or 98 percent). For process vents controlled by devices handling less than 10 tons/yr, the owner or operator can either test or use calculational methodologies to determine the uncontrolled and controlled emission rates from individual process vents. For process vents controlled by devices handling more than 10 tons/yr, tests are required to determine the reduction efficiency of each device. Performance test provisions require testing under worst-case conditions, but the final rule provides flexibility in determining these worst-case conditions. Control devices that have previously been tested under conditions required by this standard and condensers are exempt from emissions testing. Testing is not required for devices used to control emission streams from storage or wastewater sources exclusively. However, if testing is conducted, then the same methods apply.

M. Monitoring Requirements

Monitoring is required in the final rule to determine whether a source is in compliance on an ongoing basis. This monitoring is done either by continuously measuring emission

reductions directly or by continuously measuring a site-specific operating parameter, the value of which is established by the owner or operator during the initial compliance determination. The operating parameter value is defined as a single point at either a minimum or maximum value established for a control device that, if achieved on a daily average or block average by itself or in combination with one or more other operating parameter values, determines that an owner or operator is complying with the applicable operating limits. These parameters are required to be monitored at 15-minute intervals throughout the operation of the control device for devices controlling greater than 1 tons/yr. For devices controlling streams totaling less than 1 ton/yr, only a site-specific periodic verification that the devices are operating as designed is required to demonstrate continuous compliance. Owners and operators must determine the most appropriate method of verification and propose this method to the Agency for approval in the precompliance report, which is due 6 months prior to the compliance date of the standard. The monitoring requirements apply to all control devices, even those used exclusively for storage tanks or wastewater sources.

N. Recordkeeping and Reporting Requirements

Table 1 to subpart GGG was revised to clarify the specific requirements of the final rule and the referenced requirements in the General Provisions. A summary column describing the requirements of each part of the General Provisions has been added to Table 1 and additional comments address wording issues and exceptions to the General Provisions language.

V. Summary of Environmental, Energy, Cost, and Economic Impacts

These NESHAP would affect pharmaceutical production facilities that are major sources in themselves, or constitute a portion of a major source. There are 270 existing facilities manufacturing pharmaceuticals, 101 of which were assumed to be major sources for the purpose of developing these standards and calculating impacts. The expected rate of growth for the pharmaceutical industry is expected to be 2.4 percent per year through 1998.

A. Air Impacts

Today's final standards will reduce HAP emissions from existing sources by 22,000 Mg/yr (24,000 tons/yr) from the baseline level, a reduction of 65 percent from baseline, and 75 percent from uncontrolled. These reductions also will occur if facilities elect to implement the alternative pollution prevention standard. Since many of the HAP emitted by the pharmaceutical industry are also VOC, today's final standards also will reduce VOC emissions.

B. Water and Solid Waste Impacts

Much of the steam stripping operations will result in recoverable material. However, the new source requirement for very rich, soluble HAP-containing wastewater is expected to generate solid waste. The EPA estimates that an average of 900 tons of solid waste per year per facility will be generated as a result of today's final standards. However, biological treatment is a possible means of compliance.

C. Energy Impacts

Today's final standards for the pharmaceuticals source category will require an additional energy usage of $2,400 \times 10^9$ British thermal units per year (Btu/yr).

D. Cost Impacts

The emission reductions required by this regulation can be achieved using one or more of several different techniques. To determine costs, certain control scenarios were assumed. The scenarios used in costing were judged to be the most feasible scenarios possible for meeting the requirements of the standards from a technical and cost standpoint. The total control cost includes the capital cost to install the control device, the costs involved in operating the control device, and costs associated with monitoring the device to ensure compliance. Monitoring costs include the cost to purchase and operate monitoring devices, as well as reporting and recordkeeping costs required to demonstrate compliance. Nationwide, the total annual cost of this standard to the industry for existing and new sources is approximately $64 million and $11 million, respectively (1998 dollars). To estimate these annual costs, capital costs were annualized over 10 years (with no delay for installation). (The annual costs presented in the preamble to the effluent limitations guidelines and standards are lower than the above costs because they are based on a longer annualization period. Costs for the effluent guidelines limitations and standards are annualized over 16 years (a 1-year installation period plus a 15-year project life). As a result, annual costs for existing sources in the preamble to the effluent limitations guidelines and standards (referred to as pretax annualized costs for the MACT standards rule for all facilities) are reported at $58.4 million.) The EPA believes that monitoring, reporting, and recordkeeping costs will be substantially reduced for those facilities that choose to comply with today's final rule through either the P2 option or the alternative standard of 20 ppm TOC and 20 ppm hydrogen halides and halogens.

E. Economic Impacts

The economic impact analysis of this standard shows that the estimated price increase from compliance with the recommended standards for process vents, storage tanks, and wastewater is 1.1 percent. Estimated reduction in market output is 1.9 percent.

No plant closures are expected from compliance with this set of alternatives. For more information, consult the economic impact report entitled ''Economic Analysis of Air Pollution Regulation Regulations: Pharmaceutical Industry, August 1996.''

VI. Major Comments and Changes to the Proposed Standards

In response to comments received on the proposed standards, changes have been made to the final standards. While some of these changes are clarifications designed to make EPA's intent clearer, many of them are significant changes to the requirements of the proposed standards. A summary of the substantive comments and/or changes made since proposal are described in the following sections. Detailed responses to public comments are included in the promulgation BID: Summary of Public Comments and Responses (Docket Item No. V-B–01). Additional information on the final standards is contained in the docket for this rulemaking (see ADDRESSES section of this preamble).

A. Applicability Provisions and Definitions

1. General Applicability: Definition of Pharmaceutical Product

At proposal, pharmaceutical product was defined as ''any material described by the Standard Industrial Classification (SIC) Code 283, or any other fermentation, biological or natural extraction, or chemical synthesis product regulated by the Food and Drug Administration, including components (excluding excipients) of pharmaceutical formulations, or intermediates used in the production of a pharmaceutical product.'' Many commenters stated that, based on the proposed definition of pharmaceutical product, the general applicability of the standard is too broad, ambiguous, and

appears to overlap with other MACT standards that cover the chemical industry. Comments on the definition of pharmaceutical product focused on the following four areas: (1) the use of Standard Industrial Classification (SIC) codes, (2) the scope of products regulated by the FDA, (3) the meaning of the term ''intermediates,'' and (4) the exclusion of specific products/processes.

Many commenters suggested that instead of referencing SIC code 283, the definition of pharmaceutical product should be narrowed to include only SIC codes 2833 and 2834 because facilities classified under these two SIC codes produce pharmaceuticals as their primary product, and were the source of information and data that formed the basis for the proposed rule. Two other commenters stated that the use of SIC codes or the new North American Industrial Classification System (NAICS) codes in defining pharmaceutical products was inappropriate because of the ambiguous nature of SIC and NAICS code applicability, and that instead of using SIC or NAICS codes, the definition should clearly describe the characteristics of the processes that are subject to the rule. One of the commenters also provided a recommended definition of pharmaceutical product based upon the definition of ''drug product'' already established by the Food and Drug Administration at 21 CFR 210.3 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs).

Many commenters stated that the inclusion of the phrase, ''regulated by the Food and Drug Administration'' should be deleted from the definition of pharmaceutical products because many nondrug products such as cosmetics, food additives, plastics (food contact films) and dietary supplements, are regulated by the FDA and could be interpreted as being pharmaceutical products based on the proposed definition of pharmaceutical product. However, another commenter requested that EPA expand the definition of pharmaceutical products to include products regulated by the U.S. Department of Agriculture (USDA) as well as the FDA because the pharmaceutical industry produces animal biologics using the same processes used to produce human biologics, and therefore, HAP emitted from the production of animal biologics also should be regulated as part of the pharmaceutical NESHAP.

Many commenters stated that the use of the term ''intermediates'' in the definition of pharmaceutical product was confusing and brings many unintended chemicals and processes into the pharmaceutical NESHAP; and therefore, the term should be either clarified or deleted from the definition of pharmaceutical product. One commenter stated that inclusion of the term, ''intermediate,'' in the definition of pharmaceutical product makes it unclear how far back in the manufacturing chain a regulated entity must look when determining applicability. Many commenters stated that operations that manufacture raw materials (such as acids and solvents) that are not precursors to active ingredients in pharmaceutical products should not be regulated as part of the pharmaceutical NESHAP. Several commenters stated that the rule should only apply to processes which produce materials which exclusively or primarily are used to make drug active ingredients. Another commenter stated that EPA needs to clarify that intermediates already regulated by the HON are excluded from the pharmaceutical NESHAP.

Four commenters requested that EPA specifically exclude certain ''nonpharmaceutical products'' from the definition of pharmaceutical product. One commenter expressed concern that due to the inclusion of SIC code 2835 and the phrase, ''regulated by the FDA,'' in the pharmaceutical product definition, equipment used to manufacture medical devices or substances used in the manufacture of medical devices could be subject to the pharmaceutical NESHAP instead of the miscellaneous organic NESHAP (MON). Therefore, the commenter requested that ''medical devices'' be specifically excluded from the definition of pharmaceutical product. A second commenter stated that the rule should not apply to specialty chemical manufacturers who occasionally engage in tolling a pharmaceutical intermediate. The commenter further stated that tolling of pharmaceutical intermediates could be driven overseas if U.S. specialty chemical opera tions require long lead times to identify MACT requirements, develop compliance systems, and amend title V requirements. A third commenter suggested that EPA exclude contract manufacturing from the pharmaceutical rule, and allow it to be covered by the MON. The fourth commenter requested that EPA specifically exclude ''color additives and other inactive ingredients'' from the definition of pharmaceutical product because the commenter interpreted EPA's exclusion of excipients from the definition of pharmaceutical product to mean that the pharmaceutical NESHAP was only intended to cover active ingredients. The fourth commenter also provided a definition of excipients developed by the International Pharmaceutical Excipients Council.

The EPA considered all of the above comments and revised the definition of pharmaceutical product based on these and other considerations. The rationale for the revised definition is presented below.

The EPA agrees with the commenters that SIC codes may be ambiguous, were not developed with environmental regula tion in mind, and may not reflect individual processes within a facility, and therefore, that the use of SIC codes to define pharmaceutical product may introduce unintended ambiguity into applicability determinations. Also, EPA believes that the use of the newer NAICS codes in defining applicability would result in the same problems with ambiguity and intended use. However, based on industry survey responses, EPA recognizes that facilities primarily claiming SIC codes 2833 and 2834 and/or NAICS codes 325411 and 325412 produce medicinals and pharmaceuticals as their primary products. Therefore, for the sake of clarity and consistent with the survey responses, EPA has retained the SIC Codes and added the NAICS codes in the definition of pharmaceutical product.

The EPA also agrees that the term ''regulated by FDA'' is also ambiguous. As noted by one commenter, in 21 CFR section 207.10(e), FDA exempts from registration and drug listing, ''manufacturers of harmless inactive ingredients that are excipients, coloring, flavorings, emulsifiers, lubricants, preservatives, or solvents that become components of drugs, and who otherwise would not be required to register under this part.'' The EPA agrees that some of the processes used to manufacture such substances were not intended for coverage by this rule, and that was the intent of including the phrase ''regulated by FDA'' in the definition of pharmaceutical product in the proposed rule. Based on the comments, EPA believes that a less ambiguous way to define pharmaceutical product would be to base it on definitions contained in 21 CFR 210.3 (Current Good Manufacturing Practice in Manufacturing, Processing, or Holding of Drugs; General) for drug product or active ingredient. These definitions capture formulation products as well as pharmaceutical active ingredients and their precursors.

The proposed rule also was intended to cover intermediates that are manufactured prior to the final processing steps in which a compound becomes a pharma ceutical product. However, EPA recognizes the difficulty associated with defining an intermediate, especially the point at which a chemical becomes associated with pharma ceutical manufacturing. Because the pharmaceutical industry is characterized by numerous processes that may be conducted prior to the actual synthesis and isolation of active ingredients, EPA rejects the notion that, in order to simplify applicability, only those processes yielding active ingredients should be covered by the rule. Rather, EPA agrees with the suggestion that the rule be based on the primary intended use of the materials manufactured. By defining applicability according to primary use as pharmaceutical products or as their precursors, intermediates that are further processed to become active ingredients or drug components are covered. Therefore, in order to clarify the boundaries of the coverage of such precursors or intermediates, the definition of process was changed in the final rule to clarify that the provisions of the subpart apply to materials whose ''primary use'' is as a pharmaceutical product or precursor.

The ''primary use'' approach also addresses the comment regarding the exclusion of contract manufacturing from the pharmaceutical rule. Simply put, contract manufacturers will be subject to this standard during periods when they manufacture a pharmaceutical product. To simplify the determination of applicability for facilities that conduct contract manufacturing, some commenters suggested that the rule apply to processes whose primary product is a pharmaceutical active ingredient. The concept of primary product has been used in past regulations (e.g., HON, P&R IV, etc.) and was not considered in the proposed rule because there was a conscious effort to disengage production equipment from products manufactured. Because the standards are process-based, the intent of the proposal was to cover the production of pharmaceutical products, regardless of what pieces of equipment were used to manufacture them in the course of a year. Conceptually, the primary product definition makes sense for process lines that can be used to manufacture more than one product. In the pharmaceutical manufacturing industry, however, process equipment is reconfigured such that the same pieces of equipment may not always be part of the same process line. Under the current concept of primary product that appears in other rules, it would still be difficult to determine the primary product of a nondedicated process, because not all the same equipment would be associated with the ''process.'' However, by reverting back to the concept of ''primary use,'' owners and operators can clearly delineate applicability based on the intended use of materials they manufacture, and not the equipment they are manufactured in.

The revised definition for pharmaceutical product in today's final rule borrows heavily from definitions contained in 21 CFR 210.3 (Current Good Manufacturing Practice in Manufacturing, Processing, or Holding of Drugs; General). The revised definition of pharmaceutical product and a new definition for primary use are shown below. Also, definitions for ''active ingredient,'' ''component,'' and ''excipient'' have been included in today's final rule.

Pharmaceutical product means: (1) any material described by the standard industrial classification (SIC) code 2833 or 2834; (2) any material whose manufacturing process is described by the north american industrial classification system (NAICS) code 325411 or 325412; (3) a finished dosage form of a drug, for example, a tablet, capsule, solution, etc., that contains an active ingredient generally, but not necessarily, in association with inactive ingredients; or (4) any component whose intended primary use is to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals (the term does not include excipients, but includes drug components such as raw starting materials or precursors that undergo chemical change or processing before they become active ingredients).

Primary use means the single largest use of a material.

For reasons described above and in response to related comments, the applicability language in § 63.1250(a) also has been changed in the final rule such that the rule only applies to those pharmaceutical manufacturing operations that meet the following criteria: (1) they manufacture a pharmaceutical product, as defined in section 63.1251, (2) they are located at a plant site that is a major source as defined in section 112(a) of the Act, and (3) they process, use, or produce HAP. The third criterion was included in response to one commenter's concern that, while the rule covers all processes at a facility which is determined to be major source, some processes at those major sources do not emit HAP. The commenter also stated that although this situation may not pose a significant compliance problem, the lack of an exclusion for these non-HAP emitting processes posed an unwarranted regulatory burden. The EPA agreed with the commenter, and modified the applicability of the rule as described above.

2. Definition of PMPU and Pharmaceutical Manufacturing Operations

The EPA received several comments on the proposed definitions of PMPU and pharmaceutical manufacturing operations. At proposal, PMPU was defined as ''any processing equipment assembled to process materials and manufacture a pharmaceutical product and associated storage tanks, waste-water management units, or components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used in the manufacturing of a pharmaceutical product.'' Pharmaceutical manufacturing operations were defined to ''include PMPU's and other processes and operations as well as associated equipment such as heat exchange systems that are located at a facility for the purpose of manufacturing pharmaceuticals.''

One commenter stated that having both ''pharmaceutical manufacturing operation'' and PMPU in the proposed rule was confusing and redundant. The commenter stated that by having both terms, the rule implies that the definition of PMPU does not cover all of the equipment to be regulated by subpart GGG. The commenter further stated that the inclusion of the phrase ''associated equipment'' in the pharmaceutical manufacturing operations definition was unclear because the definition of PMPU already covers ''associated'' equipment. The commenter also stated that heat exchangers were given as an example of ''associated equipment'' under the definition of pharmaceutical manufacturing operation, but not included as an example in the definition of PMPU. For these reasons, the commenter suggested that the definition of pharmaceutical manufacturing operation be deleted entirely, and that heat exchangers be added to the list of examples of ''associated equipment'' in the PMPU definition.

Two commenters stated that wastewater management units should not be included in the definition of PMPU. One commenter stated that wastewater management units are not subject to the standard, but instead are used to comply with the standard. This commenter also pointed out that neither the HON's definition of chemical manufacturing process unit (CMPU) nor the Polymers and Resin I NESHAP definition of elastomer product process unit (EPPU) includes wastewater management units. The commenter further stated that including wastewater management units in the definition of PMPU could be interpreted to require new source MACT at an existing wastewater management unit if a new, major, dedicated PMPU is built that will contribute wastewaters to that unit. Another commenter stated that packaging operations (e.g., ''placement of dose forms, such as tablets, into containers, and assembly, closure, and labeling of these containers'') are not pharmaceutical manufacturing operations, and thus, should be explicitly excluded from the definition of pharmaceutical manufacturing operations.

Many commenters stated that the definition of PMPU should be modified to make it clear that a PMPU is a group of equipment. These commenters were concerned that, as written, the definition of PMPU could be interpreted to mean that an individual piece of equipment constitutes a PMPU, and thus, the addition of a single piece of equipment to an existing dedicated process line could trigger new source MACT.

Many commenters stated that a PMPU should be identified by its primary product and suggested adding language to the definition that makes it clear that PMPU's manufacture pharmaceutical products as their primary product.

After consideration of the above comments on the definitions of pharmaceutical manufacturing operations and PMPU, EPA has decided to retain both terms, but with some modifications. The terms ''Pharmaceutical Manufacturing Operations'' and ''Pharmaceutical Manufacturing Process Unit (PMPU)'' were not intended in the proposed rule to refer to the same sources entirely. While the term ''Pharmaceutical Manufacturing Operations'' is the broadest term used in the rule and covers all emission sources within a given facility that are the direct or indirect result of pharmaceutical manufacturing, the term ''PMPU'' was intended to encompass each process unit within the facility and its associated equipment. Therefore, the pharmaceutical manufacturing operations encompasse all PMPU's at a given facility as well as equipment that is not included in individual PMPU's. In the proposed rule, the PMPU was used exclusively to define new source applicability in § 63.1250(c). In today's final rule, PMPU's also have replaced ''processes'' in the pollution prevention standard, and therefore, PMPU's serve several functions in the final rule. The PMPU also serves as the basis of the wastewater cutoffs for the standard, at 1 Mg/yr applicability HAP load per PMPU. The EPA believes that the broader term for pharmaceutical manufacturing operations is necessary to include sources that cannot be associated with single PMPU's.

By including wastewater management units in the definition of PMPU at proposal, EPA intended that all wastewater streams and residuals would be considered part of the PMPU. The EPA reviewed the definition of process and PMPU for consistency with the HON and other MACT standards. Wastewater management units are subject to the standard, but manage wastewater from several PMPU. However, wastewater generated in a PMPU is not specifically defined as part of the PMPU, but rather can be associated with it. This convention is analogous to process vent emissions; although they are not specifically identified as part of the PMPU, a PMPU may generate process vent emissions. In deciding whether the PMPU has the potential to emit 10 or 25 tons of HAP, all emissions from all sources associated with the PMPU, including process vents and wastewater, must be considered. Therefore, the definition of PMPU was modified to not specify wastewater streams, residuals, and wastewater management units, as part of the PMPU.

Although EPA recognizes that rarely will one piece of equipment comprise a PMPU, the Agency disagrees with the commenters that a PMPU must always be defined as a group of equipment. The definition of PMPU in today's final rule, however, includes the term, ''process'' which is defined as a ''logical grouping of processing equipment which collectively function to produce a pharmaceutical product'' and ''may consist of one or more unit operations.'' However, a PMPU is not always associated with specific groupings of equipment associated with a given process. (See also section VI.A.3 of this preamble and § 63.1252 of the final rule for a complete definition of process.)

In response to suggestions that EPA define a PMPU by its primary product, the EPA has included a primary use concept in the definition of pharmaceutical product in the final rule as discussed previously in section VI.A.1, above. Based on the comments discussed above and related comments, the definitions of PMPU and pharmaceutical manufacturing operations in today's final rule are as follows:

Pharmaceutical manufacturing process unit (PMPU) means the process, as defined in this subpart, and any associated storage tanks, equipment identified in § 63.1252(f), and components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used in the manufacturing of a pharmaceutical product.

Pharmaceutical manufacturing operations means the facility-wide collection of PMPU's and any other equipment such as heat exchanger systems or cooling towers, that are not associated with an individual PMPU, but that are located at a facility for the purpose of manufacturing pharmaceutical products and are under common control.

3. Definition of Process

The EPA received a number of comments on the proposed definition of process. At proposal, process was defined as ''a logical grouping of processing equipment which collectively function to produce a pharmaceutical product or isolated intermediate. A process may consist of one or more unit operations. For the purposes of this subpart, process includes all or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a product or isolated intermediate. The physical boundaries of a process are flexible, providing a process ends with a product or isolated intermediate, or with cessation of onsite processing. Nondedicated solvent recovery and nondedicated formulation operations are considered single processes that are used to recover or formulate numerous materials and/or products.''

Many commenters requested that the definition of process be clarified to indicate that Quality Assurance and Quality Control (QA/QC) laboratories are not considered part of the process. These commenters were concerned that, although it may be clear that QA/QC labs are not ''processing equipment'' or ''an activity or an operation used to produce a product,'' the words, ''or

other activity, operation,'' may lead to confusion as to whether QA/QC labs are part of the process. The commenters suggested that EPA explicitly exclude QA/QC labs from the definition of process because QA/QC laboratories emit insignificant quantities of HAP, and therefore, time-consuming nonapplicability demonstrations could be avoided.

Several commenters recommended that EPA include storage tanks in the definition of process so that sources that choose to comply using the pollution prevention alternative are not exempted from the storage tank requirements in § 63.1252(b) of the proposed rule. The commenters stated that emissions from storage tanks may be significant, and that sources should be required to comply with the storage tank standards under all circumstances.

Many commenters requested that EPA modify the definition of process to clarify how the process vent provisions will apply to formulation facilities. These commenters were concerned that the use of the term ''nondedicated'' in reference to formulation facilities results in confusion as to how to apply the standard. The commenters pointed out that, unlike equipment used in pharmaceutical chemical synthesis facilities, equipment in a formulation facility are only used to formulate products, and therefore, formulation facilities are ''dedicated'' to formulation operations. However, the commenters also pointed out that the equipment at the formulation facility is used to produce many different products, and therefore, is ''nondedicated.'' For these reasons, the commenters recommended that, for formulation operations, the term, ''nondedicated,'' be applied to the equipment within the facility and not the facility itself. The commenters also requested that for formulation operations, EPA limit the definition of process to formulation activities *within a contiguous area* (such as a formulation building or a contiguous area within a multipurpose building in which formulation takes place). The commenters cited examples where separate formulation operations are located at the same plant site, but are physically separate, and thus would require separate emission control systems.

Another commenter was concerned that use of the term ''nondedicated'' could be interpreted as including solvent recovery or formulation operations that process small quantities of pharmaceutical-related materials, but whose primary use is for a process subject to another MACT rule. The commenter recommended that this issue be resolved by (1) deleting the term ''nondedicated'' from the proposed definition of process, and (2) adding the phrase, ''whose primary use is associated with the manufacture of pharmaceutical products'' after the word ''operations'' in the last sentence of the proposed definition of process.

One commenter suggested that the phrase ''or isolated intermediate'' (used throughout the definition) be deleted because ''processes produce products,'' but ''*portions* of processes produce intermediates.'' The commenter further explained that although the product of one process may be used as a raw material in another process, the product serving as the raw material is not typically thought of as an intermediate.

The EPA has modified the definition of process in the final rule in response to the comments described above. The EPA agrees with the commenters that QA/QC laboratories are not part of the process, and the definition of process in the final rule excludes QA/QC laboratories.

To clarify EPA's intention that storage tanks be included as part of the pollution prevention alternative, and in response to the comments regarding the perceived exclusion of storage tanks from the P2 alternative, today's final rule includes storage tanks in the definition of PMPU and refers to PMPU's instead of ''processes'' in the pollution prevention provisions (see also section V.A.2 of this preamble—Definition of PMPU and Pharmaceutical Manufacturing Operations, and section VI.F—Pollution Prevention Alternative).

The EPA disagrees with the commenters who believe that the term, ''nondedicated,'' as applied to formulation facilities, should be applied to the equipment within the facility and not to the facility itself. As explained in section VI.A.1 of this preamble, the pharmaceutical NESHAP regulates processes, not equipment, and the concept of primary use is applied to the pharmaceutical product, not to the equipment used to manufacture the product. However, today's final rule clarifies the intent of the proposed rule with regard to formulation and solvent recovery operations: those operations occurring within a contiguous area are to be considered as single processes, regardless of the final product of that formulation or recovery operation.

The EPA agrees with the suggestions provided by one commenter to delete all references to ''isolated intermediate'' and has incorporated these comments into the definition of process in the final rule. Also, the definition of pharmaceutical product in the final rule (see section VI.A.1—General Applicability: Definition of Pharmaceutical Product) states that pharmaceutical product ''includes drug components such as raw starting materials or precursors that undergo chemical change or processing before they become active ingredients.'' Therefore, drug components such as raw materials and precursors, which are themselves products of processes, are defined as products, rather than ''intermediates,'' thus eliminating the need for the concept of ''intermediates'' (see also section VI.A.6—Definition of Isolated Intermediate).

For the reasons stated above, the definition of ''process'' in today's final rule is as follows:

Process means all equipment which collectively function to produce a pharmaceutical product. A process may consist of one or more unit operations. For the purposes of this subpart, process includes all or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a pharmaceutical product. Cleaning operations are considered part of the process. The holding of the pharmaceutical product in tanks or other holding equipment for more than 30 consecutive days, or transfer of the pharmaceutical product to containers for shipment, marks the end of a process, and the tanks are considered part of the PMPU that produced the stored material. When material from one unit operation is used as the feedstock for the production of two or more different pharmaceutical products, the unit operation is considered the endpoint of the process that produced the material, and the unit operations into which the material is routed mark the beginning of the other processes. Nondedicated recovery devices located within a contiguous area within the affected source are considered single processes. Nondedicated formulation operations occurring within a contiguous area are considered single processes. Quality Assurance and Quality Control laboratories are not considered part of any process.

The revised definition of process provided above clarifies when a process ends. The EPA selected 30 days as a reasonable period of time, beyond which, if a material has not been further processed or reacted, a process can be considered complete for the purposes of this subpart. Applicability determinations and control requirements would be more difficult without such a time frame. The definition of process is a key element of the rule because most of the

applicability and compliance determinations are based on the process, as a unit. Because of concerns that processes could be artificially divided into smaller portions of processes in order to meet the 2,000 lb/yr limit, EPA limited the number of processes per facility that can comply with the 2,000 lb/yr limit to seven per year. However, EPA also added that processes with very low emissions (less than 100 lb/yr HAP, uncontrolled) would not be counted as part of the seven process limit. These limitations and exemptions are currently under review and may be revised at a later time.

4. Definition of Process Vent

The EPA received several comments on the proposed definition of process vent, primarily related to the following two issues: (1) the establishment of a de minimis level or cutoff below which controls would not be required and (2) how the rule applies to process vents that are manifolded together. At proposal, process vent was defined as ''a vent from a unit operation through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Process vents do not include vents on storage tanks regulated under § 63.1252(b), vents on wastewater emission sources regulated under § 63.1252(d), or pieces of equipment regulated under § 63.1252(e).''

Many commenters requested that EPA modify the definition of process vent to exempt any vent that contains a gas stream with less than 50 ppmv HAP averaged over the unit operation. These commenters cited 40 CFR part 63.113(g) of the HON, which exempts vents with less than 50 ppmv from monitoring or any other provisions of sections 63.114 through 63.118. One of these commenters provided a cost analysis, using EPA's recently released biofilter cost model, for an existing fermentation operation, the emissions from which typically contain less than 50 ppmv methanol. The cost effectiveness of biofiltration for this scenario was estimated to be $27,000/Mg, with a percent control of 60 percent (i.e., from 50 ppmv to 20 ppmv, EPA's established practical limit of control), a value that the commenter stated was ''clearly unreasonable.'' The commenter further stated that for fermenter and fermenter preparation vents, a cutoff of 100 to 200 ppmv could be justified (as opposed to 50 ppmv) and requested that EPA consider such a cutoff.

Two commenters stated that the proposed definition of process vent implies that every process vent is connected to a single piece of unit operations equipment, which often is not the case at multiproduct, multibatch facilities. One of the commenters suggested that the definition include a statement indicating that ''multiproduct facilities having multiple production trains may have large numbers of process vents, which could discharge directly to the atmosphere; discharge through a dedicated control equipment; or which can be manifolded from many process units into a common header leading to a common control equipment.'' The other commenter stated that compliance with the process vent standards would be more difficult and expensive if the definition of process vent included the combined or commingled vents from several pieces of unit operations equipment, rather than just one piece of equipment. This commenter also questioned if standard industrial hygiene type exhaust pickups and general room ventilation exhaust points are meant to be included in the definition of process vents. The commenter pointed out that those types of systems may exhaust through a stack, which may be interpreted as being an emission point, but noted that some states do not consider these emission points for the purposes of Title V permits. The commenter stated that, if these emission points were not considered in developing the MACT floors, they should not be included as process vents, and requested clarification from EPA.

As explained in section VI.C of this preamble, the definition of process vent in today's final rule includes a de minimis cutoff for uncontrolled and undiluted vent streams of 50 ppmv HAP. Regarding multiple vents (from the same process) being manifolded together into a common header, the Agency considers the common header in this rule to be a single process vent, and has revised the definition of process vent to reflect this view. In response to one commenter's question about whether or not industrial hygiene exhausts and general room ventilation exhausts would meet the definition of process vent, these sources would not be considered process vents if they are under the 50 ppmv HAP cutoff. Based on the changes discussed above, the definition of process vent in the final rule is as follows:

Process vent means a vent from a unit operation or vents from multiple unit operations within a process that are manifolded together into a common header, through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Emission streams that are undiluted and uncontrolled containing less than 50 ppmv HAP, as determined through process knowledge, test data using Methods 18 of 40 CFR part 60, appendix A, or any other test method that has been validated according to the procedures in Method 301 or appendix A of this part, are not considered process vents. Process vents do not include vents on storage tanks regulated under § 63.1253, vents on wastewater emission sources regulated under § 63.1256, or pieces of equipment regulated under § 63.1255.

5. Definition of Process Condenser

The EPA received numerous comments on the proposed definition of process condenser. These comments primarily dealt with the dual role of condensers as both process condensers and air pollution control devices, and in which category recirculating condensation systems should be class ified. At proposal, process condenser was defined as ''a condenser whose primary purpose is to recover material as an integral part of a unit operation. The condenser must support vapor-to-liquid phase change for periods of source equipment operation that are above the boiling or bubble point of substances(s). Examples of process condensers include distillation condensers, reflux condensers, process condensers in line prior to the vacuum source, and process condensers used in stripping or flashing operations.''

Many commenters took issue with the phrase ''*integral part* of a unit operation'' and ''process condensers in line prior to the vacuum source.'' These commenters cited examples where it could be concluded that a condenser is not integral to a process because it does not perform any necessary process function. The commenters also stated that if there were two condensers in series prior to a vacuum source, and the first condenser effected a phase change, then the second condenser should be considered an air pollution control device, even though it is located ''prior to a vacuum source.''

Three commenters suggested that the intended use be considered when determining whether a condenser is a process condenser or an air pollution control device. Two of these commenters stated that, ''if the condenser is acting as a control unit, so

that its presence is intended to prevent chemicals from reaching the uncontrolled environment; if the materials collected are led towards management and disposal systems; and if the collected materials are in no way used, reused, nor sold for fuel value, then the condenser is serving as a control unit regardless of the fact that the bubble point is met or not at the source.'' The other commenter disagreed with the condition that to be a process condenser, the condenser must support a vapor-to-liquid phase change for periods of source equipment operation that are above the boiling or bubble point of the substance(s). This commenter pointed out that under the proposed definition, the same condenser will sometimes be a process condenser and sometimes an air pollution control device, and tracking when the condenser switches from one to the other would be burdensome. Therefore, the commenter recommended that the facility which operates the condenser (and knows the process best) be allowed to determine whether it is a process condenser or an air pollution control device.

Another commenter suggested that EPA distinguish between process condensers and condensers serving as air pollution control devices by including a specific temperature limit (i.e., 20°C) such that condensers that lower the temperature of the exit gas stream to a colder temperature would be considered air pollution control devices instead of process condensers.

Many commenters requested that EPA specifically address process condensers that belong to recirculating drying systems. Most commenters stated that condensers in recirculating drying systems should be considered pollution control devices. However, one commenter stated that recirculating condensation systems should be defined as neither process condensers nor air pollution control devices, but defined separately, with ''management systems to account for their pollution prevention effects to be worked out at a later date for the promulgated standard.'' The major concern of all of these commenters, however, was that under the proposed definition, the recirculating condensation systems would be considered process condensers, and thus, the uncontrolled emissions and resulting emissions reductions would be considerably lower than if the condenser was considered an air pollution control device. Even though these systems generate considerably lower emissions as compared to once-through systems, owners and operators could not take advantage of the high emission reductions in the process vent standard that requires 93 percent control or 2,000 lb/yr after control from the entire process.

The EPA disagrees with the suggestion that the owner or operator should be allowed to determine whether a condenser is a process condenser or an air pollution control device based on ''intended use.'' Because one of the formats of the process vent standard requires that a reduction from uncontrolled emissions be applied across a process (i.e., achieve a 93 percent reduction in emissions from the process), EPA is concerned about the opportunity for crediting reductions achieved by condensing boiling streams on other sources in the process. In fact, in requesting data from industry (which was later used to set the MACT floor), the MACT partnership specifically confirmed from responders that the data reported was based on the definition of process condenser as described in the proposed rule. Therefore, EPA has retained the intent of the proposed definition, but has made clarifying changes. The definition of process condenser in the final rule is as follows:

Process condenser means a condenser whose primary purpose is to recover material as an integral part of a process. The condenser must support a vapor-to-liquid phase change for periods of source equipment operation that are at or above the boiling or bubble point of substance(s) at the liquid surface. Examples of process condensers include distillation condensers, reflux condensers, and condensers used in stripping or flashing operations. In a series of condensers, all condensers up to and including the first condenser with an exit gas temperature below the boiling or bubble point of the substance(s) at the liquid surface are considered to be process condensers. All condensers in line prior to a vacuum source are included in this definition.

The EPA also rejects the suggestion to use 20°C as a temperature cutoff in determining whether a condenser is a process condenser or an air pollution control device. Because of the differences in the chemical and physical properties of substances used in the manufacture of pharmaceutical products, one temperature cannot be used to represent all processes; in some cases, a condenser operating at 20°C could actually be an air pollution control device and not a process condenser. Finally, EPA disagrees with the requests that condensers in recirculating drying systems be considered as pollution control devices or defined separately. Emissions from the recirculating drying systems only occur during periodic depressurizations, and these uncontrolled emissions may be low enough such that the process may be under the 2,000 lb/yr cutoff. Processes with recirculating drying systems also may be able to take advantage of the pollution prevention standard.

6. Definition of Isolated Intermediate

At proposal, isolated intermediate was defined as ''any intermediate that is removed from the process equipment for temporary or permanent storage or transferred to shipping containers.'' The concept of an intermediate was also included in the proposed definition of pharmaceutical product which contained a reference to ''intermediates used in the production of pharmaceutical products (see section VI.A.1 of this preamble). One commenter on the proposed rule stated that EPA should not use or define the term, ''isolated intermediate,'' in the pharmaceutical NESHAP. (The same commenter also stated that the term, ''isolated intermediate,'' should be removed from the definition of process [see also section VI.A.3—Definition of Process].) The commenter pointed out that the term is ''peculiar to the Toxic Substances Control Act (TSCA), where a long history of interpretation has been developed,'' and if EPA uses this same term in the pharmaceutical NESHAP, ''inconsistencies in interpretation will be inevitable.''

Many other commenters suggested that the definition of isolated intermediate be modified so that the physical removal of an intermediate from the process equipment is not required as a condition for meeting the definition of isolated intermediate. These commenters pointed out that, in some cases, an intermediate may remain in a storage tank or other retention equipment prior to being used in a different process step, and without ever being removed from either set of process equipment. The commenters further stated that the fact that retention tanks are used as separation lines as an alternative to storing the material in drums or separate containers ''is a matter of convenience.'' Therefore, the commenters recommended the following modified definition of isolated intermediate:

Isolated intermediate means any intermediate that is stored in storage tanks or other holding equipment for later use, or that is transferred to containers for shipment or storage.

After considering these and other related comments (see section VI.A.3 of this preamble), EPA has deleted the

term, ''isolated intermediate,'' from the definition of process to avoid confusion and emphasize that products are the end result of processes. Therefore, isolated intermediates are no longer defined or referred to in today's final rule. Also, the definition of process in the final rule incorporates the commenters' suggestion above regarding the fact that physical removal of the ''product'' from the process equipment should not be a required condition for meeting the definition of ''product.'' In addition, the definition of process in the final rule specifies when a process ''ends.''

7. Research and Development Facilities

Many commenters expressed support for the proposed definition of research and development facilities because it draws a clear distinction between activities related to manufacturing (which are covered under today's final pharmaceutical production NESHAP) and those related to research and development (which are not covered by today's final rule). The commenters further stated that such a clear distinction is necessary because pharmaceutical manufacturing operations and research and development activities are often located at the same site. Many commenters requested that EPA make it clear that pilot plants are not subject to the proposed pharmaceutical standards if they meet the definition of ''research and development facility.'' In determining whether an operation of facility constitutes a research and development facility, it is EPA's intention that owners and operators and implementing agencies should refer to the definition of research and development facility which appears in Section 112(c)(7) of the Clean Air Act, rather than relying on existing company designations or facility names. For example, if a pilot plant is collocated with pharmaceutical manufacturing operations that are subject to this subpart, and the pilot plant meets the criteria outlined in the definition of research and development facility, then the pilot plant would not be subject to this subpart.

Two commenters were concerned that the term ''de minimis,'' as it is used in the definition of research and development facility, was not defined in the proposed rule. One of the commenters stated that, without clarification (of de minimis) the definition will lead to exhaustive and potentially contentious negotiations between sources and regulatory agencies, and may result in inequitable exemption decisions at similar facilities located in different jurisdictions. The commenter also pointed out that some States have included more specific provisions, such as limiting the number of products produced, establishing maximum daily emission rates, or requiring segregation of the R&D activities from the production areas. Although EPA recognizes the concerns of the commenters, today's final rule does not establish a de minimis level for research and development facilities. The EPA does not have sufficient data to establish a de minimis level, and therefore, such determinations will have to be made by the applicable permitting authorities. Also, EPA is in the process of collecting background information on the various segments of research and development facilities nationwide and is considering development of a NESHAP for one or more of these segments in the future.

8. Consistency With Other Rules

The EPA received numerous comments regarding the potential for overlapping regulations. Commenters were strongly opposed to the idea of the same sources being subject to multiple regulations and asked EPA to clarify which regulations applied to pharmaceutical manufacturing operations.

The EPA has identified several potential areas in which today's final standards, the RCRA standards (subpart AA or CC), and/or subpart I of 40 CFR part 63 could apply to the same situation. To avoid inconsistent requirements, the EPA has tried to make the regulatory language as specific as possible as to which regulation(s) the owner or operator must comply with to satisfy the requirements of all regulatory programs. For example, if an air pollution control device is subject to the pharmaceuticals production NESHAP and RCRA requirements, § 63.1250(h)(2) of today's final rule states that the owner or operator may elect to comply with the monitoring, recordkeeping and reporting requirements of either rule, as long as they identify which rule's requirements they have selected in the Notification of Compliance Status report. However, if the owner/operator elects to go with RCRA requirements, there may be additional (minimal) reporting requirements.

Similarly, §§ 63.1250(h)(1), (3) and (h)(4) address overlap with other MACT standards, subpart Kb (the NSPS for organic liquid storage tanks), and subpart I (the negotiated regulation for equipment leaks). After the compliance date for today's final rule for pharmaceuticals production, an affected source subject to Subpart I is required to comply only with the provisions of today's final rule. For sources subject to other MACT standards and NSPS Kb, reporting requirements may be streamlined to the extent that the rules are consistent.

B. Storage Tank Provisions

The proposed and final standards for storage tanks with capacities greater than 20,000 gallons (i.e., reduce HAP emissions by at least 95 percent) represent a control level that is beyond the MACT floor. In deciding to go beyond the MACT floor, EPA determined that floating roof technology was less costly than condensers (which represented the MACT floor technology and 90 percent control) and resulted in greater emission reductions. Many commenters stated that the proposed requirements for storage tanks with capacities greater than or equal to 20,000 gallons represent an increase in stringency (beyond the MACT floor) without precedent. These commenters suggested that 90 percent control of HAP emissions was more appropriate and consistent with the storage tank provisions of similar rules (e.g., the HON and 40 CFR 60, Subpart Kb). The commenters also questioned EPA's assumption that floating roof technology could and would be used to reduce emissions from storage tanks, given the general lack of storage tanks at pharmaceutical manufacturing facilities that are fitted with floating roofs and the use of horizontal storage tanks (which cannot be fitted with floating roofs) at some facilities.

In addition, commenters requested that EPA include in the final rule: (1) an exemption for storage tanks emitting less than 500 lb/yr of HAP (an alternative that was considered and then dropped during the regulatory review .process), and (2) a provision that allows vapor balancing systems as an alternative means of control. The commenters reviewed what was gained by dropping the 500 lb/yr cutoff alternative and concluded that in the top 12 percent of storage tanks, the associated emissions that would not be controlled under the 500 lb/yr cutoff alternative are 2,710 lb/yr (or 150 lb/yr/tank). Based on an annualized cost of $142,500/yr (to control the 2,710 lb/yr), the commenters determined that the cost effectiveness of controlling the emissions from storage tanks with emissions less than 500 lb/yr would be $115,913/Mg. The commenters further stated that the EPA has authority under the law to establish de minimis provisions for exceptions from statutory directives when the benefits of regulation are significantly outweighed by the associated costs and other

burdens, and the 500 lb/yr cutoff alternative meets the criteria for establishing such a de minimis provision, especially considering the fact that the proposed storage tank provisions represent a control level above the MACT floor.

Many commenters stated that the rule should specify that vapor balancing systems meet the requirements of the storage tank provisions. The commenters stated that vapor balancing systems are effective, relatively easy to use, capable of achieving control efficiencies as high as 90 to 98 percent, and are accepted under other rules (both NSPS and NESHAP), and therefore, should be accepted in the pharmaceutical NESHAP. One commenter also pointed out that, when vapor balancing is used (i.e., the storage tank vapor space is routed to the truck), the source of pollution is the vapor content of the truck; however, when the storage tank is vented to a control device, there are two sources of pollution: the HAP vapor from the truck and secondary pollutants from the control device. The same commenter recommended that the State of New Jersey requirements for vapor control (7:27–16.4 VOC Transfer Operations, Other Than Gasoline) be incorporated into the storage tank provisions.

In response to the comments on the proposed storage tank provisions, today's final rule does not include provisions for vapor balancing of storage tanks. However, this issue will be addressed in the Organic Liquids distribution MACT standard. The MACT floor for storage tanks was determined to be 90 percent control of HAP from storage tanks and did not cover tank truck vapor. The EPA also considered the commenters' request for a 500 lb/yr cutoff, but rejected it because a sufficient number of small storage tanks in service at pharmaceutical manufacturing facilities are controlled, and the 500 lb/yr cutoff represents an alternative that is less stringent than the MACT floor, and thus, is not acceptable. The control level for storage tanks with capacities greater than or equal to 20,000 gallons in the final rule is the same as proposed level (i.e., 95 percent). As explained in the Basis and Purpose Document (see Docket A–96–03, Item No. III–B–01), EPA chose 95 percent control (as opposed to the MACT floor) for storage tanks greater than 20,000 gallons because floating roof technology has been demonstrated to achieve 95 percent control and is considerably less expensive than other technologies. Although floating roofs currently may not be in use on storage tanks in the pharmaceutical industry, EPA is not aware of any technical obstacles to their use, except in the case of horizontal tanks. Also, owners or operators still have the option of using add-on controls instead of floating roofs.

C. Process Vent Provisions

The EPA received numerous comments on the proposed standards for process vents. Comments focused on the following areas: (1) establishment of a concentration-based applicability cutoff, (2) implementation of the 98 percent control requirement, (3) new source MACT for process vents, and (4) compliance periods.

1. Applicability Cutoff

Many commenters suggested that EPA establish a concentration threshold below which an emission stream would not be considered a process vent, and thus would be exempt from further applicability determinations, control or monitoring requirements. The commenters recommended a de minimis concentration of 50 ppmv or 50 ppmw for process vents.

After consideration of the above recommendations and comments related to the alternative standard (see section VI.G of this preamble), EPA decided to establish a de minimis cutoff for process vents equal to 50 ppmv HAP, based on uncontrolled, undiluted emissions. The de minimis cutoff is incorporated into the definition of process vent, which states that uncontrolled, undiluted emission streams containing less than 50 ppmv HAP are not considered process vents.

2. Implementation of the 98 Percent Control Requirement

Today's final rule requires facilities to apply an equation in § 63.1254(a)(3) to determine if emissions from the process vent must be controlled by 98 percent as opposed to 93 percent. The applicability equation uses two variables, vent flow and yearly uncontrolled HAP emissions, to calculate a flow rate. The calculated flow rate is then compared to the process vent's actual flow rate, and if the actual flow rate is less than or equal to the calculated flow rate, the process vent requires 98 percent control. A number of commenters believe that the 98 percent control applicability equation should be deleted because it will create a significant recordkeeping burden, will be practically impossible to implement, and will significantly hamper operational flexibility.

The major concern noted by the commenters was that the applicability equation, though fairly straight-forward for dedicated single-product processes, is extremely difficult if not impossible to apply to multipurpose nondedicated processes. The commenters stated that, because nondedicated processes use individual pieces of equipment to make numerous products over the course of a year, the emission stream characteristics of the associated process vents will change depending on the product being manufactured, and thus, the recordkeeping requirements for a single process vent would be burdensome. The commenters also pointed out that a facility may have 200 to 300 individual process vents.

Another concern raised by the commenters was that a slight variance from forecasted production could result in a process vent previously required to control emissions by 93 percent to become subject to the 98 percent control requirement, and the affected facility would not have sufficient lead time to upgrade their control equipment from 93 to 98 percent. The commenters were concerned that such uncertainties will hamper operational flexibility because facilities will be forced to impose limitations on production to ensure that they will not trigger 98 percent control. The commenters also stated that applying the applicability equation to manifolded vents would further complicate matters because more sources emitted through the same vent will result in greater variability of vent stream characteristics.

The commenters also requested that if EPA retains the 98 percent control requirement for existing process vents in the final rule, that § 63.1252(c)(4) in the proposed rule be revised to clearly describe how to apply the 98 percent control applicability equation. Commenters noted that using the past actual annual HAP emissions versus projected annual HAP emissions in the applicability equation is an issue because the production of many products varies from year to year, and historical and forecasted annual HAP emission estimates may be very different. The commenters also were concerned that the proposed rule did not clearly establish how to determine the process vent's actual flow rate, which will be compared to the applicability equation's calculated flow rate. Finally, the commenters suggested that EPA specify that the applicability equation applies to individual pieces of equipment in a formulation facility. The commenters were concerned with how the applicability equation would be applied to nondedicated formulation facilities. The commenters pointed out that nondedicated formulation facilities often use multiple pieces of the same equipment to perform one operation

(e.g., six tray dryers), and not all of these pieces of equipment will be used to produce every product in the formulation facility (i.e., not all trays of the dryer are always used).

After considering the comments above, EPA decided to retain the 98 percent control requirement for existing process vents that meet the applicability criteria. (For those process vents already controlled to 93 percent prior to April 2, 1997, no additional control is necessary.) The applicability equation applies to individual process vents within a process; however today's final rule considers manifolded process vents within each process to constitute a single process vent. With the exception of formulation operations and recovery devices, the definition of process is based on the product manufactured, not the equipment used to manufacture it. Therefore, the determination of which vents require control to the 98 percent level for nondedicated process vents should be straightforward; namely, owners and operators need to anticipate the total uncontrolled HAP emissions per year from each vent from each process, and the average flow rate of the vent. The total uncontrolled emissions should be based on the potential number of batches per year that the facility can run for each process. Based on this projection, the owner or operator can decide whether to install or use an existing 98 percent control device or limit the number of batches to stay below the applicability threshold. Today's final rule also requires facilities to keep track of the number of batches of products they make each year to show that their number of batches is less than the number needed to trigger 98 percent.

In response to the commenters' request, the average flow rate has been clarified in the final rule to mean the weighted average flow rate of the emission events contributing to the process vent. For solvent recovery or formulation operations, the definition of process in today's final rule has been clarified to include all operations within a contiguous area; therefore, for these operations, a single process may be associated with several products. Like other processes, the application of the 98 percent control applicability equation should be based on individual process vents or manifolded vents. Thus, if each piece of equipment that is located at a formulation facility, considering processes by contiguous areas, has a separate vent, then the applicability equation is applied to each vent separately; however, if the vents from each piece of equipment are manifolded together, then they are treated as one process vent and the equation is applied to the aggregated flow.

As part of the rationale for retaining the 98 percent requirement, EPA notes that this level of control is imposed only on vents that have the potential to emit 25 tons/yr or more, on an uncontrolled basis. Secondly, the applicability equation is indexed on cost-effectiveness. Streams that are too dilute for cost effective control would not, per the equation, be required to be controlled. Third, process vents already controlled to levels of 93 percent or greater prior to April 2, 1997, would be grandfathered and not required to increase controls to 98 percent. The EPA believes that after these considerations are made, only very large streams that are cost effective to control to 98 percent will trigger the 98 percent control requirement.

3. New Source MACT for Process Vents

At proposal, new source MACT for process vents was set at 98 percent control for process vents with uncontrolled emissions greater than or equal to 400 lb/yr. The rationale for the 400 lb/yr cutoff (uncontrolled) was that it represented the smallest controlled process considered to be a similar source. Many commenters stated that the standard for new process vents should include a 2,000 lb/yr controlled emissions compliance alternative, because it is unreasonable and unwarranted to require vents with low HAP emissions to achieve 98 percent control. The commenters agreed with EPA's conclusion that 98 percent control represents the best controls in practice for certain sources; however, the commenters believe that the applicability cutoff for new source MACT for process vents is legally flawed because the cutoff did not consider two of the four process types in the industry (fermentation and extraction). The commenters also stated that the process on which the 400 lb/yr cutoff is based is not representative of the industry's processes because the process emits primarily one HAP (methanol) and is controlled by a dedicated scrubber and appears to be only a portion of a process based on the EPA's definition of process in the proposed rule. Citing other rules that set new source MACT as the average level of control achieved by sources using new source MACT control technology, the commenters performed an analysis of the MACT floor data base and determined that the average level of controlled emissions from the best-performing 12 plants was approximately 1,400 lb/yr. The commenters excluded two processes from their analysis that had uncontrolled emissions greater than 1 million lb/yr because these processes are much larger than the typical pharmaceutical manufacturing process and would skew the data. According to the commenters, if these two (larger) processes are included in the analysis, the average level of controlled emissions from the best-performing 12 plants would equal 6,400 lb/yr.

The EPA has reviewed the data used to set the MACT floor for process vents at new sources. Based on this review, the EPA has concluded that the data support the level of the proposed standard for new sources.

The EPA based the 98 percent control requirement on the 26 processes (under the proposed definition) at 7 plants in the data base that achieve or exceed this control level. These processes include dedicated and nondedicated formulation, chemical synthesis, and fermentation processes. The EPA has concluded that these processes are representative of the control challenges faced by the industry despite the fact that the data do not include an extraction process. The EPA has further concluded that the 98 percent control level achieved at the best controlled processes is applicable to all four process types.

The EPA does not believe that the variation in exhaust gas characteristics among the four types of processes in the industry is significant enough to warrant individual evaluation of achievable control levels. In any case, extraction processes are typically solvent-intensive, resulting in the highest average HAP concentration of the four types of processes. High HAP concentrations are conducive to high percent control levels.

The commenters suggested that the EPA adopt a 2,000 lb/yr actual emissions compliance alternative to account for variability within the industry. The commenters based this alternative on the average level of controlled emissions from 24 of the processes in the data base that achieve 98 percent control or greater. (The commenters excluded the other two processes in the data base because they were atypically large.) The EPA does not believe that the analysis presented by the commenters is an appropriate basis for a new source compliance alternative. First, while the commenters imply that the alternative is needed to account for variability in the control level that is achievable by the wide variety of pharmaceutical processes, the analysis does not address control efficiency at all. Because the commenters evaluated only processes that achieve at least 98

percent control, only variability in uncontrolled emissions truly figures into the analysis. Second, the alternative standard suggested by the commenters is not equivalent to the percent reduction standard and would result in greater total emissions of HAP from the industry. Finally, the EPA analyses cited as precedents address different situations and provide scant support for the commenters' analysis.

While the EPA has rejected the alternative standard suggested by the commenters, the final rule provides a 20 ppmv outlet concentration alternative to 98 percent control for process vents at new sources. This alternative addresses the primary impediment to achieving 98 percent control, i.e., low inlet concentration gas streams.

The EPA based the proposed applicability cutoff for new source process vents on the smallest representative process in the data base that achieves 98 percent control or greater. The commenters questioned whether this operation actually qualifies as an entire process under the proposed definition of ''process'' and whether the operation is representative of processes in the industry. Although the EPA continues to believe that the formulation operation selected as the basis for the proposed cutoff is a process under the proposed definition, it may not qualify as a process under the final definition because nondedicated formulation operations occurring within a contiguous area are now considered single processes. Consequently, the EPA has reanalyzed the data based on the final definition of ''process.'' In light of the new analysis, it is no longer relevant whether the process upon which the proposed cutoff was based is representative of the industry.

The new analysis was similar to the original analysis. After revising the data base of well-controlled sources to conform to the final definition of ''process,'' the EPA identified the smallest processes that are controlled by 98 percent or more. As in the previous analysis, formulation and chemical synthesis processes are the smallest processes. Two chemical synthesis processes, one emitting 85 lb/yr uncontrolled and another emitting 304 lb/yr uncontrolled, were identified as achieving control of 98 percent. Although these processes were reported as individual (single) processes, EPA summed emissions from both, since the product name listed for each was very similar, and EPA wanted to be conservative. The total uncontrolled emissions from the sum of these two processes is 390 lb/yr, which is the same level of emissions as the proposed cutoff. Therefore, the EPA has established in the final rule the new source process applicability cutoff of 400 lb/yr of uncontrolled HAP.

Despite the fact that no fermentation or extraction processes were among the smallest well-controlled processes, the EPA believes that the analysis is representative of the control capabilities of all process types. As discussed previously, the EPA has concluded that the gas streams generated by the four types of processes in this industry are similar enough that an individual analysis by process type is not warranted. Fermentation and extraction processes are typically much larger than formulation and chemical synthesis processes. Thus, the absence of fermentation and extraction processes in the list of the smallest well-controlled processes is the result of this size differential, not a difference in the control level that can be achieved. In fact, the average uncontrolled HAP concentration of fermentation and extraction process vents exceeds those of formulation and chemical synthesis process vents. Higher concentrations are more conducive to high percent control.

Practically speaking, new source MACT will apply to low HAP-emitting processes only at new facilities, where the minimum control requirement is 98 percent for all processes. (At existing sites, new source MACT will apply only to dedicated new PMPU's with a potential to emit 10 tons/yr of a single HAP or 25 tons/yr of all HAP combined.) Thus, sources will not be faced with the need to install 98 percent-efficient controls dedicated to small new processes, which could be very costly for a small amount of emission reduction. Instead, the EPA expects that sources will achieve the new source MACT standard using large control devices that treat multiple manifolded gas streams. Because this is the control situation most typically found for the small processes in EPA's data base of well-controlled sources, the EPA believes that the final rule's applicability cutoff accurately reflects what will be achievable at new sources in this industry.

4. Compliance Period

Several commenters stated that they support the proposed annual compliance period for process vents and noted the inconsistency with the daily continuous compliance provisions. If the final rule includes a shorter compliance period, the commenters have stated that either the standards must be adjusted to avoid an increase in stringency above the floor or a demonstration must be made that the increased stringency (i.e., going above the floor) is justified according to the requirements of the Clean Air Act. The EPA, in the final rule, has clarified the compliance period of the standard to be either on a 24-hour basis, or on a batch cycle or ''block'' basis. Additionally, compliance periods for emissions averaging are on a quarterly basis, while compliance periods for the P2 standard are on an annual basis, as calculated on a monthly or 10-batch rolling average. An annual compliance period for the standards was determined by EPA to be too difficult to implement. The annual compliance period implies that owners and operators could control processes to varying degrees during the course of a year, as long as the yearly percent reduction target could be met. While this format would offer flexibility to owners and operators that would want to change control strategies to accommodate production scheduling and operational changes, EPA believes that the demonstration of compliance over such an extended time period would result in delayed compliance determinations and the possibility for extended periods of violations. The EPA notes that the final rule offers some flexibility to owners and operators in addressing variability within the processes themselves by providing numerous compliance options. Therefore, EPA does not believe that by clarifying the final rule to reflect a daily compliance period, the stringency of the standard was increased.

D. Wastewater Provisions

1. MACT Floor

The EPA estimated that 101 pharmaceuticals facilities would be major sources subject to the rule. The MACT floor is based on available information about control levels at all of these sources. One commenter asserted that the applicability section of the proposed rule covers more types of facilities than those in the original MACT floor analysis, and thus the MACT floor should be recalculated. The EPA did not recalculate the MACT floor because, as noted in section VI.A.1 of this preamble, the applicability in the final rule is clarified to eliminate the likelihood that the rule would apply to types of facilities other than those represented in the 101 in the initial analysis.

2. DeMinimis Cutoff in Definition of Wastewater

The final rule includes de minimis cutoffs for determining if a water stream is wastewater. One commenter requested that HAP concentration and

flow rate cutoffs be added, as in the HON. The commenter contended that the burden to characterize streams with very small HAP loadings would be excessive without such cutoffs. For the final rule, EPA revised the definition of wastewater to include de minimis HAP cutoffs of 5 ppmw and 0.05 kg/yr, which is consistent with the HON. Although the owner or operator is given some flexibility in the methods used to characterize these streams, the Administrator may require the owner or operator to validate this information through sampling and analysis or other appropriate means.

3. Cross-References to the HON

The wastewater provisions in the proposed rule contained numerous cross-references to the wastewater provisions in §§ 63.132 through 63.148 of the HON. Many commenters requested that the applicable provisions from the HON be included in the final rule because the extensive cross-referencing made the proposed rule hard to understand and would likely be hard to implement. Some comments also noted that many cross references were not consistent with the most current version of the HON. To address these concerns, EPA decided to incorporate the applicable provisions from the HON in the final rule. These provisions include the emission suppression requirements from §§ 63.133 through 63.137, the control device requirements from § 63.139, the general procedures for determining compliance from § 63.145, many of the compliance options for treatment systems and control devices from §§ 63.138 and 63.145 (additional information about compliance options is provided in section VI.D.4), the inspection and monitoring provisions from §§ 63.143 and 63.148, the requirements for certain liquid streams in open systems within a PMPU from § 63.149, and the tables that are referenced from all of these sections.

4. Additional Treatment Options for Demonstrating Compliance

Several commenters requested that the rule include additional treatment options for demonstrating compliance. Some comments requested that all of the options in the HON be added to the rule. Other comments specifically requested that the rule allow treatment in RCRA units and that a concentration limit be developed for soluble HAP. In response to the comments, EPA included additional treatment options in the final rule that are consistent with the standards. All of the RCRA options from the HON were added because treatment in these units will meet the standards. A concentration option of 520 ppmw for soluble HAP was added because this level is consistent with the 90 percent reduction requirement for soluble HAP.

Four options from the HON were not added to the final rule. The design steam stripper option was not added because the available stripper designs that were used to estimate impacts have not been tested in the field. The percent mass removal/destruction option based on fraction removed (Fr) values was not added because the Fr values would be identical to the percent reduction option. The 1 Mg/yr option was not added because any facility with wastewater containing a load of total partially soluble and/or soluble HAP less than 1 Mg/yr would have no affected wastewater streams. The required mass removal options were not included because wastewater discharges from batch pharmaceutical processes are much more variable than those from continuous SOCMI processes; therefore, the required mass removal is likely to be different at any given time, and is not likely to correlate well with the actual mass removal in the treatment unit at a given time.

5. General Compliance Procedures

The proposed rule cross-referenced the specific procedures in the HON for determining compliance with the standards when using various types of treatment units (i.e., noncombustion, combustion, or biological), but the general procedures used to determine compliance that are applicable to any performance test (or design evaluation) were not cross-referenced. Several commenters requested that these general procedures also be included in the rule. Specifically, the commenters requested that the rule specify that: (1) performance tests be conducted under representative operating conditions, (2) treatment may be conducted using a series of treatment devices, (3) treatment may be conducted offsite or in onsite treatment units not owned by the source, and (4) any biological units in compliance with the standards need not be covered and vented. Commenters also requested that the rule include: (1) procedures for the preparation and installation of testing equipment and (2) requirements for compounds that do not need to be considered in performance tests or design evaluations. The final rule includes all of these provisions; however, clarification of two points is provided below.

Clarification of the provision for testing under representative operating conditions is provided because the commenters misinterpreted the meaning of this provision in the HON. This provision requires a facility to conduct a single performance test under representative operating conditions. If actual operating conditions vary, such that there are multiple representative operating conditions, the owner or operator must supplement the test results with modeling and/or engineering assessments to demonstrate that the standard is met over the entire range of operating conditions. Testing under representative operating conditions does not mean the standard is an average that may be exceeded under certain conditions.

A clarification of the provision that allows open biological treatment units to be uncovered is also provided. Except for enhanced biological treatment units used to treat certain wastewater streams, an owner or operator demonstrates compliance for open biological treatment units by conducting a performance test and following the procedures in appendix C of part 63. If these procedures show the fraction biodegraded meets or exceeds the applicable control level, the treatment unit need not be covered. An enhanced biological treatment unit that is used to treat wastewater containing soluble HAP and less than 50 ppmw of partially soluble HAP is exempt from the performance test requirements and need not be covered.

6. Default Biodegradation Rate for Methanol

One commenter urged EPA to revise the default methanol biodegradation rate constant that is used in Table 37 of subpart G of the HON because it cannot be scientifically supported with available data. Based on data from a number of studies, the commenter concluded that the rate in the proposed rule is low by a factor of 10 to 100. The commenter noted that the geometric mean of the rates from the available studies was 8.6 L/g MLVSS-hr, and the lower bound of the 90 percent confidence interval was 3.5 L/g MLVSS-hr. The commenter also cited data in the scientific literature that show hexachlorobenzene, chlorobenzene, nitrobenzene, and biphenol (other list 1 compounds) to be less biodegradable than methanol, whereas Table 37 of the HON shows methanol to be less biodegradable than the other compounds.

The data submitted by the commenter show considerable variability, but they also show the higher biodegradation rate constants tend to correspond with higher methanol concentrations in the wastewater. The EPA concluded that a

methanol biodegradation rate constant higher than the default is appropriate for pharmaceutical facilities that are direct dischargers because they tend to treat wastewater with higher methanol concentrations than indirect dischargers or facilities in other industries. The final rule allows these facilities to use a methanol biodegradation rate constant of 3.5 L/g MLVSS-hr, the lower bound of the 90 percent confidence interval; this is a conservative value that minimizes the likelihood that the biodegradation rate will be overestimated.

7. Maintenance Wastewater

The wastewater provisions apply to both process and maintenance wastewater. Commenters requested that maintenance wastewater provisions be less stringent than those for process wastewater, as in the HON. According to one commenter, the same conveyance systems and controls are not practical or cost effective for maintenance wastewater. The EPA did not change the maintenance wastewater provisions because maintenance wastewater is a potential source of significant emissions. Furthermore, procedures to estimate maintenance wastewater characteristics should be the same as those for most process wastewater because both consist of batch discharges.

8. Control Requirements for Wastewater Tanks

The rule requires that wastewater tanks have either a fixed roof or additional controls, depending on tank design and/or operating characteristics. A number of commenters expressed confusion over these provisions and offered their interpretations or preferences to clarify the provisions. Under the rule, wastewater tanks that have a capacity of less than 75 m^3, a capacity between 75 and 151 m^3 that contain material with a vapor pressure less than 13.1 kPa, or a capacity greater than or equal to 151 m^3 that contain material with a vapor pressure less than 5.2 kPa are required to have a fixed roof unless the wastewater in the tank is heated, treated with an exothermic reaction, or sparged. If any of these three conditions is not satisfied, the owner or operator must install a floating roof or use control techniques that achieve equivalent emission reductions. These provisions match those in the HON. The proposed rule also included an additional provision that caused the confusion for the commenters. The intent of the provision was to exempt wastewater tanks from the additional control provisions, but not the fixed roof requirement, if the owner or operator demonstrates that the total partially soluble and/or soluble HAP emissions from a fixed roof tank that is heated, treated with an exothermic reaction, or sparged are less than 5 percent higher than the emissions would be in the absence of these activities. This additional provision is rewritten in the final rule to improve clarity.

9. Compliance Requirements for Biological Treatment Units

The EPA received numerous comments on the initial compliance procedures and monitoring requirements for enhanced biological treatment units. Some commenters requested that compliance demonstrations be based on parameters related to soluble HAP removal, not general compliance with all NPDES permit limits; the commenters suggested monitoring for surrogate parameters like COD, BOD, and/or TSS. Some commenters stated that EPA's definition of significant noncompliance in appendix A of 40 CFR 123.45 should be used as the basis for defining acceptable enhanced biotreatment operation for both POTW's and direct dischargers. One commenter stated that compliance provisions should focus on the indirect discharger, not the POTW; for example, the indirect discharger should be in compliance with the pretreatment provisions in 40 CFR 403 and 439. Several commenters stated that the provision allowing discharge to an enhanced biological treatment unit at a POTW only if the indirect discharger demonstrates that less than 5 percent of the soluble HAP in the wastewater from the POD's is emitted from the municipal sewer system is unnecessary and burdensome.

The compliance procedures for biological treatment units are rewritten in the final rule for clarity, simplification, and as noted above, to eliminate cross-references to the HON. Because the changes are extensive, all of the compliance procedures and monitoring requirements for biological treatment units, not just the issues raised by the commenters, are summarized below.

Onsite or offsite biological treatment units may be used to comply with the standards for soluble HAP, and onsite biological treatment units may be used to comply with the standard for total soluble and partially soluble HAP. The compliance requirements vary depending on the concentration of partially soluble HAP in the wastewater, whether the treatment unit is open or closed, whether the biological treatment unit is enhanced, and whether the wastewater is treated onsite or offsite.

If wastewater containing soluble HAP and any concentration of partially soluble HAP is treated in an open, onsite biological treatment unit that does not meet the definition of an enhanced biological treatment unit, the owner or operator must conduct an initial performance test to determine the fraction biodegraded (f_{bio}) in the unit; the f_{bio} for the compounds may be calculated using any of the procedures in appendix C to 40 CFR part 63, except procedure 3 (inlet and outlet concentration measurements). As noted in section VI.D.5, the treatment unit may remain open if the fraction biodegraded meets or exceeds the level of the standard. For a closed biological treatment system, the owner or operator may follow the same procedure; alternatively, the owner or operator of a closed biological treatment unit may conduct either a design evaluation using procedure 3 or a performance test to determine the mass reduction of soluble HAP (or total soluble and partially soluble HAP) in the unit. Under the proposed rule, the owner or operator of open and closed biological treatment units would have been required to specify appropriate monitoring parameters in the Notification of Compliance Status Report, subject to approval of the permitting authority. Based on consideration of the comments, EPA decided to specify continuous monitoring requirements for TSS and BOD in the final rule. To be in compliance, the TSS and BOD concentrations must not exceed the TSS and BOD criteria in 40 CFR 439 more frequently than, or by amounts greater than, allowed by the noncompliance reporting criteria in 40 CFR 123.45, appendix A.

If wastewater containing soluble HAP and more than 50 ppmw of partially soluble HAP is treated in an onsite, enhanced biological treatment system, the compliance procedures are the same as described above, except that the f_{bio} for soluble compounds may be calculated using either the default for first order biodegradation constants or any of the procedures in appendix C of 40 CFR part 63. As noted in section VI.D.6, the owner or operator may use a biodegradation rate constant of 3.5 L/g MLVSS-hr for methanol. The owner or operator also must monitor for TSS and BOD as described above. In addition, to demonstrate continuous compliance with the 1 kg/m^3 level in the definition of enhanced biological treatment unit, the owner or operator must monitor the concentration of MLVSS.

If wastewater containing soluble HAP and less than 50 ppmw of partially soluble HAP is treated in an onsite, enhanced biological treatment unit, the owner or operator is exempt from the performance test requirement for the treatment unit. Monitoring for TSS, BOD, and biomass is required as described above.

Wastewater containing soluble HAP and less than 50 ppmw of partially soluble HAP may be transferred for offsite treatment or onsite treatment in a unit not owned by the source. Before the source may transfer such wastewater, the transferee must submit to EPA written certification that the transferee will manage and treat any affected wastewater or residuals in accordance with the requirements of the rule. The initial compliance procedures and monitoring requirements to show continuous compliance are the same as for similar onsite units treating the same wastewater. In response to the comments, EPA reexamined emissions from municipal sewer systems and determined that the major potential for emissions is from the headworks. Thus, if the wastewater is discharged to a POTW, the final rule requires the owner or operator to demonstrate that less than 5 percent of HAPs are lost. However, if the headworks at the POTW are covered, no such demonstration is required. The same emission suppression requirements apply if the wastewater is discharged for treatment in any other type of offsite treatment unit or onsite treatment unit not owned by the source.

10. Control Requirements for Individual Drain Systems

The rule requires emission suppression and control measures for all individual drain systems that manage affected wastewater or residuals onsite. Several commenters requested that EPA exempt individual drain systems from these requirements, and allow them to be vented to the atmosphere, if they either manage wastewater that contains only soluble HAP compounds and de minimis amounts of partially soluble HAP compounds or demonstrate that emissions from the individual drain system and associated wastewater tanks are less than 5 percent of the loading in the affected wastewater. The commenter's rationale for this request was that: (1) a PhRMA study of municipal sewers, which was submitted to EPA, showed the potential emissions from individual drain systems that manage wastewater containing primarily soluble HAP are low; (2) the control is not cost effective; and (3) emissions of combustion products would increase because facilities would meet the requirement with steam strippers or incinerators.

For wastewater, EPA determined that MACT consists of hard-piping to a steam stripper. Because this configuration was determined to be a reasonable MACT floor requirement, any alternative must achieve equivalent emission reductions. As in the HON, a covered individual drain system is considered equivalent to hard piping. Thus, EPA did not change the requirements for individual drain systems in the final rule.

E. Equipment Leak Provisions

Several commenters raised a number of issues related to equipment leaks and EPA's proposed requirements for the LDAR program developed for the pharmaceutical manufacturing industry. The proposed general equipment leak requirements were based on subpart H (from the HON rule) and included slight changes tailored for the pharmaceutical industry. Some commenters were confused by the requirements and others were concerned that some facilities will be subject to two different LDAR programs because some pharmaceutical manufacturing operations are already subject to subpart I (which requires compliance with subpart H of the HON for components at pharmaceutical production processes that use carbon tetrachloride or methylene chloride). Today's final rule clarifies EPA's intent that affected sources that are subject to today's final rule and subpart I of 40 CFR part 63 will no longer be required to comply with subpart I after the compliance dates for today's final rule. Many commenters argued that EPA is bound by the subpart I regulatory negotiation and therefore, is not allowed to expand the LDAR requirements to include any HAP other than carbon tetrachloride and methylene chloride. The Clean Air Act requires that EPA regulate all major sources of HAP. The regulatory negotiations conducted in the development of subpart I included only a certain fraction of components from the industry because that was the extent of information that EPA had at the time the negotiations were conducted. The Agency does not agree that the negotiated rule for equipment leaks precludes further regulation of equipment leaks for pharmaceutical manufacturing operations.

Some of the changes and assumptions made in estimating the uncontrolled emissions for the industry used in determining the proposed LDAR requirements were questioned by the commenters. A group of commenters disapproved of the Agency's revised method to estimate uncontrolled emissions using the uncontrolled SOCMI average emission factors. The commenters argued that none of the studies used in developing the SOCMI emission factors involved pharmaceutical manufacturing operations.

Commenters also questioned EPA's assumptions and data used in some of the LDAR cost calculations. In general, commenters stated that the actual cost-effectiveness value associated with the proposed LDAR program was much higher than EPA's estimate due to overestimated emission reductions and underestimated costs. In response to these comments, the Agency reviewed its cost analysis and recalculated the cost effectiveness of several LDAR programs. The most acceptable program, in terms of cost effectiveness, is based on requirements similar to those of other recent regulations for similar manufacturing industries and the provisions developed for the SOCMI Consolidated Air Rule (CAR) which is yet to be proposed. The most significant difference between the CAR equipment leaks subpart and the proposed equipment leaks provisions is the innovative approach taken in the CAR to monitoring valves and connectors for leaks.

The CAR program significantly reduces the amount of burden associated with monitoring these types of equipment for leaks without increasing the emissions of regulated pollutants to the environment. In calculating the impacts of requiring an LDAR program meeting the requirements of the CAR, EPA calculated monitoring costs based on established guidance and calculated uncontrolled emissions using initial leak frequencies reported from the industry. The details of this analysis are included in the project docket (A–96–03) as Item No. IV–B–5. The EPA, in reassessing industry leak data, addressed many of the concerns of the commenters relative to the inclusion or exclusion of specific data.

Using as a starting point leak data that was confirmed as initial survey data by PhRMA, EPA reviewed the data base and further defined the pool of data. Some data from PhRMA's compilation was revised to reflect reported leak definitions, also, some data was excluded based on the facility's explanation of frequency of monitoring and calculated leak rates and the conclusion that the leak rates did not indeed reflect initial monitoring data. The resulting initial leak rate data was

1.45 percent for valves, 6.88 percent for pumps, and 1.5 percent for connectors.

The subsequent leak rates are a critical parameter in calculating the overall cost effectiveness of any LDAR program. Limited data were available to determine the leak rates at pharmaceutical manufacturing frequencies after the application of LDAR. Therefore, EPA assumed that the equipment leak frequency occurrence rate after implementation of LDAR was equal to the performance levels required in the draft CAR, that repairs were 100 percent effective, and that there were no recurrences of leaks. For the CAR rule, where several performance levels and corresponding monitoring schedules are available, occurrence rates were based on the best performance levels and longest monitoring intervals available. For flanges and valves, this performance level is 0.25 percent leakers. The corresponding monitoring interval for flanges is once every 8 years; for valves, it is once every 2 years. For light liquid pumps there is no performance level specified, therefore it was assumed that the leak occurrence rate was equal to 50 percent of the initial leak frequency. Subsequent leak frequencies for the revised EPA analysis were estimated to be 0.25 percent for valves, 3.44 percent for pumps, and 0.25 percent for connectors.

Emission reductions for the program were estimated to be the difference between the uncontrolled emission rate, as calculated using the mass emission rate, in kg/hr-source, calculated from the Average Leak Rate (ALR) equations and initial leak data, and the controlled emission rate, calculated using the ALR equations and assumed subsequent leak frequencies. The controlled emission rate was based on one-half of the occurrence rate. This assumption was necessary to account for the average leak frequency over the entire monitoring cycle.

The EPA, in the revised analysis, also addressed concerns of the commenters related to specific cost items. In general, capital and annualized costs for monitoring instruments, data management systems, and actual monitoring are not unreasonable and fall within the costs quoted by vendors and LDAR contract services, based on recent inquiries by EPA. Therefore, EPA did not revise significantly any cost items used in the model facility analysis.

Based on this revised analysis, the Agency found that the cost effectiveness of the CAR LDAR program was approximately $1000/Mg HAP for a model pharmaceutical facility.

After consideration of the above comments, EPA revised the proposed leak detection and repair provisions to be consistent with the Agency's recent efforts toward consolidation of equipment leak requirements for air regulations, the increased focus on processes with leaking components, and a general lessening of monitoring and recordkeeping and reporting requirements for processes with nonleaking components. Most of the changes to the proposed rule involve the requirements for valves and connectors in gas/vapor service and in light liquid service. These changes include the addition of 2 year monitoring (instead of once every four quarters) for those processes with less than 0.25 percent leaking valves; extending the monitoring period for connectors with low leak rates; provisions for valve subgrouping; deletion of the quality improvement program implementation requirement and the credit for valves removed; and revisions to the calculations for determining the percentage of leaking valves. The Agency believes that the equipment leak requirements included in today's final rule greatly reduce the administrative burden associated with LDAR recordkeeping and reporting, and at the same time, result in a significant reduction in emissions.

F. Pollution Prevention Alternative

Many comments were received on the proposed pollution prevention alternative, primarily relating to the proposed restrictions to the use of this alternative and the lack of specific recordkeeping and reporting requirements. The following sections summarize the commenters' concerns regarding the proposed pollution prevention alternative, EPA's response to these concerns, and subsequent changes made in today's final rule.

1. Restrictions on the Pollution Prevention (P2) Alternative

At proposal, processes emitting HAP that are generated in the process were perceived by commenters as being prohibited from using the pollution prevention alternative. Many commenters stated that processes that generate HAP should be allowed to use the P2 alternative as long as these quantities were included in the analysis. These commenters also recommended that the rule provide a de minimis HAP generation cutoff below which facilities could use the P2 alternative. The EPA agrees with the commenters that PMPU's that generate HAP emissions should be eligible for the P2 standard, provided the HAP emissions generated by the PMPU are controlled to the required levels. Therefore, today's final rule clarifies that processes that generate HAP can use the P2 alternative, provided that the HAP emissions generated in the PMPU are controlled to the required levels for storage tanks, process vents, wastewater and equipment leaks in §§ 63.1253 through 63.1256 of today's final, and the remaining requirements of the P2 alternative are met. Because the final rule requires sources to account for HAP generated in the process, a de minimis HAP generation cutoff is not needed.

No increase in the production-indexed VOC consumption factor was allowed as the result of compliance with the P2 alternative at proposal. One commenter stated that the stipulation in the P2 alternative that does not allow for an increase in the VOC consumption factor as a result of a decrease in use of HAP is unfair. According to the commenter, this restriction will eliminate many solvent replacement projects. The example that the commenter used was a 100 percent reduction in the use of methylene chloride (a non-VOC HAP) by replacing this solvent with a water-based solvent that contains trace amounts of some VOC. This trace amount of VOC would result in an increase in the VOC consumption factor. The commenter further explained that HAP solvents generally tend to have more aggressive solvent properties than non-HAP, and thus, when replacing a HAP solvent with a non-HAP solvent, the result is generally lower yields, more extensive processing, or higher quantities of solvent used. The commenter suggested that an upper limit could be set on the increase in VOC consumption, and gave a ''conservative'' limit of two times the baseline production-indexed VOC consumption factor.

In developing the pollution prevention alternative, EPA's intention was to recognize those processes that have reduced or will reduce the amount of HAP solvents used in the manufacture of pharmaceutical products as viable alternatives to add-on controls. By preventing affected sources from increasing the production-indexed VOC consumption factor, EPA intended to prevent solvent substitutions that merely swapped HAP for VOC. After reviewing the proposed pollution prevention standards in light of commenters concerns, EPA realized that the proposed standards gave an unfair advantage to affected sources that use VOC-HAP solvents as opposed to non-VOC HAP solvents. As proposed, the rule did not allow affected sources using non-VOC HAP solvents to switch to

low-VOC solvents and still qualify under the pollution prevention alternative because of the automatic increase in the production-indexed VOC consumption factor. However, affected sources that use VOC-HAP solvents could switch to low-VOC solvents as long as the production-indexed VOC consumption factor did not increase. The EPA's intention in the final rule is that pollution prevention be accomplished through reductions in solvent usage as opposed to solvent substitution. However, the EPA realized that the proposed rule gave an unfair advantage to sources using VOC-HAP solvents as opposed to non-HAP solvents because the rule did not allow affected sources using non-VOC HAP solvents to switch to VOC solvents and still qualify under the pollution prevention alternative. After consideration of this concern, EPA changed the final rule to require an equivalent reduction in the production-indexed VOC consumption factor, if the reduction in the production-indexed HAP consumption factor is achieved by reducing a HAP that is also a VOC. If the reduction in the production-indexed HAP consumption factor is achieved by reducing HAP that is not VOC, the consumption-indexed VOC factor may not be increased. In making these changes to the final rule, EPA essentially eliminated the possibility of receiving credit, through the pollution prevention alternative, for substituting VOC for HAP.

For example, a given PMPU has established its baseline production-indexed consumption factors of 10 kg/kg HAP and 20 kg/kg VOC. The 10 kg/kg HAP factor is made up of 4 kg/kg methanol and 6 kg/kg methylene chloride. The 20 kg/kg VOC factor is made up of 16 kg/kg ethanol and 4 kg/kg methanol. In order to comply with the P2 alternative, the owner/operator would be required to reduce their 10 kg/kg HAP factor to 2.5 kg/kg. This could be accomplished in a number of ways. Even if all the methanol were eliminated, a reduction of 3.5 kg/kg methylene chloride would still be required to yield 2.5 kg/kg. In this case, the production-indexed VOC consumption factor would also be decreased by the 4 kg/kg MeOH to 16 kg/kg VOC; however, no additional reductions of the ethanol would be required.

Today's final rule also changes the time period over which the baseline production-indexed HAP and VOC consumption factors are determined. At proposal, baseline production indexed consumption factors were determined based on the average values for the first full year of operation (or the first year for which data are available). The final rule requires that the baseline production-indexed HAP and VOC consumption factors be determined based on consumption and production values that are averaged over the time period from startup of the process until the present time (assuming the process has been in operation at least 1 full year), or the first 3 years of operation, whichever is the lesser time period. The changes to the baseline averaging period were made to ensure the baseline production indexed HAP consumption factor reflected normal production.

Another restriction on the pollution prevention alternative that many commenters wanted removed was the exclusion of control devices that recycle material back to the process. A number of commenters stated that the proposed restrictions on the P2 alternative would exclude multiproduct (nondedicated) processes due to strict FDA and quality control restrictions on cross-contamination, which oppose attempts to reduce the amount of solvent consumed per kilogram of product. For this reason, the commenters suggested that the P2 alternative be modified to give multiple-product facilities greater opportunity to make use of this alternative. The specific modification suggested by the commenters includes allowing solvent that is ''returned to the economy'' to be considered as an alternative for multiproduct processes. The commenters noted that, for implementation purposes, the interested party (first user of the solvent) would need to demonstrate that the required fraction of solvent was transferred to another (second) user *as a raw material*, to be used *as is*, so that the second user will purchase that much less solvent. Under this approach, the consumption of HAP would be equivalent to the amount purchased minus the amount sold. Similarly, two commenters suggested that the P2 alternative should be revised to allow credit for in-process recycling in the calculation of HAP reduction from a process. Although EPA recognizes that multiple-product facilities may not be able to take advantage of the pollution prevention alternative, the type of program whereby one entity certifies the nature and amount of the recovered solvent usage by another entity would be difficult and burdensome to implement, and would require tracking and verifying the usage of the recovered solvent at the second entity. Also, when the recovered solvent is sold to the second entity, the first entity does not achieve any real emission reduction (i.e., reduction in solvent usage), but instead, takes credit for the assumed emission reduction that would occur at the second entity. Also, the second entity may not be a pharmaceutical manufacturing facility which would result in emission reductions being moved across source categories. For these reasons, the final rule does not allow credit for sale of recovered solvents in the P2 standard. Also, EPA disagrees with the commenters that suggest credits be given for in-process recycling because giving a source ''credit'' for in-process recycling would result in ''double-counting'' of the emission reduction. By recycling solvents, the owner or operator already has reduced the amount of solvent entering the process (i.e., the more that is recycled, the less that is purchased), so further credits due to recycling are not necessary. For the reasons given above, the restrictions on solvent recycling in the proposed rule remain unchanged in today's final rule.

2. P2 Demonstration Summary

The proposed rule in § 63.1255(a)(4) would have required sources that comply with the P2 alternative to maintain records of rolling average values of kg HAP/kg production and kg VOC/kg production. The proposed rule also specified how production-indexed HAP and VOC consumption factors should be calculated (i.e., by dividing annual consumption of total HAP or VOC by the annual production rate, per process) but did not require the owner or operator to explain how the reductions in production-indexed HAP consumption factors are achieved. Several commenters stated that EPA should develop data requirements necessary to substantiate compliance with the pollution prevention alternative. Two commenters suggested that the final rule require facilities to submit a ''P2 Demonstration Summary'' that briefly describes the pollution prevention methods that were used to achieve the reduction in HAP consumption. The commenters stated that information on the facility's P2 activities was necessary to verify that (1) the HAP consumption data are directly related, on a per process basis, to each process that is complying with the P2 alternative; and (2) the reduction in HAP consumption was achieved via pollution prevention methods that meet the Agency's definition of pollution prevention. These commenters also noted that, in order to provide adequate incentive for facilities to choose the pollution prevention alternative, the EPA should ensure that data requirements are reasonable and protect confidential chemical formulation data.

In response to the above comments, today's final rule requires owners and operators seeking to comply with the P2 alter native to submit a P2 Demonstration Summary that describes how the P2 alternative will be applied at their facilities. The P2 Demonstration Summary must be included in the facility's Precompliance Report, which is submitted 6 months prior to the compliance date. The minimum requirements of the P2 Demonstration Summary are listed in § 63.1257(f) of today's final rule. These data requirements include descriptions of how each facility measures and records HAP consumption and pharmaceutical product production on a daily, monthly, and annual basis, and appropriate documentation such as operator log sheets, copies of daily, monthly, and annual inventories of materials and products, shipment and purchase records, tank-specific charts for converting tank-level measurements to volume (e.g., gallons) of HAP or product, and temperature/density charts for converting tank volume measurements into weight measurements. Also, if a facility complying with the P2 standard uses the same HAP in more than one process, the owner or operator will be required to modify existing methods of tracking HAP consumption at the plant, if necessary, to ensure that HAP consumption can be measured for each PMPU, as opposed to facility-wide.

G. Alternative Standard

Commenters requested that EPA consider an alternative standard for facilities that treat HAP emissions with add-on control devices. Industry commenters stated that an alternative standard would be especially useful for facilities that use a common control device to treat aggregated emis sion streams. The commenters further stated the use of common dedicated control systems should be encouraged rather than discouraged for the following reasons: (1) the use of common controls will ultimately result in a greater emission reduction because processes that are not required to reduce emissions under the rule would be controlled as well; (2) the use of common controls may facilitate the streamlining of monitoring, performance testing, and recordkeeping requirements and as a result reduce the resource burdens on both industry and the enforcement agencies; (3) the use of common controls may make it easier to assure and assess compliance; and (4) common controls may ultimately be more energy-efficient and result in lower emissions of secondary pollutants since fewer control devices will be employed.

The Agency agrees with the commenters and decided for the above reasons to include an alternative standard for storage tanks and process vents that are equipped with add-on control devices in §§ 63.1253(d) and 63.1254(c), respectively. The Agency also agrees with the commenters' belief that there will be a number of facilities and State regulators that will benefit from a regulatory alternative that encourages aggregating and treating emissions with a state-of-the-art common control device. The alternative standard included in the final rule can be applied to individual process vents or storage tanks that have emissions that are controlled with add-on control devices or to storage tanks and/or process vents that are manifolded together prior to treatment in an end-of-line control device (or series of devices). The control device (or last control device in a series) must achieve an outlet, undiluted TOC concentration of 20 ppmv or less, as methane, or calibrated based on the predominant HAP. The control device must also achieve an outlet concentration of 20 ppmv or less hydrogen halides and halogens. The EPA considers this level of emissions the practical level of control for the technologies on which the standard is based. The requirement to correct for 3% O2 if supplemental combustion air is used is currently under review. This requirement may be revised at a later time.

To simplify applicability of the alternative, all process vent and storage tank emissions that are manifolded to a common control device are considered as one regulated entity under the alternative standard. Nonmanifolded vents are regulated under the rule as otherwise specified without taking credit for the manifolded portion of the process.

H. Testing and Compliance Demonstrations

1. Worst-Case Conditions for Testing

Extensive comments were received on the provisions for absolute or hypothetical worst-case testing contained in the proposed rule. Many commenters stated that the provisions are not workable, especially in batch facilities where multiple streams are routed to common control devices. In these situations, owners and operators might be required to cease production in order to simulate a hypothetical worst-case test for a given device, or would have to artificially affect production in order to align emission events for testing that would meet absolute worst-case conditions. Commenters emphasized that, in both situations, there are safety concerns associated with generating such conditions, as well as practical concerns.

One safety concern raised by the commenters related to both absolute and hypothetical worst-case testing is that the manifold systems designed to carry emission streams to control devices may not be sized to handle the absolute worst-case situation, which could lead to potentially explosive situations during absolute and hypothetical worst-case testing. Many commenters stated that sources often design and install manifold systems at a lower capacity than that of the control device itself to prevent such explosion potential.

The most common practical concern expressed was that the prediction of when worst-case conditions would be occurring would be very difficult, although many commenters stated that calculating the potential maximum inlet loading scenario for a control device used to control emissions from multiple batch processing vessels would be a difficult, but manageable, task. Many commenters suggested that fluctuations related to processing, including sudden changes in temperatures or operator, could shift the timing of emission events and render any predictions about the timing of specific events invalid. The commenters believe that, for devices controlling multiple streams from moderately complex facilities, absolute worst-case test conditions might never occur within the life of the facility, nor could they reasonably be predicted. Additionally, one commenter stated that an owner or operator might encounter difficulty in proving to a compliance inspector that the conditions of a test were, indeed, run at absolute worst case.

A practical concern with hypothetical worst case conditions raised by the commenters is that testing cannot be performed while an actual batch is being produced. Based on the commenters' past experiences, testing in some cases could result in a process shutdown for 2 weeks, resulting in serious production losses.

One commenter also stated that representative worst case will also result in timing uncertainties similar to those of the absolute worst-case situation, especially when the device is controlling a single process with numerous emission episodes.

For normal testing conditions, commenters believe that the restriction to operate within conditions that existed during the test should be dropped. They stated that, because the proposed

standards include an annual compliance period, the commenters argued that the control device will constantly see variably challenging conditions and therefore, should be allowed to operate under conditions that are outside the range of conditions encountered during testing. In order to alleviate the EPA's concerns that a test under normal conditions may not indicate a control device's performance under more challenging conditions, one commenter suggested that an additional requirement to provide a design evaluation under more challenging conditions be added. Many commenters also suggested that representative worst case should be revised to include all control devices, and should not be restricted to ''the level for which it was designed.'' Additionally, one commenter believes that EPA did not mean to impose this limit on representative testing conditions and would like EPA to make the appropriate language changes to reflect their intent. Lastly, several commenters expressed approval of testing under worst-case conditions, but would like the conditions to be more clearly defined.

The Agency's intent in requiring testing under worst case conditions is to document the reduction efficiency of the control device under its most challenging conditions. Subsequent to the initial compliance test, continuous monitoring of operating parameters established during the initial test is a reasonable measure of continuous compliance with the efficiency requirement under all conditions. Presumably, the control device should function as well or better under conditions that are not as challenging.

Many of the comments regarding worst-case testing conditions are related to the restrictive language defining the worst case challenge and the difficulty associated with developing a time-dependent emissions profile to identify the appropriate test period. In an effort to provide more flexibility to owners and operators regarding the identification of the proper testing conditions, EPA has redefined the worst case ''challenge'' to include challenging conditions that are not based on high HAP load. These conditions include cases where efficiencies are dependent on other characteristics of emission streams, including the characteristics of components and the operating principles of the devices. For example, in situations in which non-HAP VOC's are present, where the efficiency of a device is most challenged by dilute steam characteristics or where specific characteristics of the compounds create limitations on control efficiency. In sizing and estimating the regeneration requirement for a carbon adsorber, for example, all material in the emission stream entering the unit must be considered in estimating bed capacity. Likewise, a limiting factor in scrubber efficiency is the solubility or reactivity of components in the scrubbing liquor. These considerations must be made at the time of evaluation of the device for compliance with the rule.

For worst-case challenges that are based on loading of HAP, EPA has also expanded the language describing the development of the emission profile. The emissions profile can be developed based on the actual processing conditions at the facility, as proposed, in which all emission events that can contribute to the control device are identified and considered to determine the highest hourly HAP load from all events that can occur at the same time. However, in the final rule, other options for the emissions profile have been developed that consider the facility's limitations based on equipment or conveyance and capture systems. Owners and operators can develop emission profiles based on equipment, in which the highest hourly HAP-producing emission streams that possibly could enter the control device, considering the facility's available equipment and HAP materials, are identified as appropriate testing conditions. Also, owners and operators have the option to develop emission profiles based on limitations of the control device or conveyance system. For example, many manifolds are limited in flows and concentration limits by fans and LEL monitors. Conducting performance tests based on conditions approaching these limits is also an option provided in the rule.

The expanded language on emission profiles eliminates the need for allowing owners and operators to test at conditions that are less than the worst-case challenge. Therefore, language referring to testing under ''representative'' and ''normal'' conditions was deleted from the batch testing provisions. Additionally, the added flexibility associated describing worst case may alleviate commenter's concerns regarding loss of production time.

2. Expedited Test Methods

Many commenters stated that the test methods referenced in the proposal under § 63.1253(b) (1) through (6) will require modification, because the methods were developed for continuous processes. Based on the commenters' past experience, obtaining approval for modifications to test methods often takes 6 to 12 months. Therefore, the industry commenters would like for EPA to consider adding explicit language in the rule allowing for the use of alternative test methods and providing some mechanism for expedited approval.

Specific suggestions from the above commenters for expediting approval were to eliminate EPA's validation Method 301 in favor of a less burdensome method and to explicitly state that approval of minor modifications do not require Method 301 validation, or that approval of alternative test methods should not trigger the need for a title V permit revision.

In response to the above comments, the Agency believes that the provisions in the final rule that require a site-specific test plan be submitted prior to any testing suffice in providing a mechanism for the presentation of, and approval of, proposed modifications to EPA test methods. In general, Method 301 should be used as a validation method for completely new and different testing procedures and instruments that have not previously been reviewed by EPA. It is not the Agency's intent to require the use of Method 301 for minor modifications to test methods such as the relocation of sampling probes.

3. Use of Method 25A

One commenter stated that Method 25A should be used only after an accurate response factor has been determined. The final rule specifies the following test methods:

1. Method 18 for control efficiency in all situations.

2. Method 25 for control efficiency determination in combustion devices.

3. Method 25A for the 20 ppmv outlet TOC concentration standard.

4. Method 25A in control efficiency determinations in the situations described in the introductory paragraphs of Part 60, Appendix A, Method 25 (when direct measurement by FID is appropriate).

The importance of calibrating a FID reading obtained using Method 25A with respect to a certain compound (adjustment by response factor) depends on how the Method will be used to demonstrate compliance with the standard. In general, the EPA believes that an accurate response factor is necessary in cases where Method 25A is used to demonstrate control efficiency across a device where the composition of the stream may change, or in situations where multiple components, including non-HAP VOC's, are present. Because the relative proportion of

organic compounds may change across the control device, appropriate response factors are needed to accurately quantify TOC at the inlet and outlet of a control device. In addition, the final rule allows owners and operators the opportunity to demonstrate compliance at the outlet of a control device by measuring 20 ppmv TOC or less. The EPA has allowed owners and operators to calibrate the FID using methane or the predominant HAP expected in the emission stream. The use of methane as a calibration gas for the 20 ppmv TOC alternative standard is based on the response factor of methane because it is similar to response factors of HAP that are predominant in this industry, such as methylene chloride and methanol. The EPA intends with this requirement to minimize the burden of recalibration for various HAP constituents that may actually change over a given period of time.

4. Emission Profiles

Many commenters requested clarification of the methodology for developing an emissions profile, which was contained in § 63.1253(b)(iii) of the proposed rule. The commenters stated that the definition of emissions profile implies that sources must prepare a graph of HAP emissions versus time. However, because EPA included the language ''the average hourly HAP loading rate may be calculated by first dividing the HAP emissions from each episode by the duration of each episode, in hours, and selecting the highest average hourly block average'', the commenters thought that EPA's intent was not to profile emissions versus time, but rather to simply list each batch episode and the average hourly HAP emissions loading from each episode. Additionally, some commenters stated that the emission profile method seemed very complicated, and that personnel with operating experience can quickly determine the worst-case conditions for a control device without producing the extensive information required by the emissions profile. One commenter suggested changing the language of § 63.1253(b)(7)(iii)(A) by eliminating the phase ''must include,'' so that sources can have the option of discussing an alternative means of determining appropriate test conditions with the permitting authority.

The Agency's intent, when requiring the development of an emissions profile, is to determine the maximum HAP loading to a control device over time. Therefore, the rule requires that the emissions to the device be evaluated by plotting HAP emissions versus time. The EPA has not, in the final rule, changed the requirements for developing the emissions profile, although EPA did clarify the exact language in the final rule to address the commenter's concerns about the clarity of the requirement. Additionally, two other methods for developing the emission profile were provided in the final rule.

I. Equations

1. Use of Equations in 1978 CTG

As part of the procedure to demonstrate compliance with the emission reduction standard for process vents, the final rule requires the owner or operator to determine uncontrolled emissions from each vent. Equations to calculate emissions from certain unit operations are provided in the rule. Numerous commenters requested that the rule also allow the use of similar equations for the same unit operations that are presented in the 1978 CTG. The commenters stated that although the two procedures give different results, they are based on the same fundamental principles and neither gives better results. The commenters provided the following additional reasons for allowing use of the equations from the 1978 CTG: (1) the MACT floor was based on data from the industry, which were estimated using the procedures in the 1978 CTG, (2) sources are already using the procedures in the 1978 CTG to comply with other regulatory programs and would incur significant costs to invest in a program and data systems to develop and maintain a second method for estimating emissions, (3) maintaining two sets of emission estimates would make State review and compliance efforts complex and confusing, possibly leading to compliance actions for perceived violations of one estimate but not the other, and (4) the emission estimation equations in the rule are based on the 1994 ACT, which has not undergone public review and comment.

The EPA reevaluated the procedures for calculating uncontrolled emissions and concluded that except for two situations, the equations in both the 1978 CTG and the 1994 ACT documents give acceptable estimates of emissions for the purposes of this rule. Therefore, both sets of equations, except as noted below, are included in the final rule for existing sources. The two situations for which emission estimation procedures in the 1978 CTG are not acceptable for this rule are: (1) purging with streams that have high flow rates and (2) heating when the final temperature is higher than 10 K below the boiling point. The EPA believes this change mitigates the commenters concerns because the two situations where the 1978 CTG procedures are not allowed affect a small number of streams. Owners and operators will have to redo calculations for existing processes under these two conditions. In addition, the owner or operator will have to calculate uncontrolled emissions for those events that the owners/operators have only controlled emission estimates. This is because the 1978 CTG uses condenser temperature instead of vessel temperature. Details about the equations for purging and heating are provided in sections VI.I.2.b and VI.I.3.

2. Procedures to Estimate Emissions from Purging

a. *Equation.* The equation for purging was changed in the final rule because the term that accounts for the increase in flow rate due to the volatilization of HAP was inadvertently left out of the equation in the proposed rule (i.e., the purge flow rate needs to be multiplied by the ratio of the total pressure to the partial pressure of noncondensables at saturation). The revised equation is identical to the equation in the 1994 ACT and gives the same results as the equation in the 1978 CTG as long as the total pressure is equal to 760 mmHg.

b. *Saturation level for large purge streams.* The rule requires an owner or operator to assume a purge stream greater than 100 scfm is 25 percent saturated. One commenter believes the assumption that the vapor phase is 25 percent saturated rather than 100 percent saturated is merely a different assumption and is not based on better information. The commenter also stated that assuming streams are 100 percent saturated is more conservative because it will overestimate emissions, whereas the 25 percent assumption will sometimes overestimate and sometimes underestimate emissions.

The assumptions that purge streams with flow rates less than or equal to 100 scfm are 100 percent saturated, and that purge streams with flow rates greater than 100 scfm are 25 percent saturated, are based on modeling analyses that are described in the 1994 ACT. In the 1994 ACT, the mass transfer (of toluene) from the liquid to the purge stream was estimated using various correlations and a range of design and operating parameters. The correlations showed the purge streams, especially purge streams with high flow rates, were well below saturation for all but the most agitated vessels or vessels with very shallow head space. Assuming these large streams are completely saturated would result in significantly overestimated uncontrolled emissions.

Overestimating uncontrolled emissions leads to at least two problems. First, for a condenser, overestimating uncontrolled emissions means the control efficiency of the condenser will be overstated (and the condenser will operate at a higher temperature than is actually needed to meet the standard). A second problem with overestimating the uncontrolled emissions is that even if the control efficiency is being met (say with an incinerator), the quantity of emissions reductions would also be overestimated, which, if this stream were used in emissions averaging, would result in overestimation of credits. To mitigate these problems, EPA reviewed the results of the modeling analyses and selected values that while still conservative greatly reduce the potential amount of overestimation. The correlations showed that under all types of conditions, the degree of saturation declines rapidly with increases in purge flow rate up to about 100 scfm, and then nearly levels off; the ''knee'' of the curve was at about 100 scfm for every scenario. For all modeled scenarios, purge flow rates greater than 100 scfm were always less than 25 percent of saturation. Based on these results, the EPA believes that assuming purge streams with flow rates greater than 100 scfm are 25 percent saturated rather than 100 percent saturated results in a better estimate of emissions, more accurate operating parameters, and reasonable credits for emissions averaging. Thus, the requirement to assume purge streams with flow rates greater than 100 scfm are 25 percent saturated was retained in the final rule; but an owner or operator also may conduct an engineering assessment to show that another value is more appropriate.

3. Procedures to Estimate Emissions from Heating

a. *Heatup temperature within 50 K of boiling.* When the contents of a vessel are heated to a temperature within 50 K of boiling, the proposed rule would require the owner or operator to calculate emissions in increments. One increment covered the range from the initial vessel temperature to the temperature 50 K below the boiling point. The procedure then required estimates for each 5 K temperature range up to the final heatup temperature. One commenter believes calculating over 5 K increments is overly conservative. Other commenters believe the approach is an error because it differs from the approach in the 1994 ACT.

As noted in section VI.I.1, EPA is changing the rule to include the equations from the 1978 CTG and the 1994 ACT as well as the approach in the proposed rule for most heatup conditions at existing sources. In response to industry concerns, the EPA is also reducing the temperature cutoff from 50 to 10 K below the boiling point. The concept of a cap is retained because the procedures in the 1978 CTG and the 1994 ACT can greatly overestimate emissions when the final heatup temperature is close to the boiling point. The equation in the 1978 CTG estimates emissions assuming equilibrium at the temperature of a receiver (i.e., the equation uses a ratio of the condensables partial pressure to the noncondensables partial pressure at equilibrium). This procedure does not specify what equilibrium conditions should be used in the absence of a condenser. If the equilibrium partial pressures at the final heatup temperature are used, the equation overestimates emissions. The overestimate is most significant when the final heatup temperature is close to the boiling point because the partial pressures ratio (condensables to noncondensables) increases exponentially with increasing temperature, and goes to infinity as the temperature approaches the boiling point. Using the average of the ratios at the initial and final temperatures, as is done in the 1994 ACT, also can overestimate emissions. The EPA believes calculating emissions over the 5 K increments when the final heatup temperature is above the temperature 10 K below the boiling point is a reasonable compromise between the accuracy of the estimate and the effort needed to perform the calculation.

b. *Emissions From Process Condenser.* Under the proposed rule, if the contents of a vessel are heated to the boiling point and the vessel operates with a process condenser, the emissions would be calculated using both the heatup and displacement equations. One commenter noted that this procedure results in negative emissions. The EPA reevaluated this equation and determined that this result occurs only if the process condenser operates at a temperature lower than the initial temperature of the vessel. To correct this problem, the final rule states that either the heatup procedure in the 1978 CTG or a variation of this procedure is to be used. The variation allows the owner or operator to use a vapor-liquid equilibrium relationship other than Raoult's law and to use the actual system pressure rather than assuming the system is at atmospheric pressure. Both procedures are also applicable when the condenser temperature is higher than the initial temperature of the vessel.

4. Vapor-Liquid Equilibrium Relationships for Multicomponent Systems

To estimate emissions, the rule specifies that owners and operators assume one of four vapor-liquid equilibrium (VLE) relationships apply, depending on the system conditions. These relationships are: (1) Raoult's law, (2) Henry's law, (3) a VLE relationship based on the use of activity coefficients (obtained experimentally or from models) to correct for nonideality in the liquid phase, and (4) the assumption that components of the system behave independently so that the sum of all HAP vapor pressures is equal to the total HAP partial pressure. Once the applicable VLE relationship is established, the HAP partial pressure(s) can be determined and used in the applicable equation to estimate the HAP emissions.

Two commenters expressed concern about some of the VLE relationships that the rule requires for estimating emissions from multicomponent systems. The commenters concur with EPA that Raoult's law is appropriate for miscible systems. The commenters also acknowledged that use of Henry's law is generally more accurate that Raoult's law in predicting vapor mole fraction for mixtures below the solubility limit, but they stated that this approach is excessively difficult and unworkable because Henry's law constants are not available for many of the solvents and reagents used in the pharmaceuticals industry. Therefore, the commenters would prefer to use Raoult's law for these mixtures. For multicomponent systems in which the compounds are not miscible or are only partially miscible, the commenters opposed the use of equilibrium relationships based on activity coefficients because developing activity coefficients is burdensome. As an alternative, the commenters recommended using an approach in which each liquid phase is treated independently, and emissions from each phase are calculated separately.

The final rule clarifies EPA's intent regarding the use of vapor-liquid equilibrium relationships. If the components are miscible in one another, Raoult's law may be used when it is applicable. However, if a miscible solution is not well characterized by Raoult's law, activity coefficients must be used. For dilute aqueous mixtures, Henry's law must be used. The EPA rejects the commenter's argument to use

Raoult's law due to the lack of Henry's law constants; Table I of appendix C in 40 CFR 63 contains Henry's law constants at 25°C and 100°C for 125 of the most common organic HAP compounds. For HAP compounds that are not on the list, the owner or operator must estimate the Henry's law constant. For systems with multiple liquid phases, the owner or operator may either use activity coefficients or, as suggested by the commenter, assume the components behave independently and assume the HAP vapor pressures and partial pressures are equal.

5. Emission Estimation Equations Versus Engineering Assessments

The rule lists two conditions under which an owner or operator may conduct an engineering assessment to show that equations in the rule are not appropriate: (1) if available test data and the results of calculations using an equation differ by more than 20 percent and (2) if the owner or operator can demonstrate through any other means that the emission estimation equations are not appropriate for a given batch emissions episode. Several commenters stated that both conditions should be deleted from the rule. The commenters rationale for deleting the conditions shows the language in the proposed rule did not convey EPA's intent. As a result, the conditions are rewritten in the final rule for clarity, and additional clarification is provided in the following paragraphs of today's notice.

Batch emission episodes may be due to a unit operation that is described by an equation in the rule or to a unit operation that is not described by an equation in the rule. Estimating emissions using the applicable equation is always the standard approach for emissions episodes that are covered by an equation. However, an owner or operator also always has the opportunity to conduct an engineering assessment to demonstrate and get approval to use another emission estimation technique. The intent of the first condition is to indicate that an owner or operator could include such a discrepancy between test data and calculations in an engineering assessment and it would be considered evidence that the equation is not appropriate (provided, of course, that the permitting authority agrees that the test data were obtained under ''representative conditions''). The purpose of the second condition is to indicate that other information may also be used in the design evaluation as evidence that an equation is not appropriate. Again, the permitting authority would have to approve the use of any proposed alternative to the equation.

The conditions have nothing to do with estimating emissions for batch emissions episodes from unit operations that are not described by equations in the rule. For such emissions episodes, an owner or operator would be required to conduct an engineering assessment to show how emissions will be estimated.

6. Calculation of Controlled Emissions

Two commenters stated that the rule should allow the use of techniques in the 1978 CTG to calculate controlled emissions from a condenser. The commenters stated that the procedures in the proposed rule cannot be used because they specify the use of system temperature, whereas the correct technique, which is used in the 1978 CTG, is to use the exit gas temperature from the condenser. One commenter also stated that even when the equations in the rule and the 1978 CTG are identical, ''implementation differences'' cause the controlled emissions estimates to differ. To address the commenters' concerns, the final rule specifies both the applicable equation and any changes to the temperature or volume that are needed for calculating controlled emissions.

J. Monitoring Requirements

Many commenters objected to the use of monitoring parameters for the determination of a source's compliance status on a continuous basis. Their central issue, for many emission streams controlled in this industry (e.g., batch, nondedicated, possibly manifolded together and routed to common control), is that an exceedance of a parameter level, as measured on 15-minute intervals and averaged over a 24-hour basis, may not necessarily constitute a violation of the 93 percent control requirement for the process for the following reasons:

1. If the parameter is conservative, the device will operate above the required efficiency;

2. The loading on the control device may be less than the assumed loading used to set the parameter, so the device provides adequate control even though the parameter has not been attained;

3. The actual compounds in the emission streams may be easier to treat than those used to set the parameter; and

4. The excursion may occur when there are little or no HAP emissions from the process routed to the device.

The EPA had solicited comment on this issue, and at that time, had questioned why the industry couldn't set multiple parametric levels for control devices to account for different operating scenarios. The commenters countered that, especially in the case of manifolded, end-of-line devices, it is not possible to predict with precision what conditions will exist at any point in time. Rather than establishing, up-front, a complex ''grid'' of parameters that will serve all potential combinations of operating scenarios, they would want to set conservative parametric levels as a screening mechanism for determining whether or not emission limits might have been exceeded, with an option to evaluate actual parameter excursions on a case-by-case basis after exceedances had occurred to determine whether an emission limit was actually exceeded.

The commenters recommended that the rule provide that a parameter exceedance must be reported to the permitting authority, with the opportunity to rebut the presumption that the emission limit(s) have been exceeded. Other commenters suggested that sources be treated in a manner consistent with the Compliance Assurance Monitoring (CAM) rule, which provides only that an excursion of a monitored parameter is an indication that an emission standard may have been exceeded, but makes no automatic finding of a violation of that emission standard.

In general, EPA recognizes two basic approaches to assuring that control devices used by the owner or operator to achieve compliance are properly operated and maintained so that the owner or operator continues to achieve compliance with applicable requirements. One method is to establish monitoring as a method for directly determining continuous compliance with the applicable requirements. The Agency has adopted this approach in part 63 standards, and is committed to following this approach whenever appropriate in future rulemakings. Another approach is to establish monitoring for the purposes of documenting continued operation of the control devices that are designed to provide a reasonable assurance of compliance, indicating excursion from these ranges, and correcting problems creating excursions. This second approach is outlined in the CAM rule, which applies to sources that are not currently subject to part 63 standards.

When determining appropriate monitoring options, EPA considers the availability and feasibility of the following monitoring strategies in a ''top-down'' fashion: (1) CEMS for the actual HAP emitted, (2) CEMS for HAP surrogates, (3) monitoring operating parameters, and (4) work practice standards. In evaluating the use of

CEMS in this standard, monitoring of individual HAP species was not found to be reasonable or technically feasible for many streams. However, in the case of continuous monitoring of surrogates, continuous TOC monitoring is considered a more viable monitoring option and is provided for some instances in the rule. (See discussion on alternative standard and on monitoring for carbon bed systems.) Monitoring of control device operating parameters is considered appropriate for many other emission sources, and therefore, most of the other monitoring options provided in the final rule are based on parametric monitoring.

The EPA has considered the commenters' argument that an exceedance of a monitoring parameter is not necessarily an exceedance of an emission limit, especially as described in the generic situations provided above. In the first three situations, EPA believes that as long as the source is given the flexibility to select operating parameters, including the option retained from the proposed rule to allow the owner or operator to set multiple parameter levels for different operating conditions, then the burden is on the source to remain within the parameter or parameter(s).

To address the potential disparity between parameter limit exceedances and emission limit exceedances, the final rule contains two different types of continuous compliance violations. Where a source is using a CEMS to monitor compliance with the 20 ppmv alternative standard, an exceedance is defined as a violation of the emission limit. Similarly, because the exit gas temperature of a condenser is so closely correlated with emissions, a condenser temperature exceedance is considered a violation of the emission limit. Exceedances of other types of parameter limits are defined as violations of an operating limit, rather than violations of the emission limit.

In response to industry's preference to evaluate parameter levels after an exceedance of a conservative parameter level to determine whether an emission limit was exceeded (thereby eliminating the need for a complex grid of preset parameter levels), EPA believes that the establishment of compliance levels *prior* to operation of the device or process is imperative; otherwise, the constant opportunity for rebutting a violation of the standard would render the standard unenforceable. While EPA is sensitive to industry's need to minimize its compliance burden, EPA believes that the burden placed on State agencies to consider the amount of information that the rebuttable presumption option would encourage is not reasonable.

In response to the fourth generic situation described by industry, EPA has provided in the final rule, clarification of situations (no flow) when exceedances of preset parameters would not constitute a violation of the standard.

For reasons described above, EPA rejects the assertion that the parametric levels should not be used as a direct indicator of compliance. The EPA believes that conditions in the proposed rule which have been retained in the final rule including options for setting parameters, coupled with clarifying the averaging times for compliance determinations and establishing valid data criteria for monitored parameters should address concerns of commenters, while retaining the enforceability of the standard. The final rule provides options for presetting multiple parameter levels to account for variation in batch emission stream characteristics within emission sources (as proposed), and to account for variability in combined stream characteristics in manifolds.

The final rule provides owners and operators with the option of setting averaging times based on either a ''block'' of time suitable for the expected variations of emission stream characteristics from a batch process (determined by the owner or operator, with some restrictions), or a 24-hour basis (as proposed).

The final rule also provides owners and operators with an opportunity to verify compliance based on a review of operating logs during periods of exceedances. Exceedances will not constitute violations of subpart GGG during periods when a parameter has been set based on worst-case conditions, or other conditions that were not representative of the conditions in the device during the exceedance, if the owner or operator has predetermined other levels that ensure compliance with the standards for these representative periods. If predetermined levels were established, the owner or operator can also determine compliance for discrete streams in manifolds by referencing to these limits.

Additionally, monitored data obtained during periods in which no flow to the control device occur should not be considered valid; during such periods, the final rule allows for the exclusion of such data from the daily or block averages. The use of a flowmeter to identify and exclude such periods from compliance average is therefore required in the final rule, if they cannot otherwise be predicted.

K. Recordkeeping and Reporting Requirements

Issues related to the amount and type(s) of recordkeeping and reporting requirements that were included in the proposed rule were raised by commenters representing both industry and enforcement agencies. The pharmaceutical manufacturing industry involves a wide variety of processes, products, and resulting emissions. In order to demonstrate compliance with the necessary MACT requirements, detailed records are needed to have a reliable, documented record of how the source complied with the regulation. The EPA has made a concerted effort to reduce the recordkeeping requirements of the final pharmaceutical rule. The EPA recognizes that unnecessary recordkeeping and reporting requirements would burden both the affected source and EPA/State enforcement agencies and will continue to review requirements to identify and implement other possible streamlining measures.

The EPA has reviewed the recordkeeping and reporting requirements required by the proposed rule and has eliminated those areas where duplicative and inapplicable requirements were proposed. Most of these changes involved areas where the referenced General Provision requirements were not directly applicable to this industry. Clarifications and/or additional language have been added to tailor the recordkeeping and reporting requirements to the relevant data needs from pharmaceutical manufacturing operations. Table 1 in today's final regulation was modified to include a summary column describing the relevant information in each part of the General Provisions, and more information was added to better relate the requirements of the final rule and those in the General Provisions.

Comments on precompliance reporting were varied depending on the commenter's perspective and experience. Some commenters viewed the precompliance reporting requirements as burdensome and restrictive. One commenter stated that submittal dates for reports and notifications due prior to the compliance date are much too early, unnecessary, and can be counterproductive. Two commenters stated that the Precompliance Report should be due only 3 months prior to the compliance date. Other commenters argued that the ''early'' due date for the Precompliance Report is valuable because it provides a practical means of

ensuring that a source is aware of the upcoming deadline. One of the commenters also stated that the description of test conditions and limits of operation for control devices tested under normal conditions and the corresponding monitoring parameter values should be submitted as part of the Pretest Notification Report rather than with the Precompliance Report. In response, the Agency revised the submittal dates for the precompliance report and the emissions averaging implementation plan to 6 months prior to the compliance date. The Agency believes the final submittal dates and data requirements for the precompliance report are adequate to provide the enforcement agencies with sufficient time to review the information.

Some commenters also suggested that the use of alternative parameters be included in the precompliance report and that periodic testing be done to correlate actual emission rates to alternative parameters. The EPA response to this issue is addressed in section VI.L of this preamble.

One commenter suggested that sources be required to establish an effective environmental management system to eliminate much of the paperwork burden associated with the proposed recordkeeping and reporting requirements. The Agency believes an effective environmental management system can be used to comply with all the requirements of the final rule provided the system is based on meeting the MACT requirements in the final rule. Sources are free to submit an alternative compliance plan to the appropriate agency to review/approve in lieu of any or all recordkeeping or reporting requirements.

Commenters also raised issues related to data availability stating that the proposed requirements were unreasonable, impracticable, and more stringent than those for other industries. The Agency does not agree with these comments.

L. Permitting and Compliance Options/ Change Management Strategy

1. Proposal Comments Received

In the April 1997 proposal, the EPA solicited comment on the interaction of this standard with the title V operating permits program, implemented at 40 CFR part 70. In addition, the Agency requested comment on an approach which would incorporate by reference the Notification of Compliance Status Report (NOCSR) into a pharmaceutical manufacturing facility's title V permit. The EPA also solicited comment on the types of operational changes that would trigger revision of the operating permit under title V. However, in soliciting comment on these issues, the Agency did not propose to revise part 70 through the establishment or implementation of subpart GGG.

Commenters to the proposed subpart GGG raised several issues with respect to process changes at pharmaceutical facilities, which they claimed would result in a potentially unmanageable title V permit administrative process. The pharmaceutical industry produces a wide range of existing and new and/or improved products primarily through the use of nondedicated equipment operated in a batch production mode. Commenters were fearful that frequent changes in the use of existing equipment as well as the additions of new equipment at pharmaceutical facilities would require frequent revisions to the operating permits for these facilities. These commenters predicted that such permit revisions would result in delays in implementing process changes and cause significant new administrative burdens on the facility and permitting authority.

The preamble to the proposed rule described the NOCSR as the compliance ''blueprint'' for implementation of the standard, containing ''[a]ll information regarding documentation of the facility's compliance status with regard to the standard. . . .'' This information would include ''process descriptions, emissions estimates from those processes, control device performance documentation, and continuous compliance demonstration strategies, including monitoring.'' The EPA solicited comment on whether the NOCSR could be initially incorporated by reference into the title V permit and whether the permit could be revised as necessary through quarterly update reports. The proposal posited that only changes requiring site-specific approval (such as the use of a monitoring parameter that was not identified in the standard) would trigger some significant review action under title V. The Agency expressed the view that this approach would allow enough flexibility for sources to make operational changes as necessary as well as changes to operating and compliance procedures without additional approval, if the changes were straightforward, and would assure that the compliance plan for the facility would always be reasonably current.

Most commenters did not support an ongoing implementation strategy based on permit revision for operational changes, even if it could be streamlined. Several industry commenters strongly reiterated concerns about the potentially huge administrative problems associated with implementing subpart GGG within title V permits.

In particular, PHRMA recommended an approach under which facilities that have been issued a title V permit before subpart GGG is finalized would be required to apply for a minor permit modification (MPM) by the due date for the NOCSR. The suggested MPM application would include: (1) a list of applicable subpart GGG requirements that should be included in the permit itself (including a ''menu'' of applicable process vent, tank, and wastewater standards); (2) a requirement for the facility to submit a compliance plan that outlines the regulated entities within the affected source (such list should include the identification of regulated processes, process vents, tanks, and wastewater PODs; a determination as to which substantive standard applies to each; and a list of corresponding testing, monitoring, record keeping, and reporting requirements); (3) a requirement for the facility to update the plan when a compliance requirement changes; (4) a requirement to submit the plan to the permitting authority every 6 months; and (5) a requirement to operate in accordance with the plan. For facilities that have not been issued a title V permit until after subpart GGG is finalized, a facility's initial permit would be issued to include these five items. Facilities that trigger new source MACT would be required to apply for a significant permit modification (SPM) prior to implementing the triggering change. Under this approach, PHRMA believes that a source could make most changes at the affected facility without triggering a title V permit revision, provided the compliance plan was updated to indicate the new regulated entities and/ or new requirements that would result from the change, thus avoiding delay while ensuring that the part 70 requirements are satisfied through timely recording of the requirements applicable to the source.

Title V requires operating permits to assure compliance with all applicable requirements at a source, including a section 112 standard such as subpart GGG. An existing source subject to subpart GGG must include in its operating permit by the time of the standard's compliance date—the latest date by which most provisions of the standard would become applicable requirements at existing affected sources-sufficient permit terms and conditions to assure compliance with the standard. If a source's initial title V permit does not include terms to assure compliance with subpart GGG by the

compliance date, the permit must be revised to incorporate the standard not later than 18 months after the standard's promulgation. *See* CAA section 502(b)(9). This will ensure that subpart GGG is reflected in title V permits for pharmaceutical facilities by the time of the compliance date and as required by statute, since the compliance date for subpart GGG is up to 36 months after the standard's promulgation (see section 63.1250(f)(1). Consistent with section 502(b)(6) of the Act, however, if the standard is promulgated when fewer than 3 years remain on a major source's permit term, a permitting authority's program may reflect the option not to require revisions to the permit to incorporate the standard. The Act permits State programs to require revisions to the permit to incorporate the standard in such instances, however, so any sources with fewer than 3 years remaining on their permits upon the promulgation of today's action, should consult their State permitting program regulations to determine whether revision to their permits is necessary to incorporate subpart GGG.

The EPA does not believe that PHRMA's recommended permitting approach would ensure that operating permits for pharmaceutical facilities assure compliance with subpart GGG by the standard's compliance date and subsequently during the permit term. PHRMA recommends including basic permit content information—such as the identification of regulated emissions units and activities, and their associated compliance requirements—in an off-permit compliance plan, when such information is appropriately required in the permit. The proposal addressed this point by soliciting comment on the incorporation by reference into the facility's permit of the NOCSR. The EPA believes that it is possible to provide the flexibility sought by pharmaceutical manufacturers while maintaining Congress' intent that the title V permit contain all of the applicable Federal requirements. However, neither the proposal nor today's final rule purports to revise part 70 to accomplish this transfer of permit content from the permit to an off-permit compliance plan, and EPA does not believe that a MACT standard such as this is the appropriate vehicle to accomplish revisions to part 70. A separate rulemaking is currently underway to revise part 70, and features of today's approach may be adopted in that rulemaking.

Moreover, for facilities that have been issued a title V permit before the MACT is promulgated, PHRMA's recommended approach would not meet the requirement that these permits assure compliance with subpart GGG by the standard's compliance date. In addition, the approach would not satisfy section 502(b)(9)'s requirement that such permits be revised not later than 18 months after the promulgation of subpart GGG. PHRMA recommended that facilities that have been issued a title V permit before the MACT is promulgated be required only to apply for a MPM by the due date for the NOCSR. The due date for the NOCSR under subpart GGG can fall as late as 150 days after the compliance date, see section 63.1260(f), and the compliance date for existing sources is within 3 years after the promulgation date of the standard, see section 63.1250(f)(1). Finally, under section 70.7(e)(2)(iv), a permitting authority may have up to 90 days following receipt of a MPM application to issue an actual MPM reflecting subpart GGG.

Therefore, PHRMA's recommended approach would allow existing sources with title V permits to delay revisions to their permits to incorporate subpart GGG as long as 44 months—36 months plus 5 months plus 3 months—after promulgation of the standard, when section 502(b)(9) requires such revisions to be accomplished not later than 18 months after promulgation of the standard. In addition, of course, PHRMA's approach would not ensure that existing sources subject to subpart GGG have permits that assure compliance with the standard by the time of the standard's compliance date. For these reasons, EPA declines to adopt PHRMA's recommended approach in its entirety. However, as stated above, EPA believes the Agency can meet the industry's needs while complying with statutory obligations and Congressional intent.

The EPA agrees that some types of pharmaceutical operational changes may be subject to frequent title V revisions. As a result, the EPA met with industry representatives to clarify industry comments received on the proposal. In response, EPA developed a recommended approach for managing changes involving reconfigurations of existing equipment and the additions of certain new equipment subject to the pharmaceutical MACT through title V permits. This change management strategy in general adopts aspects of both the EPA proposal (e.g., to incorporate the NOCSR into the title V permit) and of industry suggestions for managing change made subsequent to the NOCSR.

2. Description of Recommended Approach

a. *General strategy for change management.* This notice presents an interpretation of the current regulations at 40 CFR part 70, for purposes of an experimental permitting approach under which title V operating permits may be designed to implement subpart GGG and provide operational flexibility without frequent permit revision. This approach represents EPA's current views on these issues and, while it may include various statements that permitting authorities or sources may take certain actions, these statements are made pursuant to EPA's preliminary interpretations and, thus, are not binding on any party as a matter of law. Only if EPA makes its interpretations final through rulemaking will they be binding as a matter of law. This means that States are not required to follow this approach in implementing subpart GGG through their operating permit programs, and EPA will fully and fairly consider all comments and petitions calling upon the Agency to object to permits that rely upon the change management strategy.

Nonetheless, the Agency encourages States to use the flexibility described in this preamble wherever they believe that the change management strategy will assure compliance with subpart GGG, while implementing the MACT standard in an efficient, streamlined fashion. The EPA intends to use this strategy where requested by a pharmaceutical facility and where the Agency would to be the permitting authority of jurisdiction under 40 CFR part 71.

It should also be noted that the described change management strategy is only tailored toward meeting the requirements of subpart GGG. Additional strategies are likely to be needed to address the consequences of a particular change relative to other relevant applicable requirements [e.g., minor or major new source review (NSR)], particularly when the change would cause an increase in the type or amount of air pollutants released.

Under EPA's interpretation, the Agency envisions that all title V permits implementing the pharmaceutical MACT will contain two principal structures: the incorporated pharmaceutical MACT standard and a detailed description of the array of process equipment, control devices, and initial operating conditions at the subject facility. In addition, the title V permit may contain a third structure implementing the change management strategy through prior approval of

reasonably anticipated alternative operating scenarios [see section 70.6(a)(9)].

First, as it must under title V and part 70, the title V permit will contain permit terms and conditions that incorporate subpart GGG. These permit terms will include the requirements of the MACT rule applicable to PMPUs and other equipment that comprise pharmaceutical manufacturing operations, including all requirements for identifying affected emissions sources and applicable emission standards, calculating emissions, demonstrating compliance (e.g. requirements for the operation of control devices), and for testing, monitoring, record keeping and reporting.

The second permit structure, from the NOCSR submitted by the source owner, shows current operations and how the source is complying at that time with all the relevant requirements of subpart GGG (which were incorporated as the first permit feature). Named and described in the permit are the specific processes in operation at the time of the NOCSR and all those that will be run during the term of the permit; the PMPUs and other regulated emissions equipment and activities associated with the pharmaceutical manufacturing operations; the linkages between identified emissions points and control devices used for compliance with the standard; and the linkages between the identified emissions points and their associated compliance obligations under subpart GGG. The calculations demonstrating compliance must be submitted by the source in support of these linkages.

The third permit structure addresses the management of frequent changes at pharmaceutical facilities subject to subpart GGG. This structure generally will allow permit revisions at pharmaceutical facilities to be avoided without sacrificing compliance assurance, in instances where reasonably anticipated alternative operating scenarios can be established in title V permits and supported with detailed operating logs (onsite records). If a source owner or operator can reasonably anticipate the type of changes and operating scenarios relative to the current operations defined by the NOCSR (i.e. the baseline operating scenario) that will use the equipment identified in the permit and will occur over the life of a title V permit, part 70 provides for the permitting of such changes through alternative operating scenarios. However, because equipment configurations at pharmaceutical facilities can change frequently (and without complete predictability) in response to product changeovers, new drug introductions, and process improvements, the allowed operating scenarios need to be constructed in the title V permit in a ''menu'' format.

Under the permit menu for subpart GGG, a pharmaceutical source will be able to vary its array of processes and control devices from the permitted baseline scenario without need for permit revision, provided that these ways have been preapproved as alternative operating scenarios. This could include shifting process equipment, adding replacement process equipment, eliminating equipment within the same process, or changing the type or amount of solvent in order to improve existing processes or to add new processes. These changes, however, must not exceed the capacity of the control and process equipment as set out in the permit, and must always comply with the permit and all applicable requirements. The Agency again notes that such changes occurring under the change management strategy are preapproved for subpart GGG purposes only and other actions and/or strategies are necessary where other applicable requirements are implicated by such changes.

The change management strategy also addresses the addition of new condensers and of new process equipment subject to subpart GGG. Condensers are the only new control devices currently that may be advance approved and only in limited circumstances (see section VI.L.2.b. *Additional Considerations*). Bringing new process equipment into service may be accomplished in two situations as a reasonably anticipated alternative operating scenario for purposes of subpart GGG, provided that the new equipment is preapproved in the permit and otherwise meets the requirements below.

The first situation involves the like-kind replacement of permitted process equipment which is functionally equivalent to and provides no greater production capacity than the equipment being retired. The replacement transaction, and identification of the new process equipment, must be recorded in the OSIL along with other information necessary to reflect the changed operating scenario. Because the new process equipment is replacing the retired equipment that was specifically identified in the permit, the new process equipment need not be specifically identified in the initial permit in order to be preapproved. The preapproval approach does not allow the substitution of new process equipment for permitted equipment that will remain in service elsewhere at the source.

The second situation involves the addition of process equipment which already exists on-site but is not in current service. In order to be approved for purposes of subpart GGG, this equipment must be specifically identified in the permit in terms of its type and capacity. The Agency notes that the authority to preapprove such process equipment in the permit is limited to equipment for which the owner or operator holds a reasonable expectation that the equipment will be called into service over the 5-year life of the title V permit. Because this category of equipment already exists at the facility, and will be specifically identified in the permit with its capacity and type listed for review by the permitting authority, EPA, and public, the Agency believes such equipment may not only replace permitted, retired equipment, but may also augment permitted equipment in service and thereby increase production capacity at the source.

In both of these situations, the additions of such equipment must meet all provisions of the permit governing their operation, including the requirement to stay within the approved capacity of the control device to which their emissions are routed. Other situations involving process equipment may not be preapproved and are subject to the notice procedures of section 70.4(b) or the permit revision procedures of section 70.7. Options under the current regulations are, however, expected to change (see section VI.L.3. *Legal Considerations* for discussion of anticipated treatment of subpart GGG requirements attaching to new emissions units under the upcoming part 70 revisions).

At the time a source wishes to undertake a change that could trigger different obligations under subpart GGG or its permit, the source will evaluate first whether the change is within the scope of an approved alternative operating scenario in the permit. If so, the source will select the appropriate compliance options from the alternatives approved in the permit and implement the change consistent with the terms of the permit governing such selection. The source would not be required by the permit to route emissions from specific process equipment only to the specific control devices that were linked to them in the initial detailed compliance baseline. Instead, the menu of alternative operating scenarios, described below, in conjunction with features of subpart

GGG will allow a source to shift to the compliance obligations governing the change and, where applicable, to select among the control devices at the facility that the permitting authority has approved as capable of achieving compliance.

The menu of alternative operating scenarios is a combination of the first permit structure discussed above (i.e., the requirements of subpart GGG) and some additional features. In particular, the menu consists of: (1) a description of the emissions sources (e.g., process vents, wastewater points of determination, storage tanks, and other regulated equipment components) subject to the pharmaceutical MACT; (2) the specific emission standard or standards that potentially apply to each source; (3) all control devices that have been approved by the permitting authority through performance tests or engineering analyses (as provided by subpart GGG) to comply with those standards; (4) the parameters to be monitored and data to be recorded specified for each control device, each process or equipment, as appropriate, as well as the monitored parameter values that indicate compliance (i.e., parameter trigger levels); and (5) the testing, record keeping and reporting provisions that are relevant to each type of process or emissions source.

Whether a change can be accommodated within a preapproved alternative operating scenario from the menu depends on certain boundary conditions governing such use. These boundaries primarily depend upon: (1) the performance capabilities and any capacity limitations on control devices as approved in the permit for compliance;[1] (2) whether subpart GGG's provisions governing that change are limited to replicable operating procedures (ROPs) for determining emissions and applicable emissions limits; (3) whether changed emissions fall within the performance limits of (1) above; and (4) whether the approved monitoring approach remains applicable. The ROPs must be capable of yielding the identical compliance assessment whether applied by the source, permitting authority, EPA or member of the public. That is, the results from using these procedures are the same regardless of who uses it and when. The ROPs must be scientifically credible and be based solely on nondiscretionary steps and on objective data (where data are required). These ROPs are contained either in the standard itself or established during the title V permitting process. Where the applicable subpart GGG requirement is not already such a procedure, but one that can be established during the permit process (see later discussion as to which require ments are eligible), then the source would propose it and the permitting authority would specifically need to approve it, including any limits on its use, during a title V permit process that is subject to EPA and public review.

Where a permit would contain the change management structure, the source's on-site documentation, as required by subpart GGG (section 63.1259(b)(9)), will include an up-to-date operating log for alternative operating scenarios, [also required by section 70.6(a)(9)(i)]. The on-site implementation log (OSIL) must record sufficient information to show the compliance obligations of each specific operating scenario in advance of its operation. Accordingly, the OSIL must include for each process: (1) a description of the process and the type of process equipment used; (2) an identification of related process vents and their associated emissions episodes and durations, wastewater PODs, and tanks; (3) the applicable control requirements of this subpart, including the level of required control; (4) the control or treatment devices used, as applicable, including a description of operating and/or testing conditions for any associated control device; (5) the process vents, wastewater PODs, and tanks (including those from other processes) that are simultaneously routed to the control or treatment device(s); (6) the applicable monitoring requirements of this subpart and any parametric level that assures compliance for all emissions routed to the control or treatment device; (7) calculations and engineering analyses required to demonstrate compliance; and (8) a verification that the operating conditions for any associated control or treatment device have not been exceeded and that any required calculations and engineering analyses have been performed.

The OSIL, in conjunction with and the information contained in the permit, monitoring records, and any other available information and belief formed after reasonable inquiry, will provide the basis for making annual compliance certifications under section 70.5(d). Moreover, this information will allow an enforcement authority to verify when processes were being operated, to identify which emissions points from each process were controlled and how, and to determine whether the control devices were operated at performance levels that assured compliance with subpart GGG. The permit would require the source to submit a quarterly report of the new operating scenarios contained in to the OSIL to the permitting authority and to certify to its truth, accuracy and completeness pursuant to section 70.5(d). For reporting purposes, a change to any of the elements defining an operating scenario (see above) which have not previously been reported, except for element (5) above, shall constitute a new operating scenario. The permit shall also require that monitoring data, including that relevant to the identified parameter trigger levels, be submitted semiannually (except that deviations must be reported promptly). The source or the permitting authorities would then make compliance information and the OSIL reports available to EPA or members of the public upon request, consistent with confidential business information protections.

In establishing alternative operating scenarios in a title V permit, the source would propose performance levels and operating limits for control devices to be used for compliance. Except for condensers (see section VI.L.2.b. *Additional Considerations*), sources would then demonstrate compliance using control devices operated to accommodate the range of anticipated emissions episodes [i.e., a worst-case scenario(s) as provided in section 63.1257(b)(8)(i)]. The source must provide to the permitting authority in the NOCSR control device testing information and results (or other prescribed documentation), and monitoring provisions with parameters to be monitored to show compliance with the rule. Establishing monitoring parameter levels correlated to the required emissions reduction (i.e., trigger levels for compliance) assures compliance for anticipated worst-case emissions. This provides a source with considerable flexibility since most, if not all, changes to the source are likely to fall within the permitted worst-case emissions boundary and would not trigger a permit revision.

In some situations, the source may wish to establish multiple trigger levels for the same monitored parameter within the normal operating range of an existing control device, each of which would assure compliance for different specifically defined emissions profiles. Thus, within the constraints of a control device's capacity, the title V permit may establish more than one enforceable

[1] **Note** that these limitations must include restrictions on the amount of HAPs and, where relevant, the type of HAPs which can be routed to the device. It may be necessary to include other restrictions, e.g., total organic compounds that define the capacity and the performance of the control device.

trigger level for an operating parameter to accommodate most common kinds of anticipated operations without the need for a permit revision. A ROP in the permit must be used to calculate the emissions profile of any proposed change and match the new emissions profile to the appropriate operating parameter trigger level that assures compliance with subpart GGG. For example, in a system with three separate trigger levels for the same parameter, which have been predetermined in the permit, assume that the projected emissions associated with a particular change would require the level of control corresponding to the second trigger level. As a result, the calculated emissions would exceed the emissions profile associated with the first cutoff (and its lower level of control), would correspond to the emissions profile covered by the second and meet its required parameter trigger level, and would not meet the emissions profile characteristics and not require the greater control associated with the third trigger level.

For sources employing the change management strategy, the permit shall provide that a violation of the ROPs, a violation of other conditions implementing the change management strategy, or a violation of the monitored parameter trigger levels (as applicable and recorded in the OSIL) would be a violation of the permit and of the control device trigger operating limit, and a violation of the emissions limit where specifically provided for by the standard (e.g., an exceedance of the outlet gas temperature for a condenser). The EPA notes that neither the change management strategy nor the OSIL can alter any obligations that the source has to comply with either the permit or the MACT standard itself. While permitting authorities may extend the permit shield in section 70.6(f) to the permit terms and conditions of each alternative operating scenario contained in the permit, assuming the State program has a permit shield provision, this permit shield may not be applied to the specific compliance-related changes which are only recorded by the source in its OSIL (see section VI.L.3. *Legal Considerations*). Like CAA section 502(b)(10) changes, most administrative permit amendments, and MPMs which do not undergo prior public review [*see* sections 70.4(b)(12)(i)(B), 70.7(d)(4) and 70.7(e)(2)(vi)], the part 70 permit shield may not extend to an OSIL or source determinations made pursuant to the change management approach that have failed to undergo prior EPA and public review. The source's compliance with those parameter levels recorded in the OSIL will not shield the source against challenges to the source's compliance with subpart GGG.

To illustrate the change management permitting strategy, suppose a pharmaceutical source undertakes a process improvement project that replaces two steps in an existing pharmaceutical process with one new step. This project results in the elimination of two existing process vents from the process and the addition of a new vent. No new equipment is involved. Further, suppose that subpart GGG requires the existing process and the proposed process change to meet the 93 percent reduction requirement for process vents, and the source opts to meet that limit by ducting all vents from the process to an existing thermal oxidizer. As a first step, the source owner/operator must determine whether and to what extent the previously established baseline emissions profile for the process will change. To do this, the owner/operator will calculate the uncontrolled emissions from the new vent using the equations provided in the MACT rule (and incorporated into the permit). The new process step involves the following emissions-related activities: vapor displacement (Equation 8 in section 63.1257(d)(2)(i)(A) of the rule), heating (Equations 10–17), and depressurization (Equations 18–29). In calculating emissions, the owner/operator must supply the physical characteristics from the process batch production procedures as inputs to the required equations. This description is the material used and the procedures followed exactly by the source to perform the process each time the specific product is produced. The process batch description includes details such as: the amount and type of raw materials to be used in each batch, the mixing and heating cycle durations, the final temperature of the heated ingredients, reflux rates, and the temperature of the reflux condenser.

Once the emissions from the new process step are calculated, the owner/operator adds these emissions to the previously documented emissions from the process and subtracts the emissions from the two process steps that were eliminated to determine the total emissions to be routed to the thermal oxidizer. A revised emissions profile for the process is now established. Next, the owner/operator must evaluate whether the thermal oxidizer still assures compliance with the 93 percent reduction requirement. Under the source's title V permit, the owner/operator will have calculated and documented (and the permitting authority would have approved) the worst-case emissions profile that could be accommodated by the thermal oxidizer. The owner/operator compares the emissions profile in the worst-case analysis with the improved process emissions. If the worst-case emissions profile will not be exceeded, the changed process will comply with the standard, and the existing title V permit does not have to be revised (unless required to assure compliance with applicable requirements other than those of subpart GGG). If a new worst-case scenario would be created by the change, a permit revision must be undertaken to determine whether the change can be made. In order to support the permit revision, the owner/operator will have to perform additional analysis or testing, as required by the MACT rule and/or the permitting authority, to show that the oxidizer has sufficient capacity to control the new scenario to meet subpart GGG. This may require a corresponding revision to the monitored parameter compliance trigger level in the permit as well.

As stated earlier, the owner/operator is required by the MACT rule to keep records of all calculations performed to support the process improvement change. Thus, the on-site records include results of calculations to determine emissions from the new process step and total emissions from the improved process, and the comparison of emissions from the improved process with the previously established worst-case emissions analysis. If the change can be made without permit revision, the owner/operator also is required to maintain records in the OSIL showing when the change was made and how the new vent is controlled. In addition, the permit must require that the source operate consistently with the calculations made for the operating scenario described in the OSIL. Such consistency, however, does not protect a source from violations of the standard, where the calculations are in error or otherwise fail to assure compliance with subpart GGG.

In the example presented above, the new process involves emissions-related activities that are covered by the ROPs contained in subpart GGG. However, some activities may not fall under operations for which equations have been provided in the standard. In many such cases, the change management strategy allows the source to submit for approval its proposed methodology for quantifying these emissions. Under this approach, the permitting authority would have the opportunity to evaluate the proposed methodology and, if

judged replicable, by the permitting authority—with EPA and public review, establish this methodology in the title V permit. The ROPs could be established in the permit only through the permit issuance, permit renewal, or significant permit modification process. Where they are approved and upon their incorporation into the permit, the source must then use these procedures, as applicable, to determine if subsequent changes qualify for advance approval without need for permit revision under the change management strategy. The EPA intends to issue additional guidance to inform the development, review, and approval of such ROPs during the permitting process.

For example, the MACT rule does not give exact procedures or formulae for calculating wastewater characteristics needed to determine control requirements. Instead, the rule states that HAP concentrations in wastewater are to be determined based on testing, knowledge of the wastewater stream (using a mass balance approach or one relying on published water solubility data), or bench-scale or pilot-scale testing (see section 63.1257(e)(1)). To explain the development of ROPs to address this requirement, a more specific situation must be described. Suppose that the process improvement project above includes an extraction that was not previously part of the process, resulting in a new wastewater stream which the owner/ operator wishes to treat using an existing steam stripper. In order to create the necessary ROP for determining the wastewater characteristics of streams, the owner/ operator must first establish a methodology to determine this for the baseline scenario. During the initial compliance demonstration/permitting process, the owner/operator in this example would do so by proposing to determine the concentration of a partially soluble HAP in the aqueous phase of an extraction when a single organic compound is present by assuming that the concentration will be at the maximum possible value based on the solubility value found in standard reference texts. This procedure, along with the batch description and the number of batches to be produced each year, provides a ROP for determining the characteristics of the extraction step wastewater stream (i.e., HAP concentration and annual HAP load). After approval by the permitting authority, the ROP can be used for new or modified extraction wastewater streams to characterize the stream and to determine whether the stream is subject to treatment under the MACT standard per § 63.1256(a)(1)(i). [Note that this ROP would apply only when a single organic compound is present. A separate ROP would have to be developed and applied in other cases.]

In addition to this procedure, the owner/operator must also establish a replicable procedure to compare the wastewater characteristics associated with a change to the worst-case capabilities of the treatment unit. Accordingly, the appropriate operating parameter and the trigger level necessary to assure compliance with the standard must be established in the permit. The owner/operator may wish to establish more than one such trigger level to allow steam stripper operating parameters to be varied according to the ability of the treatment unit to treat different streams being routed to it. In this example, assume that an existing process at the facility uses methyl ethyl ketone (MEK) and generates an affected wastewater stream with 125,000 ppm MEK (based on the published solubility of MEK in water). Published data show that the Henry's Law Constant for MEK is 4.36×10^{-5} atm/gmole/m^3. Assume further that the initial steam stripper compliance demonstration for MEK removal indicated that a liquid/vapor (L/V) ratio of 12.7 and an average steam feed of 2,900 pounds per hour (not to fall below an instantaneous minimum of 2,300 pounds per hour) are required to achieve compliance.

Next, assume that a second existing process at the facility uses N,N-Dimethylanaline (DMA) and generates an affected wastewater stream with 16,000 ppm (based on the published water solubility for DMA). Published data show that the Henry's Law Constant for DMA is 1.75×10^{-5} atm/gmole/m^3. Assume further that the initial steam stripper compliance demonstration for DMA removal indicated that an L/V ratio of 10.0 and an average steam feed of 3,100 pounds per hour (not to fall below an instantaneous minimum of 2,400 pounds per hour) are required to achieve compliance.

The Henry's Law Constant is a measure of the partition of a compound between air and water (i.e., the ''strippability'' of the compound). Thus, based on the compliance demonstration results above, the owner/operator could propose, and the permitting authority approve, the conditions below for inclusion in the title V operating permit to assure compliance with subpart GGG for new and modified wastewater streams routed to the steam stripper. Note that these conditions would apply only to partially soluble HAPs with Henry's Law Constants equal to or greater than that of DMA. Other provisions would have to be made for soluble HAPs and for partially soluble HAPs with lower Henry's Law Constants, or the source would have to undertake a permit revision to address new streams containing HAPs of these types.

1. When the steam stripping unit is receiving wastewater containing one or more partially soluble HAP (and no soluble HAPs) and the lowest Henry's Law Constant for any of the HAPs is greater than or equal to 1.75×10^{-5} atm/gmole/m^3 but less than 4.36×10^{-5} atm/gmole/m^3, the stripper will maintain a maximum L/V ratio of 10.0 and an average steam feed of 3,100 pounds per hour (not to fall below an instantaneous minimum of 2,400 pounds per hour).

2. When the steam stripping unit is receiving wastewater containing one or more partially soluble HAP (and no soluble HAPs) and the lowest Henry's Law Constant for any of the HAPs is greater than or equal to 4.36×10^{-5} atm/gmole/m^3, the stripper will maintain a maximum L/V ratio of 12.7 and an average steam feed of 2,900 pounds per hour (not to fall below an instantaneous minimum 2,300 pounds per hour).

To illustrate the change management strategy for the wastewater requirements, assume in this example that a new extraction step will use methylene chloride which is listed as a partially soluble HAP in Table 2 of subpart GGG. Using the operating procedure already approved in the title V permit, the owner/operator determines that the new extraction step will generate a wastewater stream with 20,000 ppm methylene chloride (based on the published solubility of methylene chloride in water) and an annual load of more than 1 Megagram per year (based on the process ''recipe'' and maximum possible production rate or as limited by permit conditions). Thus, the new wastewater stream is subject to treatment under the MACT standard pursuant to section 63.1256(a)(1)(i)(A). Published data show that the Henry's Law Constant for methylene chloride is 2.68×10^{-3} atm/gmole/m^3. Since the Henry's Law Constant is greater than 4.36×10^{-5} atm/gmole/m^3, this stream can be discharged to the existing steam stripper provided the stripper is operated within the operating parameter trigger level established in the permit [i.e., maintaining a maximum L/V ratio of 12.7 and an average steam feed of 2,900 pounds per hour (not to fall below an instantaneous minimum of 2,300 pounds per hour)].

Based on this analysis, the new extraction step can be controlled by the steam stripper to assure compliance with the MACT standard and the change can be instituted without a permit revision. The owner/operator shall maintain in the on-site log records of all the procedures used (including the characterization of the new wastewater stream, the determination that the stream is subject to treatment under subpart GGG, and the comparison with the stripper's two-level Henry's Law Constant cutoffs) and the process and treatment unit parameters needed to verify ongoing compliance (including when the process change was instituted, when the modified process is in operation, how the wastewater stream is controlled, and the L/V ratio and average steam feed rate for the stripper). Moreover, the permit shall require the recordation in the log of additional applicability and compliance information, as necessary to assure compliance with subpart GGG.

b. *Additional considerations.* Additional options are available to permitting authorities designing flexible title V permits to accommodate, without permit revision, emissions changes controlled by a condenser. Instead of requiring that all changes affecting emissions must meet the MACT standard under constant operation of an existing condenser at worst-case conditions, a permitting authority may issue permits where the condenser may be operated at different temperatures correlated to actual emissions profiles. Permits (through their terms which incorporate subpart GGG) will already contain the replicable means to calculate emissions profiles for process changes and the condenser exit temperatures required to control them. The Agency may explore development of similar approaches for other control devices, but recognizes that any such approaches before being incorporated into the permit would have to: (1) be calibrated in the field for a particular site; (2) meet rigorous tests to demonstrate scientific credibility, replicability, and practical usage; (3) ultimately assure compliance with subpart GGG and all other relevant applicable requirements; and (4) be evaluated by EPA to determine whether such an approach is possible for other control devices.

New control devices are, in general, not preapproved and their operational limits must be the subject of a permit revision which incorporates this information into the title V permit. The Agency, based on its ongoing efforts to assure compliance, has found that the proposed new control devices must be subject to a prior site-specific evaluation by a reviewing authority in order to assure that the control device is adequately sized and that reasonable assumptions were used related to its performance. This general limitation is not related to change management except where the addition of new productive capacity (e.g., a new process using new process equipment) would require control capacity beyond that previously approved in the permit. Currently, the only exception to this limitation under the change management strategy involves the preapproval of certain new condensers. Here the permitting authority may advance approve new condensers but only to the extent that they are like-kind replacements for those currently approved in the permit or are specifically identified from an inventory of preapproved, existing (but not currently in-service) devices at the facility.

With respect to Leak Detection and Repair (LDAR) work practice standards under subpart GGG, changing to a new process or modifying an existing one would not affect the content of the title V permit. These LDAR requirements apply broadly across a site as a work practice standard to the fugitive emissions of many types of equipment components at a facility. This equipment typically includes pumps, pressure relief devices, valves, and connectors, which typically number in the thousands at pharmaceutical facilities. The individual components subject to the LDAR requirements do not need to be specifically listed in a facility's title V permit.[2]

Instead, the title V permit shall contain a general identification in the title V permit of the equipment covered and the associated compliance obligations that will suffice to assure compliance with the LDAR requirements. Accordingly, a separate up-to-date list of affected equipment components must be maintained as required by the extensive LDAR record keeping provisions. Given that no specific list of components is required in the permit, and the permit shall comprehensively cover the equipment component types subject to LDAR requirements, the content of the permit will be unaffected by changes to such components that occur in the course of introducing a new process or modifying an existing one.

Finally, the promulgated rule features alternative standards for any process vent and storage tank emissions sources that are ducted to control devices. These alternative standards require achieving a specific total organic carbon (TOC) concentration of 20 ppmv and a concentration of hydrogen halides and halogens of 20 ppmv from the outlet of control devices. Sources using these alternative compliance options are likely to reduce significantly (particularly where a single control device services multiple processes using nondedicated equipment) the required record keeping and reporting and to simplify the change management strategy. For example, a source could specify processes (which do not emit hydrogen halides or halogens), each of which vents to a carbon adsorption bed documented to achieve 20 ppmv TOC. In this case, several of the permit elements implementing the previously described change management strategy could be eliminated (e.g., provisions related to the menu of compliance options and suitable control devices, and the monitoring of parameter values), and much of the record keeping could be reduced to tracking which processes are routed to the common control device and monitoring TOC outlet concentrations to show compliance with the 20 ppmv standard. However, other monitoring and record keeping requirements (e.g., flow rate maximum through the control equipment) may be needed in the permit to address periodic monitoring or compliance assurance monitoring and non-MACT applicable requirements (e.g., minor NSR) which limit the total atmospheric loading from the source.

3. Legal Considerations

The management of change strategies set forth in this preamble represent the Agency's effort to devise an innovative approach to deal with the frequent process changes that take place at pharmaceutical manufacturing facilities without the need for equally frequent revisions to their permits. The strategies rely upon a number of factors (see section VI.L.4. *Supporting Rationale for Recommended Strategy*) that, while perhaps not unique in this industry and

[2] The rule's LDAR provisions apply to significant numbers of emissions units, and typically do not involve different emissions control levels for equipment components subject to LDAR requirements. The LDAR requirements typically are written as a set of work practice standards that either apply to a piece of equipment or do not apply. To ensure that an affected source properly identifies those pieces of equipment subject to the LDAR requirements under subpart GGG, the regulation is including a requirement to maintain a separate list of affected equipment components within the LDAR recordkeeping provisions. For these reasons, and because the LDAR requirements apply to so many equipment components at pharmaceutical facilities, the Agency believes it is appropriate not to require the individual components to be specifically listed in the title V permit for these facilities.

in subpart GGG, are specific to it, and the Agency is uncertain whether and to what extent they may have application in other contexts. These factors underlie the Agency's present belief that the change management strategy in its practical application will assure compliance with subpart GGG through title V permits, and satisfy the objectives of part 70 and title V of the Act.

This approach is frankly an experimental one. Although EPA believes that the legal interpretations upon which the Agency is relying are consistent with the Clean Air Act and existing regulations, some aspects of this approach strike out in new and untried directions. In effect, EPA is conducting a pilot program to demonstrate whether permits that allow changes under subpart GGG can be made: (1) without permit revision or 7-day advance notification under section 502(b)(10); (2) based on the source's application of clear, simple definitions and ROPs; and (3) while contemporaneously being recorded in detailed operating logs. The EPA will therefore be testing its belief that such an approach will be practicably enforceable, will assure compliance with the standard-obtaining the emissions reductions required by the standard, and will satisfy the objectives of title V of the Act.

The 40 CFR parts 70 and 71 provide for the establishment in title V operating permits of terms and conditions for reasonably anticipated operating scenarios at a source.[3] A source may then preapprove alternative operating scenarios in its permit and switch among these scenarios in response to operational demands, without obtaining a permit revision to account for the previously approved new operating scenarios and their different applicable requirements. All title V permits, including those implementing alternative scenarios, must contain terms and conditions sufficient to assure that each operating scenario will comply with all applicable requirements and will meet the requirements of part 70. Pursuant to section 70.6(a)(9), the source must identify such scenarios in its permit application and the permitting authority must approve the scenarios for inclusion in the permit. The permit terms and conditions necessary to implement the alternative operating scenarios must also require the source to record contemporaneously in an on-site log the scenario under which it is operating, upon changing from one scenario to another. The contemporaneous record of the present operating scenario that the source maintains on-site serves to document for important inspection and enforcement purposes that the source is in compliance with the source's permit terms and conditions.

The determination of when alternative scenarios are ''reasonably anticipated'' and would meet the requirements of section 70.6(a)(9) is not amenable to a rigid legal formula that can dictate through general guidance what types of permit terms and conditions will ensure that a source's future operations comply with these requirements. Instead, there must be legal and practical considerations that inform this determination within EPA's reasonably broad discretion to do so. The Agency has identified certain preliminary legal boundary considerations and conditions for implementing reasonably anticipated operating scenarios to meet subpart GGG, pending further experience with pilot projects and permits and further guidance or rulemaking on the subject.

The structure and nature of title V permitting will determine how permit terms and conditions may be developed to reasonably anticipate alternative operating scenarios. The part 70 regulations govern the content requirements for permit applications and permits in section 70.5 and 70.6, respectively, and these sections will govern how reasonably anticipated alternative operating scenarios must be addressed in permit applications and permits as well. For example, all part 70 permit applications must contain information ''for each emissions unit at a part 70 source,'' which includes a description of the source's processes and products for each alternate scenario identified by the source [sections 70.5(c) and (c)(2)]. Section 70.6(a)(9) in turn makes clear that a source must identify in its application each reasonably anticipated operating scenario for which it intends to include permit terms and conditions.

Along the same lines, section 70.6 requires that all part 70 permits include emissions limitations and standards, monitoring, record keeping, reporting, compliance and other requirements to assure compliance with all applicable requirements. Section 70.6(a)(9) again makes clear that the permit terms and conditions governing alternative scenarios must meet these requirements. Applicable requirements generally fix a source's compliance obligations on an emissions unit or activity, control equipment, process, or combination thereof. Permitting alternative scenarios requires the ability to reasonably anticipate future emissions units, future operational details, and the compliance obligations under each applicable requirement associated with each operational state, as necessary to assure compliance with each applicable requirement.

The permit terms and conditions governing each alternative operating scenario must assure compliance with all part 70 and applicable requirements at all times. This means that the permit terms and conditions must assure compliance with all relevant requirements at the time of initial permit issuance and at the time that changes to alternative operating scenarios are undertaken in the future. Upon a source's change from one operating scenario to another, the terms and conditions of the permit must continue to fully and accurately reflect the source's compliance obligations under all requirements applicable to the change. If a source changes to an operating scenario that was not provided for in its permit, or if a change undertaken by a source triggers compliance obligations that are not fully and accurately reflected in the permit, then the source would be subject to the permit revision, permit reopening, or section 70.4(b) notification provisions, as applicable, under the part 70 regulations prior to making the change.

The permitting of established operating scenarios at a part 70 source that are fully known, identified and expected is straightforward. Such situations are accounted for in part 70 permits through terms and conditions that specify the emissions units and activities, provide required citations to applicable requirements, and supply the additional range of permit provisions required in a complete title V permit. Reflecting current equipment and activities, existing operating configurations, and presently applicable regulatory requirements, these operating scenarios present no difficulty to incorporating into an operating permit sufficient terms to meet the permit content requirements of part 70.

The preapproval and permitting of reasonably anticipated alternative operating scenarios is somewhat different in that their associated emissions units and activities, operational configurations, and applicable requirements may not be known with the same specificity as

[3] Because part 71 addresses alternative operating scenarios in the same fashion as part 70, the Agency believes that part 71 is equally amenable to the management of change approach described in this section. For ease of discussion, this section will refer to the relevant provisions of part 70 in discussing the management of change approach. The EPA intends, however, that the part 70 discussions in this section should have equal force and application to the corresponding provisions of part 71.

previously established operating scenarios. Nonetheless, in order to be included in the permit as alternative operating scenarios, the source must provide sufficient specificity for those scenarios to allow the permitting authority to determine the applicable requirement(s) and establish permit terms and conditions assuring compliance with those applicable requirements and the requirements of part 70. The EPA believes that it is a reasonable interpretation of section 70.6(a)(9) to require only that permit terms and conditions reasonably anticipate the emissions units and activities, operational configurations, compliance obligations, and other relevant information associated with each alternative operating scenario, so long as the permit terms and conditions assure compliance with relevant applicable requirements at all times. Conversely, there may be new or different requirements that attach to an operating scenario at the time that the source changes to that scenario, or other material differences from the permitted operating scenario may have arisen, such that the change and its regulatory requirements are not covered by the permit. If the permit does not reflect those requirements because they were not previously established, then the source, as provided for under the part 70 regulation, must account for all requirements applicable to that operating scenario, whether through a permit revision or advance notification or in response to a permit reopening.

The permit terms needed to approve alternative operating scenarios to assure compliance with all applicable requirements and to be reasonably anticipated may, in general, be expected to vary by source category, the different types of emissions units and operating scenarios present at sources, and the inherent uncertainty of predicting future operating conditions and market demands. In particular, the authorizing permit limits might vary based on several factors which primarily include, but are not necessarily limited to: the types and specific terms of the applicable requirement(s); the complexity of the facility; whether the type or quantity of emissions will change widely; whether different pollution control devices will be needed; the ability of the permitting authority to develop practicably enforceable permit terms for alternative scenarios and to define the limitations of the control and monitoring approaches; the potential for future technology advances (where such advances are linked to the nature of the applicable requirements); and the presence of discretion in determining the applicability and/or the compliance status of the change. These factors are not always present, are often interdependent, and can range widely in their ability to affect whether compliance with the applicable requirements can be assured and whether operating scenarios can be reasonably anticipated.

Because permit terms and conditions for reasonably anticipated operating scenarios implementing subpart GGG will be based in part upon ROPs that are designed to yield site-specific compliance details at the time of a change, EPA believes these procedures must be capable of yielding the identical compliance details, such as compliance triggers for monitored control device parameters, whether applied by the source, permitting authority, EPA or member of the public. Thus, the permit terms and conditions which incorporate such procedures will produce predictable and certain compliance results at the time of a change.

The EPA is testing this approach to determine in practice the appropriateness of allowing pharmaceutical facilities to determine the specific compliance obligation(s) under subpart GGG that apply to a particular process change through reliance on the standard's ROPs and ROPs that gained earlier approval through the permitting process. The form of the ROPs in subpart GGG and the nature of pharmaceutical manufacturing operations, in conjunction with the other safeguards and features of the change management strategy, are central to the Agency's willingness to conduct this pilot strategy here.

A source's compliance with permit terms and conditions for reasonably anticipated operating scenarios based upon properly implementing ROPs derived from subpart GGG will be ''deemed'' compliance with the applicable requirement for section 70.6(f)'s permit shield only to the extent that the source applies the procedures correctly. While permitting authorities may extend the permit shield to the permit terms and conditions of each alternate operating scenario implementing subpart GGG, assuming the State program has a permit shield provision and assuming it is applied in the permit consistent with section 70.6(f), part 70's permit shield may not extend to on-site implementation logs required by section 70.6(a)(9)(i). Like section 502(b)(10) changes, most administrative permit amendments, and MPMs that do not undergo prior public review [*see* sections 70.4(b)(12)(i)(B), 70.7(d)(4) and 70.7(e)(2)(vi)], the part 70 permit shield may not extend to an implementation log that has failed to undergo prior public review. Nor may the shield extend to the outcomes of ROP equations, applicability or nonapplicability determinations, or other compliance determinations recorded only in the OSIL. While a source will be required to use the implementation log to follow compliance triggers that implement the permit and one or more applicable requirements, the permit shield is not available to deem the source's compliance with those compliance triggers to be compliance with the permit or the applicable requirement.

In addition to permitting authority review, part 70 permits are subject to public and EPA review to ensure that the permit terms and conditions assure compliance with all applicable requirements and the requirements of part 70. An essential consideration in determining whether permit terms and conditions reasonably anticipate operating scenarios is whether the permit provides sufficient information and opportunity for the public and EPA to determine and comment in a meaningful fashion whether the terms and conditions of reasonably anticipated operating scenarios meet, and will continue to meet, all applicable requirements (including those of subpart GGG) and part 70 requirements.

Permit terms and conditions reflecting alternative operating scenarios, like all part 70 permit terms and conditions, are subject to the possibility of EPA objection and public petition under section 505(b) of the Act. In addition, operating permits are subject to the possibility of reopening by permitting authorities or EPA under sections 502(b)(5) and 505(e) of the Act. Permit terms and conditions of alternative operating scenarios that fail to reasonably anticipate future operating scenarios, emissions units and activities, and their associated compliance obligations may be subject to EPA objection, public petition, or reopening for cause. Failure by permitting authorities to submit information necessary for the public and EPA to review proposed permits adequately constitutes grounds for an EPA objection under section 70.8(c)(3)(ii), but information necessary for the review of alternative operating scenarios should be guided by the principle that permit terms and conditions must reasonably, but not perfectly, anticipate alternative operating scenarios. (Note, however, that the permit and any alternative

operating scenarios must fully and accurately govern changes that a source believes to be pre-approved at the time of the change, or else the part 70 permit revision, permit reopening, or 502(b)(10) notification provisions, as applicable, must be followed prior to making the change.)

Section 70.6(a)(9) affords permitting authorities the latitude to impose permit terms and conditions to assure that alternative operating scenarios meet all applicable requirements and the requirements of part 70. Such terms and conditions may go beyond compliance obligations strictly incorporated from applicable requirements being implemented pursuant to the alternative scenario. For example, in order to assure compliance with an applicable requirement or part 70, a permitting authority may determine that it is necessary to impose additional safeguards for alternative scenarios, such as requiring new emissions units or emissions units operating under different scenarios to be routed to a common, existing control device with preapproved capacities and operating parameter limitations. A permit might also require additional monitoring, record keeping, or reporting, or require that the source undertake a permit revision should future changes deviate materially from the reasonably anticipated scenarios in a manner that jeopardizes the permit's ability to meet all part 70 and applicable requirements. Finally, the permitting authority may require additional details and compliance information in the source's on-site log to ensure that the record of the source's current operating scenario, in conjunction with the permit terms and conditions, assures compliance with all requirements in a manner that serves important compliance, inspection, and enforcement purposes. If the permitting authority determines that these additional safeguards are necessary for an alternative operating scenario to assure compliance with one or more applicable requirements, the permitting authority need not approve the alternative scenario in the permit without such measures.

The preceding legal considerations apply in general to alternative operating scenarios implementing subpart GGG. It is also important to distinguish further among categories of alternative operating scenarios, on the basis of whether new versus existing process equipment or control devices are involved, and on the basis of the specificity of the equipment identification, operational configurations, and linkages to applicable requirements in the permit. Of the three categories of alternative operating scenarios described below, the Agency is prepared to test the appropriateness of the second and third approaches under section 70.6(a)(9) for purposes of implementing subpart GGG.

First, there are alternative operating scenarios for existing emissions units and activities at a part 70 source, covering specifically identified operational states or configurations for specified emissions units. In its simplest form, this category is exemplified by an emissions unit such as a fossil fuel-fired boiler that has two fuel burning options, which are each subject to a different applicable requirement with different monitoring obligations. The task of reasonably anticipating the terms and conditions of an alternative operating scenario such as this is furthered by the relative ease of specifying the emissions unit and its activities, operational configurations and conditions, and associated applicable requirements. A source's past operating experience as well as future operational certainty, founded upon existing emissions units and activities, will make permitting of such alternative scenarios more like the task of permitting a source's current operating scenario.

The second category of alternative operating scenario, being tested to implement subpart GGG, covers the combination and reconfiguration of existing emissions units and control devices in alternative operational states and configurations that are not specifically identified in the permit. As described in greater detail in section VI.L.2.a *General Strategy for Change Management*, a permit menu of alternative operating scenarios may be constructed to govern only the subpart GGG compliance obligations of process equipment and control devices specifically identified in the permit. If a change to an alternative operating scenario preapproved in a permit menu involves only the reconfiguration of existing, permitted emissions units or control devices, and the change remains within the capacity of an approved control device to which it is routed; if subpart GGG's provisions governing that change are limited to ROPs; and if the other criteria of the change management strategy are satisfied (including the contemporaneous recordation of compliance information in the OSIL), then EPA is willing to test whether such an approach will assure compliance with subpart GGG through title V permitting. While this approach will not specify future applicability determinations and establish the specific compliance obligations of particular process configurations to the same degree as the first category of alternative operating scenarios, EPA anticipates that the approach will nonetheless assure compliance with subpart GGG and otherwise meet the requirements of part 70.

The third category of alternative operating scenario, again tested in this pilot permitting approach to subpart GGG, covers new emissions units and condensers that are not in service at the time the operating scenario is established in the permit, but that may be preapproved (with respect to subpart GGG requirements) in two circumstances only. First, the permit may preapprove future like-kind emissions units or condensers that will replace retired emissions units or condensers without increasing permitted capacity. Second, the permit may preapprove specifically identified, on-site surplus processing equipment that may replace retired equipment or augment in-service equipment by increasing production capacity. The Agency believes that it is a viable interpretation of the existing section 70.6(a)(9) to allow alternative operating scenarios implementing today's standard to include permit terms and conditions approving in advance these categories and usages of new emissions units and condensers that will be subject to subpart GGG, if they meet the criteria discussed earlier in section L.2.a.

The EPA, in August 1994, proposed to allow use of the concept of alternative operating scenarios under section 70.6(a)(9) to provide advance approval to construct and operate new or modified units subject to NSR and section 112(g) (referred to as ''advance NSR''). (59 FR 44460, 44472, Aug. 29, 1994). Under this proposal, advance NSR would have allowed permitting authorities to establish the applicable NSR or section 112(g) requirements before a reasonably anticipated project or class of projects was constructed or modified, and then include that project's requirements in the part 70 permit for the facility. As a result, the project would be ''preapproved'' by the permitting authority, without the need for a later part 70 permit revision since the part 70 permit would already contain the relevant construction and operation requirements for the project.

In August 1995, EPA further clarified its advance NSR proposal by proposing to add a definition of advance NSR to section 70.2, and by explaining that, in EPA's view, a change subject to an advance approval scenario would not be a change under section 502(b)(10) of the Act (60 FR 45530, 45544–45, Aug. 31, 1995). Rather, it would constitute a

switch to an alternative operating scenario under section 70.6(a)(9). As the 1995 preamble noted, this interpretation would have two advantages. First, it would allow the use of advance NSR for title I modifications, and avoid the limitation that changes made under section 502(b)(10) cannot be title I modifications. Second, and more important, the 7-day advance notification under section 502(b)(10) which attaches to each change made under that section would not apply to changes under the advance NSR approval. Consequently, where the State operating permit program allows for advance approval, and the permitting authority approves an alternative scenario containing advance approval, the part 70 permit could allow a source to make the approved change without an advance notice or a part 70 permit revision.

Although the Agency has not finalized revisions to the part 70 regulations to adopt the proposed amendments to sections 70.2 and 70.6(a)(9) discussed above, the Agency is prepared to interpret the existing part 70 regulations for purposes of the change management strategy for subpart GGG approach to enable alternative operating scenarios to encompass advance approvals in the limited manner described in this notice. In other words, for purposes of the approach described in this section, EPA believes that it is a reasonable interpretation of existing section 70.6(a)(9) to cover the advance approval of the categories of new process equipment and condensers described in this notice, within the scope of alternative operating scenarios that may be included in part 70 permits. The concept of ''reasonably anticipated operating scenarios'' is expansive enough to encompass not only existing equipment that may operate under a different operating scenario reasonably anticipated to occur, but also to encompass new equipment that replaces permitted equipment (without increasing permitted capacity), and new surplus equipment that is on-site and specifically identified and pre-approved in the permit.

The Agency is prepared to advance these interpretations under the current regulations prior to any final action on the part 70 revisions that might adopt the proposed amendments, for purposes of implementing subpart GGG through the pilot approach for the change management strategy described herein. This interpretation may not be relied upon for purposes of implementing applicable requirements other than subpart GGG through title V permits. The EPA may extend this interpretation to other applicable requirements, however, in the context of an individual permitting pilot project in order to facilitate the development and evaluation of the change management strategy, along with other flexible permitting opportunities, for the pharmaceutical industry. The policies set forth in this section are intended solely as guidance for purposes of implementing subpart GGG, do not represent final Agency action, and cannot be relied upon to create any rights enforceable by any party.

Other changes that a pharmaceutical facility undertakes that implicate subpart GGG requirements and that are not preapproved in the permit through the change management strategy or ordinary alternative operating scenarios, must be accounted for through part 70's permit revision or section 70.4(b)(12) or (b)(14) notice procedures, as appropriate. Such changes would include, but are not necessarily limited to: changes among permitted, in-service equipment involving subpart GGG's provisions governing the change that are not limited to ROPs; changes that would exceed the performance capabilities or capacity limitations of approved control devices; changes involving the addition of new emissions units or control devices (including any control device other than condensers) that have not been approved pursuant to the categories discussed in section L.2.a; and other changes that are not otherwise preapproved in the permit. Finally, of course, changes that implicate applicable requirements other than or in addition to subpart GGG must be addressed in the manner required by the part 70 regulations.

In the proposed revisions to part 70 in August 1995, 60 FR 45530, EPA proposed an expeditious permit revision process for the incorporation of requirements that would not need source-specific tailoring. The process was referred to as ''notice-and-go,'' since the source could operate the change as soon as it submitted a notice to the permitting authority, and would not need to wait for review or approval of the change by the permitting authority. The EPA further elaborated on the concept in a **Federal Register** notice announcing the availability of its May 14, 1997 draft final revisions to part 70, published on June 3, 1997, 62 FR 30289, where the process was called ''notice-only.''

As currently envisioned, the process would be available for changes that are: (1) subject to requirements taken directly from the applicable requirement; (2) where there is no creation of any source-specific requirements; and (3) the permitting authority allows the change to take place without the need for its review or approval. For example, incorporation into the permit of a compliance option specified in a MACT standard would be eligible for notice-only procedures, but the establishment of source-specific parameter ranges for monitoring the performance of a control device would not be eligible. The installation of a degreasing unit subject to the halogenated solvent cleaning MACT standard under subpart T of Part 63 would also be eligible, if the facility elects to meet the standard through one or more of the compliance options specified in the MACT standard. This change would be eligible for the notice-only process because the permit terms that apply to the change would be taken straight from the underlying requirement, and there would be no need to add monitoring requirements.

In the May 1997 draft, EPA would have required the source to certify compliance in the notice with all applicable requirements that apply to the change (in the case of subpart GGG, for example, a new unit being added). This certification requirement helps offset the lack of review by the permit authority prior to operation of the change, since a source making a false certification would be subject to penalties, or to criminal fines in the case of a knowing violation. There would also be no permit shield available for ''notice-only'' changes, so if a source failed to identify one or more requirements that apply to a new unit, the requirements are nonetheless applicable, and the source would be liable for any violations of applicable requirements to which the change is subject.

The Agency anticipates that the notice-only category of the third tier of the part 70 revisions, if adopted as presently conceived, would accommodate the application of subpart GGG requirements to new process equipment and control devices through part 70 permit revisions. Part 70 permits implementing subpart GGG through the management of change approach described in today's notice likely will have established source-specific requirements for existing control devices in the initial permit. The purpose of the notice-only procedures would be to revise the permit so as to identify new process equipment or control devices being added at the source, and to match up relevant permit requirements that apply to the new units. As noted at the outset of this section, however, it still may be

necessary to address the consequences of a particular change relative to other relevant applicable requirements that may attach to that change. Thus, changes must be evaluated under the part 70 permit revisions to determine what level of permit revision might be required to address other regulatory consequences of the change.

4. Supporting Rationale for Recommended Strategy

a. *Overview.* The EPA has initiated this pilot permitting strategy for subpart GGG based upon a preliminary view that the recommended approach will satisfy section 70.6(a)(9)'s expectations for ''reasonably anticipated'' alternative operating scenarios, and comport with title V's mandate that operating permits assure compliance with applicable requirements. In general, the Agency believes the change management strategy meets these criteria by relying upon the basic design and provisions of subpart GGG; the additional requirements under the policy for permits to contain terms that assure the proper identification and compliance of all alternative operating scenarios covered by the strategy; and the title V permit issuance, significant permit modification, or renewal processes, along with quarterly reporting to permitting authorities, to afford meaningful opportunities for the permitting authority, EPA, and the public to review the strategy proposed by a source, and oversee its implementation, for a particular location.

Notwithstanding these provisions and protections, the Agency is recommending that permitting authorities use the change management strategy only on a trial basis, and only with respect to subpart GGG. The EPA notes that the need to match that changes in emissions correctly to their applicable subpart GGG requirements is central to the purpose of section 70.6(a)(9). As a critical first step, certain key definitions (e.g., process vent, process) and other rule provisions must be interpreted by EPA or the permitting authority in the permit process before applying the relevant ROPs. The ROPs then objectively size and sort emissions changes relative to their subpart GGG obligations and assure compliance in part by routing the new emissions, as appropriate, to a control device with sufficient capacity. Use of these definitions and regulatory provisions could be open to interpretive disputes and misapplication of the standard. However, due to several factors (including the homogeneity of process equipment in the industry, the high accuracy with which emissions resulting from changes can be characterized, the existence of ROPs for determining emissions and the effects of emissions controls, and the validation of a source's use of the relevant definitions, regulatory provisions, and ROPs during the title V permit process), EPA believes that there is a sufficiently low probability that sources will make errors in applying these definitions and provisions during the implementation of the change management strategy. Accordingly, the Agency will determine on the basis of empirical results whether this strategy needs additional protections, whether it is an appropriate approach to permitting, and/or whether and on what basis it can be made available to a broader range of sources and standards.

b. *Detailed Rationale.* Subpart GGG is a process-based standard which has been carefully designed to provide the framework needed by the change management strategy to establish the preapproved family of alternative operating scenarios for reconfiguration of existing process equipment and to define the compliance obligations of operating scenarios involving the addition of certain new process equipment. This framework is defined primarily from three types of features found in subpart GGG. In total, these three features establish a means for demonstrating continuous compliance that must be repeatedly applied for process and operational changes at the source.

The first feature is comprised of requirements relating to the use of equations to estimate emissions from various pharmaceutical operations. These equations provide the ability to characterize a process or operational change's effect on emissions in a replicable and accurate fashion. The equations incorporate proven chemical and physical principles such as the Ideal Gas Law and Raoult's Law, and have previously been approved by the Agency (most recently in MACT standards for the Polymers and Resins Industry, subparts U and JJJ of 40 CFR part 63). Upon their incorporation into the permit and approval by the permitting authority, a source must use these equations to determine applicability of the standard and to demonstrate initial compliance with it. Subsequently, the source must use the equations to determine the emissions from changes in operations together with those from ongoing operations. Anyone using the level of emissions predicted from these equations would then determine in exactly the same objective fashion how to maintain compliance with subpart GGG while manufacturing different intermediate or final products.

The second feature providing flexibility is the requirement that control devices be designed to accommodate reasonable worst-case operating scenarios without need for revised operating parameters or operating conditions. This means that most changes that affect emissions can be handled by the devices. In all cases, compliance assurance is achieved by virtue of the requirement to compare the emissions profile associated with the change with the worst-case operation approved for the relevant control device(s) and to require a permit revision where the changed operation would present a need for greater control.

The third feature of the rule that facilitates operating changes is the record keeping requirements. In the OSIL, as described earlier (see section VI.L.2.a. *General Strategy for Change Management*) sources must keep a precise log of the operation of batches, the occurrence of any process or operational changes and associated changes in emissions, the requirements of subpart GGG contemporaneously applicable to each process under its new operational state, and the controls used to comply with these requirements. The information required by the permit, together with on-site records and the required calculations for the sizing of emissions sources and the sorting of changes relative to their subpart GGG requirements allows an inspector to determine initially and for any subsequent time period which activities from a listed process require control and the level of control that is required for each.

The rule enables the company's basic framework for the change management strategy to be incorporated into the title V permit. In addition, other permit terms are needed to assure that an appropriately useful scope of alternative scenarios can be reasonably anticipated and preapproved to meet section 70.6(a)(9) and that the compliance obligations of certain new process equipment (i.e., like-kind replacements and on-site surplus equipment identified in the permit) can be defined. The first of these terms applies to operations that are not covered by ROPs as taken directly from the requirements in subpart GGG. Previous discussions of ROPs have alluded to two types, those that are included in detail in subpart GGG and those that are established in the title V permitting process to meet subpart GGG. The latter category is necessary because of the compliance flexibility that subpart GGG contains.

For the methodology that the source proposes to receive the status of a permit-required ROP for purposes of the change management strategy, the permitting authority must determine that the methodology is scientifically credible and is objectively replicable. The bottom line is that the ROP must be a procedure based solely on nondiscretionary steps and on objective data (where data are required) to accomplish these steps. Accordingly, the results from using these procedures are the same regardless of who uses them and when. Where the permitting authority preapproves ROPs, the permit shall require the source to use them over the defined range of similar operations (unless, of course, the source wishes to obtain approval of a different method under the permit revision process). The EPA would like to stress that the ROPs are only an important part of the compliance process established by following the standard and are not an alternative standard, monitoring, or test method.

Section 504 (a) of the Act provides the legal basis for establishing ROPs during the permit process. This section requires that title V permits contain emissions limits/ standards and other terms as needed to assure compliance with applicable requirements. In its White Paper Number Two issued in March 1996, EPA stated that title V permits pursuant to section 504(a) may contain terms which are not necessarily the terms of a particular applicable requirement, provided that such terms assure compliance with this requirement. (see section II.A.2.d. and II.A.5.) The Agency believes that this same authority also supports development of a methodology as a ROP during the title V permit process, provided that its development is consistent with the provisions of the applicable requirement, following the methodology would provide the same degree of compliance assurance as would following the applicable requirement directly, and sufficient procedural safeguards are followed in its establishment.

Subpart GGG is consistent with establishing such methodologies. For example, it empowers the permitting authority to review and approve, as appropriate, a source's proposed emissions estimating procedures for operations not covered by the standard's equations. In addition, as part of the initial compliance determination process laid out in subpart GGG, the source is required to provide the specifics of its calculations and engineering analysis procedures to the permitting authority as a matter of course. Subject to certain boundary conditions on its applicability and use, the specific source proposal can often be extended into a methodology to address future qualifying changes.

The EPA is testing whether reliance on this approach also provides equivalent compliance assurance to that provided from a case-by-case review implemented for the same change by the permitting authority. In the absence of the change management strategy, the permitting authority would evaluate the procedures used by the source each time a change was to be made. Thus, the permitting authority would be called upon to make the same judgements in either case; only the timing and frequency of the review and approval process would change. In the context of the strategy, the permitting authority and the source simply agree ahead of time on the replicable procedures that are to be used for a range of changes.

Finally, by requiring that the approval to take place during permit issuance, permit renewal, or significant permit modification, the change management strategy ensures that adequate oversight by the public and EPA occurs. This determination and approval by the permitting authority must take place during a process in which EPA and the public are afforded the opportunity to review and comment on the methodology and upon its initial use. The EPA requires that the streamlining process contained in its White Paper Number Two issued March 1996 be used to accomplish this review (including the submittal of the demonstration to EPA while a complete application containing the demonstration is otherwise submitted to the permitting authority). Application of the methodology and its outcomes must also be reflected in the OSIL. Verification of its use as well as the supporting calculations and analyses will be included (consistent with confidential business information protections) as part of the quarterly OSIL report describing changes since the last report. This report shall be submitted to the permitting authority on a quarterly basis and be made available to the public and EPA.

It should be noted that subpart GGG, while not specifying enough details to make some procedures replicable, typically does include guidance on what will be required. For example, the standard allows sources to demonstrate compliance for small control devices using a design evaluation and specifies for each type of control device the factors that must be included in this evaluation. This guidance facilitates the permitting authority's review of the design evaluation that the source subsequently submits. Thus, in many cases, the standard provides the target for the design of a ROP, but leaves the details to be proposed by the source and approved by the permitting authority.

While the mentioned ROPs should enable the vast majority of expected changes to be preapproved in the title V permit with respect to compliance with the MACT standard, some exceptions do exist. Changes governed by MACT provisions which are affected by any meaningful subjective judgments cannot be preapproved. This would include all procedures which are not replicable as contained in subpart GGG and are not otherwise approved during the permit issuance or revision process to be ROPs. In addition, certain requirements apply in a very event-specific fashion and cannot be preapproved without a precise advance understanding of a particular change. The EPA has already identified some requirements and procedures in the final MACT rule that cannot be relied upon or developed as ROPs, and thus may not be employed under the change management strategy.

For example, for any process unit complying with the pollution prevention alternative standard, an owner/operator must establish baseline production-indexed HAP consumption factors from which to apply the 75 percent consumption reduction requirement. Such baseline factors are determined from historical information, and the acceptability of the value depends on which historical years are selected to represent the baseline and on the methods used for the involved material balance around the process unit. It is highly probable that each baseline consumption factor demonstration will encompass unique, process-specific information and methodologies that significantly affect the final value of the factor. With that in mind, the Agency feels that generic preapproval is not possible for changes whereby existing process units switch from complying with individual emission standards on emissions sources (such as a 93 percent reduction requirement for process vents) to complying with the pollution prevention alternative standard. It is appropriate that the permit revision process be used for making such changes.

An additional category not eligible for conversion to ROPs consists of determinations or approvals which have not been delegated to the permitting authority and must be submitted to EPA for approval. For example, the Administrator must review and approve, as appropriate, any source

proposal for an alternative emissions limit or test method. Such reviews cannot therefore be addressed in advance by a ROP defined by the permitting authority.

The Agency has preliminarily reviewed the requirements of subpart GGG in the context of defining which of them contain: (1) ROPs as written; (2) requirements that can be established during the permit process as a ROP; and (3) requirements which are ineligible for developing such procedures. Tables 3, 4, and 5 follow which describe this initial categorization. The EPA expects to address this subject more in its implementation guidance for subpart GGG.

TABLE 3.—PROCEDURES THAT ARE REPLICABLE AS WRITTEN IN SUBPART GGG

Procedure	40 CFR part 63 citation
Calculating uncontrolled emissions from process vents—equations for eight types of operations	63.1257(d)(2)(i)(A) through (H).
Calculating controlled emissions from process vents discharged through a condenser—equations for eight types of operations.	63.1257(d)(3)(i)(B) (*1*) through (*8*).
Equations for determining whether an existing vent is subject to 98% control	63.1254(a)(3)(i).
EPA performance test methods and calculations	63.1257(a)(2), (a)(3), (b)(1) through (8), and (b)(10)(i) through (iii).

TABLE 4.—POTENTIALLY REPLICABLE OPERATING PROCEDURES THAT CAN BE ESTABLISHED THROUGH PERMITTING WHERE APPROVED BY PERMITTING AUTHORITY, AND SUBJECT TO REVIEW BY EPA AND THE PUBLIC

Procedure	40 CFR part 63 citation
Evaluation of an air pollution control device capability for new scenario (not subject to testing)	63.1257(b)(8)(ii).
Establishing the emissions profile for inlet to control device	63.1257(a)(i).
Determining uncontrolled process vent emissions from an operation not covered by the eight equations in subpart GGG.	63.1257(d)(2)(ii).
Determining whether a new/modified process vent is within the worst-case emissions approved for a control device.	None.
Determining annual HAP load in a wastewater stream	63.1257(e)(1)(iii).
Determining annual average HAP concentration in a wastewater stream	63.1257(e)(1)(ii).
Identification of wastewater streams that require control	63.1256(a)(1).
Evaluation of wastewater treatment unit capability for new scenario	63.1257(e)(2)(ii).
Demonstrating that wastewater tank emissions are increased no more than 5 percent by heating, treating with an exothermic reaction, or sparging.	63.1256(b)(1).
Determining storage tank design capacity	63.1253(a) (1) and (2).
Maximum true vapor pressure for determining storage tank applicability	63.1251.
Methodology for determining individual HAP partial pressures in nonstandard situations	63.1257(d)(2)(i).
Emissions averaging compliance alternative	63.1252(d).
Pollution prevention compliance alternative	63.1252(e).
Demonstrating that an equation in the rule is not appropriate in a specific case for an operation covered by one of the eight equations.	63.1257(d)(2)(ii).
Demonstrating alternative test methods or emissions limits (or any other determinations which the Administrator has not delegated).	63.1261.

The recommended approach for permits also assures that alternative operating scenarios are reasonably anticipated for the reconfigurations of permit-listed equipment by requiring the initial detailed linkages among processes, vents, PODs, tanks, control obligations, and eligible controls contained in the NOCSR to be incorporated into the permit. This incorporation of the baseline operation serves to define an important benchmark from which to anticipate similar, but different future operating scenarios using the same equipment.

The Agency believes that the more general description of equipment within each particular alternative operating scenario in the menu may be appropriate under the particular design of the pharmaceutical MACT standard. That is, a description of process equipment in less detail can be justified here where the determination of process emissions is clear and a highly effective control approach is used, which is also versatile and effective enough to accommodate a wide range of inlet loadings (and the range is documented and specified on permits). Thus, a conservative approach to emissions reduction (e.g., most devices would operate as if the worst-case scenario were occurring), coupled with a replicable, objective basis (i.e., a required ROP for emissions calculation) to assure that each new change in operation is no more demanding on the control device than the previously established worst case, inherently allows more flexibility under which to ''anticipate'' a family of alternative operating scenarios.

One potential weakness of the change management strategy is that, before the mentioned ROPs can be relied upon to establish compliance obligations and to assure compliance with them, the strategy depends on the correct application of certain key definitions (e.g., process vent, process) and other regulatory provisions when a change in emissions occurs. Although EPA has carefully designed these definitions to be clear in their meaning, interpretive disputes could still conceivably arise. The Agency believes for several reasons, however, that there is an extremely low probability for such disputes to occur and that the change management strategy should assure compliance with subpart GGG.

First, the industry, in its basic operations and how subpart GGG definitions will apply to them, is relatively well known. While this assertion may appear to run counter to previous statements regarding the constantly changing processes and equipment configurations that characterize much of the industry, in actuality, the process steps that make up

the wide range of processes in the industry are confined to a relatively limited number of different chemical engineering unit operations. Thus, while the number of process steps, their order, and the specific conditions of each (e.g., temperature, solvents, etc.) may vary widely from process to process, the individual steps are basic, standard unit operations. The chemical engineering principles that govern these unit operations (and their air and wastewater emissions) are well understood. In addition, the FDA independently requires processes to be well defined which limits further any variations in definitional interpretations.

In addition to the significant protections that these inherent safeguards and the OSIL provide, the probability of misinterpreting the use of a particular definition is further reduced during the permit action that establishes the change management strategy. As mentioned, the initial linkages among processes, vents, PODs, tanks, control obligations, and eligible controls contained in the NOCSR would be incorporated into the title V permit to establish the baseline scenario from which to envision future changes. This incorporation also serves to demonstrate an appropriate working knowledge with the key definitions governing the applicability of subpart GGG. More importantly, the permitting authority must specifically approve the source's use of these definitions and this approval is subject to review by EPA and the public. The result will be that the source and the permitting authority will have a well validated common understanding of how these definitions work and how to apply them to future changes.

The recommended approach also fulfills the need to provide adequate review opportunities. In the permit issuance process, the permitting authority, EPA, and the public all have an opportunity to review how the current source operations would comply with the standard and how the proposed permit conditions establish alternative operating scenarios to manage changes occurring with respect to this compliance baseline. In particular, these groups will have the opportunity to review the operating boundaries to assure equal or greater controllability of other emissions profiles and to determine any further need to add specific operational constraints to safeguard against overloading the particular control device(s), for example, or additional permit terms or descriptions in order to assure compliance with the standard. The alternative operating scenarios as described in the permit must reasonably anticipate reconfigurations of existing emissions units and activities and the additions of certain other preapproved equipment and must contain the associated compliance obligations for these changes under subpart GGG, in order to afford permitting authorities, EPA and the public meaningful opportunity to ensure that the permit's alternative scenarios assure compliance with the MACT standard. To provide an ongoing opportunity to understand which alternative operating scenarios have been operated by the source and the specific corresponding compliance obligations that apply, the permit shall require quarterly transmission of the OSIL changes to the permitting authority, which shall make copies available to the public and EPA upon request.

The Agency is considering whether and to what extent the change management strategy for implementing subpart GGG might also be appropriate for other sources and applicable requirements. Preliminarily, EPA believes that the recommended permitting approach for subpart GGG will be essentially limited to the pharmaceutical and other similar batch chemical industries but it could be extended to industries subject to other emission standards to the extent that EPA believes the same level of compliance assurance associated with the change management strategy described for subpart GGG would be achieved. The EPA expects to evaluate other situations individually, using the mentioned factors and other considerations as appropriate. Affected parties are encouraged to comment on the adequacy of other EPA rulemakings (including those for other MACT standards), to address issues related to the change management strategy where similar needs for operational flexibility potentially exist. Certainly, the same legal constraints together with several situation specific factors (such as those involving the replicability of operating procedures contained in, or derived from, the applicable requirements, the potential for misapplication of the standard, the expectation for detailed descriptions and emissions reduction from the applicable requirement itself for subject equipment, and the ability of the control and monitoring approaches to accommodate changes) would again be relevant to defining whether a strategy for such applicable requirements based on alternative operating scenarios is possible under section 70.6(a)(9).

The EPA believes that the change management strategy should presumptively be limited to the pharmaceutical MACT, since other standards do not initially appear to produce equivalent opportunities to create alternative operating scenarios under such a strategy. The most limiting element is the ability to predict accurately, using relatively simple, repeatable procedures, the effect a particular change has on emissions and compliance obligations. In the pharmaceutical industry, it is possible to do so in an extremely accurate fashion since HAP emissions nearly exclusively result from nonreactant solvent use. It may be more difficult, for example, to predict the effect of process changes in chemical manufacturing industries other than pharmaceutical manufacturing. Changes in these industries often involve complex reaction theory and reaction kinetics and other factors, which must be applied individually to the specific situation at hand to determine how HAP emissions will change. For most changes, it would be difficult to distill these chemical dynamics into an equation that would predict emissions variations for a source's process changes accurately. Without an accurate ROP, the applicable permit revision process would be necessary to reevaluate compliance under the change.

As previously mentioned, the Agency's decision whether to extend the availability of a change management strategy similar to that for subpart GGG to other standards will also depend on the empirical results achieved from implementing subpart GGG through such a strategy. In particular, EPA expects to learn whether and how frequently interpretive disputes result from using the blend of definitions and approved ROPs relied upon to carry out the change management strategy and how to develop permit terms that establish and implement ROPs.

Finally, the Agency supports the testing of the recommended subpart GGG strategy since it is consistent with the Agency's program objectives to reinvent regulations, to eliminate delays and paperwork burdens, and to implement more efficiently the title V program. The development of the recommended approach benefited to a significant extent through the activities of a permitting pilot project which EPA initiated with the Environmental Quality Board of Puerto Rico and Merck Corporation. Considering the implementation of subpart GGG through title V permits in the context of this project has been extremely valuable in defining the type and frequency of

anticipated operational changes and evaluating the appropriate permit content to assure compliance for these changes. The Agency is grateful to the participants in this Reinvention project and expects that its final results (in the form of more detailed guidance and/or model permit conditions) will be useful to others seeking to implement subpart GGG.

VII. Technical Amendment to 40 CFR Part 9

In compliance with the Paperwork Reduction Act (PRA), this technical correction amends the table that lists the Office of Management and Budget (OMB) control numbers issued under the RPA for this final rule.

The EPA is today amending the table in 40 CFR part 9 (Section 9.1) of currently approved information collection request (ICR) control numbers issued by OMB for various regulation. The affected regulations are codified at 40 CFR part 63 subpart GGG, sections 63.1259 and 63.1260 (recordkeeping and reporting requirements, respectively). The OMB control (tracking) number for this final rule is 2060–0358. The EPA will continue to present OMB control numbers in a consolidated table format to be codified in 40 CFR part 9 of the Agency's regulations, and in each CFR volume containing EPA regulations. The table lists the section numbers with reporting and recordkeeping requirements, and the current OMB control numbers. The listing of the OMB control numbers and their subsequent codification in the CFR satisfy the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and OMB's implementing regulations at 5 CFR part 1320.

This ICR was previously subject to public notice and comment prior to OMB approval. As a result, EPA finds that there is ''good cause'' under section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)) to amend this table without prior notice and comment. Due to the technical nature of the table, further notice and comment would be necessary.

VIII. Administrative Requirements

A. Docket

The docket is an organized and complete file of all the information submitted to or otherwise considered by EPA in the development of this proposed rulemaking. The principal purposes of the docket are:

1. To allow interested parties to readily identify and locate documents so that they can intelligently and effectively participate in the rulemaking process; and

2. To serve as the record in case of judicial review (except for interagency review materials [section 307(d)(7)(A)]).

B. Executive Order 12866

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

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

2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

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

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

Pursuant to the terms of the Executive Order, the OMB has notified the EPA that it considers this a ''significant regulatory action'' within the meaning of the Executive Order. The EPA submitted this action to the OMB for review. Changes made in response to suggestions or recommendations from the OMB were documented and included in the public record.

C. Enhancing the Intergovernmental Partnership Under Executive Order 12875

In compliance with Executive Order 12875, EPA has involved State governments in the development of this rule. These governments will be required to implement the rule. They will collect permit fees which will be used to offset the resource burden of implementing the rule. Representatives of six State governments are members of the MACT partnership. This partnership group was consulted through out the development of this final regulation. Comments from the partnership members were carefully considered. In addition, all States were encouraged to comment on the proposed rule during the public comment period, and the EPA fully considered all the comments submitted by States in this final rulemaking.

D. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq* and has assigned OMB control No. 2060–0358. An information collection request (ICR) document has been prepared by EPA (ICR No. 1781.01), and a copy may be obtained from Sandy Farmer, Regulatory Information Division, U.S. Environmental Protection Agency (Mail Code 2137), 401 M Street SW., Washington, DC 20460, or by calling 202–260–2740.

The EPA is required under section 112(d) of the Clean Air Act to regulate emissions of HAPs listed in section 112(b). The requested information is needed as part of the overall compliance and enforcement program. The ICR requires that pharmaceuticals production facilities retain records of control device monitoring or HAP emissions calculations records at facilities for a period of 5 years, which is consistent with the General Provisions to 40 CFR part 63 and the permit requirements under 40 CFR part 70. All sources subject to this rule will be required to obtain operating permits either through the State-approved permitting program or, if one does not exist, in accordance with the provisions of 40 CFR part 71, when promulgated.

The public reporting burden for this collection of information is estimated to average 4,800 hours per respondent for the first year and 2,600 hours per respondent for each of the second and third years. It is also estimated that there are approximately 100 facilities that are likely respondents. 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. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of

information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. The EPA is amending Table 9.1 in 40 CFR part 9 of currently approved ICR control numbers issued by OMB for various regulations to list the information requirements contained in this final rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) provides that, whenever an agency promulgates a final rule under 5 U.S.C. 553, after being required to publish a general notice of proposed rulemaking, an agency must prepare a final regulatory flexibility analysis unless the head of the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Agency certifies that this rule will not have a significant impact on a substantial number of small entities.

The EPA analyzed the potential impact of the rule on small entities and determined that only 16 of 56 pharmaceutical producing firms are small entities—not a substantial number of entities. Of these 16 firms, only 4 will experience an increase in costs as a result of the promulgation of today's rule that are greater than 1 percent of revenues. Therefore, the Agency did not prepare an initial regulatory flexibility analysis.

Although the statute does not require EPA to prepare an RFA because the Administrator has certified that the rule will not have a significant economic impact on a substantial number of small entities, EPA did undertake a limited assessment, to the extent it could, of possible outcomes and the economic effect of these on small pharmaceutical entities. That evaluation is available in the administrative record for today's action.

F. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments, and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The EPA has determined that the final standards do not include a Federal mandate that may result in estimated costs of, in the aggregate, $100 million or more to either State, local or Tribal governments, or to the private sector, nor do the standards significantly or uniquely impact small governments, because they contain no requirements that apply to such governments or impose obligations upon them. Therefore, the requirements of the Unfunded Mandates Act do not apply to this final rule.

G. Submission to Congress and the Comptroller General

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

H. National Technology Transfer and Advancement Act (NTTAA)

Under section 12(d) of the National Technology Transfer and Advancement Act (''NTTAA)'', the Agency is required to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. Where available and potentially applicable voluntary consensus standards are not used by EPA, the Act requires the Agency to provide Congress, through the Office of Management and Budget, an explanation of the reasons for not using such standards.

The Agency does not believe that this Notice addresses any technical standards subject to the NTTAA.

I. Executive Order 13045

The Executive Order 13045 applies to any rule that EPA determines (1) ''economically significant'' as defined under Executive Order 12866, and (2) the environmental health or safety risk addressed by the rule has a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children; and National Emission Standards for Hazardous Air Pollutants Pharmaceuticals Production—explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is not subject to Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it does not involve decisions on environmental health risks or safety risks that may disproportionately affect children.

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Incorporation by reference, Reporting and recordkeeping requirements.

Dated: July 30, 1998.

Carol M. Browner,

Administrator.

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

PART 9—[AMENDED]

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

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

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

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
National Emission Standards for Hazardous Air Pollutants for Source Categories.[3]	
* * * * *	
63.1259–63.1260	2060–0314
* * * * *	

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

* * * * *

PART 63—[AMENDED]

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

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

4. Section 63.14 is amended by adding paragraphs (b)(19) and (c)(3) to read as follows:

§ 63.14 Incorporations by reference.

* * * * *

(b) * * *

(19) ASTM D2879–97, Standard Test Method for Vapor Pressure-Temperature Relationship and Initial Decomposition Temperature of Liquids by Isoteniscope, IBR approved for § 63.1251 of subpart GGG of this part.

(c) * * *

(3) API Manual of Petroleum Measurement Specifications (MPMS) Chapter 19.2, Evaporative Loss From Floating-Roof Tanks (formerly API Publications 2517 and 2519), First Edition, April 1997, IBR approved for § 63.1251 of subpart GGG of this part.

* * * * *

5. Part 63 is amended by adding a new subpart GGG to read as follows:

Subpart GGG—National Emission Standards for Pharmaceuticals Production

Sec.

§ 63.1250 Applicability.

(a) *Definition of affected source.* The affected source subject to this subpart is the pharmaceutical manufacturing operation, as defined in § 63.1251. Except as specified in paragraph (d) of this section, the provisions of this subpart apply to pharmaceutical manufacturing operations that meet the criteria specified in paragraphs (a)(1) through (a)(3) of this section as follows:

(1) Manufacture a pharmaceutical product, as defined in § 63.1251;

(2) Are located at a plant site that is a major source as defined in section 112(a) of the Act; and

(3) Process, use, or produce HAP.

(b) *New source applicability.* A new affected source subject to this subpart and to which the requirements for new sources apply is: an affected source for which construction or reconstruction commenced after April 2, 1997 and the standard was applicable at the time of construction or reconstruction; or a pharmaceutical manufacturing process unit (PMPU), dedicated to manufacturing a single product, that has the potential to emit 10 tons per year of any one HAP or 25 tons per year of combined HAP, for which construction commenced after April 2, 1997.

(c) *General Provisions.* Table 1 of this subpart specifies the provisions of subpart A of this part that apply to an owner or operator of an affected source subject to this subpart, and clarifies specific provisions in subpart A of this part as necessary for this subpart.

(d) *Processes exempted from the affected source.* The provisions of this subpart do not apply to research and development facilities.

(e) *Storage tank ownership determination.* The owner or operator shall follow the procedures specified in paragraphs (e)(1) through (e)(5) of this section to determine to which PMPU a storage tank shall belong.

(1) If a storage tank is dedicated to a single PMPU, the storage tank shall belong to that PMPU.

(2) If a storage tank is shared among PMPU's, then the storage tank shall belong to that PMPU located on the same plant site as the storage tank that has the greatest annual volume input into or output from the storage tank (i.e., said PMPU has the predominant use of the storage tank).

(3) If predominant use cannot be determined for a storage tank that is shared among PMPU's and if one of those PMPU's is subject to this subpart, the storage tank shall belong to said PMPU.

(4) If the predominant use of a storage tank varies from year to year, then predominant use shall be determined based on the utilization that occurred during the year preceding September 21, 1998 for existing affected sources. For new affected sources, predominant use will be based on the first year after initial startup. The determination of predominant use shall be reported in the Notification of Compliance Status required by § 63.1260(f). If the predominant use changes, the redetermination of predominant use

shall be reported in the next Periodic Report.

(5) If the storage tank begins receiving material from (or sending material to) another PMPU; or ceases to receive material from (or send material to) a PMPU; or if the applicability of this subpart to a storage tank has been determined according to the provisions of paragraphs (e)(1) through (4) of this section and there is a significant change in the use of the storage tank that could reasonably change the predominant use, the owner or operator shall reevaluate the applicability of this subpart to the storage tank, and report such changes to EPA in the next Periodic report.

(f) *Compliance dates.* The compliance dates for affected sources are as follows:

(1) An owner or operator of an existing affected source must comply with the provisions of this subpart within 3 years after September 21, 1998.

(2) An owner or operator of a new or reconstructed affected source must comply with the provisions of this subpart on September 21, 1998 or upon startup, whichever is later.

(3) Notwithstanding the requirements of paragraphs (f)(1) and (2) of this section, a new source which commences construction or reconstruction after April 2, 1997 and before September 21, 1998 shall not be required to comply with such promulgated standard until 3 years after September 21, 1998 if:

(i) The promulgated standard is more stringent than the proposed standard; and

(ii) The owner or operator complies with the standard as proposed during the 3-year period immediately after September 21, 1998.

(4) Pursuant to section 112(i)(3)(B) of the Act, an owner or operator may request an extension allowing the existing source up to 1 additional year to comply with section 112(d) standards.

(i) For purposes of this subpart, a request for an extension shall be submitted no later than 120 days prior to the compliance dates specified in paragraphs (f)(1) through (3) of this section, except as provided in paragraph (f)(4)(ii) of this section. The dates specified in § 63.6(i) for submittal of requests for extensions shall not apply to sources subject to this subpart.

(ii) An owner or operator may submit a compliance extension request after the date specified in paragraph (f)(4)(i) of this section provided the need for the compliance extension arose after that date and before the otherwise applicable compliance date, and the need arose due to circumstances beyond reasonable control of the owner or operator. This request shall include the data described in § 63.6(i)(6)(i)(A), (B), (C), and (D).

(g) *Applicability of this subpart except during periods of startup, shutdown, and malfunction.* (1) Each provision set forth in this subpart shall apply at all times except that emission limitations shall not apply during periods of: startup; shutdown; and malfunction, if the startup, shutdown, and malfunction precludes the ability of a particular emission point of an affected source to comply with one or more specific emission limitations to which it is subject and the owner or operator follows the provisions for periods of startup, shutdown, and malfunction, as specified in §§ 63.1259(a)(3) and 63.1260(i). Startup, shutdown, and malfunction are defined in § 63.1251.

(2) The provisions set forth in § 63.1255 of this subpart shall apply at all times except during periods of nonoperation of the PMPU (or specific portion thereof) in which the lines are drained and depressurized resulting in the cessation of the emissions to which § 63.1255 of this subpart applies.

(3) The owner or operator shall not shut down items of equipment that are required or utilized for compliance with the emissions limitations of this subpart during times when emissions (or, where applicable, wastewater streams or residuals) are being routed to such items of equipment, if the shutdown would contravene emissions limitations of this subpart applicable to such items of equipment. This paragraph does not apply if the item of equipment is malfunctioning, or if the owner or operator must shut down the equipment to avoid damage due to a malfunction of the PMPU or portion thereof.

(4) During startups, shutdowns, and malfunctions when the emissions limitations of this subpart do not apply pursuant to paragraphs (g)(1) through (3) of this section, the owner or operator shall implement, to the extent reasonably available, measures to prevent or minimize excess emissions to the extent practical. For purposes of this paragraph, ''excess emissions'' means emissions in excess of those that would have occurred if there were no startup, shutdown, or malfunction and the owner or operator complied with the relevant provisions of this subpart. The measures to be taken shall be identified in the applicable startup, shutdown, and malfunction plan, and may include, but are not limited to, air pollution control technologies, work practices, pollution prevention, monitoring, and/or changes in the manner of operation of the source. Back-up control devices are not required, but may be used if available.

(h) *Consistency with other regulations.* (1) *Consistency with other MACT standards.* After the compliance dates specified in this section, an affected source subject to the provisions of this subpart that is also subject to the provisions of any other subpart of 40 CFR part 63 may elect, to the extent the subparts are consistent, which subpart under which to maintain records and report to EPA. The affected source shall identify in the Notification of Compliance Status report required by § 63.1260(f) under which authority such records will be maintained.

(2) *Consistency with 40 CFR parts 264 and 265, subparts AA, BB, and/or CC.* After the compliance dates specified in this section, if any affected source subject to this subpart is also subject to monitoring, recordkeeping, and reporting requirements in 40 CFR part 264, subpart AA, BB, or CC, or is subject to monitoring and recordkeeping requirements in 40 CFR part 265, subpart AA, BB, or CC and the owner or operator complies with the periodic reporting requirements under 40 CFR part 264, subpart AA, BB, or CC that would apply to the device if the facility had final-permitted status, the owner or operator may elect to comply either with the monitoring, recordkeeping, and reporting requirements of this subpart, or with the monitoring, recordkeeping, and reporting requirements in 40 CFR parts 264 and/or 265, as described in this paragraph, which shall constitute compliance with the monitoring, record keeping, and reporting requirements of this subpart. If the owner or operator elects to comply with the monitoring, recordkeeping, and reporting requirements in 40 CFR parts 264 and/or 265, the owner or operator shall report all information required by § 63.1260(g). The owner or operator shall identify in the Notification of Compliance Status required by § 63.1260(f) the monitoring, recordkeeping, and reporting authority under which the owner or operator will comply.

(3) *Consistency with 40 CFR 60.112b.* After the compliance dates specified in this section, a storage tank controlled with a floating roof and in compliance with the provisions of 40 CFR 60.112b, subpart Kb, constitutes compliance with the provisions of this subpart GGG. A storage tank with a fixed roof, closed vent system, and control device in compliance with the provisions of 40 CFR 60.112b, subpart Kb must comply with the monitoring, recordkeeping, and reporting provisions of this subpart GGG. The owner or operator shall identify in the Notification of Compliance Status report required by

§ 63.1260(f) which tanks are in compliance with subpart Kb.

(4) *Consistency with subpart I of this part.* After the compliance dates specified in this section, for equipment at an affected source subject to this subpart that is also subject to subpart I of this part, an owner or operator may elect to comply with either the provisions of this subpart GGG or the provisions of subpart I of this part. The owner or operator shall identify in the Notification of Compliance Status report required by § 63.1260(f) the provisions with which the owner elects to comply.

(5) *Consistency with other regulations for wastewater.* After the compliance dates specified in this section, the owner or operator of an affected wastewater that is also subject to provisions in 40 CFR parts 260 through 272 shall comply with the more stringent control requirements (e.g., waste management units, numerical treatment standards, etc.) and the more stringent testing, monitoring, recording, and recordkeeping requirements that overlap between the provisions of this subpart and the provisions of 40 CFR parts 260 through 272. The owner or operator shall keep a record of the information used to determine which requirements were the most stringent and shall submit this information if requested by the Administrator.

(i) For the purposes of establishing whether a person is in violation of this subpart, nothing in this subpart shall preclude the use of any credible evidence or information relevant to whether a source would have been in compliance with applicable requirements.

§ 63.1251 Definitions.

Terms used in this subpart are defined in the Act, in subpart A of this part, or in this section. If the same term is defined in subpart A of this part and in this section, it shall have the meaning given in this section for the purposes of this subpart.

Active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the pharmaceutical product and be present in the pharmaceutical product in a modified form intended to furnish the specified activity or effect.

Actual HAP emissions means the HAP emitted to the atmosphere from either uncontrolled or controlled emission points.

Air pollution control device or Control device means equipment installed on a process vent, storage tank, wastewater treatment exhaust stack, or combination thereof that reduces the mass of HAP emitted to the air. The equipment may consist of an individual device or a series of devices. Examples include, but are not limited to, incinerators, carbon adsorption units, condensers, flares, boilers, process heaters, and gas absorbers. Process condensers are not considered air pollution control devices or control devices.

Annual average concentration, as used in the wastewater provisions, means the annual average concentration as determined according to the procedures specified in § 63.1257(e)(1).

Automated monitoring and recording system means any means of measuring values of monitored parameters and creating a hard copy or computer record of the measured values that does not require manual reading of monitoring instruments and manual transcription of data values. Automated monitoring and recording systems include, but are not limited to, computerized systems and strip charts.

Batch emission episode means a discrete venting episode that may be associated with a single unit operation. A unit operation may have more than one batch emission episode. For example, a displacement of vapor resulting from the charging of a vessel with HAP will result in a discrete emission episode that will last through the duration of the charge and will have an average flowrate equal to the rate of the charge. If the vessel is then heated, there will also be another discrete emission episode resulting from the expulsion of expanded vapor. Both emission episodes may occur in the same vessel or unit operation. There are possibly other emission episodes that may occur from the vessel or other process equipment, depending on process operations.

Batch operation or Batch process means a noncontinuous operation involving intermittent or discontinuous feed into equipment, and, in general, involves the emptying of the equipment after the batch operation ceases and prior to beginning a new operation. Addition of raw material and withdrawal of product do not occur simultaneously in a batch operation.

Bench-scale batch process means a batch process (other than a research and development facility) that is capable of being located on a laboratory bench top. This bench-scale equipment will typically include reagent feed vessels, a small reactor and associated product separator, recovery and holding equipment. These processes are only capable of producing small quantities of product.

Block means a time period that comprises a single batch.

Cleaning operation means routine rinsing, washing, or boil-off of equipment in batch operations between batches.

Closed biological treatment process means a tank or surface impoundment where biological treatment occurs and air emissions from the treatment process are routed to either a control device by means of a closed-vent system or by means of hard-piping. The tank or surface impoundment has a fixed roof, as defined in this section, or a floating flexible membrane cover that meets the requirements specified in § 63.1256(c).

Closed-loop system means an enclosed system that returns process fluid to the process and is not vented to the atmosphere except through a closed-vent system.

Closed-purge system means a system or combination of system and portable containers, to capture purged liquids. Containers must be covered or closed when not being filled or emptied.

Closed-vent system means 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.

Combustion device means an individual unit of equipment, such as a flare, incinerator, process heater, or boiler, used for the combustion of HAP vapors.

Component means any ingredient for use in the manufacture of a drug product, including those that may not appear in such drug product.

Connector means flanged, screwed, or other joined fittings used to connect two pipe lines or a pipe line and a piece of equipment. A common connector is a flange. Joined fittings welded completely around the circumference of the interface are not considered connectors for the purpose of this regulation. For the purpose of reporting and recordkeeping, connector means joined fittings that are not inaccessible, ceramic, or ceramic-lined as described in § 63.1255(b)(1)(vii) and § 63.1255(f)(3).

Construction means the onsite fabrication, erection, or installation of an affected source or a PMPU.

Consumption means the quantity of HAP entering a process that is not used as reactant (makeup). If the same HAP component is generated in the process

as well as added as makeup, consumption shall include the quantity generated in the process, as calculated assuming 100 theoretical conversion. The quantity of material used as reactant is the theoretical amount needed assuming a 100 percent stoichiometric conversion. Makeup is the net amount of material that must be added to the process to replenish losses.

Container, as used in the wastewater provisions, means any portable waste management unit that has a capacity greater than or equal to 0.1 m^3 in which a material is stored, transported, treated, or otherwise handled. Examples of containers are drums, barrels, tank trucks, barges, dumpsters, tank cars, dump trucks, and ships.

Continuous process means a process where the inputs and outputs flow continuously throughout the duration of the process. Continuous processes are typically steady state.

Continuous recorder means a data recording device that either records an instantaneous data value at least once every 15 minutes or records 15-minute or more frequent block average values.

Continuous seal means a seal that forms a continuous closure that completely covers the space between the wall of the storage tank and the edge of the floating roof. A continuous seal may be a vapor-mounted, liquid-mounted, or metallic shoe seal.

Control device, for purposes of this § 63.1255, means any equipment used for recovering or oxidizing organic hazardous air pollutant vapors. Such equipment includes, but is not limited to, absorbers, carbon adsorbers, condensers, flares, boilers, and process heaters.

Controlled HAP emissions means the quantity of HAP discharged to the atmosphere from an air pollution control device.

Cover, as used in the wastewater provisions, means a device or system which is placed on or over a waste management unit containing wastewater or residuals so that the entire surface area is enclosed to minimize air emissions. A cover may have openings necessary for operation, inspection, and maintenance of the waste management unit such as access hatches, sampling ports, and gauge wells provided that each opening is closed when not in use. Examples of covers include a fixed roof installed on a wastewater tank, a lid installed on a container, and an air-supported enclosure installed over a waste management unit.

Dedicated PMPU means a PMPU that is composed of equipment that is used to manufacture the same product for a continuous period of 6 months or greater. The PMPU includes any shared storage tank(s) that are determined to belong to the PMPU according to the procedures in § 63.1250(e).

Double block and bleed system means two block valves connected in series with a bleed valve or line that can vent the line between the two block valves.

Duct work means a conveyance system such as those commonly used for heating and ventilation systems. It is often made of sheet metal and often has sections connected by screws or crimping. Hard-piping is not ductwork.

Enhanced biological treatment system or enhanced biological treatment process means an aerated, thoroughly mixed treatment unit(s) that contains biomass suspended in water followed by a clarifier that removes biomass from the treated water and recycles recovered biomass to the aeration unit. The mixed liquor volatile suspended solids (biomass) is greater than 1 kilogram per cubic meter throughout each aeration unit. The biomass is suspended and aerated in the water of the aeration unit(s) by either submerged air flow or mechanical agitation. A thoroughly mixed treatment unit is a unit that is designed and operated to approach or achieve uniform biomass distribution and organic compound concentration throughout the aeration unit by quickly dispersing the recycled biomass and the wastewater entering the unit.

Equipment, for purposes of § 63.1255, means each pump, compressor, agitator, pressure relief device, sampling connection system, open-ended valve or line, valve, connector, and instrumentation system in organic hazardous air pollutant service; and any control devices or closed-vent systems required by this subpart.

Excipient means any substance other than the active drug or product which have been appropriately evaluated for safety and are included in a drug delivery system to either aid the processing of the drug delivery system during its manufacture; protect, support or enhance stability, bioavailability, or patient acceptability; assist in product identification; or enhance any other attribute of the overall safety and effectiveness of the drug delivery system during storage or use.

External floating roof means a pontoon-type or double-deck type cover that rests on the liquid surface in a storage tank or waste management unit with no fixed roof.

Fill or filling means the introduction of material into a storage tank or the introduction of a wastewater stream or residual into a waste management unit, but not necessarily to complete capacity.

First attempt at repair means to take action for the purpose of stopping or reducing leakage of organic material to the atmosphere.

Fixed roof means a cover that is mounted on a waste management unit or storage tank in a stationary manner and that does not move with fluctuations in liquid level.

Floating roof means a cover consisting of a double deck, pontoon single deck, internal floating cover or covered floating roof, which rests upon and is supported by the liquid being contained, and is equipped with a closure seal or seals to close the space between the roof edge and waste management unit or storage tank wall.

Flow indicator means a device which indicates whether gas flow is, or whether the valve position would allow gas flow to be, present in a line.

Formulation means the process of mixing, blending, or diluting one or more active or inert ingredients with one or more active or inert ingredients, without an intended chemical reaction, to obtain a pharmaceutical dosage form. Formulation operations include mixing, compounding, blending, and tablet coating.

Group of processes means all of the equipment associated with processes in a building, processing area, or facility-wide. For a dedicated process, a group of processes may consist of a single process.

Halogen atoms mean atoms of chlorine or fluorine.

Halogenated compounds means organic HAP compounds that contain halogen atoms.

Halogenated vent stream or Halogenated stream means a process, storage tank, or waste management unit vent determined to have a concentration of halogenated compounds of greater than 20 ppmv, as determined through process knowledge, test results using Method 18 of 40 CFR part 60, appendix A, or test results using any other test method that has been validated according to the procedures in Method 301 of appendix A of this part.

Hard-piping means piping or tubing that is manufactured and properly installed using good engineering judgment and standards, such as ANSI B31–3.

Hydrogen halides and halogens means hydrogen chloride (HCl), chlorine (Cl^2), and hydrogen fluoride (HF).

In gas/vapor service means that a piece of equipment in organic hazardous air pollutant service contains a gas or vapor at operating conditions.

In heavy liquid service means that a piece of equipment in organic

hazardous air pollutant service is not in gas/vapor service or in light liquid service.

In light liquid service means that a piece of equipment in organic hazardous air pollutant service contains a liquid that meets the following conditions:

(1) The vapor pressure of one or more of the organic compounds is greater than 0.3 kilopascals at 20°C;

(2) The total concentration of the pure organic compounds constituents having a vapor pressure greater than 0.3 kilopascals at 20°C is equal to or greater than 20 percent by weight of the total process stream; and

(3) The fluid is a liquid at operating conditions. (Note: Vapor pressures may be determined by the methods described in 40 CFR 60.485(e)(1).)

In liquid service means that a piece of equipment in organic hazardous air pollutant service is not in gas/vapor service.

In organic hazardous air pollutant or in organic HAP service means that a piece of equipment either contains or contacts a fluid (liquid or gas) that is at least 5 percent by weight of total organic HAP's as determined according to the provisions of § 63.180(d). The provisions of § 63.180(d) also specify how to determine that a piece of equipment is not in organic HAP service.

In vacuum service means that equipment is operating at an internal pressure which is at least 5 kilopascals below ambient pressure.

In-situ sampling systems means nonextractive samplers or in-line samplers.

Individual drain system means the stationary system used to convey wastewater streams or residuals to a waste management unit. The term includes hard piping; all process drains and junction boxes; and associated sewer lines, other junction boxes, manholes, sumps, and lift stations conveying wastewater streams or residuals. A segregated stormwater sewer system, which is a drain and collection system designed and operated for the sole purpose of collecting rainfall-runoff at a facility, and which is segregated from all other individual drain systems, is excluded from this definition.

Initial startup means the first time a new or reconstructed source begins production. Initial startup does not include operation solely for testing equipment. Initial startup does not include subsequent start ups (as defined in this section) of processes following malfunctions or process shutdowns.

Internal floating roof means a cover that rests or floats on the liquid surface (but not necessarily in complete contact with it) inside a storage tank or waste management unit that has a permanently affixed roof.

Instrumentation system means a group of equipment components used to condition and convey a sample of the process fluid to analyzers and instruments for the purpose of determining process operating conditions (e.g., composition, pressure, flow, etc.). Valves and connectors are the predominant type of equipment used in instrumentation systems; however, other types of equipment may also be included in these systems. Only valves nominally 0.5 inches and smaller, and connectors nominally 0.75 inches and smaller in diameter are considered instrumentation systems for the purposes of this subpart. Valves greater than nominally 0.5 inches and connectors greater than nominally 0.75 inches associated with instrumentation systems are not considered part of instrumentation systems and must be monitored individually.

Junction box means a manhole or access point to a wastewater sewer system line or a lift station.

Large control device means a control device that controls process vents with total emissions of greater than or equal to 10 tons of HAP per year, before control.

Liquid-mounted seal means a foam- or liquid-filled seal mounted in contact with the liquid between the wall of the storage tank or waste management unit and the floating roof. The seal is mounted continuously around the tank or unit.

Liquids dripping means any visible leakage from the seal including dripping, spraying, misting, clouding, and ice formation. Indications of liquid dripping include puddling or new stains that are indicative of an existing evaporated drip.

Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, emissions monitoring equipment, process equipment, or a process to operate in a normal or usual manner. Failures that are caused all or in part by poor maintenance or careless operation are not malfunctions.

Maximum true vapor pressure means the equilibrium partial pressure exerted by the total organic HAP in the stored or transferred liquid at the temperature equal to the highest calendar-month average of the liquid storage or transferred temperature for liquids stored or transferred above or below the ambient temperature or at the local maximum monthly average temperature as reported by the National Weather Service for liquids stored or transferred at the ambient temperature, as determined:

(1) In accordance with methods described in Chapter 19.2 of the American Petroleum Institute's Manual of Petroleum Measurement Standards, Evaporative Loss From Floating-Roof Tanks (incorporated by reference as specified in § 63.14); or

(2) As obtained from standard reference texts; or

(3) As determined by the American Society for Testing and Materials Method D2879–97, Test Method for Vapor Pressure-Temperature Relationship and Initial Decomposition Temperature of Liquids by Isoteniscope (incorporated by reference as specified in § 63.14); or

(4) Any other method approved by the Administrator.

Metallic shoe seal or mechanical shoe seal means metal sheets that are held vertically against the wall of the storage tank by springs, weighted levers, or other mechanisms and connected to the floating roof by braces or other means. A flexible coated fabric (envelope) spans the annular space between the metal sheet and the floating roof.

Nondedicated formulation operations means equipment used to formulate numerous products.

Nondedicated recovery device(s) means a recovery device that receives material from more than one PMPU.

Nonrepairable means that it is technically infeasible to repair a piece of equipment from which a leak has been detected without a process shutdown.

Open biological treatment process means a biological treatment process that is not a closed biological treatment process as defined in this section.

Open-ended valve or line means any valve, except pressure relief valves, having one side of the valve seat in contact with process fluid and one side open to atmosphere, either directly or through open piping.

Operating scenario for the purposes of reporting and recordkeeping, means any specific operation of a PMPU and includes for each process:

(1) A description of the process and the type of process equipment used;

(2) An identification of related process vents and their associated emissions episodes and durations, wastewater PODs, and storage tanks;

(3) The applicable control requirements of this subpart, including the level of required control;

(4) The control or treatment devices used, as applicable, including a

description of operating and/or testing conditions for any associated control device;

(5) The process vents, wastewater PODs, and storage tanks (including those from other processes) that are simultaneously routed to the control or treatment device(s);

(6) The applicable monitoring requirements of this subpart and any parametric level that assures compliance for all emissions routed to the control or treatment device;

(7) Calculations and engineering analyses required to demonstrate compliance; and

(8) A verification that the operating conditions for any associated control or treatment device have not been exceeded and that any required calculations and engineering analyses have been performed. For reporting purposes, a change to any of these elements not previously reported, except for paragraph (5) of this definition, shall constitute a new operating scenario.

Partially soluble HAP means a HAP listed in Table 2 of this subpart.

Pharmaceutical manufacturing operations means the facility-wide collection of PMPU's and any other equipment such as heat exchanger systems, or cooling towers that are not associated with an individual PMPU, but that are located at a facility for the purpose of manufacturing pharmaceutical products and are under common control.

Pharmaceutical manufacturing process unit (PMPU) means the process, as defined in this subpart, and any associated storage tanks, equipment identified in § 63.1252(f), and components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used in the manufacturing of a pharmaceutical product.

Pharmaceutical product means:

(1) Any material described by the standard industrial classification (SIC) code 2833 or 2834;

(2) Any material whose manufacturing process is described by north american industrial classification system (NAICS) code 325411 or 325412;

(3) A finished dosage form of a drug, for example, a tablet, capsule, solution, etc., that contains an active ingredient generally, but not necessarily, in association with inactive ingredients; or

(4) Any component whose intended primary use is to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals (the term does not include excipients, but includes drug components such as raw starting materials or precursors that undergo chemical change or processing before they become active ingredients).

Plant site means all contiguous or adjoining property that is under common control, including properties that are separated only by a road or other public right-of-way. Common control includes properties that are owned, leased, or operated by the same entity, parent entity, subsidiary, or any combination thereof.

Point of determination (POD) means the point where a wastewater stream exits the process, storage tank, or last recovery device. If soluble and/or partially soluble HAP compounds are not recovered from water before discharge, the discharge point from the process equipment or storage tank is a POD. If water streams are routed to a recovery device, the discharge from the recovery device is a POD. There can be more than 1 POD per process or PMPU.

Pressure release means the emission of materials resulting from the system pressure being greater than the set pressure of the pressure relief device. This release can be one release or a series of releases over a short time period due to a malfunction in the process.

Pressure relief device or valve means a safety device used to prevent operating pressures from exceeding the maximum allowable working pressure of the process equipment. A common pressure relief device is a spring-loaded pressure relief valve. Devices that are actuated either by a pressure of less than or equal to 2.5 psig or by a vacuum are not pressure relief devices.

Primary use means the single largest use of a material.

Process means all equipment which collectively function to produce a pharmaceutical product. A process may consist of one or more unit operations. For the purposes of this subpart, process includes all or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a pharmaceutical product. Cleaning operations conducted are considered part of the process. The holding of the pharmaceutical product in tanks or other holding equipment for more than 30 consecutive days, or transfer of the pharmaceutical product to containers for shipment, marks the end of a process, and the tanks are considered part of the PMPU that produced the stored material. When material from one unit operation is used as the feedstock for the production of two or more different pharmaceutical products, the unit operation is considered the endpoint of the process that produced the material, and the unit operations into which the material is routed mark the beginning of the other processes. Nondedicated recovery devices located within a contiguous area within the affected source are considered single processes. Nondedicated formulation operations occurring within a contiguous area are considered a single process that is used to formulate numerous materials and/or products. Quality Assurance and Quality Control laboratories are not considered part of any process.

Process condenser means a condenser whose primary purpose is to recover material as an integral part of a process. The condenser must support a vapor-to-liquid phase change for periods of source equipment operation that are at or above the boiling or bubble point of substance(s) at the liquid surface. Examples of process condensers include distillation condensers, reflux condensers, and condensers used in stripping or flashing operations. In a series of condensers, all condensers up to and including the first condenser with an exit gas temperature below the boiling or bubble point of the substance(s) at the liquid surface are considered to be process condensers. All condensers in line prior to a vacuum source are included in this definition.

Process shutdown means a work practice or operational procedure that stops production from a process or part of a process during which it is technically feasible to clear process material from a process or part of a process consistent with safety constraints and during which repairs can be effected. An unscheduled work practice or operational procedure that stops production from a process or part of a process for less than 24 hours is not a process shutdown. An unscheduled work practice or operational procedure that would stop production from a process or part of a process for a shorter period of time than would be required to clear the process or part of the process of materials and start up the process, and would result in greater emissions than delay of repair of leaking components until the next scheduled process shutdown, is not a process shutdown. The use of spare equipment and technically feasible bypassing of equipment without stopping production are not process shutdowns.

Process tank means a tank that is used to collect material discharged from a feedstock storage tank or unit operation

within the process and transfer this material to another unit operation within the process or to a product storage tank. Surge control vessels and bottoms receivers that fit these conditions are considered process tanks.

Process vent means a vent from a unit operation or vents from multiple unit operations within a process that are manifolded together into a common header, through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Emission streams that are undiluted and uncontrolled containing less than 50 ppmv HAP, as determined through process knowledge that no HAP are present in the emission stream or using an engineering assessment as discussed in § 63.1257(d)(2)(ii), test data using Methods 18 of 40 CFR part 60, appendix A, or any other test method that has been validated according to the procedures in Method 301 of appendix A of this part, are not considered process vents. Process vents do not include vents on storage tanks regulated under § 63.1253, vents on wastewater emission sources regulated under § 63.1256, or pieces of equipment regulated under § 63.1255.

Production-indexed HAP consumption factor is the result of dividing the annual consumption of total HAP by the annual production rate, per process.

Production-indexed volatile organic compound (VOC) consumption factor is the result of dividing the annual consumption of total VOC by the annual production rate, per process.

Publicly owned treatment works (POTW) means any devices and systems used in the storage, treatment, recycling, and reclamation of municipal sewage or industrial wastes of a liquid nature as defined in section 212(2)(A) of the Clean Water Act, as amended [33 U.S.C. § 1292(2)(A)]. A POTW includes the treatment works, intercepting sewers, outfall sewers, sewage collection systems, pumping, power, and other equipment. The POTW is defined at 40 CFR 403.3(o).

Reactor means a device or vessel in which one or more chemicals or reactants, other than air, are combined or decomposed in such a way that their molecular structures are altered and one or more new organic compounds are formed.

Recovery device, as used in the wastewater provisions, means an individual unit of equipment used for the purpose of recovering chemicals for fuel value (i.e., net positive heating value), use, reuse, or for sale for fuel value, use or reuse. Examples of equipment that may be recovery devices include organic removal devices such as decanters, strippers, or thin-film evaporation units. To be a recovery device, a decanter and any other equipment based on the operating principle of gravity separation must receive only two-phase liquid streams.

Repaired means that equipment is adjusted, or otherwise altered, to eliminate a leak as defined in the applicable sections of § 63.1255.

Research and development facility means any stationary source whose primary purpose is to conduct research and development into new processes and products, where such source is operated under the close supervision of technically trained personnel, and is not engaged in the manufacture of products for commercial sale in commerce, except in a de minimis manner.

Residual means any HAP-containing liquid or solid material that is removed from a wastewater stream by a waste management unit or treatment process that does not destroy organics (nondestructive unit). Examples of residuals from nondestructive waste management units are: the organic layer and bottom residue removed by a decanter or organic-water separator and the overheads from a steam stripper or air stripper. Examples of materials which are not residuals are: silt; mud; leaves; bottoms from a steam stripper or air stripper; and sludges, ash, or other materials removed from wastewater being treated by destructive devices such as biological treatment units and incinerators.

Safety device means a closure device such as a pressure relief valve, frangible disc, fusible plug, or any other type of device which functions exclusively to prevent physical damage or permanent deformation to a unit or its air emission control equipment by venting gases or vapors directly to the atmosphere during unsafe conditions resulting from an unplanned, accidental, or emergency event. For the purposes of this subpart, a safety device is not used for routine venting of gases or vapors from the vapor headspace underneath a cover such as during filling of the unit or to adjust the pressure in this vapor headspace in response to normal daily diurnal ambient temperature fluctuations. A safety device is designed to remain in a closed position during normal operations and open only when the internal pressure, or another relevant parameter, exceeds the device threshold setting applicable to the air emission control equipment as determined by the owner or operator based on manufacturer recommendations, applicable regulations, fire protection and prevention codes, standard engineering codes and practices, or other requirements for the safe handling of flammable, combustible, explosive, reactive, or hazardous materials.

Sampling connection system means an assembly of equipment within a process unit used during periods of representative operation to take samples of the process fluid. Equipment used to take nonroutine grab samples is not considered a sampling connection system.

Sensor means a device that measures a physical quantity or the change in a physical quantity, such as temperature, pressure, flow rate, pH, or liquid level.

Set pressure means the pressure at which a properly operating pressure relief device begins to open to relieve atypical process system operating pressure.

Sewer line means a lateral, trunk line, branch line, or other conduit including, but not limited to, grates, trenches, etc., used to convey wastewater streams or residuals to a downstream waste management unit.

Shutdown means the cessation of operation of a PMPU or an individual piece of equipment required or used to comply with this part or for emptying and degassing storage tanks. Shutdown occurs for purposes including but not limited to: periodic maintenance, replacement of equipment, or repair. Shutdown does not apply to routine batch operations or the rinsing or washing of equipment in batch operations between batches.

Single-seal system means a floating roof having one continuous seal that completely covers the space between the wall of the storage tank and the edge of the floating roof. This seal may be a vapor-mounted, liquid-mounted, or metallic shoe seal.

Small control device means a control device that controls process vents with total emissions of less than 10 tons of HAP per year, before control.

Soluble HAP means a HAP listed in Table 3 of this subpart.

Startup means the first time a new or reconstructed source begins production, or, for new equipment added, including equipment used to comply with this subpart, the first time the equipment is put into operation, or for the introduction of a new product/process, the first time the product or process is run in equipment. As used in § 63.1255, startup means the setting in operation of

a piece of equipment or a control device that is subject to this subpart.

Storage tank means a tank or other vessel that is used to store organic liquids that contain one or more HAP as feedstocks or products of a PMPU. The following are not considered storage tanks for the purposes of this subpart:

(1) Vessels permanently attached to motor vehicles such as trucks, railcars, barges, or ships;

(2) Pressure vessels designed to operate in excess of 204.9 kilopascals and without emissions to the atmosphere;

(3) Vessels storing organic liquids that contain HAP only as impurities;

(4) Wastewater storage tanks; and

(5) Process tanks.

Surface impoundment means a waste management unit which is a natural topographic depression, manmade excavation, or diked area formed primarily of earthen materials (although it may be lined with manmade materials), which is designed to hold an accumulation of liquid wastes or waste containing free liquids. A surface impoundment is used for the purpose of treating, storing, or disposing of wastewater or residuals, and is not an injection well. Examples of surface impoundments are equalization, settling, and aeration pits, ponds, and lagoons.

Total organic compounds (TOC) means those compounds measured according to the procedures of Method 18 or Method 25A, 40 CFR part 60, appendix A.

Treatment process means a specific technique that removes or destroys the organics in a wastewater or residual stream such as a steam stripping unit, thin-film evaporation unit, waste incinerator, biological treatment unit, or any other process applied to wastewater streams or residuals to comply with § 63.1256. Most treatment processes are conducted in tanks. Treatment processes are a subset of waste management units.

Uncontrolled HAP emissions means a gas stream containing HAP which has exited the process (or process condenser, if any), but which has not yet been introduced into an air pollution control device to reduce the mass of HAP in the stream. If the process vent is not routed to an air pollution control device, uncontrolled emissions are those HAP emissions released to the atmosphere.

Unit operation means those processing steps that occur within distinct equipment that are used, among other things, to prepare reactants, facilitate reactions, separate and purify products, and recycle materials. Equipment used for these purposes includes but is not limited to reactors, distillation columns, extraction columns, absorbers, decanters, dryers, condensers, and filtration equipment.

Vapor-mounted seal means a continuous seal that completely covers the annular space between the wall, the storage tank or waste management unit and the edge of the floating roof and is mounted such that there is a vapor space between the stored liquid and the bottom of the seal.

Volatile organic compounds (VOC) means those materials defined in 40 CFR 51.100.

Waste management unit means the equipment, structure(s),and or devices used to convey, store, treat, or dispose of wastewater streams or residuals. Examples of waste management units include wastewater tanks, air flotation units, surface impoundments, containers, oil-water or organic-water separators, individual drain systems, biological wastewater treatment units, waste incinerators, and organic removal devices such as steam and air stripper units, and thin film evaporation units. If such equipment is used for recovery then it is part of a pharmaceutical process and is not a waste management unit.

Wastewater means any portion of an individual wastewater stream or any aggregation of wastewater streams.

Wastewater stream means water that is discarded from a PMPU through a single POD, that contains an annual average concentration of partially soluble and/or soluble HAP compounds of at least 5 parts per million by weight and a load of at least 0.05 kg/yr, and that is not exempted by the provisions of § 63.1256(a)(3). For the purposes of this subpart, noncontact cooling water is not considered a wastewater stream. Wastewater streams are generated by both process operations and maintenance activities.

Wastewater tank means a stationary waste management unit that is designed to contain an accumulation of wastewater or residuals and is constructed primarily of nonearthen materials (e.g., wood, concrete, steel, plastic) which provide structural support. Wastewater tanks used for flow equalization are included in this definition.

Water seal controls means a seal pot, p-leg trap, or other type of trap filled with water (e.g., flooded sewers that maintain water levels adequate to prevent air flow through the system) that creates a water barrier between the sewer line and the atmosphere. The water level of the seal must be maintained in the vertical leg of a drain in order to be considered a water seal.

§ 63.1252 Standards: General.

Each owner or operator of any affected source subject to the provisions of this subpart shall control HAP emissions to the level specified in this section on and after the compliance dates specified in § 63.1250(f). Compliance with the emission limits may be demonstrated initially through the provisions of § 63.1257 (Test methods and compliance procedures) and continuously through the provisions of § 63.1258 (Monitoring requirements).

(a) *Opening of a safety device.* Opening of a safety device, as defined in § 63.1251, is allowed at any time conditions require it to do so to avoid unsafe conditions.

(b) *Closed-vent systems.* The owner or operator of a closed-vent system that contains bypass lines that could divert a vent stream away from a control device used to comply with the requirements in §§ 63.1253, 63.1254, and 63.1256 shall comply with the requirements of Table 4 to this subpart and paragraph (b)(1) or (2) of this section. Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and pressure relief valves needed for safety purposes are not subject to this paragraph.

(1) Install, calibrate, maintain, and operate a flow indicator that determines whether vent stream flow is present at least once every 15 minutes. Records shall be maintained as specified in § 63.1259(i)(6)(i). The flow indicator shall be installed at the entrance to any bypass line that could divert the vent stream away from the control device to the atmosphere; or

(2) Secure the bypass line valve in the closed position with a car seal or lock and key type configuration. A visual inspection of the seal or closure mechanism shall be performed at least once every month to ensure that the valve is maintained in the closed position and the vent stream is not diverted through the bypass line. Records shall be maintained as specified in § 63.1259(i)(6)(ii).

(c) *Heat exchange systems.* Except as provided in paragraph (c)(2) of this section, owners and operators of affected sources shall comply with the requirements in paragraph (c)(1) of this section for heat exchange systems that cool process equipment or materials used in pharmaceutical manufacturing operations.

(1) The heat exchange system shall be treated according to the provisions of

§ 63.104, except that the monitoring frequency shall be no less than quarterly.

(2) For identifying leaking equipment, the owner or operator of heat exchange systems on equipment which meet current good manufacturing practice (CGMP) requirements of 21 CFR part 211 may elect to use the physical integrity of the reactor as the surrogate indicator of heat exchange system leaks around the reactor.

(d) *Emissions averaging provisions.* Except as specified in paragraphs (d)(1) through (5) of this section, owners or operators of storage tanks or processes subject to the provisions of §§ 63.1253 and 63.1254 may choose to comply by using emissions averaging requirements specified in § 63.1257(g) or (h) for any storage tank or process.

(1) A State may prohibit averaging of HAP emissions and require the owner or operator of an existing source to comply with the provisions in §§ 63.1253 and 63.1254.

(2) Only emission sources subject to the requirements of § 63.1253(b)(1) and (c)(1) or § 63.1254(a)(2), (a)(3)(ii)(A) or (a)(3)(iii) may be included in any averaging group.

(3) Processes which have been permanently shutdown or storage tanks permanently taken out of HAP service may not be included in any averaging group.

(4) Processes and storage tanks already controlled on or before November 15, 1990 may not be included in an emissions averaging group, except where the level of control is increased after November 15, 1990. In these cases, the uncontrolled emissions shall be the controlled emissions as calculated on November 15, 1990 for the purpose of determining the uncontrolled emissions as specified in § 63.1257(g) and (h).

(5) Emission points controlled to comply with a State or Federal rule other than this subpart may not be included in an emission averaging group, unless the level of control has been increased after November 15, 1990 above what is required by the other State or Federal rule. Only the control above what is required by the other State or Federal rule will be credited. However, if an emission point has been used to generate emissions averaging credit in an approved emissions average, and the point is subsequently made subject to a State or Federal rule other than this subpart, the point can continue to generate emissions averaging credit for the purpose of complying with the previously approved average.

(6) Not more than 20 processes subject to § 63.1254(a)(2)(i), 20 storage tanks subject to § 63.1253(b)(1), and 20 storage tanks subject to § 63.1253(c)(1)(i) at an affected source may be included in an emissions averaging group.

(7) Compliance with the emissions standards in § 63.1253 shall be satisfied when the annual percent reduction efficiency is greater than or equal to 90 percent for those tanks meeting the requirements of § 63.1253(a)(1) and 95 percent for those tanks meeting the requirements of § 63.1253(a)(2), as demonstrated using the test methods and compliance procedures specified in § 63.1257(g).

(8) Compliance with the emissions standards in § 63.1254(a)(2) shall be satisfied when the annual percent reduction efficiency is greater than or equal to 93 percent, as demonstrated using the test methods and compliance procedures specified in § 63.1257(h).

(e) *Pollution prevention alternative.* Except as provided in paragraph (e)(1) of this section, owners and operators may choose to meet the pollution prevention alternative requirement specified in either paragraph (e)(2) or (3) of this section for any PMPU, in lieu of the requirements specified in §§ 63.1253, 63.1254, 63.1255, and 63.1256. Compliance with paragraphs (e)(2) and (3) of this section shall be demonstrated through the procedures in § 63.1257(f).

(1) The HAP that are generated in the PMPU that are not part of the production-indexed consumption factor must be controlled according to the requirements of §§ 63.1253, 63.1254, 63.1255, and 63.1256. The HAP that are generated as a result of combustion control of emissions must be controlled according to the requirements of paragraph (g) of this section.

(2) The production-indexed HAP consumption factor (kg HAP consumed/kg produced) shall be reduced by at least 75 percent from a 3 year average baseline established no earlier than the 1987 calendar year, or for the time period from startup of the process until the present in which the PMPU was operational and data are available, whichever is the lesser time period. If a time period less than 3 years is used to set the baseline, the data must represent at least 1 year's worth of data. For any reduction in the HAP factor achieved by reducing a HAP that is also a VOC, an equivalent reduction in the VOC factor is also required. For any reduction in the HAP factor that is achieved by reducing a HAP that is not a VOC, the VOC factor may not be increased.

(3) Both requirements specified in paragraphs (e)(3)(i) and (ii) of this section are met.

(i) The production-indexed HAP consumption factor (kg HAP consumed/kg produced) shall be reduced by at least 50 percent from a 3-year average baseline established no earlier than the 1987 calendar year, or for the time period from startup of the process until the present in which the PMPU was operational and data are available, whichever is less. If a time period less than 3 years is used to set the baseline, the data must represent at least 1 year's worth of data. For any reduction in the HAP factor achieved by reducing a HAP that is also a VOC, an equivalent reduction in the VOC factor is also required. For any reduction in the HAP factor that is achieved by reducing a HAP that is not a VOC, the VOC factor may not be increased.

(ii) The total PMPU HAP emissions shall be reduced by an amount, in kg/yr, that, when divided by the annual production rate, in kg/yr, and added to the reduction of the production-indexed HAP consumption factor, in kg/kg, yields a value of at least 75 percent of the average baseline HAP production-indexed consumption factor established according to paragraph (e)(3)(i) of this section according to the equation provided in § 63.1257(f)(2)(ii)(A). The total PMPU VOC emissions shall be reduced by an amount calculated according to the equation provided in § 63.1257(f)(2)(ii)(B). The annual reduction in HAP and VOC air emissions must be due to the use of the following control devices:

(A) Combustion control devices such as incinerators, flares or process heaters.

(B) Control devices such as condensers and carbon adsorbers whose recovered product is destroyed or shipped offsite for destruction.

(C) Any control device that does not ultimately allow for recycling of material back to the PMPU.

(D) Any control device for which the owner or operator can demonstrate that the use of the device in controlling HAP emissions will have no effect on the production-indexed consumption factor for the PMPU.

(f) *Control requirements for certain liquid streams in open systems within a PMPU.* (1) The owner or operator shall comply with the provisions of Table 5 of this subpart, for each item of equipment meeting all the criteria specified in paragraphs (f)(2) through (4) and either paragraph (f)(5)(i) or (ii) of this section.

(2) The item of equipment is of a type identified in Table 5 of this subpart;

(3) The item of equipment is part of a PMPU, as defined in § 63.1251;

(4) The item of equipment is controlled less stringently than in Table

5 of this subpart and the item of equipment is not otherwise exempt from controls by the provisions of this subpart or subpart A of this part; and

(5) The item of equipment:

(i) Is a drain, drain hub, manhole, lift station, trench, pipe, or oil/water separator that conveys water with an annual average concentration greater than or equal to 1,300 parts per million by weight (ppmw) of partially soluble HAP compounds; or an annual average concentration greater than or equal to 5,200 ppmw of partially soluble and/or soluble HAP compounds. The annual average concentration shall be determined according to the procedures in § 63.1257(e)(1)(ii).

(ii) Is a tank that receives one or more streams that contain water with an annual average concentration greater than or equal to 1,300 ppmw of partially soluble HAP compounds, or greater than or equal to 5,200 ppmw of total partially soluble and/or soluble HAP compounds. The owner or operator of the source shall determine the average concentration of the stream at the inlet to the tank and according to the procedures in § 63.1257(e)(1)(ii).

(g) *Control requirements for halogenated vent streams that are controlled by combustion devices.* If a combustion device is used to comply with the provisions of §§ 63.1253 (storage tanks), 63.1254 (process vents), 63.1256(h) (wastewater vent streams) for a halogenated vent stream, then the vent stream shall be ducted to a halogen reduction device such as, but not limited to, a scrubber, before it is discharged to the atmosphere. The halogen reduction device must reduce emissions by the amounts specified in either paragraph (g)(1) or (2) of this section.

(1) A halogen reduction device after the combustion control device must reduce overall emissions of hydrogen halides and halogens, as defined in § 63.1251, by 95 percent or to a concentration less than or equal to 20 ppmv.

(2) A halogen reduction device located before the combustion control device must reduce the halogen atom content of the vent stream to a concentration less than or equal to 20 ppmv.

§ 63.1253 Standards: Storage tanks.

(a) Except as provided in paragraphs (d) and (e) of this section, the owner or operator of a storage tank meeting the criteria of paragraph (a)(1) of this section is subject to the requirements of paragraph (b) of this section. Except as provided in paragraphs (d) and (e) of this section, the owner or operator of a storage tank meeting the criteria of paragraph (a)(2) of this section is subject to the requirements of paragraph (c) of this section. Compliance with the provisions of paragraphs (b) and (c) of this section is demonstrated using the initial compliance procedures in § 63.1257(c) and the monitoring requirements in § 63.1258.

(1) A storage tank with a design capacity greater than or equal to 38 m^3 (10,000 gallons [gal]) but less than 75 m^3 (20,000 gal), and storing a liquid for which the maximum true vapor pressure of total HAP is greater than or equal to 13.1 kPa (1.9 psia).

(2) A storage tank with a design capacity greater than or equal to 75 m^3 (20,000 gal) storing a liquid for which the maximum true vapor pressure of total HAP is greater than or equal to 13.1 kPa (1.9 psia).

(b) The owner or operator of a storage tank shall equip the affected storage tank with either a fixed roof with internal floating roof, an external floating roof, an external floating roof converted to an internal floating roof, or a closed-vent system meeting the conditions of § 63.1252(b) with a control device that meets any of the following conditions:

(1) Reduces inlet emissions of total HAP by 90 percent by weight or greater;

(2) Is an enclosed combustion device that provides a minimum residence time of 0.5 seconds at a minimum temperature of 760° C;

(3) Is a flare that meets the requirements of § 63.11(b); or

(4) Is a control device specified in § 63.1257(a)(4).

(c) The owner or operator of a storage tank shall equip the affected storage tank with either a fixed roof with internal floating roof, an external floating roof, an external floating roof converted to an internal floating roof, or a closed-vent system meeting the conditions of § 63.1252(b) with a control device that meets any of the following conditions:

(1) Reduces inlet emissions of total HAP as specified in paragraph (c)(1) (i) or (ii) of this section:

(i) By 95 percent by weight or greater; or (ii) If the owner or operator can demonstrate that a control device installed on a storage tank on or before April 2, 1997 is designed to reduce inlet emissions of total HAP by greater than or equal to 90 percent by weight but less than 95 percent by weight, then the control device is required to be operated to reduce inlet emissions of total HAP by 90 percent or greater.

(2) Is an enclosed combustion device that provides a minimum residence time of 0.5 seconds at a minimum temperature of 760° C;

(3) Is a flare that meets the requirements of § 63.11(b); or

(4) Is a control device specified in § 63.1257(a)(4).

(d) As an alternative standard, the owner or operator of an existing or new affected source may comply with the storage tank standards by routing storage tank vents to a control device achieving an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 20 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 20 ppmv or less. Compliance with the outlet concentrations shall be determined by the initial compliance procedures of § 63.1257(c)(4) and the continuous emission monitoring requirements of § 63.1258(b)(5).

(e) *Planned routine maintenance.* The specifications and requirements in paragraphs (b) through (d) of this section for control devices do not apply during periods of planned routine maintenance. Periods of planned routine maintenance of the control devices, during which the control device does not meet the specifications of paragraphs (b) through (d) of this section, as applicable, shall not exceed 240 hours per year.

§ 63.1254 Standards: Process vents.

(a) *Existing sources.* Except as provided in paragraph (c) of this section, the owner or operator of an existing affected source must control the collection of all gas streams originating from processes subject to this standard so as to comply with the requirements in paragraph (a)(1) or the requirements of paragraphs (a)(2) and (a)(3) of this section. If any vent within a process meets the criteria of paragraph (a)(3)(i) of this section, the owner or operator must comply with the provisions in paragraphs (a)(2) and (a)(3) for that process. The requirements of paragraphs (a) (1) and (2) of this section apply to all process vents within a process, as a group, and do not apply to individual vents. An owner or operator may switch from compliance with paragraph (a)(1) of this section to compliance with paragraphs (a) (2) and (3) of this section only after at least 1 year of operation in compliance with paragraph (a)(1) of this section. An owner or operator may switch from compliance with paragraphs (a) (2) and (3) of this section to compliance with paragraph (a)(1) of this section at any time. Notification of such a change in the compliance method shall be reported according to the procedures in § 63.1260(h) of this subpart. Compliance with the required

emission limits or reductions in paragraphs (a) (1) through (3) of this section may be demonstrated using the initial compliance procedures described in § 63.1257(d) and the monitoring requirements described in § 63.1258.

(1) Except for processes with a vent that meets the conditions in paragraph (a)(3)(i) of this section, actual HAP emissions shall not exceed 900 kilograms (kg) per year [2,000 pounds per year] from the sum of all process vents within a process.

(i) Except as provided in paragraph (a)(1)(ii) of this section, the owner or operator is limited to 7 processes in any 365-day period that can be selected to comply with paragraph (a)(1) of this section.

(ii) The owner or operator may exclude processes with less than 100 lb/yr HAP, on an uncontrolled basis, from the 7-process limit described in paragraph (a)(1)(i) of this section.

(2) Uncontrolled HAP emissions from the sum of all process vents within a process that do not meet the conditions in paragraph (a)(3)(i) of this section or are not controlled according to any of the requirements of paragraphs (a)(2)(i), (a)(2)(ii), (a)(2)(iii), or (c) of this section shall be reduced by 93 percent or greater by weight.

(i) To outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens;

(ii) By a flare that meets the requirements of § 63.11(b); or (iii) By a control device specified in § 63.1257(a)(4).

(3) Except as provided in paragraph (a)(3)(iii) of this section, uncontrolled HAP emissions from each process vent that meets the conditions in paragraph (a)(3)(i) of this section shall be reduced as specified in paragraph (a)(3)(ii) of this section.

(i) Uncontrolled HAP emissions from a process vent shall be reduced as specified in paragraph (a)(3)(ii) if the vent meets either of the criteria described in paragraph (a)(3)(i) (A) or (B) of this section:

(A) The flow-weighted average flowrate calculated using Equation 1 of this subpart is less than or equal to the flowrate calculated using Equation 2 of this subpart.

$$FR_a = \frac{\sum_{i=1}^{n}(D_i)(FR_i)}{\sum_{i=1}^{n} D_i} \qquad \text{(Eq. 1)}$$

$$FR = 0.02 * (HL) - 1{,}000 \qquad \text{(Eq. 2)}$$

Where:

FR_a = flow-weighted average flowrate for the vent, scfm

D_i = duration of each emission event, min

FR_i = flowrate of each emission event, scfm

n = number of emission events

FR = flowrate, scfm

HL = annual uncontrolled HAP emissions, lb/yr, as defined in § 63.1251

(B) As an alternative to the criteria described in paragraph (a)(3)(i)(A) of this section, uncontrolled HAP emissions from a process vent shall be reduced or controlled as specified in paragraph (a)(3)(ii) of this section if the process vent meets the criteria specified in paragraphs (a)(3)(i)(B)(*1*) and (*2*) of this section or the criteria specified in paragraphs (a)(3)(i)(B)(*1*) and (*3*) of this section.

(*1*) Uncontrolled HAP emissions from the process vent exceed 25 tons per year.

(*2*) The flow-weighted average flowrate for the vent, as calculated in Equation 1 of this section, is less than or equal to 100 scfm.

(*3*) The flow weighted average is greater than 100 scfm and less than or equal to the flowrate calculated using Equation 2 of this section.

(ii) Uncontrolled HAP emissions shall be reduced:

(A) By 98 percent by weight or greater; or

(B) To outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens; or

(C) By a flare that meets the requirements of § 63.11(b); or

(D) By a control device specified in § 63.1257(a)(4).

(iii) If the owner or operator can demonstrate that a control device, installed on a process vent that meets the conditions of paragraph (a)(3)(i) of this section on or before April 2, 1997, was designed to reduce uncontrolled HAP emissions of total HAP by greater than or equal to 93 percent by weight, but less than 98 percent by weight, then the control device is required to be operated to reduce inlet emissions of total HAP by 93 percent by weight or greater.

(b) *New sources.* Uncontrolled HAP emissions from the sum of all process vents within a process at a new affected source that are not controlled according to any of the requirements of paragraphs (b)(1), (2), or (3) of this section or paragraph (c) of this section shall be reduced by 98 percent or greater by weight if the uncontrolled HAP emissions from the sum of all process vents within a process is greater than 180 kg/yr (400 lb/yr). Compliance with the required emission limit or reduction is demonstrated using the initial compliance procedures in § 63.1257(d) and the monitoring requirements described in § 63.1258.

(1) To outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens;

(2) By a flare that meets the requirements of § 63.11(b); or

(3) By a control device specified in § 63.1257(a)(4).

(c) As an alternative standard, the owner or operator of an existing or new affected source may comply with the process vent standards by routing all vents from a process to a control device achieving an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 20 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 20 ppmv or less. Any process vents within a process that are not routed to this control device must be controlled in accordance with the provisions of paragraphs (a)(2),(a)(3), and (b) of this section, as applicable. Compliance with the outlet concentrations shall be determined by the initial compliance procedures described in § 63.1257(d)(1)(iv) and the continuous emission monitoring requirements described in § 63.1258(b)(5).

§ 63.1255 Standards: Equipment leaks.

(a) *General Equipment Leak Requirements.* (1) The provisions of this section apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems required by this subpart that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year within a source subject to the provisions of this subpart.

(2) *Consistency with other regulations.* After the compliance date for a process, equipment subject to both this section and either of the following will be required to comply only with the provisions of this subpart:

(i) 40 CFR part 60.

(ii) 40 CFR part 61.

(3) [Reserved]

(4) The provisions in § 63.1(a)(3) of subpart A of this part do not alter the provisions in paragraph (a)(2) of this section.

(5) Lines and equipment not containing process fluids are not subject

to the provisions of this section. Utilities, and other nonprocess lines, such as heating and cooling systems which do not combine their materials with those in the processes they serve, are not considered to be part of a process.

(6) The provisions of this section do not apply to bench-scale processes, regardless of whether the processes are located at the same plant site as a process subject to the provisions of this subpart.

(7) Each piece of equipment to which this section applies shall be identified such that it can be distinguished readily from equipment that is not subject to this section. Identification of the equipment does not require physical tagging of the equipment. For example, the equipment may be identified on a plant site plan, in log entries, or by designation of process boundaries by some form of weatherproof identification. If changes are made to the affected source subject to the leak detection requirements, equipment identification for each type of component shall be updated, if needed, within 15 calendar days of the end of each monitoring period for that component.

(8) Equipment that is in vacuum service is excluded from the requirements of this section.

(9) Equipment that is in organic HAP service, but is in such service less than 300 hours per calendar year, is excluded from the requirements of this section if it is identified as required in paragraph (g)(9) of this section.

(10) When each leak is detected by visual, audible, or olfactory means, or by monitoring as described in § 63.180(b) or (c), the following requirements apply:

(i) A weatherproof and readily visible identification, marked with the equipment identification number, shall be attached to the leaking equipment.

(ii) The identification on a valve or connector in light liquid or gas/vapor service may be removed after it has been monitored as specified in paragraph (e)(7)(iii) of this section and § 63.174(e), and no leak has been detected during the follow-up monitoring.

(iii) The identification on equipment, except on a valve or connector in light liquid or gas/vapor service, may be removed after it has been repaired.

(b) *References.* (1) The owner or operator of a source subject to this section shall comply with the following sections of subpart H, except for § 63.160, § 63.161, § 63.162, § 63.163, § 63.167, § 63.168, § 63.170, § 63.171, § 63.172, § 63.173, § 63.181, and § 63.182 of this subpart. In place of § 63.160 and § 63.162, the owner or operator shall comply with paragraph (a) of this section; in place of § 63.161, the owner or operator shall comply with § 63.1251 of this subpart; in place of § 63.163 and § 63.173, the owner or operator shall comply with paragraph (c) of this section; in place of § 63.167, the owner or operator shall comply with paragraph (d) of this section; in place of § 63.168, the owner or operator shall comply with paragraph (e) of this section; in place of § 63.170, the owner or operator shall comply with § 63.1254 of this subpart; in place of § 63.171, the owner or operator shall comply with paragraph (b)(1)(v) of this section; in place of § 63.172, the owner or operator shall comply with paragraph (b)(1)(vi) of this section; in place of § 63.181, the owner or operator shall comply with paragraph (g) of this section; in place of § 63.182, the owner or operator shall comply with paragraph (h) of this section. The term ''process unit'' as used in subpart H shall be considered to be defined the same as ''group of processes'' for sources subject to this subpart GGG.

(i) Section 63.164, Compressors;

(ii) Section 63.165, Pressure relief devices in gas/vapor service;

(iii) Section 63.166, Sampling connection systems;

(iv) Section 63.169, Pumps, valves, connectors, and agitators in heavy liquid service; instrumentation systems; and pressure relief devices in liquid service;

(v) Section 63.171, Delay of repair, shall apply except § 63.171(a) shall not apply. Instead, delay of repair of equipment for which leaks have been detected is allowed if one of the following conditions exist:

(A) The repair is technically infeasible without a process shutdown. Repair of this equipment shall occur by the end of the next scheduled process shutdown.

(B) The owner or operator determines that repair personnel would be exposed to an immediate danger if attempting to repair without a process shutdown. Repair of this equipment shall occur by the end of the next scheduled process shutdown.

(vi) Section 63.172, Closed-vent systems and control devices, for closed-vent systems used to comply with this subpart, and for control devices used to comply with this section only, except

(A) Sections 63.172(k) and (l) shall not apply. In place of § 63.172(k) and (l), the owner or operator shall comply with paragraph (f) of this section.

(B) Owners or operators may, instead of complying with the provisions of § 63.172(f), design a closed-vent system to operate at a pressure below atmospheric pressure. The system shall be equipped with at least one pressure gage or other pressure measurement device that can be read from a readily accessible location to verify that negative pressure is being maintained in the closed-vent system when the associated control device is operating.

(vii) Section 63.174, Connectors, except:

(A) Sections 63.174(f) and (g) shall not apply. In place of § 63.174(f) and (g), the owner or operator shall comply with paragraph (f) of this section.

(B) Days that the connectors are not in organic HAP service shall not be considered part of the 3 month period in § 63.174(e).

(C) Section 63.174(b)(3)(ii) shall not apply. Instead, if the percent leaking connectors in the process unit was less than 0.5 percent, but equal to or greater than 0.25 percent, during the last required monitoring period, monitoring shall be performed once every 4 years. An owner or operator may comply with the requirements of this paragraph by monitoring at least 40 percent of the connectors in the first 2 years and the remainder of the connectors within the next 2 years. The percent leaking connectors will be calculated for the total of all monitoring performed during the 4 year period.

(D) Section 63.174(b)(3)(iv) shall not apply. Instead, the owner or operator shall increase the monitoring frequency to once every 2 years for the next monitoring period if leaking connectors comprise at least 0.5 percent but less than 1.0 percent of the connectors monitored within the 4 years specified in paragraph (b)(1)(vii)(C) of this section or the first 4 years specified in § 63.174(b)(3)(iii). At the end of that 2 year monitoring period, the owner or operator shall monitor once per year while the percent leaking connectors is greater than or equal to 0.5 percent; if the percent leaking connectors is less than 0.5 percent, the owner or operator may return to monitoring once every 4 years or may monitor in accordance with § 63.174(b)(3)(iii), if appropriate.

(E) Section 63.174(b)(3)(v) shall not apply. Instead, if an owner or operator complying with the requirements of paragraph (b)(1)(vii)(C) and (D) of this section or § 63.174 (b)(3)(iii) for a group of processes determines that 1 percent or greater of the connectors are leaking, the owner or operator shall increase the monitoring frequency to one time per year. The owner or operator may again elect to use the provisions of paragraphs (b)(1)(vii)(C) or (D) of this section after a monitoring period in which less than

0.5 percent of the connectors are determined to be leaking.

(F) Section 63.174(b)(3)(iii) shall not apply. Instead, monitoring shall be required once every 8 years, if the percent leaking connectors in the process unit was less than 0.25 percent during the last required monitoring period. An owner or operator shall monitor at least 50 percent of the connectors in the first 4 years and the remainder of the connectors within the next 4 years. If the percent leaking connectors in the first 4 years is equal to or greater than 0.35 percent, the monitoring program shall revert at that time to the appropriate monitoring frequency specified in paragraphs (b)(1)(vii)(C), (D), or (E) of this section.

(viii) Section 63.177, Alternative means of emission limitation: General;

(ix) Section 63.178, Alternative means of emission limitation: Batch processes, except that § 63.178(b), requirements for pressure testing, shall apply to all processes, not just batch processes;

(x) Section 63.179, Alternative means of emission limitation: Enclosed-vented process units;

(xi) Section 63.180, Test methods and procedures, except § 63.180(b)(4)(ii)(A) through (C) shall not apply. Instead calibration gases shall be a mixture of methane and air at a concentration of approximately, but less than, 10,000 parts per million methane for agitators; 2,000 parts per million for pumps; and 500 parts per million for all other equipment, except as provided in section 63.180(b)(4)(iii).

(2) [Reserved]

(c) *Standards for Pumps in Light Liquid Service and Agitators in Gas/Vapor Service and in Light Liquid Service.* (1) The provisions of this section apply to each pump that is in light organic HAP liquid service, and to each agitator in organic HAP gas/vapor service or in light organic HAP liquid service.

(2)(i) *Monitoring.* Each pump and agitator subject to this section shall be monitored quarterly to detect leaks by the method specified in § 63.180(b) of subpart H, except as provided in § 63.177 of subpart H, paragraph (f) of this section, and paragraphs (c)(5) through (c)(9) of this section.

(ii) *Leak definition.* The instrument reading, as determined by the method as specified in § 63.180(b), that defines a leak is:

(A) For agitators, an instrument reading of 10,000 parts per million or greater.

(B) For pumps, an instrument reading of 2,000 parts per million or greater.

(iii) *Visual Inspections.* Each pump and agitator shall be checked by visual inspection each calendar week for indications of liquids dripping from the pump or agitator seal. If there are indications of liquids dripping from the seal, a leak is detected.

(3) *Repair provisions.* (i) When a leak is detected, it shall be repaired as soon as practicable, but not later than 15 calendar days after it is detected, except as provided in paragraph (b)(1)(v) of this section.

(ii) A first attempt at repair shall be made no later than 5 calendar days after the leak is detected. First attempts at repair include, but are not limited to, the following practices where practicable:

(A) Tightening of packing gland nuts.

(B) Ensuring that the seal flush is operating at design pressure and temperature.

(4) *Calculation of percent leakers.* (i) The owner or operator shall decide no later than the end of the first monitoring period what groups of processes will be developed. Once the owner or operator has decided, all subsequent percent calculations shall be made on the same basis.

(ii) If, calculated on a 1 year rolling average, the greater of either 10 percent or three of the pumps in a group of processes leak, the owner or operator shall monitor each pump once per month.

(iii) The number of pumps in a group of processes shall be the sum of all the pumps in organic HAP service, except that pumps found leaking in a continuous process within 1 quarter after startup of the pump shall not count in the percent leaking pumps calculation for that one monitoring period only.

(iv) Percent leaking pumps shall be determined by the following Equation 3:

$$\%P_L = [(P_L — P_S)/(P_T — P_S)] \times 100 \quad \text{(Eq. 3)}$$

Where:

$\%P_L$ = percent leaking pumps

P_L = number of pumps found leaking as determined through quarterly monitoring as required in paragraphs (c)(2)(i) and (c)(2)(ii) of this section.

P_T = total pumps in organic HAP service, including those meeting the criteria in paragraphs (c)(5) and (c)(6) of this section

PS = number of pumps in a continuous process leaking within 1 quarter of startup during the current monitoring period

(5) *Exemptions.* Each pump or agitator equipped with a dual mechanical seal system that includes a barrier fluid system is exempt from the requirements of paragraphs (c)(1) through (c)(4)(iii) of this section, provided the following requirements are met:

(i) Each dual mechanical seal system is:

(A) Operated with the barrier fluid at a pressure that is at all times greater than the pump/agitator stuffing box pressure; or

(B) Equipped with a barrier fluid degassing reservoir that is connected by a closed-vent system to a control device that complies with the requirements of paragraph (b)(1)(vi) of this section; or

(C) Equipped with a closed-loop system that purges the barrier fluid into a process stream.

(ii) The barrier fluid is not in light liquid service.

(iii) Each barrier fluid system is equipped with a sensor that will detect failure of the seal system, the barrier fluid system, or both.

(iv) Each pump/agitator is checked by visual inspection each calendar week for indications of liquids dripping from the pump/agitator seal.

(A) If there are indications of liquids dripping from the pump/agitator seal at the time of the weekly inspection, the pump/agitator shall be monitored as specified in § 63.180(b) to determine if there is a leak of organic HAP in the barrier fluid.

(B) If an instrument reading of 2,000 parts per million or greater is measured for pumps, or 10,000 parts per million or greater is measured for agitators, a leak is detected.

(v) Each sensor as described in paragraph (c)(5)(iii) of this section is observed daily or is equipped with an alarm unless the pump is located within the boundary of an unmanned plant site.

(vi)(A) The owner or operator determines, based on design considerations and operating experience, criteria applicable to the presence and frequency of drips and to the sensor that indicate failure of the seal system, the barrier fluid system, or both.

(B) If indications of liquids dripping from the pump/agitator seal exceed the criteria established in paragraph (c)(5)(vi)(A) of this section, or if, based on the criteria established in paragraph (c)(5)(vi)(A) of this section, the sensor indicates failure of the seal system, the barrier fluid system, or both, a leak is detected.

(C) When a leak is detected, it shall be repaired as soon as practicable, but not later than 15 calendar days after it is detected, except as provided in paragraph (b)(1)(v) of this section.

(D) A first attempt at repair shall be made no later than 5 calendar days after each leak is detected.

(6) Any pump/agitator that is designed with no externally actuated

shaft penetrating the pump/agitator housing is exempt from the requirements of paragraphs (c)(1) through (c)(4) of this section, except for the requirements of paragraph (c)(2)(iii) and, for pumps, paragraph (c)(4)(iv).

(7) Any pump/agitator equipped with a closed-vent system capable of capturing and transporting any leakage from the seal or seals back to the process or to a control device that complies with the requirements of paragraph (b)(1)(vi) of this section is exempt from the requirements of paragraphs (c)(2) through (c)(5) of this section.

(8) Any pump/agitator that is located within the boundary of an unmanned plant site is exempt from the weekly visual inspection requirement of paragraphs (c)(2)(iii) and (c)(5)(iv) of this section, and the daily requirements of paragraph (c)(5)(v) of this section, provided that each pump/agitator is visually inspected as often as practicable and at least monthly.

(9) If more than 90 percent of the pumps in a group of processes meet the criteria in either paragraph (c)(5) or (c)(6) of this section, the process is exempt from the requirements of paragraph (c)(4) of this section.

(d) *Standards: Open-Ended Valves or Lines.* (1)(i) Each open-ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve, except as provided in § 63.177 and paragraphs (d)(4) through (6) of this section.

(ii) The cap, blind flange, plug, or second valve shall seal the open end at all times except during operations requiring process fluid flow through the open-ended valve or line, or during maintenance or repair. The cap, blind flange, plug, or second valve shall be in place within 1 hour of cessation of operations requiring process fluid flow through the open-ended valve or line, or within 1 hour of cessation of maintenance or repair.

(2) Each open-ended valve or line equipped with a second valve shall be operated in a manner such that the valve on the process fluid end is closed before the second valve is closed.

(3) When a double block and bleed system is being used, the bleed valve or line may remain open during operations that require venting the line between the block valves but shall comply with paragraph (d)(1) of this section at all other times.

(4) Open-ended valves or lines in an emergency shutdown system which are designed to open automatically in the event of a process upset are exempt from the requirements of paragraphs (d)(1) through (d)(3) of this section.

(5) Open-ended valves or lines containing materials which would autocatalytically polymerize are exempt from the requirements of paragraphs (d)(1) through (d)(3) of this section.

(6) Open-ended valves or lines containing materials which could cause an explosion, serious overpressure, or other safety hazard if capped or equipped with a double block and bleed system as specified in paragraphs (d)(1) through (d)(3) of this section are exempt from the requirements of paragraphs (d)(1) through (d)(3) of this section.

(e) *Standards: Valves in Gas/Vapor Service and in Light Liquid Service.* (1) The provisions of this section apply to valves that are either in gas organic HAP service or in light liquid organic HAP service.

(2) For existing and new affected sources, all valves subject to this section shall be monitored, except as provided in paragraph (f) of this section and in § 63.177, by no later than 1 year after the compliance date.

(3) *Monitoring.* The owner or operator of a source subject to this section shall monitor all valves, except as provided in paragraph (f) of this section and in § 63.177, at the intervals specified in paragraph (e)(4) of this section and shall comply with all other provisions of this section, except as provided in paragraph (b)(1)(v) of this section, § 63.178, and § 63.179.

(i) The valves shall be monitored to detect leaks by the method specified in § 63.180(b).

(ii) An instrument reading of 500 parts per million or greater defines a leak.

(4) *Subsequent monitoring frequencies.* After conducting the initial survey required in paragraph (e)(2) of this section, the owner or operator shall monitor valves for leaks at the intervals specified below:

(i) For a group of processes with 2 percent or greater leaking valves, calculated according to paragraph (e)(6) of this section, the owner or operator shall monitor each valve once per month, except as specified in paragraph (e)(9) of this section.

(ii) For a group of processes with less than 2 percent leaking valves, the owner or operator shall monitor each valve once each quarter, except as provided in paragraphs (e)(4)(iii) through (e)(4)(v) of this section.

(iii) For a group of processes with less than 1 percent leaking valves, the owner or operator may elect to monitor each valve once every 2 quarters.

(iv) For a group of processes with less than 0.5 percent leaking valves, the owner or operator may elect to monitor each valve once every 4 quarters.

(v) For a group of processes with less than 0.25 percent leaking valves, the owner or operator may elect to monitor each valve once every 2 years.

(5) *Calculation of percent leakers.* For a group of processes to which this subpart applies, an owner or operator may choose to subdivide the valves in the applicable group of processes and apply the provisions of paragraph (e)(4) of this section to each subgroup. If the owner or operator elects to subdivide the valves in the applicable group of processes, then the provisions of paragraphs (e)(5)(i) through (e)(5)(viii) of this section apply.

(i) The overall performance of total valves in the applicable group of processes must be less than 2 percent leaking valves, as detected according to paragraphs (e)(3) (i) and (ii) of this section and as calculated according to paragraphs (e)(6) (ii) and (iii) of this section.

(ii) The initial assignment or subsequent reassignment of valves to subgroups shall be governed by the provisions of paragraphs (e)(5)(ii) (A) through (C) of this section.

(A) The owner or operator shall determine which valves are assigned to each subgroup. Valves with less than 1 year of monitoring data or valves not monitored within the last 12 months must be placed initially into the most frequently monitored subgroup until at least 1 year of monitoring data has been obtained.

(B) Any valve or group of valves can be reassigned from a less frequently monitored subgroup to a more frequently monitored subgroup provided that the valves to be reassigned were monitored during the most recent monitoring period for the less frequently monitored subgroup. The monitoring results must be included with the less frequently monitored subgroup's monitoring event and associated next percent leaking valves calculation for that group.

(C) Any valve or group of valves can be reassigned from a more frequently monitored subgroup to a less frequently monitored subgroup provided that the valves to be reassigned have not leaked for the period of the less frequently monitored subgroup (e.g., for the last 12 months, if the valve or group of valves is to be reassigned to a subgroup being monitored annually). Nonrepairable valves may not be reassigned to a less frequently monitored subgroup.

(iii) The owner or operator shall determine every 6 months if the overall performance of total valves in the applicable group of processes is less than 2 percent leaking valves and so indicate the performance in the next periodic report. If the overall performance of total valves in the

applicable group of processes is 2 percent leaking valves or greater, the owner or operator shall revert to the program required in paragraphs (e)(2) through (e)(4) of this section. The overall performance of total valves in the applicable group of processes shall be calculated as a weighted average of the percent leaking valves of each subgroup according to the following Equation 4:

$$\%V_{LO} = \frac{\sum_{i=1}^{n}(\%V_{Li} \times V_i)}{\sum_{i=1}^{n} V_i} \qquad \text{(Eq. 4)}$$

where:

$\%V_{LO}$ = overall performance of total valves in the applicable process or group of processes

$\%V_{Li}$ = percent leaking valves in subgroup I, most recent value calculated according to the procedures in paragraphs (e)(6) (ii) and (iii) of this section

V_i = number of valves in subgroup I

n = number of subgroups

(iv) *Records.* In addition to records required by paragraph (g) of this section, the owner or operator shall maintain records specified in paragraphs (e)(5)(iv)(A) through (D) of this section.

(A) Which valves are assigned to each subgroup,

(B) Monitoring results and calculations made for each subgroup for each monitoring period,

(C) Which valves are reassigned and when they were reassigned, and

(D) The results of the semiannual overall performance calculation required in paragraph (e)(5)(iii) of this section.

(v) The owner or operator shall notify the Administrator no later than 30 days prior to the beginning of the next monitoring period of the decision to subgroup valves. The notification shall identify the participating processes and the valves assigned to each subgroup.

(vi) *Semiannual reports.* In addition to the information required by paragraph (h)(3) of this section, the owner or operator shall submit in the periodic reports the information specified in paragraphs (e)(5)(vi)(A) and (B) of this section.

(A) Valve reassignments occurring during the reporting period, and

(B) Results of the semiannual overall performance calculation required by paragraph (e)(5)(iii) of this section.

(vii) To determine the monitoring frequency for each subgroup, the calculation procedures of paragraph (e)(6)(iii) of this section shall be used.

(viii) Except for the overall performance calculations required by paragraphs (e)(5)(i) and (e)(5)(iii) of this section, each subgroup shall be treated as if it were a process for the purposes of applying the provisions of this section.

(6)(i) The owner or operator shall decide no later than the implementation date of this subpart or upon revision of an operating permit how to group the processes. Once the owner or operator has decided, all subsequent percentage calculations shall be made on the same basis.

(ii) Percent leaking valves for each group of processes or subgroup shall be determined by the following Equation 5:

$$\%V_L = [V_L/V_T] \times 100 \qquad \text{(Eq. 5)}$$

Where:

$\%V_L$ = percent leaking valves

V_L = number of valves found leaking excluding nonrepairables as provided in paragraph (e)(6)(iv)(A) of this section

V_T = total valves monitored, in a monitoring period excluding valves monitored as required by (e)(7)(iii) of this section

(iii) When determining monitoring frequency for each group of processes or subgroup subject to monthly, quarterly, or semiannual monitoring frequencies, the percent leaking valves shall be the arithmetic average of the percent leaking valves from the last two monitoring periods. When determining monitoring frequency for each group of processes or subgroup subject to annual or biennial (once every 2 years) monitoring frequencies, the percent leaking valves shall be the arithmetic average of the percent leaking valves from the last three monitoring periods.

(iv)(A) Nonrepairable valves shall be included in the calculation of percent leaking valves the first time the valve is identified as leaking and nonrepairable and as required to comply with paragraph (e)(6)(iv)(B) of this section. Otherwise, a number of nonrepairable valves (identified and included in the percent leaking calculation in a previous period) up to a maximum of 1 percent of the total number of valves in organic HAP service at a process may be excluded from calculation of percent leaking valves for subsequent monitoring periods.

(B) If the number of nonrepairable valves exceeds 1 percent of the total number of valves in organic HAP service at a process, the number of nonrepairable valves exceeding 1 percent of the total number of valves in organic HAP service shall be included in the calculation of percent leaking valves.

(7) *Repair provisions.* (i) When a leak is detected, it shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in paragraph (b)(1)(v) of this section.

(ii) A first attempt at repair shall be made no later than 5 calendar days after each leak is detected.

(iii) When a leak is repaired, the valve shall be monitored at least once within the first 3 months after its repair. Days that the valve is not in organic HAP service shall not be considered part of this 3 month period.

(8) First attempts at repair include, but are not limited to, the following practices where practicable:

(i) Tightening of bonnet bolts,

(ii) Replacement of bonnet bolts,

(iii) Tightening of packing gland nuts, and

(iv) Injection of lubricant into lubricated packing.

(9) Any equipment located at a plant site with fewer than 250 valves in organic HAP service in the affected source is exempt from the requirements for monthly monitoring specified in paragraph (e)(4)(i) of this section. Instead, the owner or operator shall monitor each valve in organic HAP service for leaks once each quarter, or comply with paragraphs (e)(4)(iii) or (e)(4)(iv) of this section.

(f) *Unsafe to Monitor, Difficult to Monitor, and Inaccessible Equipment.* (1) Equipment that is designated as unsafe to monitor, difficult to monitor, or inaccessible is exempt from the monitoring requirements specified in paragraphs (f)(1)(i) through (iv) of this section provided the owner or operator meets the requirements specified in paragraph (f)(2), (f)(3), or (f)(4) of this section, as applicable. Ceramic or ceramic-lined connectors are subject to the same requirements as inaccessible connectors.

(i) For pumps and agitators, paragraphs (c)(2), (c)(3), and (c)(4) of this section do not apply.

(ii) For valves, paragraphs (e)(2) through (e)(7) of this section do not apply.

(iii) For closed-vent systems, § 63.172(f)(1) and (2), and (g) do not apply.

(iv) For connectors, § 63.174(b) through (e) do not apply.

(2) *Equipment that is unsafe to monitor.* (i) Equipment may be designated as unsafe to monitor if the owner or operator determines that monitoring personnel would be exposed to an immediate danger as a consequence of complying with the monitoring requirements in paragraphs (f)(1)(i) through (iv) of this section.

(ii) The owner or operator of equipment that is designated as unsafe-to-monitor must have a written plan that requires monitoring of the equipment as frequently as practicable during safe-to-monitor times, but not more frequently than the periodic monitoring schedule otherwise applicable.

(3) *Equipment that is difficult to monitor.* (i) Equipment may be designated as difficult to monitor if the owner or operator determines that the equipment cannot be monitored without elevating the monitoring personnel more than 2 meters above a support surface or it is not accessible at anytime in a safe manner;

(ii) At an existing source, any equipment within a group of processes that meets the criteria of paragraph (f)(3)(i) of this section may be designated as difficult to monitor. At a new affected source, an owner or operator may designate no more than 3 percent of each type of equipment as difficult to monitor.

(iii) The owner or operator of equipment designated as difficult to monitor must follow a written plan that requires monitoring of the equipment at least once per calendar year.

(4) *Inaccessible equipment and ceramic or ceramic-lined connectors.* (i) A connector, agitator, or valve may be designated as inaccessible if it is:

(A) Buried;

(B) Insulated in a manner that prevents access to the equipment by a monitor probe;

(C) Obstructed by equipment or piping that prevents access to the equipment by a monitor probe;

(D) Unable to be reached from a wheeled scissor-lift or hydraulic-type scaffold which would allow access to equipment up to 7.6 meters (25 feet) above the ground; or

(E) Not able to be accessed at any time in a safe manner to perform monitoring. Unsafe access includes, but is not limited to, the use of a wheeled scissor-lift on unstable or uneven terrain, the use of a motorized man-lift basket in areas where an ignition potential exists, or access would require near proximity to hazards such as electrical lines, or would risk damage to equipment.

(ii) At an existing source, any connector, agitator, or valve that meets the criteria of paragraph (f)(4)(i) of this section may be designated as inaccessible. At a new affected source, an owner or operator may designate no more than 3 percent of each type of equipment as inaccessible.

(iii) If any inaccessible equipment or ceramic or ceramic-lined connector is observed by visual, audible, olfactory, or other means to be leaking, the leak shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in paragraph (g) of this section.

(g) *Recordkeeping Requirements.* (1) An owner or operator of more than one group of processes subject to the provisions of this section may comply with the recordkeeping requirements for the groups of processes in one recordkeeping system if the system identifies with each record the program being implemented (e.g., quarterly monitoring) for each type of equipment. All records and information required by this section shall be maintained in a manner that can be readily accessed at the plant site. This could include physically locating the records at the plant site or accessing the records from a central location by computer at the plant site.

(2) *General recordkeeping.* Except as provided in paragraph (e) of this section and in paragraph (a)(9) of this section, the following information pertaining to all equipment subject to the requirements in this section shall be recorded:

(i)(A) A list of identification numbers for equipment (except connectors that are not subject to paragraph (f) of this section and instrumentation systems) subject to the requirements of this section. Connectors, except those subject to paragraph (f) of this section, need not be individually identified if all connectors in a designated area or length of pipe subject to the provisions of this section are identified as a group, and the number of subject connectors is indicated. The list for each type of equipment shall be completed no later than the completion of the initial survey required for that component. The list of identification numbers shall be updated, if needed, to incorporate equipment changes within 15 calendar days of the completion of each monitoring survey for the type of equipment component monitored.

(B) A schedule for monitoring connectors subject to the provisions of § 63.174(a) and valves subject to the provisions of paragraph (e)(4) of this section.

(C) Physical tagging of the equipment to indicate that it is in organic HAP service is not required. Equipment subject to the provisions of this section may be identified on a plant site plan, in log entries, or by other appropriate methods.

(ii)(A) A list of identification numbers for equipment that the owner or operator elects to equip with a closed-vent system and control device, under the provisions of paragraph (c)(7) of this section, § 63.164(h), or § 63.165(c).

(B) A list of identification numbers for compressors that the owner or operator elects to designate as operating with an instrument reading of less than 500 parts per million above background, under the provisions of § 63.164(i).

(iii)(A) A list of identification numbers for pressure relief devices subject to the provisions in § 63.165(a).

(B) A list of identification numbers for pressure relief devices equipped with rupture disks, under the provisions of § 63.165(d).

(iv) Identification of instrumentation systems subject to the provisions of this section. Individual components in an instrumentation system need not be identified.

(v) The owner or operator may develop a written procedure that identifies the conditions that justify a delay of repair. The written procedures may be included as part of the startup/shutdown/malfunction plan, required by § 63.1260(i), for the source or may be part of a separate document that is maintained at the plant site. Reasons for delay of repair may be documented by citing the relevant sections of the written procedure.

(vi) The following information shall be recorded for each dual mechanical seal system:

(A) Design criteria required by paragraph (c)(5)(vi)(A) of this section and § 63.164(e)(2), and an explanation of the design criteria; and

(B) Any changes to these criteria and the reasons for the changes.

(vii) A list of equipment designated as unsafe to monitor, difficult to monitor, or inaccessible under paragraphs (f) or (b)(1)(v)(B) of this section and a copy of the plan for monitoring or inspecting this equipment.

(viii) A list of connectors removed from and added to the process, as described in § 63.174(i)(1), and documentation of the integrity of the weld for any removed connectors, as required in § 63.174(j). This is not required unless the net credits for removed connectors is expected to be used.

(ix) For batch processes that the owner or operator elects to monitor as provided under § 63.178(c), a list of equipment added to batch product processes since the last monitoring period required in §§ 63.178(c)(3)(ii) and (3)(iii). This list must be completed for each type of equipment within 15 calendar days of the completion of each monitoring survey for the type of equipment monitored.

(3) *Records of visual inspections.* For visual inspections of equipment subject to the provisions of paragraphs (c)(2)(iii) and (c)(5)(iv)(A) of this section, the

owner or operator shall document that the inspection was conducted and the date of the inspection. The owner or operator shall maintain records as specified in paragraph (g)(4) of this section for leaking equipment identified in this inspection, except as provided in paragraph (g)(5) of this section. These records shall be retained for 2 years.

(4) *Monitoring records.* When each leak is detected as specified in paragraph (c) of this section and § 63.164; paragraph (e) of this section and § 63.169; and §§ 63.172 and 63.174 of subpart H, the following information shall be recorded and kept for 2 years onsite and 3 years offsite (5 years total):

(i) The instrument and the equipment identification number and the operator name, initials, or identification number.

(ii) The date the leak was detected and the date of the first attempt to repair the leak.

(iii) The date of successful repair of the leak.

(iv) If postrepair monitoring is required, the maximum instrument reading measured by Method 21 of 40 CFR part 60, appendix A after the leak is successfully repaired or determined to be nonrepairable.

(v) ''Repair delayed'' and the reason for the delay if a leak is not repaired within 15 calendar days after discovery of the leak.

(A) The owner or operator may develop a written procedure that identifies the conditions that justify a delay of repair. In such cases, reasons for delay of repair may be documented by citing the relevant sections of the written procedure.

(B) If delay of repair was caused by depletion of stocked parts, there must be documentation that the spare parts were sufficiently stocked onsite before depletion and the reason for depletion.

(vi) If repairs were delayed, dates of process shutdowns that occur while the equipment is unrepaired.

(vii)(A) If the alternative in § 63.174(c)(1)(ii) is not in use for the monitoring period, identification, either by list, location (area or grouping), or tagging of connectors disturbed since the last monitoring period required in § 63.174(b), as described in § 63.174(c)(1).

(B) The date and results of follow-up monitoring as required in § 63.174(c). If identification of disturbed connectors is made by location, then all connectors within the designated location shall be monitored.

(viii) The date and results of the monitoring required in § 63.178(c)(3)(i) for equipment added to a batch process since the last monitoring period required in §§ 63.178(c)(3)(ii) and (c)(3)(iii). If no leaking equipment is found in this monitoring, the owner or operator shall record that the inspection was performed. Records of the actual monitoring results are not required.

(ix) Copies of the periodic reports as specified in paragraph (h)(3) of this section, if records are not maintained on a computerized data base capable of generating summary reports from the records.

(5) *Records of pressure tests.* The owner or operator who elects to pressure test a process equipment train and supply lines between storage and processing areas to demonstrate compliance with this section is exempt from the requirements of paragraphs (g)(2), (g)(3), (g)(4), and (g)(6) of this section. Instead, the owner or operator shall maintain records of the following information:

(i) The identification of each product, or product code, produced during the calendar year. It is not necessary to identify individual items of equipment in the process equipment train.

(ii) Records demonstrating the proportion of the time during the calendar year the equipment is in use in the process that is subject to the provisions of this subpart. Examples of suitable documentation are records of time in use for individual pieces of equipment or average time in use for the process unit. These records are not required if the owner or operator does not adjust monitoring frequency by the time in use, as provided in § 63.178(c)(3)(iii).

(iii) Physical tagging of the equipment to identify that it is in organic HAP service and subject to the provisions of this section is not required. Equipment in a process subject to the provisions of this appendix may be identified on a plant site plan, in log entries, or by other appropriate methods.

(iv) The dates of each pressure test required in § 63.178(b), the test pressure, and the pressure drop observed during the test.

(v) Records of any visible, audible, or olfactory evidence of fluid loss.

(vi) When a process equipment train does not pass two consecutive pressure tests, the following information shall be recorded in a log and kept for 2 years:

(A) The date of each pressure test and the date of each leak repair attempt.

(B) Repair methods applied in each attempt to repair the leak.

(C) The reason for the delay of repair.

(D) The expected date for delivery of the replacement equipment and the actual date of delivery of the replacement equipment.

(E) The date of successful repair.

(6) *Records of compressor compliance tests.* The dates and results of each compliance test required for compressors subject to the provisions in § 63.164(i) and the dates and results of the monitoring following a pressure release for each pressure relief device subject to the provisions in §§ 63.165(a) and (b). The results shall include:

(i) The background level measured during each compliance test.

(ii) The maximum instrument reading measured at each piece of equipment during each compliance test.

(7) *Records for closed-vent systems.* The owner or operator shall maintain records of the information specified in paragraphs (g)(7)(i) through (g)(7)(iii) of this section for closed-vent systems and control devices subject to the provisions of paragraph (b)(1)(vi) of this section. The records specified in paragraph (g)(7)(i) of this section shall be retained for the life of the equipment. The records specified in paragraphs (g)(7)(ii) and (g)(7)(iii) of this section shall be retained for 2 years.

(i) The design specifications and performance demonstrations specified in paragraphs (g)(7)(i)(A) through (g)(7)(i)(D) of this section.

(A) Detailed schematics, design specifications of the control device, and piping and instrumentation diagrams.

(B) The dates and descriptions of any changes in the design specifications.

(C) The flare design (i.e., steam assisted, air assisted, or nonassisted) and the results of the compliance demonstration required by § 63.11(b).

(D) A description of the parameter or parameters monitored, as required in paragraph (b)(1)(vi) of this section, to ensure that control devices are operated and maintained in conformance with their design and an explanation of why that parameter (or parameters) was selected for the monitoring.

(ii) Records of operation of closed-vent systems and control devices.

(A) Dates and durations when the closed-vent systems and control devices required in paragraph (c) of this section and §§ 63.164 through 63.166 are not operated as designed as indicated by the monitored parameters, including periods when a flare pilot light system does not have a flame.

(B) Dates and durations during which the monitoring system or monitoring device is inoperative.

(C) Dates and durations of startups and shutdowns of control devices required in paragraph (c)(7) of this section and §§ 63.164 through 63.166.

(iii) Records of inspections of closed-vent systems subject to the provisions of § 63.172.

(A) For each inspection conducted in accordance with the provisions of § 63.172(f)(1) or (f)(2) during which no leaks were detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected.

(B) For each inspection conducted in accordance with the provisions of § 63.172(f)(1) or (f)(2) during which leaks were detected, the information specified in paragraph (g)(4) of this section shall be recorded.

(8) *Records for components in heavy liquid service.* Information, data, and analysis used to determine that a piece of equipment or process is in heavy liquid service shall be recorded. Such a determination shall include an analysis or demonstration that the process fluids do not meet the criteria of ''in light liquid or gas service.'' Examples of information that could document this include, but are not limited to, records of chemicals purchased for the process, analyses of process stream composition, engineering calculations, or process knowledge.

(9) *Records of exempt components.* Identification, either by list, location (area or group) of equipment in organic HAP service less than 300 hours per year subject to the provisions of this section.

(10) *Records of alternative means of compliance determination.* Owners and operators choosing to comply with the requirements of § 63.179 shall maintain the following records:

(i) Identification of the process(es) and the organic HAP they handle.

(ii) A schematic of the process, enclosure, and closed-vent system.

(iii) A description of the system used to create a negative pressure in the enclosure to ensure that all emissions are routed to the control device.

(h) *Reporting Requirements.*

(1) Each owner or operator of a source subject to this section shall submit the reports listed in paragraphs (h)(1)(i) through (ii) of this section.

(i) A Notification of Compliance Status Report described in paragraph (h)(2) of this section,

(ii) Periodic Reports described in paragraph (h)(3) of this section, and

(2) *Notification of compliance report.* Each owner or operator of a source subject to this section shall submit the information specified in paragraphs (h)(2)(i) through (iii) of this section in the Notification of Compliance Status Report described in § 63.1260(f).

(i) The notification shall provide the information listed in paragraphs (h)(2)(i)(A) through (C) of this section for each process subject to the requirements of paragraphs (b) through (g) of this section.

(A) Process group identification.

(B) Approximate number of each equipment type (e.g., valves, pumps) in organic HAP service, excluding equipment in vacuum service.

(C) Method of compliance with the standard (for example, ''monthly leak detection and repair'' or ''equipped with dual mechanical seals'').

(ii) The notification shall provide the information listed in paragraphs (h)(2)(ii)(A) and (B) of this section for each process subject to the requirements of paragraph (b)(1)(ix) of this section and § 63.178(b).

(A) Products or product codes subject to the provisions of this section, and

(B) Planned schedule for pressure testing when equipment is configured for production of products subject to the provisions of this section.

(iii) The notification shall provide the information listed in paragraphs (h)(2)(iii)(A) and (B) of this section for each process subject to the requirements in § 63.179.

(A) Process identification.

(B) A description of the system used to create a negative pressure in the enclosure and the control device used to comply with the requirements of paragraph (b)(1)(vi) of this section.

(iv) Any change in the information submitted under paragraph (h) of this section shall be provided to the Administrator as a part of subsequent Periodic Reports. Section 63.9(j) shall not apply to the Notification of Compliance Status Report described in this paragraph (h)(2) of this section.

(3) *Periodic reports.* The owner or operator of a source subject to this section shall submit Periodic Reports.

(i) A report containing the information in paragraphs (h)(3)(ii), (h)(3)(iii), and (h)(3)(iv) of this section shall be submitted semiannually starting 6 months after the Notification of Compliance Status Report, as required in paragraph (h)(2) of this section. The first periodic report shall cover the first 6 months after the compliance date specified in § 63.1250(e). Each subsequent periodic report shall cover the 6 month period following the preceding period.

(ii) For equipment complying with the provisions of paragraphs (b) through (g) of this section, the summary information listed in paragraphs (h)(3)(ii)(A) through (L) of this section for each monitoring period during the 6-month period.

(A) The number of valves for which leaks were detected as described in paragraph (e)(3) of this section, the percent leakers, and the total number of valves monitored;

(B) The number of valves for which leaks were not repaired as required in paragraph (e)(7) of this section, identifying the number of those that are determined nonrepairable;

(C) The number of pumps and agitators for which leaks were detected as described in paragraph (c)(2) of this section, the percent leakers, and the total number of pumps and agitators monitored;

(D) The number of pumps and agitators for which leaks were not repaired as required in paragraph (c)(3) of this section;

(E) The number of compressors for which leaks were detected as described in § 63.164(f);

(F) The number of compressors for which leaks were not repaired as required in § 63.164(g);

(G) The number of connectors for which leaks were detected as described in § 63.174(a), the percent of connectors leaking, and the total number of connectors monitored;

(H) The number of connectors for which leaks were not repaired as required in § 63.174(d), identifying the number of those that are determined nonrepairable;

(I) The facts that explain any delay of repairs and, where appropriate, why a process shutdown was technically infeasible.

(J) The results of all monitoring to show compliance with §§ 63.164(i), 63.165(a), and 63.172(f) conducted within the semiannual reporting period.

(K) If applicable, the initiation of a monthly monitoring program under either paragraph (c)(4)(ii) or paragraph (e)(4)(i) of this section.

(L) If applicable, notification of a change in connector monitoring alternatives as described in § 63.174(c)(1).

(iii) For owners or operators electing to meet the requirements of § 63.178(b), the report shall include the information listed in paragraphs (h)(3)(iii)(A) through (E) of this paragraph for each process.

(A) Product process equipment train identification;

(B) The number of pressure tests conducted;

(C) The number of pressure tests where the equipment train failed either the retest or two consecutive pressure tests;

(D) The facts that explain any delay of repairs; and

(E) The results of all monitoring to determine compliance with § 63.172(f) of subpart H.

(iv) Any revisions to items reported in earlier Notification of Compliance

Status Report, if the method of compliance has changed since the last report or any other changes to the information reported has occurred.

§ 63.1256 Standards: Wastewater.

(a) *General.* Each owner or operator of any affected source (existing or new) shall comply with the general wastewater requirements in paragraphs (a)(1) and (2) of this section.

(1) *Identify wastewater that requires control.* For each POD, the owner or operator shall comply with the requirements in either paragraph (a)(1)(i), or (ii) of this section to determine whether a wastewater stream is an affected wastewater stream that requires control for soluble and/or partially soluble HAP compounds or to designate the wastewater stream as an affected wastewater stream, respectively. The owner or operator may use a combination of the approaches in paragraphs (a)(1)(i) and (ii) of this section for different affected wastewater generated at the source. The owner or operator shall also comply with the requirements for multiphase discharges in paragraph (a)(4) of this section. Wastewater identified in paragraph (a)(3) of this section is exempt from the provisions of this subpart.

(i) *Determine characteristics of a wastewater stream.* At new and existing sources, a wastewater stream is an affected wastewater stream if the annual average concentration and annual load exceed any of the criteria specified in paragraph (a)(1)(i)(A) through (C) of this section. At new sources, a wastewater stream is subject to additional control requirements if the annual average concentration and annual load exceed the criteria specified in paragraphs (a)(1)(i)(D) of this section. The owner or operator shall comply with the provisions of § 63.1257(e)(1) to determine the annual average concentrations and annual load of partially soluble and soluble HAP compounds.

(A) The wastewater stream contains partially soluble HAP compounds at an annual average concentration greater than 1,300 ppmw, and the total soluble and partially soluble HAP load in all wastewater from the PMPU exceeds 1 Mg/yr.

(B) The wastewater stream contains partially soluble and/or soluble HAP compounds at an annual average concentration of 5,200 ppmw, and the total soluble and partially soluble HAP load in all wastewater from the PMPU exceeds 1 Mg/yr.

(C) The wastewater stream contains partially soluble and/or soluble HAP at an annual average concentration of greater than 10,000 ppmw, and the total partially soluble and/or soluble HAP load in all wastewater from the affected source is greater than 1 Mg/yr.

(D) The wastewater stream contains soluble HAP compounds at an annual average concentration greater than 110,000 ppmw, and the total soluble and partially soluble HAP load in all wastewater from the PMPU exceeds 1 Mg/yr.

(ii) *Designate wastewater as affected wastewater.* For existing sources, the owner or operator may elect to designate wastewater streams as meeting the criteria of either paragraphs (a)(1)(i)(A),(B), or (C) of this section. For new sources, the owner or operator may elect to designate wastewater streams meeting the criterion in paragraph (a)(1)(i)(D) or for wastewater known to contain no soluble HAP, as meeting the criterion in paragraph (a)(1)(i)(A) of this section. For designated wastewater the procedures specified in paragraphs (a)(1)(ii)(A) and (B) of this section shall be followed, except as specified in paragraphs (g)(8)(i), (g)(9)(i), and (g)(10) of this section. The owner or operator is not required to determine the annual average concentration or load for each designated wastewater stream for the purposes of this section.

(A) From the POD for the wastewater stream that is designated as an affected wastewater stream to the location where the owner or operator elects to designate such wastewater stream as an affected wastewater stream, the owner or operator shall comply with all applicable emission suppression requirements specified in paragraphs (b) through (f) of this section.

(B) From the location where the owner or operator designates a wastewater stream as an affected wastewater stream, such wastewater stream shall be managed in accordance with all applicable emission suppression requirements specified in paragraphs (b) through (f) of this section and with the treatment requirements in paragraph (g) of this section.

(iii) *Scrubber Effluent.* Effluent from a water scrubber that has been used to control Table 2 HAP-containing vent streams that are controlled in order to meet the process vent requirements in § 63.1254 of this subpart is considered an affected wastewater stream.

(2) *Requirements for affected wastewater.* (i) An owner or operator of a facility shall comply with the applicable requirements for wastewater tanks, surface impoundments, containers, individual drain systems, and oil/water separators as specified in paragraphs (b) through (f) of this section, except as provided in paragraph (g)(3) of this section.

(ii) Comply with the applicable requirements for control of soluble and partially soluble compounds as specified in paragraph (g) of this section. Alternatively, the owner or operator may elect to comply with the treatment provisions specified in paragraph (a)(5) of this section.

(iii) Comply with the applicable monitoring and inspection requirements specified in § 63.1258.

(iv) Comply with the applicable recordkeeping and reporting requirements specified in §§ 63.1259 and 63.1260.

(3) *Exempt wastewater.* The following wastewaters are not subject to the wastewater provisions of this part:

(i) Stormwater from segregated sewers;

(ii) Water from fire-fighting and deluge systems, including testing of such systems;

(iii) Spills; and

(iv) Water from safety showers.

(4) *Requirements for multiphase discharges.* The owner or operator shall not discharge a separate phase that can be isolated through gravity separation from the aqueous phase to a waste management or treatment unit, unless the stream is discharged to a treatment unit in compliance with paragraph (g)(13) of this section.

(5) *Offsite treatment or onsite treatment not owned or operated by the source.* The owner or operator may elect to transfer affected wastewater streams that contain less than 50 ppmw of partially soluble HAP or a residual removed from such affected wastewater to an onsite treatment operation not owned or operated by the owner or operator of the source generating the wastewater or residual, or to an offsite treatment operation, provided that the waste management units up to the activated sludge unit are covered or the owner or operator demonstrates that less than 5 percent of the total soluble HAP is emitted from the these units.

(i) The owner or operator transferring the wastewater or residual shall:

(A) Comply with the provisions specified in paragraphs (b) through (f) of this section for each waste management unit that receives or manages affected wastewater or a residual removed from affected wastewater prior to shipment or transport.

(B) Include a notice with each shipment or transport of affected wastewater or residual removed from affected wastewater. The notice shall state that the affected wastewater or residual contains organic HAP that are to be treated in accordance with the

provisions of this subpart. When the transport is continuous or ongoing (for example, discharge to a publicly-owned treatment works), the notice shall be submitted to the treatment operator initially and whenever there is a change in the required treatment. The owner or operator shall keep a record of the notice in accordance with § 63.1259(g).

(ii) The owner or operator may not transfer the affected wastewater or residual unless the transferee has submitted to the EPA a written certification that the transferee will manage and treat any affected wastewater or residual removed from affected wastewater received from a source subject to the requirements of this subpart in accordance with the requirements of either:

(A) Paragraphs (b) through (i) of this section; or

(B) Subpart D of this part if alternative emission limitations have been granted the transferor in accordance with those provisions; or

(C) Section 63.6(g).

(iii) The certifying entity may revoke the written certification by sending a written statement to the EPA and the owner or operator giving at least 90 days notice that the certifying entity is rescinding acceptance of responsibility for compliance with the regulatory provisions listed in this paragraph. Upon expiration of the notice period, the owner or operator may not transfer the wastewater stream or residual to the treatment operation.

(iv) By providing this written certification to the EPA, the certifying entity accepts responsibility for compliance with the regulatory provisions listed in paragraph (a)(5)(ii) of this section with respect to any shipment of wastewater or residual covered by the written certification. Failure to abide by any of those provisions with respect to such shipments may result in enforcement action by the EPA against the certifying entity in accordance with the enforcement provisions applicable to violations of these provisions by owners or operators of sources.

(v) Written certifications and revocation statements, to the EPA from the transferees of wastewater or residuals shall be signed by the responsible official of the certifying entity, provide the name and address of the certifying entity, and be sent to the appropriate EPA Regional Office at the addresses listed in § 63.13. Such written certifications are not transferable by the treater.

(b) *Wastewater tanks.* For each wastewater tank that receives, manages, or treats affected wastewater or a residual removed from affected wastewater, the owner or operator shall comply with the requirements of either paragraph (b)(1) or (2) of this section as specified in Table 6 of this subpart.

(1) The owner or operator shall operate and maintain a fixed roof except when the contents of the wastewater tank are heated, treated by means of an exothermic reaction, or sparged, during which time the owner or operator shall comply with the requirements specified in paragraph (b)(2) of this section. For the purposes of this paragraph, the requirements of paragraph (b)(2) of this section are satisfied by operating and maintaining a fixed roof if the owner or operator demonstrates that the total soluble and partially soluble HAP emissions from the wastewater tank are no more than 5 percent higher than the emissions would be if the contents of the wastewater tank were not heated, treated by an exothermic reaction, or sparged.

(2) The owner or operator shall comply with the requirements in paragraphs (b)(3) through (9) of this section and shall operate and maintain one of the emission control techniques listed in paragraphs (b)(2)(i) through (iii) of this section.

(i) A fixed roof and a closed-vent system that routes the organic HAP vapors vented from the wastewater tank to a control device; or

(ii) A fixed roof and an internal floating roof that meets the requirements specified in § 63.119(b), with the differences noted in § 63.1257(c)(3)(i) through (iii) for the purposes of this subpart; or

(iii) An external floating roof that meets the requirements specified in §§ 63.119(c), 63.120(b)(5), and 63.120(b)(6), with the differences noted in § 63.1257(c)(3)(i) through (v) for the purposes of this subpart.

(3) If the owner or operator elects to comply with the requirements of paragraph (b)(2)(i) of this section, the fixed roof shall meet the requirements of paragraph (b)(3)(i) of this section, the control device shall meet the requirements of paragraph (b)(3)(ii) of this section, and the closed-vent system shall meet the requirements of paragraph (b)(3)(iii) of this section.

(i) The fixed roof shall meet the following requirements:

(A) Except as provided in paragraph (b)(3)(iv) of this section, the fixed roof and all openings (e.g., access hatches, sampling ports, and gauge wells) shall be maintained in accordance with the requirements specified in § 63.1258(h).

(B) Each opening shall be maintained in a closed position (e.g., covered by a lid) at all times that the wastewater tank contains affected wastewater or residual removed from affected wastewater except when it is necessary to use the opening for wastewater sampling, removal, or for equipment inspection, maintenance, or repair.

(ii) The control device shall be designed, operated, and inspected in accordance with the requirements of paragraph (h) of this section.

(iii) Except as provided in paragraph (b)(3)(iv) of this section, the closed-vent system shall be inspected in accordance with the requirements of § 63.1258(h).

(iv) For any fixed roof tank and closed-vent system that is operated and maintained under negative pressure, the owner or operator is not required to comply with the requirements specified in § 63.1258(h).

(4) If the owner or operator elects to comply with the requirements of paragraph (b)(2)(ii) of this section, the floating roof shall be inspected according to the procedures specified in § 63.120(a)(2) and (3), with the differences noted in § 63.1257(c)(3)(iv) for the purposes of this subpart.

(5) Except as provided in paragraph (b)(6) of this section, if the owner or operator elects to comply with the requirements of paragraph (b)(2)(iii) of this section, seal gaps shall be measured according to the procedures specified in § 63.120(b)(2)(i) through (b)(4) and the wastewater tank shall be inspected to determine compliance with § 63.120(b)(5) and (6) according to the schedule specified in § 63.120(b)(1)(i) through (iii).

(6) If the owner or operator determines that it is unsafe to perform the seal gap measurements specified in § 63.120(b)(2)(i) through (b)(4) or to inspect the wastewater tank to determine compliance with § 63.120(b)(5) and (6) because the floating roof appears to be structurally unsound and poses an imminent or potential danger to inspecting personnel, the owner or operator shall comply with the requirements in either paragraph (b)(6)(i) or (ii) of this section.

(ii) The owner or operator shall empty and remove the wastewater tank from service within 45 calendar days of determining that the roof is unsafe. If the wastewater tank cannot be emptied within 45 calendar days, the owner or operator may utilize up to two extensions of up to 30 additional calendar days each. Documentation of a decision to utilize an extension shall include an explanation of why it was unsafe to perform the inspection or seal gap measurement, shall document that alternate storage capacity is unavailable, and shall specify a schedule of actions that will ensure that the wastewater

tank will be emptied as soon as possible.

(7) Except as provided in paragraph (b)(6) of this section, each wastewater tank shall be inspected initially, and semiannually thereafter, for improper work practices in accordance with § 63.1258(g). For wastewater tanks, improper work practice includes, but is not limited to, leaving open any access door or other opening when such door or opening is not in use.

(8) Except as provided in paragraph (b)(6) of this section, each wastewater tank shall be inspected for control equipment failures as defined in paragraph (b)(8)(i) of this section according to the schedule in paragraphs (b)(8)(ii) and (iii) of this section in accordance with § 63.1258(g).

(i) Control equipment failures for wastewater tanks include, but are not limited to, the conditions specified in paragraphs (b)(8)(i)(A) through (I) of this section.

(A) The floating roof is not resting on either the surface of the liquid or on the leg supports.

(B) There is stored liquid on the floating roof.

(C) A rim seal is detached from the floating roof.

(D) There are holes, tears, cracks or gaps in the rim seal or seal fabric of the floating roof.

(E) There are visible gaps between the seal of an internal floating roof and the wall of the wastewater tank.

(F) There are gaps between the metallic shoe seal or the liquid mounted primary seal of an external floating roof and the wall of the wastewater tank that exceed 212 square centimeters per meter of tank diameter or the width of any portion of any gap between the primary seal and the tank wall exceeds 3.81 centimeters.

(G) There are gaps between the secondary seal of an external floating roof and the wall of the wastewater tank that exceed 21.2 square centimeters per meter of tank diameter or the width of any portion of any gap between the secondary seal and the tank wall exceeds 1.27 centimeters.

(H) Where a metallic shoe seal is used on an external floating roof, one end of the metallic shoe does not extend into the stored liquid or one end of the metallic shoe does not extend a minimum vertical distance of 61 centimeters above the surface of the stored liquid.

(I) A gasket, joint, lid, cover, or door has a crack or gap, or is broken.

(ii) The owner or operator shall inspect for the control equipment failures in paragraphs (b)(8)(i)(A) through (H) according to the schedule specified in paragraphs (b)(4) and (5) of this section.

(iii) The owner or operator shall inspect for the control equipment failures in paragraph (b)(8)(i)(I) of this section initially, and semiannually thereafter.

(9) Except as provided in paragraph (i) of this section, when an improper work practice or a control equipment failure is identified, first efforts at repair shall be made no later than 5 calendar days after identification and repair shall be completed within 45 calendar days after identification. If a failure that is detected during inspections required by this section cannot be repaired within 45 calendar days and if the tank cannot be emptied within 45 calendar days, the owner or operator may utilize up to two extensions of up to 30 additional calendar days each. Documentation of a decision to utilize an extension shall include a description of the failure, shall document that alternate storage capacity is unavailable, and shall specify a schedule of actions that will ensure that the control equipment will be repaired or the tank will be emptied as soon as practical.

(c) *Surface impoundments.* For each surface impoundment that receives, manages, or treats affected wastewater or a residual removed from affected wastewater, the owner or operator shall comply with the requirements of paragraphs (c)(1), (2), and (3) of this section.

(1) The owner or operator shall operate and maintain on each surface impoundment either a cover (e.g., air-supported structure or rigid cover) and a closed-vent system that routes the organic hazardous air pollutants vapors vented from the surface impoundment to a control device in accordance with paragraphs (c)(1)(i), (iii), (iv), and (v) of this section, or a floating flexible membrane cover as specified in paragraph (c)(1)(ii) of this section.

(i) The cover and all openings shall meet the following requirements:

(A) Except as provided in paragraph (c)(1)(iv) of this section, the cover and all openings (e.g., access hatches, sampling ports, and gauge wells) shall be maintained in accordance with the requirements specified in § 63.1258(h).

(B) Each opening shall be maintained in a closed position (e.g., covered by a lid) at all times that affected wastewater or residual removed from affected wastewater is in the surface impoundment except when it is necessary to use the opening for sampling, removal, or for equipment inspection, maintenance, or repair.

(C) The cover shall be used at all times that affected wastewater or residual removed from affected wastewater is in the surface impoundment except during removal of treatment residuals in accordance with 40 CFR 268.4 or closure of the surface impoundment in accordance with 40 CFR 264.228.

(ii) Floating flexible membrane covers shall meet the requirements specified in paragraphs (c)(1)(ii)(A) through (F) of this section.

(A) The floating flexible cover shall be designed to float on the liquid surface during normal operations, and to form a continuous barrier over the entire surface area of the liquid.

(B) The cover shall be fabricated from a synthetic membrane material that is either:

(*1*) High density polyethylene (HDPE) with a thickness no less than 2.5 millimeters (100 mils); or

(*2*) A material or a composite of different materials determined to have both organic permeability properties that are equivalent to those of the material listed in paragraph (c)(1)(ii)(B)(*1*) of this section, and chemical and physical properties that maintain the material integrity for the intended service life of the material.

(C) The cover shall be installed in a manner such that there are no visible cracks, holes, gaps, or other open spaces between cover section seams or between the interface of the cover edge and its foundation mountings.

(D) Except as provided for in paragraph (c)(1)(ii)(E) of this section, each opening in the floating membrane cover shall be equipped with a closure device designed to operate such that when the closure device is secured in the closed position there are no visible cracks, holes, gaps, or other open spaces in the closure device or between the perimeter of the cover opening and the closure device.

(E) The floating membrane cover may be equipped with one or more emergency cover drains for removal of stormwater. Each emergency cover drain shall be equipped with a slotted membrane fabric cover that covers at least 90 percent of the area of the opening or a flexible fabric sleeve seal.

(F) The closure devices shall be made of suitable materials that will minimize exposure of organic HAP to the atmosphere, to the extent practical, and will maintain the integrity of the equipment throughout its intended service life. Factors to be considered in designing the closure devices shall include: the effects of any contact with the liquid and its vapor managed in the surface impoundment; the effects of outdoor exposure to wind, moisture, and sunlight; and the operating

practices used for the surface impoundment on which the floating membrane cover is installed.

(G) Whenever affected wastewater or residual from affected wastewater is in the surface impoundment, the floating membrane cover shall float on the liquid and each closure device shall be secured in the closed position. Opening of closure devices or removal of the cover is allowed to provide access to the surface impoundment for performing routine inspection, maintenance, or other activities needed for normal operations and/or to remove accumulated sludge or other residues from the bottom of surface impoundment. Openings shall be maintained in accordance with § 63.1258(h).

(iii) The control device shall be designed, operated, and inspected in accordance with paragraph (h) of this section.

(iv) Except as provided in paragraph (c)(1)(v) of this section, the closed-vent system shall be inspected in accordance with § 63.1258(h).

(v) For any cover and closed-vent system that is operated and maintained under negative pressure, the owner or operator is not required to comply with the requirements specified in § 63.1258(h).

(2) Each surface impoundment shall be inspected initially, and semiannually thereafter, for improper work practices and control equipment failures in accordance with § 63.1258(g).

(i) For surface impoundments, improper work practice includes, but is not limited to, leaving open any access hatch or other opening when such hatch or opening is not in use.

(ii) For surface impoundments, control equipment failure includes, but is not limited to, any time a joint, lid, cover, or door has a crack or gap, or is broken.

(3) Except as provided in paragraph (i) of this section, when an improper work practice or a control equipment failure is identified, first efforts at repair shall be made no later than 5 calendar days after identification and repair shall be completed within 45 calendar days after identification.

(d) *Containers.* For each container that receives, manages, or treats affected wastewater or a residual removed from affected wastewater, the owner or operator shall comply with the requirements of paragraphs (d)(1) through (5) of this section.

(1) The owner or operator shall operate and maintain a cover on each container used to handle, transfer, or store affected wastewater or a residual removed from affected wastewater in accordance with the following requirements:

(i) Except as provided in paragraph (d)(3)(iv) of this section, if the capacity of the container is greater than 0.42 m^3, the cover and all openings (e.g., bungs, hatches, sampling ports, and pressure relief devices) shall be maintained in accordance with the requirements specified in § 63.1258(h).

(ii) If the capacity of the container is less than or equal to 0.42 m^3, the owner or operator shall comply with either paragraph (d)(1)(ii)(A) or (B) of this section.

(A) The container must meet existing Department of Transportation specifications and testing requirements under 49 CFR part 178; or

(B) Except as provided in paragraph (d)(3)(iv) of this section, the cover and all openings shall be maintained without leaks as specified in § 63.1258(h).

(iii) The cover and all openings shall be maintained in a closed position (e.g., covered by a lid) at all times that affected wastewater or a residual removed from affected wastewater is in the container except when it is necessary to use the opening for filling, removal, inspection, sampling, or pressure relief events related to safety considerations.

(2) For containers with a capacity greater than or equal to 0.42 m^3, either a submerged fill pipe shall be used when a container is being filled by pumping with affected wastewater or a residual removed from affected wastewater or the container shall be located within an enclosure with a closed-vent system that routes the organic HAP vapors vented from the container to a control device.

(i) The submerged fill pipe outlet shall extend to no more than 6 inches or within two fill pipe diameters of the bottom of the container while the container is being filled.

(ii) The cover shall remain in place and all openings shall be maintained in a closed position except for those openings required for the submerged fill pipe and for venting of the container to prevent physical damage or permanent deformation of the container or cover.

(3) During treatment of affected wastewater or a residual removed from affected wastewater, including aeration, thermal or other treatment, in a container, whenever it is necessary for the container to be open, the container shall be located within an enclosure with a closed-vent system that routes the organic HAP vapors vented from the container to a control device.

(i) Except as provided in paragraph (d)(3)(iv) of this section, the enclosure and all openings (e.g., doors, hatches) shall be maintained in accordance with the requirements specified in § 63.1258(h).

(ii) The control device shall be designed, operated, and inspected in accordance with paragraph (h) of this section.

(iii) Except as provided in paragraph (d)(3)(iv) of this section, the closed-vent system shall be inspected in accordance with § 63.1258(h).

(iv) For any enclosure and closed-vent system that is operated and maintained under negative pressure, the owner or operator is not required to comply with the requirements specified in § 63.1258(h).

(4) Each container shall be inspected initially, and semiannually thereafter, for improper work practices and control equipment failures in accordance with § 63.1258(g).

(i) For containers, improper work practice includes, but is not limited to, leaving open any access hatch or other opening when such hatch or opening is not in use.

(ii) For containers, control equipment failure includes, but is not limited to, any time a cover or door has a gap or crack, or is broken.

(5) Except as provided in paragraph (i) of this section, when an improper work practice or a control equipment failure is identified, first efforts at repair shall be made no later than 5 calendar days after identification and repair shall be completed within 15 calendar days after identification.

(e) *Individual drain systems.* For each individual drain system that receives or manages affected wastewater or a residual removed from affected wastewater, the owner or operator shall comply with the requirements of paragraphs (e) (1), (2), and (3) or with paragraphs (e) (4), (5), and (6) of this section.

(1) If the owner or operator elects to comply with this paragraph, the owner or operator shall operate and maintain on each opening in the individual drain system a cover and if vented, route the vapors to a process or through a closed-vent system to a control device. The owner or operator shall comply with the requirements of paragraphs (e)(1) (i) through (v) of this section.

(i) The cover and all openings shall meet the following requirements:

(A) Except as provided in paragraph (e)(1)(iv) of this section, the cover and all openings (e.g., access hatches, sampling ports) shall be maintained in accordance with the requirements specified in § 63.1258(h).

(B) The cover and all openings shall be maintained in a closed position at all

times that affected wastewater or a residual removed from affected wastewater is in the drain system except when it is necessary to use the opening for sampling or removal, or for equipment inspection, maintenance, or repair.

(ii) The control device shall be designed, operated, and inspected in accordance with paragraph (h) of this section.

(iii) Except as provided in paragraph (e)(1)(iv) of this section, the closed-vent system shall be inspected in accordance with § 63.1258(h).

(iv) For any cover and closed-vent system that is operated and maintained under negative pressure, the owner or operator is not required to comply with the requirements specified in § 63.1258(h).

(v) The individual drain system shall be designed and operated to segregate the vapors within the system from other drain systems and the atmosphere.

(2) Each individual drain system shall be inspected initially, and semiannually thereafter, for improper work practices and control equipment failures, in accordance with § 63.1258(g).

(i) For individual drain systems, improper work practice includes, but is not limited to, leaving open any access hatch or other opening when such hatch or opening is not in use for sampling or removal, or for equipment inspection, maintenance, or repair.

(ii) For individual drain systems, control equipment failure includes, but is not limited to, any time a joint, lid, cover, or door has a gap or crack, or is broken.

(3) Except as provided in paragraph (i) of this section, when an improper work practice or a control equipment failure is identified, first efforts at repair shall be made no later than 5 calendar days after identification and repair shall be completed within 15 calendar days after identification.

(4) If the owner or operator elects to comply with this paragraph, the owner or operator shall comply with the requirements in paragraphs (e)(4) (i) through (iii) of this section:

(i) Each drain shall be equipped with water seal controls or a tightly fitting cap or plug. The owner or operator shall comply with paragraphs (e)(4)(i)(A) and (B) of this section.

(A) For each drain equipped with a water seal, the owner or operator shall ensure that the water seal is maintained. For example, a flow-monitoring device indicating positive flow from a main to a branch water line supplying a trap or water being continuously dripped into the trap by a hose could be used to verify flow of water to the trap. Visual observation is also an acceptable alternative.

(B) If a water seal is used on a drain receiving affected wastewater, the owner or operator shall either extend the pipe discharging the wastewater below the liquid surface in the water seal of the receiving drain, or install a flexible shield (or other enclosure which restricts wind motion across the open area between the pipe and the drain) that encloses the space between the pipe discharging the wastewater to the drain receiving the wastewater. (Water seals which are used on hubs receiving wastewater that is not subject to the provisions of this subpart for the purpose of eliminating cross ventilation to drains carrying affected wastewater are not required to have a flexible cap or extended subsurface discharging pipe.)

(ii) Each junction box shall be equipped with a tightly fitting solid cover (i.e., no visible gaps, cracks, or holes) which shall be kept in place at all times except during inspection and maintenance. If the junction box is vented, the owner or operator shall comply with the requirements in paragraph (e)(4)(ii) (A) or (B) of this section.

(A) The junction box shall be vented to a process or through a closed-vent system to a control device. The closed-vent system shall be inspected in accordance with the requirements of § 63.1258(h) and the control device shall be designed, operated, and inspected in accordance with the requirements of paragraph (h) of this section.

(B) If the junction box is filled and emptied by gravity flow (i.e., there is no pump) or is operated with no more than slight fluctuations in the liquid level, the owner or operator may vent the junction box to the atmosphere provided that the junction box complies with the requirements in paragraphs (e)(4)(ii)(B) (*1*) and (*2*) of this section.

(*1*) The vent pipe shall be at least 90 centimeters in length and no greater than 10.2 centimeters in nominal inside diameter.

(*2*) Water seals shall be installed and maintained at the wastewater entrance(s) to or exit from the junction box restricting ventilation in the individual drain system and between components in the individual drain system. The owner or operator shall demonstrate (e.g., by visual inspection or smoke test) upon request by the Administrator that the junction box water seal is properly designed and restricts ventilation.

(iii) Each sewer line shall not be open to the atmosphere and shall be covered or enclosed in a manner so as to have no visible gaps or cracks in joints, seals, or other emission interfaces. (Note: This provision applies to sewers located inside and outside of buildings.)

(5) Equipment used to comply with paragraphs (e)(4) (i), (ii), or (iii) of this section shall be inspected as follows:

(i) Each drain using a tightly fitting cap or plug shall be visually inspected initially, and semiannually thereafter, to ensure caps or plugs are in place and that there are no gaps, cracks, or other holes in the cap or plug.

(ii) Each junction box shall be visually inspected initially, and semiannually thereafter, to ensure that there are no gaps, cracks, or other holes in the cover.

(iii) The unburied portion of each sewer line shall be visually inspected initially, and semiannually thereafter, for indication of cracks or gaps that could result in air emissions.

(6) Except as provided in paragraph (i) of this section, when a gap, hole, or crack is identified in a joint or cover, first efforts at repair shall be made no later than 5 calendar days after identification, and repair shall be completed within 15 calendar days after identification.

(f) *Oil-water separators.* For each oil-water separator that receives, manages, or treats affected wastewater or a residual removed from affected wastewater, the owner or operator shall comply with the requirements of paragraphs (f)(1) through (6) of this section.

(1) The owner or operator shall maintain one of the following:

(i) A fixed roof and a closed-vent system that routes the organic HAP vapors vented from the oil-water separator to a control device. The fixed roof, closed-vent system, and control device shall meet the requirements specified in paragraph (f)(2) of this section;

(ii) A floating roof that meets the requirements in 40 CFR 60.693–2(a)(1)(i), (a)(1)(ii), (a)(2), (a)(3), and (a)(4). For portions of the oil-water separator where it is infeasible to construct and operate a floating roof, such as over the weir mechanism, the owner or operator shall operate and maintain a fixed roof, closed-vent system, and control device that meet the requirements specified in paragraph (f)(2) of this section.

(2) A fixed roof shall meet the requirements of paragraph (f)(2)(i) of this section, a control device shall meet the requirements of paragraph (f)(2)(ii) of this section, and a closed-vent system shall meet the requirements of (f)(2)(iii) of this section.

(i) The fixed roof shall meet the following requirements:

(A) Except as provided in (f)(2)(iv) of this section, the fixed roof and all openings (e.g., access hatches, sampling ports, and gauge wells) shall be maintained in accordance with the requirements specified in § 63.1258(h).

(B) Each opening shall be maintained in a closed, sealed position (e.g., covered by a lid that is gasketed and latched) at all times that the oil-water separator contains affected wastewater or a residual removed from affected wastewater except when it is necessary to use the opening for sampling or removal, or for equipment inspection, maintenance, or repair.

(ii) The control device shall be designed, operated, and inspected in accordance with the requirements of paragraph (h) of this section.

(iii) Except as provided in paragraph (f)(2)(iv) of this section, the closed-vent system shall be inspected in accordance with the requirements of § 63.1258(h).

(iv) For any fixed-roof and closed-vent system that is operated and maintained under negative pressure, the owner or operator is not required to comply with the requirements of § 63.1258(h).

(3) If the owner or operator elects to comply with the requirements of paragraph (f)(1)(ii) of this section, seal gaps shall be measured according to the procedures specified in 40 CFR part 60, subpart QQQ § 60.696(d)(1) and the schedule specified in paragraphs (f)(3)(i) and (ii) of this section.

(i) Measurement of primary seal gaps shall be performed within 60 calendar days after installation of the floating roof and introduction of affected wastewater or a residual removed from affected wastewater and once every 5 years thereafter.

(ii) Measurement of secondary seal gaps shall be performed within 60 calendar days after installation of the floating roof and introduction of affected wastewater or a residual removed from affected wastewater and once every year thereafter.

(4) Each oil-water separator shall be inspected initially, and semiannually thereafter, for improper work practices in accordance with § 63.1258(g). For oil-water separators, improper work practice includes, but is not limited to, leaving open or ungasketed any access door or other opening when such door or opening is not in use.

(5) Each oil-water separator shall be inspected for control equipment failures as defined in paragraph (f)(5)(i) of this section according to the schedule specified in paragraphs (f)(5)(ii) and (iii) of this section.

(i) For oil-water separators, control equipment failure includes, but is not limited to, the conditions specified in paragraphs (f)(5)(i)(A) through (G) of this section.

(A) The floating roof is not resting on either the surface of the liquid or on the leg supports.

(B) There is stored liquid on the floating roof.

(C) A rim seal is detached from the floating roof.

(D) There are holes, tears, or other open spaces in the rim seal or seal fabric of the floating roof.

(E) There are gaps between the primary seal and the separator wall that exceed 67 square centimeters per meter of separator wall perimeter or the width of any portion of any gap between the primary seal and the separator wall exceeds 3.8 centimeters.

(F) There are gaps between the secondary seal and the separator wall that exceed 6.7 square centimeters per meter of separator wall perimeter or the width of any portion of any gap between the secondary seal and the separator wall exceeds 1.3 centimeters.

(G) A gasket, joint, lid, cover, or door has a gap or crack, or is broken.

(ii) The owner or operator shall inspect for the control equipment failures in paragraphs (f)(5)(i)(A) through (F) according to the schedule specified in paragraph (f)(3) of this section.

(iii) The owner or operator shall inspect for control equipment failures in paragraph (f)(5)(i)(G) of this section initially, and semiannually thereafter.

(6) Except as provided in paragraph (i) of this section, when an improper work practice or a control equipment failure is identified, first efforts at repair shall be made no later than 5 calendar days after identification and repair shall be completed within 45 calendar days after identification.

(g) *Performance standards for treatment processes managing wastewater and/or residuals removed from wastewater.* This section specifies the performance standards for treating affected wastewater. The owner or operator shall comply with the requirements as specified in paragraphs (g)(1) through (6) of this section. Where multiple compliance options are provided, the options may be used in combination for different wastewater and/or for different compounds (e.g., soluble versus partially soluble compounds) in the same wastewater, except where otherwise provided in this section. Once affected wastewater or a residual removed from affected wastewater has been treated in accordance with this subpart, it is no longer subject to the requirements of this subpart.

(1) *Existing source.* For a wastewater stream at an existing source that exceeds or is designated to exceed the concentration and load criteria in paragraph (a)(1)(i)(A) of this section, the owner or operator shall comply with a control option in paragraph (g)(8) of this section. For a wastewater stream at an existing source that exceeds the concentration and load criteria in either paragraph (a)(1)(i)(B) or (C) of this section, the owner or operator shall comply with a control option in paragraph (g)(8) of this section and a control option in paragraph (g)(9) of this section. As an alternative to the control options in paragraphs (g)(8) and (g)(9) of this section, the owner or operator may comply with a control option in either paragraph (g)(10), (11) or (13) of this section, as applicable.

(2) *New source.* For a wastewater stream at a new source that exceeds or is designated to exceed the concentration and load criteria in paragraph (a)(1)(i)(A) of this section, the owner or operator shall comply with a control option in paragraph (g)(8) of this section. For wastewater at a new source that exceeds the concentration and load criteria in either paragraph (a)(1)(i)(B) or (C) of this section, but does not exceed the criteria in paragraph (a)(1)(i)(D) of this section, the owner or operator shall comply with a control option in paragraph (g)(8) of this section and a control option in paragraph (g)(9) of this section. As an alternative to the control options in paragraphs (g)(8) and/or (9) of this section, the owner or operator may comply with a control option in either paragraph (g)(10), (11), or (13) of this section, as applicable. For a wastewater stream at a new source that exceeds or is designated to exceed the concentration and load criteria in paragraph (a)(1)(i)(D) of this section, the owner or operator shall comply with a control option in paragraph (g)(12) or (13) of this section.

(3) *Biological treatment processes.* Biological treatment processes in compliance with this section may be either open or closed biological treatment processes as defined in § 63.1251. An open biological treatment process in compliance with this section need not be covered and vented to a control device. An open or a closed biological treatment process in compliance with this section and using § 63.1257(e)(2)(iii)(E) or (F) to demonstrate compliance is not subject to the requirements of paragraphs (b) and (c) of this section. A closed biological treatment process in compliance with this section and using § 63.1257(e)(2)(iii)(G) to demonstrate compliance shall comply with the

requirements of paragraphs (b) and (c) of this section. Waste management units upstream of an open or closed biological treatment process shall meet the requirements of paragraphs (b) through (f) of this section, as applicable.

(4) *Performance tests and design evaluations.* If the Resource Conservation and Recovery Act (RCRA) option [paragraph (g)(13) of this section] or the enhanced biological treatment process for soluble HAP compounds option [paragraph (g)(10) of this section] is selected to comply with this section, neither a design evaluation nor a performance test is required. For any other nonbiological treatment process, and for closed biological treatment processes as defined in § 63.1251, the owner or operator shall conduct either a design evaluation as specified in § 63.1257(e)(2)(ii) or performance test as specified in § 63.1257(e)(2)(iii). For each open biological treatment process as defined in § 63.1251, the owner or operator shall conduct a performance test as specified in § 63.1257(e)(2)(iii)(E) or (F).

(5) *Control device requirements.* When gases are vented from the treatment process, the owner or operator shall comply with the applicable control device requirements specified in paragraph (h) of this section and § 63.1257(e)(3), and the applicable leak inspection provisions specified in § 63.1258(h). This requirement is in addition to the requirements for treatment systems specified in paragraphs (g)(8) through (14) of this section. This requirement does not apply to any open biological treatment process that meets the mass removal requirements.

(6) *Residuals: general.* When residuals result from treating affected wastewater, the owner or operator shall comply with the requirements for residuals specified in paragraph (g)(14) of this section.

(*7) Treatment using a series of treatment processes.* In all cases where the wastewater provisions in this subpart allow or require the use of a treatment process or control device to comply with emissions limitations, the owner or operator may use multiple treatment processes or control devices, respectively. For combinations of treatment processes where the wastewater stream is conveyed by hard-piping, the owner or operator shall comply with either the requirements of paragraph (g)(7)(i) or (ii) of this section. For combinations of treatment processes where the wastewater stream is not conveyed by hard-piping, the owner or operator shall comply with the requirements of paragraph (g)(7)(ii) of this section. For combinations of control devices, the owner or operator shall comply with the requirements of paragraph (g)(7)(i) of this section.

(i) *Compliance across the combination of all treatment units or control devices in series.* (A) For combinations of treatment processes, the wastewater stream shall be conveyed by hard-piping between the treatment processes. For combinations of control devices, the vented gas stream shall be conveyed by hard-piping between the control devices.

(B) For combinations of treatment processes, each treatment process shall meet the applicable requirements of paragraphs (b) through (f) of this section, except as provided in paragraph (g)(3) of this section.

(C) The owner or operator shall identify, and keep a record of, the combination of treatment processes or of control devices, including identification of the first and last treatment process or control device. The owner or operator shall include this information as part of the treatment process description reported in the Notification of Compliance Status.

(D) The performance test or design evaluation shall determine compliance across the combination of treatment processes or control devices. If a performance test is conducted, the ''inlet'' shall be the point at which the wastewater stream or residual enters the first treatment process, or the vented gas stream enters the first control device. The ''outlet'' shall be the point at which the treated wastewater stream exits the last treatment process, or the vented gas stream exits the last control device.

(ii) *Compliance across individual units.* (A) For combinations of treatment processes, each treatment process shall meet the applicable requirements of paragraphs (b) through (f) of this section except as provided in paragraph (g)(3) of this section.

(B) The owner or operator shall identify, and keep a record of, the combination of treatment processes, including identification of the first and last treatment process. The owner or operator shall include this information as part of the treatment process description reported in the Notification of Compliance Status report.

(C) The owner or operator shall determine the mass removed or destroyed by each treatment process. The performance test or design evaluation shall determine compliance for the combination of treatment processes by adding together the mass removed or destroyed by each treatment process and determine the overall control efficiency of the treatment system.

(8) *Control options: Wastewater containing partially soluble HAP compounds.* The owner or operator shall comply with either paragraph (g)(8)(i) or (ii) of this section for the control of partially soluble HAP compounds at new or existing sources.

(i) *50 ppmw concentration option.* The owner or operator shall comply with paragraphs (g)(8)(i)(A) and (B) of this section.

(A) Reduce, by removal or destruction, the concentration of total partially soluble HAP compounds to a level less than 50 ppmw as determined by the procedures specified in § 63.1257(e)(2)(iii)(B).

(B) This option shall not be used when the treatment process is a biological treatment process. This option shall not be used when the wastewater is designated as an affected wastewater as specified in paragraph (a)(1)(ii) of this section. Dilution shall not be used to achieve compliance with this option.

(ii) *Percent mass removal/destruction option.* The owner or operator shall reduce, by removal or destruction, the mass of total partially soluble HAP compounds by 99 percent or more. The removal destruction efficiency shall be determined by the procedures specified in § 63.1257(e)(2)(iii)(C), for noncombustion, nonbiological treatment processes; § 63.1257(e)(2)(iii)(D), for combustion processes; and § 63.1257(e)(2)(iii)(F) or (G) for biological treatment processes.

(9) *Control options: Wastewater containing soluble HAP compounds.* The owner or operator shall comply with either paragraph (g)(9)(i) or (ii) of this section for the control of soluble HAP compounds at new or existing sources.

(i) *520 ppmw concentration option.* The owner or operator shall comply with paragraphs (g)(9)(i)(A) and (B) of this section.

(A) Reduce, by removal or destruction, the concentration of total soluble HAP compounds to a level less than 520 ppmw as determined in the procedures specified in § 63.1257(e)(2)(iii)(B).

(B) This option shall not be used when the treatment process is a biological treatment process. This option shall not be used when the wastewater is designated as an affected wastewater as specified in paragraph (a)(1)(ii) of this section. Dilution shall not be used to achieve compliance with this option.

(ii) *Percent mass removal/destruction option.* The owner or operator shall reduce, by removal or destruction, the mass of total soluble HAP by 90 percent

or more. The removal/destruction efficiency shall be determined by the procedures in § 63.1257(e)(2)(iii)(C), for noncombustion, nonbiological treatment processes; § 63.1257(e)(2)(iii)(D), for combustion processes; and § 63.1257(e)(2)(iii)(F) or (G) for biological treatment processes.

(10) *Control option: Enhanced biotreatment for wastewater containing soluble HAP.* The owner or operator may elect to treat affected wastewater streams containing soluble HAP and less than 50 ppmw partially soluble HAP in an enhanced biological treatment system, as defined in § 63.1251. This option shall not be used when the wastewater is designated as an affected wastewater as specified in paragraph (a)(1)(ii) of this section. These treatment processes are exempt from the design evaluation or performance tests requirements specified in paragraph (g)(4) of this section.

(11) *95-percent mass reduction option, for biological treatment processes.* The owner or operator of a new or existing source using biological treatment for any affected wastewater shall reduce the mass of total soluble and partially soluble HAP sent to that biological treatment unit by at least 95 percent. All wastewater as defined in § 63.1251 entering such a biological treatment unit from PMPU's subject to this subpart shall be included in the demonstration of the 95-percent mass removal. The owner or operator shall comply with paragraphs (g)(11)(i) through (iv) of this section.

(i) Except as provided in paragraph (g)(11)(iv) of this section, the owner or operator shall ensure that all wastewater from PMPU's subject to this subpart entering a biological treatment unit are treated to destroy at least 95-percent total mass of all soluble and partially soluble HAP compounds.

(ii) For open biological treatment processes, compliance shall be determined using the procedures specified in § 63.1257(e)(2)(iii)(E). For closed aerobic biological treatment processes compliance shall be determined using the procedures specified in § 63.1257(e)(2)(iii)(E) or (G). For closed anaerobic biological treatment processes compliance shall be determined using the procedures specified in § 63.1257(e)(2)(iii)(G).

(iii) For each treatment process or waste management unit that receives, manages, or treats wastewater subject to this paragraph, from the POD to the biological treatment unit, the owner or operator shall comply with paragraphs (b) through (f) of this section for control of air emissions. When complying with this paragraph, the term affected wastewater in paragraphs (b) through (f) of this section shall mean all wastewater from PMPU's, not just affected wastewater.

(iv) If wastewater is in compliance with the requirements in paragraph (g)(8), (9), or (12) of this section before entering the biological treatment unit, the hazardous air pollutants mass of that wastewater is not required to be included in the total mass flow rate entering the biological treatment unit for the purpose of demonstrating compliance.

(12) *Percent mass removal/destruction option for soluble HAP compounds at new sources.* The owner or operator of a new source shall reduce, by removal or destruction, the mass flow rate of total soluble HAP from affected wastewater by 99 percent or more. The removal/destruction efficiency shall be determined by the procedures in § 63.1257(e)(2)(iii)(C), for noncombustion, nonbiological treatment processes; § 63.1257(e)(2)(iii)(D), for combustion processes; and § 63.1257(e)(2)(iii)(F) or (G) for biological treatment processes.

(13) *Treatment in a RCRA unit option.* The owner or operator shall treat the affected wastewater or residual in a unit identified in, and complying with, paragraph (g)(13)(i), (ii), or (iii) of this section. These units are exempt from the design evaluation or performance tests requirements specified in paragraph (g)(4) of this section and § 63.1257(e)(2), and from the monitoring requirements specified in paragraph (a)(2)(iii) of this section, as well as recordkeeping and reporting requirements associated with monitoring and performance tests.

(i) The wastewater or residual is discharged to a hazardous waste incinerator for which the owner or operator has been issued a final permit under 40 CFR part 270 and complies with the requirements of 40 CFR part 264, subpart O, or has certified compliance with the interim status requirements of 40 CFR part 265, subpart O;

(ii) The wastewater or residual is discharged to a process heater or boiler burning hazardous waste for which the owner or operator:

(A) Has been issued a final permit under 40 CFR part 270 and complies with the requirements of 40 CFR part 266, subpart H; or

(B) Has certified compliance with the interim status requirements of 40 CFR part 266, subpart H.

(iii) The wastewater or residual is discharged to an underground injection well for which the owner or operator has been issued a final permit under 40 CFR part 270 or 40 CFR part 144 and complies with the requirements of 40 CFR part 122. The owner or operator shall comply with all applicable requirements of this subpart prior to the point where the wastewater enters the underground portion of the injection well.

(14) *Residuals.* For each residual removed from affected wastewater, the owner or operator shall control for air emissions by complying with paragraphs (b) through (f) of this section and by complying with one of the provisions in paragraphs (g)(14)(i) through (iv) of this section.

(i) Recycle the residual to a production process or sell the residual for the purpose of recycling. Once a residual is returned to a production process, the residual is no longer subject to this section.

(ii) Return the residual to the treatment process.

(iii) Treat the residual to destroy the total combined mass flow rate of soluble and/or partially soluble HAP compounds by 99 percent or more, as determined by the procedures specified in § 63.1257(e)(2)(iii)(C) or (D).

(iv) Comply with the requirements for RCRA treatment options specified in paragraph (g)(13) of this section.

(h) *Control devices.* For each control device or combination of control devices used to comply with the provisions in paragraphs (b) through (f) and (g)(5) of this section, the owner or operator shall operate and maintain the control device or combination of control devices in accordance with the requirements of paragraphs (h) (1) through (4) of this section.

(1) Whenever organic HAP emissions are vented to a control device which is used to comply with the provisions of this subpart, such control device shall be operating.

(2) The control device shall be designed and operated in accordance with paragraph (h)(2) (i), (ii), (iii), (iv), or (v) of this section, as demonstrated by the provisions in § 63.1257(e)(3).

(i) An enclosed combustion device (including but not limited to a vapor incinerator, boiler, or process heater) shall meet the conditions in paragraph (h)(2)(i) (A), (B), or (C) of this section, alone or in combination with other control devices. If a boiler or process heater is used as the control device, then the vent stream shall be introduced into the flame zone of the boiler or process heater.

(A) Reduce the organic HAP emissions vented to the control device by 95 percent by weight or greater;

(B) Achieve an outlet TOC concentration of 20 ppmv on a dry basis corrected to 3 percent oxygen. The

owner or operator shall use either Method 18 of 40 CFR part 60, appendix A, or any other method or data that has been validated according to the applicable procedures in Method 301 of appendix A of this part; or

(C) Provide a minimum residence time of 0.5 seconds at a minimum temperature of 760°C.

(ii) A vapor recovery system (including but not limited to a carbon adsorption system or condenser), alone or in combination with other control devices, shall reduce the organic HAP emissions vented to the control device by 95 percent by weight or greater or achieve an outlet TOC concentration of 20 ppmv. The 20 ppmv performance standard is not applicable to compliance with the provisions of paragraphs (c) or (d) of this section.

(iii) A flare shall comply with the requirements of § 63.11(b).

(iv) A scrubber, alone or in combination with other control devices, shall reduce the organic HAP emissions in such a manner that 95 weight-percent is either removed, or destroyed by chemical reaction with the scrubbing liquid, or achieve an outlet TOC concentration of 20 ppmv. The 20 ppmv performance standard is not applicable to compliance with the provisions of paragraphs (c) or (d) of this section.

(v) Any other control device used shall, alone or in combination with other control devices, reduce the organic HAP emissions vented to the control device by 95 percent by weight or greater or achieve an outlet TOC concentration of 20 ppmv. The 20 ppmv performance standard is not applicable to compliance with the provisions of paragraphs (c) or (d) of this section.

(3) If the control device is a combustion device, the owner or operator shall comply with the requirements in § 63.1252(g) to control halogenated vent streams.

(4) Except as provided in paragraph (i) of this section, if gaps, cracks, tears, or holes are observed in ductwork, piping, or connections to covers and control devices during an inspection, a first effort to repair shall be made as soon as practical but no later than 5 calendar days after identification. Repair shall be completed no later than 15 calendar days after identification or discovery of the defect.

(i) *Delay of repair.* Delay of repair of equipment for which a control equipment failure or a gap, crack, tear, or hole has been identified, is allowed if the repair is technically infeasible without a shutdown, as defined in § 63.1251, or if the owner or operator determines that emissions of purged material from immediate repair would be greater than the emissions likely to result from delay of repair. Repair of this equipment shall occur by the end of the next shutdown.

(1) Delay of repair of equipment for which a control equipment failure or a gap, crack, tear, or hole has been identified, is allowed if the equipment is emptied or is no longer used to treat or manage affected wastewater or residuals removed from affected wastewater.

(2) Delay of repair of equipment for which a control equipment failure or a gap, crack, tear, or hole has been identified is also allowed if additional time is necessary due to the unavailability of parts beyond the control of the owner or operator. Repair shall be completed as soon as practical. The owner or operator who uses this provision shall comply with the requirements of § 63.1259(h) to document the reasons that the delay of repair was necessary.

§ 63.1257 Test methods and compliance procedures.

(a) *General.* Except as specified in paragraph (a)(5) of this section, the procedures specified in paragraphs (c), (d), (e), and (f) of this section are required to demonstrate initial compliance with §§ 63.1253, 63.1254, 63.1256, and 63.1252(e), respectively. The provisions in paragraphs (a) (2) through (3) apply to performance tests that are specified in paragraphs (c), (d), and (e) of this section. The provisions in paragraph (a)(5) of this section are used to demonstrate initial compliance with the alternative standards specified in §§ 63.1253(d) and 63.1254(c). The provisions in paragraph (a)(6) of this section are used to comply with the outlet concentration requirements specified in §§ 63.1253(c), 63.1254 (a)(2)(i) and (a)(3)(ii)(B), 63.1254(b)(i) and 63.1256(h)(2).

(1) *Design evaluation.* To demonstrate that a control device meets the required control efficiency, a design evaluation must address the composition and organic HAP concentration of the vent stream entering the control device. A design evaluation also must address other vent stream characteristics and control device operating parameters as specified in any one of paragraphs (a)(1)(i) through (vi) of this section, depending on the type of control device that is used. If the vent stream is not the only inlet to the control device, the efficiency demonstration also must consider all other vapors, gases, and liquids, other than fuels, received by the control device.

(i) For an enclosed combustion device used to comply with the provisions of 63.1253 (b)(2) or (c)(2), or 63.1256(h)(2)(i)(C) with a minimum residence time of 0.5 seconds and a minimum temperature of 760°C, the design evaluation must document that these conditions exist.

(ii) For a combustion control device that does not satisfy the criteria in paragraph (a)(1)(i) of this section, the design evaluation must document control efficiency and address the following characteristics, depending on the type of control device:

(A) For a thermal vapor incinerator, the design evaluation must consider the autoignition temperature of the organic HAP, must consider the vent stream flow rate, and must establish the design minimum and average temperature in the combustion zone and the combustion zone residence time.

(B) For a catalytic vapor incinerator, the design evaluation shall consider the vent stream flow rate and shall establish the design minimum and average temperatures across the catalyst bed inlet and outlet.

(C) For a boiler or process heater, the design evaluation shall consider the vent stream flow rate; shall establish the design minimum and average flame zone temperatures and combustion zone residence time; and shall describe the method and location where the vent stream is introduced into the flame zone.

(iii) For a condenser, the design evaluation shall consider the vent stream flow rate, relative humidity, and temperature and shall establish the design outlet organic HAP compound concentration level, design average temperature of the condenser exhaust vent stream, and the design average temperatures of the coolant fluid at the condenser inlet and outlet. The temperature of the gas stream exiting the condenser must be measured and used to establish the outlet organic HAP concentration.

(iv) For a carbon adsorption system that regenerates the carbon bed directly onsite in the control device such as a fixed-bed adsorber, the design evaluation shall consider the vent stream flow rate, relative humidity, and temperature and shall establish the design exhaust vent stream organic compound concentration level, adsorption cycle time, number and capacity of carbon beds, type and working capacity of activated carbon used for carbon beds, design total regeneration stream mass or volumetric flow over the period of each complete carbon bed regeneration cycle, design carbon bed temperature after regeneration, design carbon bed regeneration time, and design service

life of carbon. For vacuum desorption, the pressure drop shall be included.

(v) For a carbon adsorption system that does not regenerate the carbon bed directly onsite in the control device such as a carbon canister, the design evaluation shall consider the vent stream mass or volumetric flow rate, relative humidity, and temperature and shall establish the design exhaust vent stream organic compound concentration level, capacity of carbon bed, type and working capacity of activated carbon used for carbon bed, and design carbon replacement interval based on the total carbon working capacity of the control device and source operating schedule.

(vi) For a scrubber, the design evaluation shall consider the vent stream composition; constituent concentrations; liquid-to-vapor ratio; scrubbing liquid flow rate and concentration; temperature; and the reaction kinetics of the constituents with the scrubbing liquid. The design evaluation shall establish the design exhaust vent stream organic compound concentration level and will include the additional information in paragraphs (a)(1)(vi)(A) and (B) of this section for trays and a packed column scrubber.

(A) Type and total number of theoretical and actual trays;

(B) Type and total surface area of packing for entire column, and for individual packed sections if column contains more than one packed section.

(2) *Calculation of TOC or total organic HAP concentration.* The TOC concentration or total organic HAP concentration is the sum of the concentrations of the individual components. If compliance is being determined based on TOC, the owner or operator shall compute TOC for each run using Equation 6 of this subpart. If compliance with the wastewater provisions is being determined based on total organic HAP, the owner or operator shall compute total organic HAP using Equation 6 of this subpart, except that only the organic HAP compounds shall be summed; when determining compliance with paragraph (e)(3)(i) of this section, only the soluble and partially soluble HAP compounds shall be summed.

$$CG_T = \frac{1}{m}\sum_{j=1}^{m}\left(\sum_{i=1}^{n} CGS_{i,j}\right) \qquad \text{(Eq. 6)}$$

where:

CG_T=total concentration of TOC in vented gas stream, average of samples, dry basis, ppmv

$CGS_{i,j}$=concentration of sample components in vented gas stream for sample j, dry basis, ppmv

i=identifier for a compound

n=number of components in the sample

j=identifier for a sample

m=number of samples in the sample run

(3) *Percent oxygen correction for combustion control devices.* If the control device is a combustion device, the TOC or total organic HAP concentrations must be corrected to 3 percent oxygen. The integrated sampling and analysis procedures of Method 3B of 40 CFR part 60, appendix A shall be used to determine the actual oxygen concentration ($\%0_{2d}$). The samples shall be taken during the same time that the TOC or total organic HAP samples are taken. The concentration corrected to 3 percent oxygen (C_d) shall be computed using Equation 7 of this subpart:

$$C_c = C_m\left(\frac{17.9}{20.9 - \%O_{2d}}\right) \qquad \text{(Eq. 7)}$$

where:

C_c = concentration of TOC or total organic HAP corrected to 3 percent oxygen, dry basis, ppmv

C_m = total concentration of TOC in vented gas stream, average of samples, dry basis, ppmv

$\%0_{2d}$ = concentration of oxygen measured in vented gas stream, dry basis, percent by volume

(4) *Exemptions from compliance demonstrations.* An owner or operator using any control device specified in paragraphs (a)(4)(i) through (iv) of this section is exempt from the initial compliance provisions in paragraphs (c), (d), and (e) of this section.

(i) A boiler or process heater with a design heat input capacity of 44 megawatts or greater.

(ii) A boiler or process heater into which the emission stream is introduced with the primary fuel.

(iii) A boiler or process heater burning hazardous waste for which the owner or operator:

(A) Has been issued a final permit under 40 CFR part 270 and complies with the requirements of 40 CFR part 266, subpart H, or

(B) Has certified compliance with the interim status requirements of 40 CFR part 266, subpart H.

(iv) A hazardous waste incinerator for which the owner or operator has been issued a final permit under 40 CFR part 270 and complies with the requirements of 40 CFR part 264, subpart O, or has certified compliance with the interim status requirements of 40 CFR part 265, subpart O.

(5) *Initial compliance with alternative standard.* Initial compliance with the alternative standards in §§ 63.1253(d) and 63.1254(c) is demonstrated when the outlet TOC concentration is 20 ppmv or less, and the outlet hydrogen halide and halogen concentration is 20 ppmv or less. To demonstrate initial compliance, the owner or operator shall be in compliance with the monitoring provisions in § 63.1258(b)(5) on the initial compliance date. The owner or operator shall use Method 18 to determine the predominant organic HAP in the emission stream if the TOC monitor is calibrated on the predominant HAP.

(6) *Initial compliance with the 20 ppmv outlet limit.* Initial compliance with the 20 ppmv TOC and hydrogen halide and halogen concentration is demonstrated when the outlet TOC concentration is 20 ppmv or less, and the outlet hydrogen halide and halogen concentration is 20 ppmv or less. To demonstrate initial compliance, the operator shall use test methods described in paragraph (b) of this section. The owner or operator shall comply with the monitoring provisions in § 63.1258(b)(1) through (5) of this subpart on the initial compliance date.

(b) *Test methods.* When testing is conducted to measure emissions from an affected source, the test methods specified in paragraphs (b)(1) through (10) of this section shall be used.

(1) EPA Method 1 or 1A of appendix A of part 60 is used for sample and velocity traverses.

(2) EPA Method 2, 2A, 2C, or 2D of appendix A of part 60 is used for velocity and volumetric flow rates.

(3) EPA Method 3 of appendix A of part 60 is used for gas analysis.

(4) EPA Method 4 of appendix A of part 60 is used for stack gas moisture.

(5) [Reserved]

(6) Concentration measurements shall be adjusted to negate the dilution effects of introducing nonaffected gaseous streams into the vent streams prior to control or measurement. The following methods are specified for concentration measurements:

(i) Method 18 may be used to determine HAP concentration in any control device efficiency determination.

(ii) Method 25 of appendix A of part 60 may be used to determine total gaseous nonmethane organic concentration for control efficiency determinations in combustion devices.

(iii) Method 26 of appendix A of part 60 shall be used to determine hydrogen chloride concentrations in control device efficiency determinations or in the 20 ppmv outlet hydrogen halide concentration standard.

(iv) Method 25A of appendix A of part 60 may be used to determine the HAP or TOC concentration for control device

efficiency determinations under the conditions specified in Method 25 of appendix A for direct measurement of an effluent with a flame ionization detector, or in demonstrating compliance with the 20 ppmv TOC outlet standard. If Method 25A is used to determine the concentration of TOC for the 20 ppmv standard, the instrument shall be calibrated on methane or the predominant HAP. If calibrating on the predominant HAP, the use of Method 25A shall comply with paragraphs (b)(6)(iv)(A) through (C) of this section.

(A) The organic HAP used as the calibration gas for Method 25A, 40 CFR part 60, appendix A, shall be the single organic HAP representing the largest percent by volume.

(B) The use of Method 25A, 40 CFR part 60, appendix A, is acceptable if the response from the high level calibration gas is at least 20 times the standard deviation of the response from the zero calibration gas when the instrument is zeroed on the most sensitive scale.

(C) The span value of the analyzer must be less than 100 ppmv.

(7) *Testing conditions for continuous processes.* Testing of emissions on equipment operating as part of a continuous process will consist of three l-hour runs. Gas stream volumetric flow rates shall be measured every 15 minutes during each 1-hour run. The HAP concentration shall be determined from samples collected in an integrated sample over the duration of each l-hour test run, or from grab samples collected simultaneously with the flow rate measurements (every 15 minutes). If an integrated sample is collected for laboratory analysis, the sampling rate shall be adjusted proportionally to reflect variations in flow rate. For continuous gas streams, the emission rate used to determine compliance shall be the average emission rate of the three test runs.

(8) *Testing and compliance determination conditions for batch processes.* Testing of emissions on equipment where the flow of gaseous emissions is intermittent (batch operations) shall be conducted as specified in paragraphs (b)(8)(i) through (iii) of this section.

(i) Except as provided in paragraph (b)(9) of this section for condensers, testing shall be conducted at absolute worst-case conditions or hypothetical worst-case conditions. Gas stream volumetric flow rates shall be measured at 15-minute intervals. The HAP or TOC concentration shall be determined from samples collected in an integrated sample over the duration of the test, or from grab samples collected simultaneously with the flow rate measurements (every 15 minutes). If an integrated sample is collected for laboratory analysis, the sampling rate shall be adjusted proportionally to reflect variations in flow rate. The absolute worst-case or hypothetical worst-case conditions shall be characterized by the criteria presented in paragraphs (b)(8)(i)(A) and (B)of this section. In all cases, a site-specific plan shall be submitted to the Administrator for approval prior to testing in accordance with § 63.7(c) and § 63.1260(l). The test plan shall include the emission profile described in paragraph (b)(8)(ii) of this section.

(A) Absolute worst-case conditions are defined by the criteria presented in paragraph (b)(8)(i)(A)(*1*) or (*2*) of this section if the maximum load is the most challenging condition for the control device. Otherwise, absolute worst-case conditions are defined by the conditions in paragraph (b)(8)(i)(A)(*3*) of this section.

(*1*) The period in which the inlet to the control device will contain at least 50 percent of the maximum HAP load (in lb) capable of being vented to the control device over any 8 hour period. An emission profile as described in paragraph (b)(8)(ii)(A) of this section shall be used to identify the 8-hour period that includes the maximum projected HAP load.

(*2*) A 1-hour period of time in which the inlet to the control device will contain the highest HAP mass loading rate, in lb/hr, capable of being vented to the control device. An emission profile as described in paragraph (b)(8)(ii)(A) of this section shall be used to identify the 1-hour period of maximum HAP loading.

(*3*) The period of time when the HAP loading or stream composition (including non-HAP) is most challenging for the control device. These conditions include, but are not limited to the following:

(*i*) Periods when the stream contains the highest combined VOC and HAP load, in lb/hr, described by the emission profiles in (b)(8)(ii);

(*ii*) Periods when the streams contain HAP constituents that approach limits of solubility for scrubbing media;

(*iii*) Periods when the streams contain HAP constituents that approach limits of adsorptivity for carbon adsorption systems.

(B) Hypothetical worst-case conditions are simulated test conditions that, at a minimum, contain the highest hourly HAP load of emissions that would be predicted to be vented to the control device from the emissions profile described in paragraph (b)(8)(ii)(B) or (C) of this section.

(ii) *Emissions profile.* The owner or operator may choose to perform tests only during those periods of the worst-case conditions that the owner or operator selects to control as part of achieving the required emission reduction. The owner or operator must develop an emission profile for the vent to the control device that describes the characteristics of the vent stream at the inlet to the control device under worst case conditions. The emission profile shall be developed based on any one of the procedures described in (b)(8)(ii)(A) through (C) of this section, as required by paragraph (b)(8)(i).

(A) *Emission profile by process.* The emission profile must consider all emission episodes that could contribute to the vent stack for a period of time that is sufficient to include all processes venting to the stack and shall consider production scheduling. The profile shall describe the HAP load to the device that equals the highest sum of emissions from the episodes that can vent to the control device in any given hour. Emissions per episode shall be calculated using the procedures specified in paragraph (d)(2) of this section. Emissions per episode shall be divided by the duration of the episode only if the duration of the episode is longer than 1 hour.

(B) *Emission profile by equipment.* The emission profile must consist of emissions that meet or exceed the highest emissions, in lb/hr, that would be expected under actual processing conditions. The profile shall describe equipment configurations used to generate the emission events, volatility of materials processed in the equipment, and the rationale used to identify and characterize the emission events. The emissions may be based on using a compound more volatile than compounds actually used in the process(es), and the emissions may be generated from all equipment in the process(es) or only selected equipment.

(C) *Emission profile by capture and control device limitation.* The emission profile shall consider the capture and control system limitations and the highest emissions, in lb/hr, that can be routed to the control device, based on maximum flowrate and concentrations possible because of limitations on conveyance and control equipment (e.g., fans, LEL alarms and safety bypasses).

(iii) Three runs, at a minimum of 1 hour each and a maximum of 8 hours each, are required for performance testing. Each run must occur over the same worst-case conditions, as defined in paragraph (b)(8)(i) of this section.

(9) *Testing requirements for condensers.* For emission streams controlled using condensers, continuous direct measurement of condenser outlet gas temperature to be used in determining concentrations per the design evaluation described in § 63.1257(a)(1)(iii) is required.

(10) *Wastewater testing.* Wastewater analysis shall be conducted in accordance with paragraph (b)(10)(i), (ii), (iii), or (iv) of this section.

(i) *Method 305.* Use procedures specified in Method 305 of 40 CFR part 63, appendix A and comply with requirements specified in paragraph (b)(10)(v) of this section.

(ii) *Method 624, 625, 1624, 1625, or 8270.* Use procedures specified in Method 624, 625, 1624, 1625, or 8270 of 40 CFR part 136, appendix A and comply with requirements in paragraph (b)(10)(v) of this section.

(iii) *Other EPA Methods.* Use procedures specified in the method, validate the method using the procedures in paragraph (b)(10)(iii)(A) or (B) of this section, and comply with the procedures in paragraph (b)(10)(v) of this section.

(A) Validate the method according to section 5.1 or 5.3 of Method 301 of 40 CFR part 63, appendix A.

(B) Follow the procedure as specified in ''Alternative Validation Procedure for EPA Waste Methods'' 40 CFR part 63, appendix D.

(iv) *Methods other than an EPA method.* Use procedures specified in the method, validate the method using the procedures in paragraph (b)(10)(iii)(A) of this section, and comply with the requirements in paragraph (b)(10)(v) of this section.

(v) *Sampling plan.* The owner or operator shall prepare a sampling plan. Wastewater samples shall be collected using sampling procedures which minimize loss of organic compounds during sample collection and analysis and maintain sample integrity. The sample plan shall include procedures for determining recovery efficiency of the relevant partially soluble and soluble HAP compounds. An example of an acceptable sampling plan would be one that incorporates similar sampling and sample handling requirements to those of Method 25D of 40 CFR part 60, appendix A. The sampling plan shall be maintained at the facility.

(c) *Initial compliance with storage tank provisions.* The owner or operator of an affected storage tank shall demonstrate initial compliance with § 63.1253(b) or (c), as applicable, by fulfilling the requirements of paragraph (c)(1),or (c)(2), or (c)(3) of this section.

(1) *Performance test.* If this option is chosen to demonstrate initial compliance with the percent reduction requirement of § 63.1253(b)(1) or (c)(1)(i), the efficiency of the control device shall be calculated using performance test data as specified in paragraphs (c)(1)(i) through (iii) of this section. Initial compliance with the outlet concentration requirement of § 63.1253(b)(2) or (c)(1)(ii) is demonstrated by fulfilling the requirements of paragraph (a)(6) of this section.

(i) Equations 8 and 9 of this subpart shall be used to calculate the mass rate of total HAP reasonably expected maximum filling rate at the inlet and outlet of the control device for standard conditions of 20°C: where:

$$E_i = K_2\left(\sum_{j=1}^{n} C_{ij}M_{ij}\right)Q_i \qquad \text{(Eq. 8)}$$

$$E_o = K_2\left(\sum_{j=1}^{n} C_{oj}M_{oj}\right)Q_o \qquad \text{(Eq. 9)}$$

where:

C_{ij}, C_{oj} = concentration of sample component j of the gas stream at the inlet and outlet of the control device, respectively, dry basis, ppmv

E_i, E_o = mass rate of total HAP at the inlet and outlet of the control device, respectively, dry basis, kg/hr

M_{ij}, M_{oj} = molecular weight of sample component j of the gas stream at the inlet and outlet of the control device, respectively, gram/gram-mole

Q_i, Q_o = flow rate of gas stream at the inlet and outlet of the control device, respectively, dry standard cubic meter per minute

K_2 = constant, 2.494×10^{-6} (parts per million)$^{-1}$ (gram-mole per standard cubic meter) (kilogram/gram) (minute/hour), where standard temperature is 20°C

n = number of sample components in the gas stream

(ii) The percent reduction in total HAP shall be calculated using Equation 10 of this subpart:

$$R = \frac{E_i - E_o}{E_i}(100) \qquad \text{(Eq. 10)}$$

where:

R = control efficiency of control device, percent

E_i = mass rate of total HAP at the inlet to the control device as calculated under paragraph (c)(1)(i) of this section, kilograms organic HAP per hour

E_o = mass rate of total HAP at the outlet of the control device, as calculated under paragraph (c)(1)(i) of this section, kilograms organic HAP per hour

(iii) A performance test is not required to be conducted if the control device used to comply with § 63.1253 (storage tank provisions) is also used to comply with § 63.1254 (process vent provisions), and compliance with § 63.1254 has been demonstrated in accordance with paragraph (d) of this section.

(2) *Design evaluation.* If this option is chosen to demonstrate initial compliance with the percent reduction requirement of § 63.1253(b) or (c), a design evaluation shall be prepared in accordance with the provisions in paragraph (a)(1) of this section. The design evaluation shall include documentation demonstrating that the control device being used achieves the required control efficiency during reasonably expected maximum filling rate.

(3) *Floating roof.* If the owner or operator of an affected source chooses to comply with the provisions of § 63.1253(b) or (c) by installing a floating roof, the owner or operator shall comply with the procedures described in §§ 63.119(b), (c), (d), and 63.120(a), (b), and (c), with the differences noted in paragraphs (c)(3)(i) through (v) of this section for the purposes of this subpart.

(i) When the term ''storage vessel'' is used in §§ 63.119 and 63.120, the definition of ''storage tank'' in § 63.1251 shall apply for the purposes of this subpart.

(ii) When December 31, 1992 is referred to in § 63.119, April 2, 1997 shall apply instead for the purposes of this subpart.

(iii) When April 22, 1994 is referred to in § 63.119, September 21, 1998 shall apply instead for the purposes of this subpart.

(iv) When the phrase ''the compliance date specified in § 63.100 of subpart F of this part'' is referred to in § 63.120, the phrase ''the compliance date specified in § 63.1250'' shall apply for the purposes of this subpart.

(v) When the phrase ''the maximum true vapor pressure of the total organic HAP's in the stored liquid falls below the values defining Group 1 storage vessels specified in table 5 or table 6 of this subpart'' is referred to in § 63.120(b)(1)(iv), the phrase ''the maximum true vapor pressure of the total organic HAP in the stored liquid

falls below 13.1 kPa (1.9 psia)'' shall apply for the purposes of this subpart.

(4) *Initial compliance with alternative standard.* Initial compliance with § 63.1253(d) is demonstrated by fulfilling the requirements of paragraph (a)(5) of this section.

(5) *Planned maintenance.* The owner or operator shall demonstrate compliance with the requirements of § 63.1253(e) by including the periods of planned routine maintenance specified by date and time in each Periodic Report required by § 63.1260.

(d) *Initial compliance with process vent provisions.* An owner or operator of an affected source complying with the process vent standards in § 63.1254 shall demonstrate compliance using the procedures described in paragraphs (d)(1) through (4) of this section.

(1) Except as provided in paragraph (a)(4) of this section, initial compliance with the process vent standards in § 63.1254 shall be demonstrated using the procedures specified in paragraphs (d)(1)(i) through (iv), as applicable.

(i) Initial compliance with § 63.1254(a)(1)(i) is demonstrated when the actual emissions of HAP from the sum of all process vents within a process that do not meet the criteria specified in § 63.1254(a)(3) is less than or equal to 2,000 lb/yr. Initial compliance with § 63.1254(a)(1)(ii) is demonstrated when the uncontrolled emissions of HAP from the sum of all process vents within a process is less than or equal to 100 lb/yr. Uncontrolled HAP emissions and controlled HAP emissions shall be determined using the procedures described in paragraphs (d)(2) and (3) of this section.

(ii) Initial compliance with the percent reduction requirements in §§ 63.1254(a)(2), (a)(3), and (b) is demonstrated by:

(A) Determining controlled HAP emissions using the procedures described in paragraph (d)(3) of this section and uncontrolled HAP emissions determined using the procedures described in paragraph (d)(2) of this section and demonstrating that the reductions required by §§ 63.1254(a)(2), (a)(3), and (b) are met; or

(B) Controlling the process vents using a device meeting the criteria specified in paragraph (a)(4) of this section.

(iii) Initial compliance with the outlet concentration requirements in § 63.1254(a)(2)(ii) and (3) is demonstrated when the outlet TOC concentration is 20 ppmv or less and the outlet hydrogen halide and halogen concentration is 20 ppmv or less. The owner or operator shall demonstrate compliance by fulfilling the requirements in paragraph (a)(6) of this section.

(iv) Initial compliance with § 63.1254(c) is demonstrated by fulfilling the requirements of paragraph (a)(5) of this section.

(2) *Uncontrolled emissions.* An owner or operator of an affected source complying with the emission limitation required by § 63.1254(a)(1), or emissions reductions specified in § 63.1254(a)(2), (a)(3), or (b), for each process vent within a process, shall calculate uncontrolled emissions from all equipment in the process according to the procedures described in paragraph (d)(2)(i) or (ii) of this section, as appropriate.

(i) *Emission estimation procedures.* Owners or operators shall determine uncontrolled emissions of HAP using measurements and/or calculations for each batch emission episode within each unit operation according to the engineering evaluation methodology in paragraphs (d)(2)(i)(A) through (H) of this section. Except where variations are noted, individual HAP partial pressures in multicomponent systems shall be determined by the following methods: If the components are miscible in one another, use Raoult's law to calculate the partial pressures; if the solution is a dilute aqueous mixture, use Henry's law to calculate partial pressures; if Raoult's law or Henry's law are not appropriate or available, use experimentally obtained activity coefficients or models such as the group-contribution models, to predict activity coefficients, or assume the components of the system behave independently and use the summation of all vapor pressures from the HAP as the total HAP partial pressure. Chemical property data can be obtained from standard reference texts.

(A) *Vapor displacement.* Emissions from vapor displacement due to transfer of material shall be calculated using Equation 11 of this subpart. The individual HAP partial pressures may be calculated using Raoult's law.

$$E = \frac{(V)}{(R)(T)} \times \sum_{i=1}^{n} \left(P_i\right)\left(MW_i\right) \qquad \text{(Eq. 11)}$$

where:

E = mass of HAP emitted

V = volume of gas displaced from the vessel

R = ideal gas law constant

T = temperature of the vessel vapor space; absolute

P_i = partial pressure of the individual HAP

MW_i = molecular weight of the individual HAP

n = number of HAP compounds in the emission stream i = identifier for a HAP compound

(B) *Purging.* Emissions from purging shall be calculated using Equation 12 of this subpart. The partial pressures of individual condensable compounds may be calculated using Raoult's law, the pressure of the vessel vapor space may be set equal to 760 mmHg, and the partial pressure of HAP shall be assumed to be 25 percent of the saturated value if the purge flow rate is greater than 100 standard cubic feet per minute (scfm).

$$E = \sum_{i=1}^{n} P_i MW_i \times \frac{(V)(t)}{(R)(T)} \times \frac{P_T}{P_T - \sum_{j=1}^{m} \left(P_j\right)} \qquad \text{(Eq. 12)}$$

Where:

E = mass of HAP emitted

V = purge flow rate at the temperature and pressure of the vessel vapor space

R = ideal gas law constant

T = temperature of the vessel vapor space; absolute

P_i = partial pressure of the individual HAP

P_j = partial pressure of individual condensable VOC compounds (including HAP)

P_T = pressure of the vessel vapor space

MW_i = molecular weight of the individual HAP

t = time of purge

n = number of HAP compounds in the emission stream

i = identifier for a HAP compound

j = identifier for a condensable compound

m = number of condensable compounds (including HAP) in the emission stream

(C) *Heating.* Emissions caused by the heating of a vessel to a temperature equal to or lower than 10 K below the boiling point shall be calculated using the procedures in either paragraph (d)(2)(i)(C)(*1*) or (*3*) of this section. Emissions caused by heating a vessel to a temperature that is higher than 10 K below the boiling point and less than the boiling point, must be calculated using the procedures in either paragraph (d)(2)(i)(C) (*2*) or (*3*) of this section. If the contents of a vessel are heated to the boiling point, emissions must be calculated using the procedures in paragraph (d)(2)(i)(C)(*4*) of this section.

(*1*) This paragraph describes procedures to calculate emissions if the final temperature to which the vessel contents are heated is 10 K below the boiling point of the HAP in the vessel, or lower. The owner or operator shall calculate the mass of HAP emitted per episode using either Equation 13 or 14 of this subpart. The moles of noncondensable gas displaced are calculated using Equation 15 of this subpart. The initial and final pressure of the noncondensable gas in the vessel shall be calculated using Equation 16 of this subpart. The average molecular weight of HAP in the displaced gas shall be calculated using Equation 17 of this subpart.

$$E = \frac{\sum_{i=1}^{n}\left((P_i^*)(x_i)\right)}{760 - \sum_{j=1}^{m}\left((P_j^*)(x_j)\right)} \times \Delta\eta \times MW_{HAP} \qquad \text{(Eq. 13)}$$

$$E = \frac{\frac{\sum_{i=1}^{n}(P_i)_{T1}}{Pa_1} + \frac{\sum_{i=1}^{n}(P_i)_{T2}}{Pa_2}}{2} \times \Delta\eta \times MW_{HAP} \qquad \text{(Eq. 14)}$$

$$\Delta\eta = \frac{V}{R}\left[\left(\frac{Pa_1}{T_1}\right) - \left(\frac{Pa_2}{T_2}\right)\right] \qquad \text{(Eq. 15)}$$

$$Pa_n = P_{atm} - \sum_{j=1}^{m}\left(P_j\right)_{Tn} \qquad \text{(Eq. 16)}$$

$$MW_{HAP} = \sum_{i=1}^{n}\frac{\left((P_i)_{T_1} + (P_i)_{T_2}\right)MW_i}{\sum_{i=1}^{n}\left((P_i)_{T_1} + (P_i)_{T_2}\right)} \qquad \text{(Eq. 17)}$$

Where:

E = mass of HAP vapor displaced from the vessel being heated

x_i = mole fraction of each HAP in the liquid phase

x_j = mole fraction of each condensable VOC (including HAP) in the liquid phase

(P_i^*) = vapor pressure of each HAP in the vessel headspace at any temperature between the initial and final heatup temperatures, mmHg

(P_j^*) = vapor pressure of each condensable VOC (including HAP) in the vessel headspace at any temperature between the initial and final heatup temperatures, mmHg

760 = atmospheric pressure, mmHg

MW_{HAP} = the average molecular weight of HAP present in the displaced gas

$\Delta\eta$ = number of moles of noncondensable gas displaced

V = volume of free space in the vessel

R = ideal gas law constant

T_1 = initial temperature of vessel contents, absolute

T_2 = final temperature of vessel contents, absolute

Pa_n = partial pressure of noncondensable gas in the vessel headspace at initial (n=1) and final (n=2) temperature

P_{atm} = atmospheric pressure (when $\Delta\eta$ is used in Equation 13 of this subpart, P_{atm} may be set equal to 760 mmHg for any vessel)

$(P_j)_{Tn}$ = partial pressure of each condensable compound (including HAP) in the vessel headspace at the initial temperature (n=1) and final (n=2) temperature

m = number of condensable compounds (including HAP) in the displaced vapor

j = identifier for a condensable compound

$(P_i)_{Tn}$ = partial pressure of each HAP in the vessel headspace at initial (T_1) and final (T_2) temperature; [for use in Equation 13, replace $(P_i)_{T1}+(P_i)_{T2}$ with P_i at the temperature used to calculate vapor pressure of HAP in Equation 13]

MW_i = molecular weight of each HAP

n = number of HAP compounds in the emission stream

i = identifier for a HAP compound

(*2*) If the vessel contents are heated to a temperature that is higher than 10 K below the boiling point and less than the boiling point, emissions must be calculated using the procedures in

paragraph (d)(2)(i)(C)(*2*)(*i*), or (*ii*), or (*iii*) of this section.

(*i*) Use Equation 13 of this subpart. In Equation 13 of this subpart, the HAP vapor pressures must be determined at the temperature 10 K below the boiling point. In the calculation of $\Delta\eta$ for Equation 13 of this subpart, T_2 must be the temperature 10 K below the boiling point, and Pa_2 must be determined at the temperature 10 K below the boiling point. In the calculation of MW_{HAP}, the HAP partial pressures must be determined at the temperature 10 K below the boiling point.

(*ii*) Use Equation 14 of this subpart. In Equation 14 of this subpart, the HAP partial pressures must be deter mined at the temperature 10 K below the boiling point. In the calculation of $\Delta\eta$ for Equation 14 of this subpart, T_2 must be the temperature 10 K below the boiling point, and Pa_2 must be determined at the temperature 10 K below the boiling point. In the calculation of MW_{HAP}, the HAP partial pressures must be determined at the temperature 10 K below the boiling point.

(*iii*) Use Equation 14 of this subpart over specific temperature increments. If the initial temperature is lower than 10 K below the boiling point, emissions must be calculated as the sum over two increments; one increment is from the initial temperature to 10 K below the boiling point, and the second is from 10 K below the boiling point to the lower of either the final temperature or the temperature 5 K below the boiling point. If the initial temperature is higher than 10 K below the boiling point, emissions are calculated over one increment from the initial temperature to the lower of either the final temperature or the temperature 5 K below the boiling point.

(*3*)(*i*) Emissions caused by heating a vessel are calculated using Equation 18 of this subpart.

$$E = MW_{HAP} \times \left(N_{avg} \times \ln\left(\frac{P_T - \sum_{i=1}^{n}\left(P_{i,1}\right)}{P_T - \sum_{i=1}^{n}\left(P_{i,2}\right)} \right) - \left(n_{i,2} - n_{i,1}\right) \right) \qquad \text{(Eq. 18)}$$

Where:

E = mass of HAP vapor displaced from the vessel being heated

N_{avg} = average gas space molar volume during the heating process

P_T= total pressure in the vessel

$P_{i,1}$ = partial pressure of the individual HAP compounds at T_1

$P_{i,2}$ = partial pressure of the individual HAP compounds at T_2

MW_{HAP} = average molecular weight of the HAP compounds

$n_{i,1}$ = number of moles of condensable in the vessel headspace at T_1

$n_{i,2}$ = number of moles of condensable in the vessel headspace at T_2

n = number of HAP compounds in the emission stream

(*ii*) The average gas space molar volume during the heating process is calculated using Equation 19 of this subpart.

$$N_{avg} = \frac{VP_T}{2R}\left(\frac{1}{T_1} + \frac{1}{T_2}\right) \qquad \text{(Eq. 19)}$$

Where:

N_{avg} = average gas space molar volume during the heating process

V = volume of free space in vessel

P_T = total pressure in the vessel

R = ideal gas law constant

T_1 = initial temperature of the vessel

T_2 = final temperature of the vessel

(*iii*) The difference in the number of moles of condensable in the vessel headspace between the initial and final temperatures is calculated using Equation 20 of this subpart.

$$\left(n_{i,2} - n_{i,1}\right) = \frac{V}{(R)(T_2)}\sum_{i=1}^{n} P_{i,2} - \frac{V}{(R)(T_1)}\sum_{i=1}^{n} P_{i,1} \qquad \text{(Eq. 20)}$$

Where:

V = volume of free space in vessel

R = ideal gas law constant

T_1 = initial temperature in the vessel

T_2 = final temperature in the vessel

$P_{i,1}$ = partial pressure of the individual HAP compounds at T_1

$P_{i,2}$ = partial pressure of the individual HAP compounds at T_2

n = number of HAP compounds in the emission stream

(*4*) If the vessel contents are heated to the boiling point, emissions must be calculated using the procedure in paragraphs (d)(2)(i)(c)(4)(*i*) and (*ii*) of this section.

(*i*) Use either of the procedures in paragraph (d)(3)(i)(B)(*3*) of this section to calculate the emissions from heating to the boiling point (note that Pa_2=0 in the calculation of $\Delta\eta$); and

(*ii*) While boiling, the vessel must be operated with a properly operated process condenser. An initial demonstration that a process condenser is properly operated is required for vessels that operate process condensers without secondary condensers that are air pollution control devices. The owner or operator must either measure the condenser exhaust gas temperature and show it is less than the boiling point of the substance(s) in the vessel, or perform a material balance around the vessel and condenser to show that at least 99 percent of the material vaporized while boiling is condensed. Uncontrolled emissions are assumed to be zero under these conditions. The initial demonstration shall be conducted for all appropriate operating scenarios and documented in the Notification of Compliance report described in § 63.1260(f).

(D) *Depressurization.* Emissions from depressurization shall be calculated using the procedures in either paragraphs (d)(2)(i)(D)(*1*) through (*4*), paragraphs (d)(2)(i)(D)(*5*) through (*9*), or paragraph (d)(2)(i)(D)(*10*) of this section.

(*1*) Equations 21 and 22 of this subpart are used to calculate the initial and final volumes of noncondensable gas present in the vessel, adjusted to atmospheric pressure. The HAP partial pressures may be calculated using Raoult's law.

$$V_{nc1} = \frac{VP_{nc_1}}{760} \qquad \text{(Eq. 21)}$$

$$V_{nc2} = \frac{VP_{nc_2}}{760} \qquad \text{(Eq. 22)}$$

Where:

V_{nc1} = initial volume of noncondensable gas in the vessel

V_{nc2} = final volume of noncondensable gas in the vessel

V = free volume in the vessel being depressurized

P_{nc1} = initial partial pressure of the noncondensable gas, as calculated using Equation 23 of this subpart, mmHg

P_{nc2} = final partial pressure of the noncondensable gas, as calculated using Equation 24 of this subpart, mmHg

760 = atmospheric pressure, mmHg

(*2*) The initial and final partial pressures of the noncondensable gas in the vessel are determined using Equations 23 and 24 of this subpart:

$$P_{nc1} = P_1 - \sum_{j=1}^{m}\left(P_j*\right)\left(x_j\right) \qquad \text{(Eq. 23)}$$

$$P_{nc2} = P_2 - \sum_{j=1}^{m}\left(P_j*\right)\left(x_j\right) \qquad \text{(Eq. 24)}$$

Where:

P_{nc1} = initial partial pressure of the noncondensable gas

P_{nc2} = final partial pressure of the noncondensable gas

P_1 = initial vessel pressure

P_2 = final vessel pressure

P_j* = vapor pressure of each condensable (including HAP) in the emission stream

x_j = mole fraction of each condensable (including HAP) in the emission stream

m = number of condensable compounds (including HAP) in the emission stream

j = identifier for a condensable compound

(*3*) The average ratio of moles of noncondensable to moles of HAP is calculated using Equation 25 of this subpart:

$$n_R = \frac{\left(\dfrac{P_{nc1}}{\sum_{i=1}^{n}\left(P_i*\right)\left(x_i\right)} + \dfrac{P_{nc2}}{\sum_{i=1}^{n}\left(P_i*\right)\left(x_i\right)}\right)}{2} \qquad \text{(Eq. 25)}$$

Where:

n_R = average ratio of moles of noncondensable to moles of HAP

P_{nc1} = initial partial pressure of the noncondensable gas, as calculated using Equation 23 of this subpart

P_{nc2} = final partial pressure of the noncondensable gas, as calculated using Equation 24 of this subpart

P_i* = vapor pressure of each individual HAP

x_i = mole fraction of each individual HAP in the liquid phase

n = number of HAP compounds

i = identifier for a HAP compound

(*4*) The mass of HAP emitted shall be calculated using Equation 26 of this subpart:

$$E = \frac{V_{nc1} - V_{nc2}}{n_R} \times \frac{P_{atm}}{RT} \times MW_{HAP} \qquad \text{(Eq. 26)}$$

Where:

E = mass of HAP emitted

V_{nc1} = initial volume of noncondensable gas in the vessel, as calculated using Equation 21 of this subpart

V_{nc2} = final volume of noncondensable gas in the vessel, as calculated using Equation 22 of this subpart n_R = average ratio of moles of noncondensable to moles of HAP, as calculated using Equation 25 of this subpart

P_{atm} = atmospheric pressure, standard

R = ideal gas law constant

T = temperature of the vessel, absolute

MW_{HAP} = average molecular weight of the HAP, as calculated using Equation 17 of this subpart

(*5*) The moles of HAP vapor initially in the vessel are calculated using the ideal gas law using Equation 27 of this subpart:

$$n_{HAP} = \frac{\left(Y_{HAP}\right)\left(V\right)\left(P_1\right)}{R\,T} \qquad \text{(Eq. 27)}$$

Where:

Y_{HAP} = mole fraction of HAP (the sum of the individual HAP fractions, ΣY_i)

V = free volume in the vessel being depressurized

P_1 = initial vessel pressure

R = ideal gas law constant

T = vessel temperature, absolute

(*6*) The initial and final moles of noncondensable gas present in the vessel are calculated using Equations 28 and 29 of this subpart:

$$n_1 = \frac{VP_{nc_1}}{RT} \qquad \text{(Eq. 28)}$$

$$n_2 = \frac{VP_{nc_2}}{RT} \qquad \text{(Eq. 29)}$$

Where:

n_1 = initial number of moles of noncondensable gas in the vessel

n_2 = final number of moles of noncondensable gas in the vessel

V = free volume in the vessel being depressurized
P_{nc1} = initial partial pressure of the noncondensable gas, as calculated using Equation 23 of this subpart
P_{nc2} = final partial pressure of the noncondensable gas, as calculated using Equation 24 of this subpart
R = ideal gas law constant
T = temperature, absolute

(*7*) The initial and final partial pressures of the noncondensable gas in the vessel are determined using Equations 23 and 24 of this subpart.

(*8*) The moles of HAP emitted during the depressurization are calculated by taking an approximation of the average ratio of moles of HAP to moles of noncondensable and multiplying by the total moles of noncondensables released during the depressurization, using Equation 30 of this subpart:

where:

$$n_{HAP} = \frac{\left(\frac{n_{HAP,1}}{n_1} + \frac{n_{HAP,2}}{n_2}\right)}{2}\left[n_1 - n_2\right] \qquad \text{(Eq. 30)}$$

n_{HAP} = moles of HAP emitted
n_1 = initial number of moles of noncondensable gas in the vessel, as calculated using Equation 28 of this subpart
n_2 = final number of moles of noncondensable gas in the vessel, as calculated using Equation 29 of this subpart

(*9*) The mass of HAP emitted can be calculated using Equation 31 of this subpart:

$E = N_{HAP} * MW_{HAP}$ (Eq. 31)

where:
E = mass of HAP emitted
n_{HAP} = moles of HAP emitted, as calculated using Equation 30 of this subpart
MW_{HAP} = average molecular weight of the HAP as calculated using Equation 17 of this subpart

(*10*) Emissions from depressurization may be calculated using Equation 32 of this subpart:

$$E = \frac{V}{(R)(T)} \times \ln\left(\frac{P_1 - \sum_{i=1}^{n}(P_i)}{P_2 - \sum_{i=1}^{n}(P_i)}\right) \times \sum_{i=1}^{n}(P_i)(MW_i) \qquad \text{(Eq. 32)}$$

where:
V = free volume in vessel being depressurized
R = ideal gas law constant
T = temperature of the vessel, absolute
P_1 = initial pressure in the vessel
P_2 = final pressure in the vessel
P_i = partial pressure of the individual HAP compounds
MW_i = molecular weight of the individual HAP compounds
n = number of HAP compounds in the emission stream
i = identifier for a HAP compound

(E) *Vacuum systems.* Emissions from vacuum systems may be calculated using Equation 33 of this subpart if the air leakage rate is known or can be approximated.

$$E = \frac{(MW_{HAP})(La)(t)}{MW_{nc}}\left(\frac{P_{system}}{P_{system} - P_i*} - 1\right) \qquad \text{(Eq. 33)}$$

where:
E = mass of HAP emitted
P_{system} = absolute pressure of receiving vessel or ejector outlet conditions, if there is no receiver
P_i* = vapor pressure of the HAP at the receiver temperature or the ejector outlet conditions
La = total air leak rate in the system, mass/time
MW_{nc} = molecular weight of noncondensable gas
t = time of vacuum operation
MW_{HAP} = average molecular weight of HAP in the emission stream, as calculated using Equation 17 of this subpart, with HAP partial pressures calculated at the temperature of the receiver or ejector outlet, as appropriate

(F) *Gas evolution.* Emissions from gas evolution shall be calculated using Equation 12 of this subpart with V calculated using Equation 34 of this subpart:

$$V = \frac{(W_g)(R)(T)}{(P_T)(MW_g)} \qquad \text{(Eq. 34)}$$

Where:
V = volumetric flow rate of gas evolution
W_g = mass flow rate of gas evolution
R = ideal gas law constant
T = temperature at the exit, absolute
P_T = vessel pressure
MW_g = molecular weight of the evolved gas

(G) *Air drying.* Emissions from air drying shall be calculated using Equation 35 of this subpart:

$$E = B \times \left(\frac{PS_1}{100 - PS_1} - \frac{PS_2}{100 - PS_2} \right) \qquad \text{(Eq. 35)}$$

Where:

E = mass of HAP emitted
B = mass of dry solids
PS_1 = HAP in material entering dryer, weight percent
PS_2 = HAP in material exiting dryer, weight percent

(H) *Empty vessel purging.* Emissions from empty vessel purging shall be calculated using Equation (36) of this subpart (Note: The term -Ft/v can be assumed to be 1):

$$E = \left(\frac{V}{RT} \times \left(\sum_{i=1}^{n} (P_i)(MW_i) \right) \left(1 - e^{-Ft/v}\right) \right) \qquad \text{(Eq. 36)}$$

Where:

V = volume of empty vessel
R = ideal gas law constant
T = temperature of the vessel vapor space; absolute
P_i = partial pressure of the individual HAP at the beginning of the purge
(MW_i) = molecular weight of the individual HAP
F = flowrate of the purge gas
t = duration of the purge
n = number of HAP compounds in the emission stream
i = identifier for a HAP compound

(ii) *Engineering assessments.* The owner or operator shall conduct an engineering assessment to calculate uncontrolled HAP emissions for each emission episode that is not due to vapor displacement, purging, heating, depressurization, vacuum operations, gas evolution, or air drying. For emission episodes caused by any of these types of activities, the owner or operator also may calculate uncontrolled HAP emissions based on an engineering assessment if the owner or operator can demonstrate to the Administrator that the methods in paragraph (d)(2)(i) of this section are not appropriate. One criterion the owner or operator could use to demonstrate that the methods in paragraph (d)(2)(i) of this section are not appropriate is if previous test data are available that show a greater than 20 percent discrepancy between the test value and the estimated value. An engineering assessment includes, but is not limited to, the following:

(A) Previous test results, provided the tests are representative of current operating practices at the process unit.

(B) Bench-scale or pilot-scale test data representative of the process under representative operating conditions.

(C) Maximum flow rate, HAP emission rate, concentration, or other relevant parameter specified or implied within a permit limit applicable to the process vent.

(D) Design analysis based on accepted chemical engineering principles, measurable process parameters, or physical or chemical laws or properties. Examples of analytical methods include, but are not limited to:

(*1*) Use of material balances based on process stoichiometry to estimate maximum organic HAP concentrations.

(*2*) Estimation of maximum flow rate based on physical equipment design such as pump or blower capacities.

(*3*) Estimation of HAP concentrations based on saturation conditions.

(E) All data, assumptions, and procedures used in the engineering assessment shall be documented in accordance with § 63.1260(e). Data or other information supporting a finding that the emissions estimation equations are inappropriate shall be reported in the Precompliance report.

(3) *Controlled emissions.* An owner or operator shall determine controlled emissions using the procedures in either paragraph (d)(3)(i) or (ii) of this section. For condensers, controlled emissions shall be calculated using the emission estimation equations described in paragraph (d)(3)(i)(B) of this section.

(i) *Small control devices.* Except for condensers, controlled emissions for each process vent that is controlled using a small control device shall be determined by using the design evaluation described in paragraph (d)(3)(i)(A) of this section, or conducting a performance test in accordance with paragraph (d)(3)(ii) of this section. Whenever a small control device becomes a large control device, the owner or operator must comply with the provisions in paragraph (d)(3)(ii) of this section and submit the test report in the next Periodic report.

(A) *Design evaluation.* The design evaluation shall include documentation demonstrating that the control device being used achieves the required control efficiency under worst-case conditions, as determined from the emission profile described in § 63.1257(b)(8)(ii). The control efficiency determined from this design evaluation shall be applied to uncontrolled emissions to estimate controlled emissions. The documentation must be conducted in accordance with the provisions in paragraph (a)(1) of this section. The design evaluation shall also include the value(s) and basis for the parameter(s) monitored under § 63.1258.

(B) *Emission estimation equations.* An owner or operator using a condenser as a control device shall determine controlled emissions using exhaust gas temperature measurements and calculations for each batch emission episode within each unit operation according to the engineering methodology in paragraphs (d)(3)(i)(B)(*1*) through (*8*) of this section. Individual HAP partial pressures shall be calculated as specified in paragraph (d)(2)(i) of this section.

(*1*) Emissions from vapor displacement shall be calculated using Equation 11 of this subpart with T set equal to the temperature of the receiver and the HAP partial pressures determined at the temperature of the receiver.

(*2*) Emissions from purging shall be calculated using Equation 12 of this subpart with T set equal to the temperature of the receiver and the HAP partial pressures determined at the temperature of the receiver.

(*3*) Emissions from heating shall be calculated using either Equation 13 of this subpart or Equation 37 of this subpart. In Equation 13, the HAP vapor pressures shall be determined at the temperature of the receiver. In Equations 13 and 37 of this subpart, $\Delta\eta$ is equal to the number of moles of noncondensable displaced from the vessel, as calculated using Equation 15 of this subpart. In Equations 13 and 37 of this subpart, the HAP average molecular weight shall be calculated using Equation 17 with the HAP partial pressures determined at the temperature of the receiver.

$$E = \Delta\eta \times \frac{\sum_{i=1}^{n} P_i}{P_T - \sum_{j=1}^{m} P_j} \times MW_{HAP} \quad \text{(Eq. 37)}$$

Where:

E = mass of HAP emitted

$\Delta\eta$ = moles of noncondensable gas displaced

P_T = pressure in the receiver

P_i = partial pressure of the individual HAP at the receiver temperature

P_j = partial pressure of the individual condensable (including HAP) at the receiver temperature

n = number of HAP compounds in the emission stream

i = identifier for a HAP compound

MW_{HAP} = the average molecular weight of HAP in vapor exiting the receiver, as calculated using Equation 17 of this subpart

m = number of condensable compounds (including HAP) in the emission stream

(*4*)(*i*) Emissions from depressurization shall be calculated using Equation 38 of this subpart.

$$E = \left(V_{nc1} - V_{nc2}\right) \times \frac{\sum_{i=1}^{n} \left(P_i\right)}{P_T - \sum_{j=1}^{m} \left(P_j\right)} \times \frac{P_T}{RT} \times MW_{HAP} \quad \text{(Eq. 38)}$$

Where:

E = mass of HAP vapor emitted

V_{nc1} = initial volume of noncondensable in the vessel, corrected to the final pressure, as calculated using Equation 39 of this subpart

V_{nc2} = final volume of noncondensable in the vessel, as calculated using Equation 40 of this subpart

P_i = partial pressure of each individual HAP at the receiver temperature

P_j = partial pressure of each condensable (including HAP) at the receiver temperature

P_T = receiver pressure

T = temperature of the receiver

R = ideal gas law constant

MW_{HAP} = the average molecular weight of HAP calculated using Equation 17 of this subpart with partial pressures determined at the receiver temperature

i = identifier for a HAP compound

n = number of HAP compounds in the emission stream

m = number of condensable compounds (including HAP) in the emission stream

j = identifier for a condensable compound

(*ii*) The initial and final volumes of noncondensable gas present in the vessel, adjusted to the pressure of the receiver, are calculated using Equations 39 and 40 of this subpart.

$$V_{nc1} = \frac{VP_{nc_1}}{P_T} \quad \text{(Eq. 39)}$$

$$V_{nc2} = \frac{VP_{nc_2}}{P_T} \quad \text{(Eq. 40)}$$

Where:

V_{nc1} = initial volume of noncondensable gas in the vessel

V_{nc2} = final volume of noncondensable gas in the vessel

V = free volume in the vessel being depressurized

P_{nc1} = initial partial pressure of the noncondensable gas, as calculated using Equation 41 of this subpart

P_{nc2} = final partial pressure of the noncondensable gas, as calculated using Equation 42 of this subpart

P_T = pressure of the receiver

(*iii*) Initial and final partial pressures of the noncondensable gas in the vessel are determined using Equations 41 and 42 of this subpart.

$$P_{nc1} = P_1 - \sum_{j=1}^{m} P_j \quad \text{(Eq. 41)}$$

$$P_{nc2} = P_2 - \sum_{j=1}^{m} P_j \quad \text{(Eq. 42)}$$

Where:

P_{nc1} = initial partial pressure of the noncondensable gas in the vessel

P_{nc2} = final partial pressure of the noncondensable gas in the vessel

P_1 = initial vessel pressure

P_2 = final vessel pressure

P_j = partial pressure of each condensable compound (including HAP) in the vessel

m = number of condensable compounds (including HAP) in the emission stream

j = identifier for a condensable compound

(*5*) Emissions from vacuum systems shall be calculated using Equation 33 of this subpart.

(*6*) Emissions from gas evolution shall be calculated using Equation 12 with V calculated using Equation 34 of this subpart, T set equal to the receiver temperature, and the HAP partial pressures determined at the receiver temperature. The term for time, t, in Equation 12 of this subpart is not needed for the purposes of this calculation.

(*7*) Emissions from air drying shall be calculated using Equation 11 of this subpart with V equal to the air flow rate and P_i determined at the receiver temperature.

(*8*) Emissions from empty vessel purging shall be calculated using equation 43 of this subpart:

$$E = \frac{V}{R}\left[\left(\sum_{i=1}^{n}\frac{(P_i)_{T_1}(MW_i)}{T_1}\right)\left(-e^{-Ft/V}\right)-\left(\sum_{i=1}^{n}\frac{(P_i)_{T_2}(MW_i)}{T_2}\right)\left(\ln\left(\frac{\sum_{i=1}^{n}(P_i)_{T_2}}{\sum_{i=1}^{n}(P_i)_{T_1}}\right)+1\right)\right] \qquad \text{(Eq. 43)}$$

Where:

V = volume of empty vessel
R = ideal gas law constant
T_1 = temperature of the vessel vapor space at beginning of purge
T_2 = temperature of the receiver, absolute
$(P_i)_{T1}$ = partial pressure of the individual HAP at the beginning of the purge
$(P_i)_{T2}$ = partial pressure of the individual HAP at the receiver temperature
MW_i = molecular weight of the individual HAP
F = flowrate of the purge gas
t = duration of the purge
n = number of HAP compounds in the emission stream
i = identifier for a HAP compound

(ii) *Large control devices.* Except for condensers, controlled emissions for each process vent that is controlled using a large control device shall be determined by applying the control efficiency of the large control device to the estimated uncontrolled emissions. The control efficiency shall be determined by conducting a performance test on the control device as described in paragraphs (d)(3)(ii)(A) through (C) of this section, or by using the results of a previous performance test as described in paragraph (d)(4) of this section. If the control device is intended to control only hydrogen halides and halogens, the owner or operator may assume the control efficiency of organic HAP is zero percent. If the control device is intended to control only organic HAP, the owner or operator may assume the control efficiency for hydrogen halides and halogen is zero percent. Owners and operators are not required to conduct performance tests for devices described in paragraphs (a)(4) and (d)(4) of this section that are large control devices, as defined in § 63.1251.

(A) The performance test shall be conducted by performing emission testing on the inlet and outlet, or, if complying with the provisions of § 63.1254(c), on the outlet of the control device, following the test methods and procedures of § 63.1257(b). Concentrations shall be calculated from the data obtained through emission testing according to the procedures in paragraph (a)(2) of this section. If the control device is a combustion device that uses supplemental combustion air, the concentrations shall be corrected to 3 percent oxygen according to the procedures in paragraph (a)(3) of this section.

(B) Performance testing shall be conducted under absolute, or hypothetical worst-case conditions, as defined in paragraphs (b)(8)(i)(A) through (B) of this section.

(C) The owner or operator may elect to conduct more than one performance test on the control device for the purpose of establishing more than one operating condition at which the control device achieves the required control efficiency.

(4) An owner or operator is not required to conduct a performance test for the following:

(i) Any control device for which a previous performance test was conducted, provided the test was conducted using the same procedures specified in § 63.1257(b) over conditions typical of the appropriate worst-case, as defined in § 63.1257(b)(8)(i). The results of the previous performance test shall be used to demonstrate compliance.

(e) *Compliance with wastewater provisions.* (1) *Determining annual average concentration and annual load.* To determine the annual average concentration and annual load of partially soluble and/or soluble HAP compounds in a wastewater stream, as required by § 63.1256(a)(1), an owner or operator shall comply with the provisions in paragraphs (e)(1)(i) through (iii) of this section. A wastewater stream is exempt from the requirements of § 63.1256(a)(2) if the owner or operator determines the annual average concentration and annual load are below all of the applicability cutoffs specified in § 63.1256(a)(1)(i)(A) through (D). For annual average concentration, only initial rinses are included. Concentration measurements based on Method 305 shall be adjusted by dividing each concentration by the compound-specific Fm factor listed in Table 8 of this subpart. Concentration measurements based on methods other than Method 305 may not be adjusted by the compound-specific Fm factor listed in Table 8 of this subpart.

(i) *Annual average concentration definition.* (A) When complying with § 63.1256(a)(1)(i)(A), the annual average concentration means the total mass of partially soluble HAP compounds occurring in the wastewater stream during the calendar year divided by the total mass of the wastewater stream discharged during the same calendar year.

(B) When complying with § 63.1256(a)(1)(i) (B) or (C), the annual average concentration means the total mass of partially soluble and/or soluble HAP compounds occurring in the wastewater stream during the calendar year divided by the total mass of the wastewater stream discharged during the same calendar year.

(C) When complying with § 63.1256(a)(1)(i)(D), the annual average concentration means the total mass of soluble HAP compounds occurring in the wastewater stream during the calendar year divided by the total mass of the wastewater stream discharged during the same calendar year.

(ii) *Determination of annual average concentration.* An owner or operator shall determine annual average concentrations of partially soluble and/or soluble HAP compounds in accordance with the provisions specified in paragraph (e)(1)(ii)(A), (B), or (C) of this section. The owner or operator may determine annual average concentrations by process simulation. Data and other information supporting the simulation shall be reported in the Precompliance Report for approval by the Administrator. The annual average concentration shall be determined either at the POD or downstream of the POD with adjustment for concentration changes made according to paragraph (e)(1)(ii)(D) of this section.

(A) *Test methods.* The concentration of partially soluble HAP, soluble HAP, or total HAP shall be measured using any of the methods described in paragraphs (b)(10)(i) through (iv) of this section.

(B) *Knowledge of the wastewater stream.* The concentration of partially soluble HAP, soluble HAP, or total HAP shall be calculated based on knowledge of the wastewater stream according to the procedures in paragraphs (e)(1)(ii)(B)(*1*) and (*2*) of this section. The owner or operator shall document concentrations in the Notification of Compliance Status report described in § 63.1260(f).

(*1*) *Mass balance.* The owner or operator shall calculate the concentrations of HAP compounds in wastewater considering the total quantity of HAP discharged to the water, the amount of water at the POD, and the amounts of water and solvent lost to other mechanisms such as reactions, air emissions, or uptake in product or other processing materials. The quantities of HAP and water shall be based on batch sheets, manufacturing tickets, or FDA bills of materials. In cases where a chemical reaction occurs that generates or consumes HAP, the amount of HAP remaining after a reaction shall be based on stoichometry assuming 100 percent theoretical consumption or yield, as applicable.

(2) *Published water solubility data.* For single components in water, owners and operators may use the water solubilities published in standard reference texts at the POD temperature to determine maximum HAP concentration.

(C) *Bench scale or pilot-scale test data.* The concentration of partially soluble HAP, soluble HAP, or total HAP shall be calculated based on bench scale or pilot-scale test data. The owner or operator shall provide sufficient information to demonstrate that the bench-scale or pilot-scale test concentration data are representative of actual HAP concentrations. The owner or operator shall also provide documentation describing the testing protocol, and the means by which sample variability and analytical variability were accounted for in the determination of HAP concentrations. Documentation of the pilot-scale or bench scale analysis shall be provided in the precompliance report.

(D) *Adjustment for concentrations determined downstream of the POD.* The owner or operator shall make corrections to the annual average concentration when the concentration is determined downstream of the POD at a location where: two or more wastewater streams have been mixed; one or more wastewater streams have been treated; or, losses to the atmosphere have occurred. The owner or operator shall make the adjustments either to the individual data points or to the final annual average concentration.

(iii) *Determination of annual load.* An owner or operator shall calculate the partially soluble and/or soluble HAP load in a wastewater stream based on the annual average concentration determined in paragraph (e)(1)(ii) (A), (B), or (C) of this section and the total volume of the wastewater stream, based on knowledge of the wastewater stream in accordance with paragraphs (e)(1)(ii)(B) of this section. The owner or operator shall maintain records of the total liters of wastewater discharged per year as specified in § 63.1259(b).

(2) *Compliance with treatment unit control provisions.* (i) *Performance tests and design evaluations-general.* To comply with the control options in § 63.1256(g) (10) or (13), neither a design evaluation nor a performance test is required. For any other nonbiological treatment process, the owner or operator shall conduct either a design evaluation as specified in paragraph (e)(2)(ii) of this section, or a performance test as specified in paragraph (e)(2)(iii) of this section to demonstrate that each nonbiological treatment process used to comply with § 63.1256(g) (8), (9), and/or (12) achieves the conditions specified for compliance. The owner or operator shall demonstrate by the procedures in either paragraph (e)(2) (ii) or (iii) of this section that each closed biological treatment process used to comply with § 63.1256 (g)(8)(ii), (g)(9)(ii), (g)(11), or (g)(12) achieves the conditions specified for compliance. If an open biological treatment unit is used to comply with § 63.1256 (g)(8)(ii), (g)(9)(ii), (g)(11), or (g)(12), the owner or operator shall comply with the performance test requirements in paragraph (e)(2)(iii) of this section.

(ii) *Design evaluation.* A design evaluation and supporting documentation that addresses the operating characteristics of the treatment process and that is based on operation at a wastewater stream flow rate and a concentration under which it would be most difficult to demonstrate compliance. For closed biological treatment processes, the percent reduction from removal/destruction in the treatment unit and control device shall be determined by a mass balance over the unit. The mass flow rate of soluble and/or partially soluble HAP compounds exiting the treatment process shall be the sum of the mass flow rate of soluble and/or partially soluble HAP compounds in the wastewater stream exiting the biological treatment process and the mass flow rate of the vented gas stream exiting the control device. The mass flow rate entering the treatment process minus the mass flow rate exiting the process determines the actual mass removal. Compounds that meet the requirements specified in paragraph (e)(2)(iii)(A)(*4*) of this section are not required to be included in the design evaluation; the term ''performance test'' in paragraph (e)(2)(iii)(A)(*4*) of this section shall mean ''design evaluation'' for the purposes of this paragraph.

(iii) *Performance tests.* Performance tests shall be conducted using test methods and procedures that meet the applicable requirements specified in paragraphs (e)(2)(iii)(A) through (G) of this section.

(A) *General.* This paragraph specifies the general procedures for performance tests that are conducted to demonstrate compliance of a treatment process with the control requirements specified in § 63.1256(g).

(*1*) *Representative process unit operating conditions.* Compliance shall be demonstrated for representative operating conditions. Operations during periods of malfunction and periods of nonoperation shall not constitute representative conditions. The owner or operator shall record the process information that is necessary to document operating conditions during the test.

(*2*) *Representative treatment process operating conditions.* Performance tests shall be conducted when the treatment process is operating at a representative inlet flow rate and concentration. If the treatment process will be operating at several different sets of representative operating conditions, the owner or operator shall comply with paragraphs (e)(2)(iii)(A)(*2*)(*i*) and (*ii*) of this section. The owner or operator shall record information that is necessary to document treatment process or control device operating conditions during the test.

(*i*) *Range of operating conditions.* If the treatment process will be operated at several different sets of representative operating conditions, performance testing over the entire range is not required. In such cases, the performance test results shall be supplemented with modeling and/or engineering assessments to demonstrate performance over the operating range.

(*ii*) *Consideration of residence time.* If concentration and/or flow rate to the treatment process are not relatively constant (i.e., comparison of inlet and outlet data will not be representative of performance), the owner or operator shall consider residence time, when determining concentration and flow rate.

(*3*) *Testing equipment.* All testing equipment shall be prepared and installed as specified in the applicable test methods, or as approved by the Administrator.

(*4*) *Compounds not required to be considered in performance tests.* Compounds that meet the requirements specified in (e)(2)(iii)(A)(*4*)(*i*), (*ii*), or (*iii*) of this section are not required to be included in the performance test. Concentration measurements based on

Method 305 shall be adjusted by dividing each concentration by the compound-specific Fm factor listed in Table 8 of this subpart. Concentration measurements based on methods other than Method 305 shall not be adjusted by the compound-specific Fm factor listed in Table 8 of this subpart.

(*i*) Compounds not used or produced by the PMPU; or

(*ii*) Compounds with concentrations at the POD that are below 1 ppmw; or

(*iii*) Compounds with concentrations at the POD that are below the lower detection limit where the lower detection limit is greater than 1 ppmw. The method shall be an analytical method for wastewater which has the compound of interest as a target analyte.

(*5*) *Treatment using a series of treatment processes.* In all cases where the wastewater provisions in this subpart allow or require the use of a treatment process to comply with emissions limitations, the owner or operator may use multiple treatment processes. The owner or operator complying with the requirements of § 63.1256(g)(7)(i), when wastewater is conveyed by hard-piping, shall comply with either paragraph (e)(2)(iii)(A)(*5*)(*i*) or (*ii*) of this section. The owner or operator complying with the requirements of § 63.1256(g)(7)(ii) shall comply with the requirements of paragraph (e)(2)(iii)(A)(*5*)(*ii*) of this section.

(*i*) The owner or operator shall conduct the performance test across each series of treatment processes. For each series of treatment processes, inlet concentration and flow rate shall be measured either where the wastewater enters the first treatment process in a series of treatment processes, or prior to the first treatment process as specified in paragraph (e)(2)(iii)(A)(*6*) of this section. For each series of treatment processes, outlet concentration and flow rate shall be measured where the wastewater exits the last treatment process in the series of treatment processes, except when the last treatment process is an open or a closed aerobic biological treatment process demonstrating compliance by using the procedures in paragraphs (e)(2)(iii)(E) or (F) of this section. When the last treatment process is either an open or a closed aerobic biological treatment process demonstrating compliance by using the procedures in paragraphs (e)(2)(iii)(E) or (F) of this section, inlet and outlet concentrations and flow rates shall be measured at the inlet and outlet to the series of treatment processes prior to the biological treatment process and at the inlet to the biological treatment process, except as provided in paragraph (e)(2)(iii)(A)(6)(ii) of this section. The mass flow rate destroyed in the biological treatment process for which compliance is demonstrated using paragraph (e)(2)(iii)(E) or (F) of this section shall be added to the mass flow rate removed or destroyed in the series of treatment units before the biological treatment unit. This sum shall be used to calculate the overall control efficiency.

(*ii*) The owner or operator shall conduct the performance test across each treatment process in the series of treatment processes. The mass flow rate removed or destroyed by each treatment process shall be added together and the overall control efficiency calculated to determine whether compliance has been demonstrated using paragraphs (e)(2)(iii)(C), (D), (E), (F), or (G) of this section, as applicable. If a biological treatment process is one of the treatment processes in the series of treatment processes, the inlet to the biological treatment process shall be the point at which the wastewater enters the biological treatment process, or the inlet to the equalization tank if all the criteria of paragraph (e)(2)(iii)(A)(*6*)(*ii*) of this section are met.

(*6*) The owner or operator determining the inlet for purposes of demonstrating compliance with paragraph (e)(2)(iii)(E), or (F)of this section may elect to comply with paragraph (e)(2)(iii)(A)(*6*)(*i*) or (*ii*) of this section.

(*i*) When wastewater is conveyed exclusively by hard-piping from the point of determination to a treatment process that is either the only treatment process or the first in a series of treatment processes (i.e., no treatment processes or other waste management units are used upstream of this treatment process to store, handle, or convey the wastewater), the inlet to the treatment process shall be at any location from the point of determination to where the wastewater stream enters the treatment process. When samples are taken upstream of the treatment process and before wastewater streams have converged, the owner or operator shall ensure that the mass flow rate of all affected wastewater is accounted for when using § 63.1256(g)(8)(ii), (g)(9)(ii) or (g)(12) of this subpart to comply and that the mass flow rate of all wastewater, not just affected wastewater, is accounted for when using § 63.1256(g)(11) to comply, except as provided in paragraph (e)(2)(iii)(A)(*4*) of this section.

(*ii*) The owner or operator may consider the inlet to the equalization tank as the inlet to the biological treatment process if the wastewater is conveyed by hard-piping from either the last previous treatment process or the point of determination to the equalization tank; or the wastewater is conveyed from the equalization tank exclusively by hard-piping to the biological treatment process and no treatment processes or other waste management units are used to store, handle, or convey the wastewater between the equalization tank and the biological treatment process; or the equalization tank is equipped with a fixed roof and a closed-vent system that routes emissions to a control device that meets the requirements of § 63.1256(b)(1)(i) through (iv) and § 63.1256(b)(2)(i). The outlet from the series of treatment processes prior to the biological treatment process is the point at which the wastewater exits the last treatment process in the series prior to the equalization tank, if the equalization tank and biological treatment process are part of a series of treatment processes. The owner or operator shall ensure that the mass flow rate of all affected wastewater is accounted for when using § 63.1256(g)(9)(ii) or (12) to comply and that the mass flow rate of all wastewater, not just affected wastewater is accounted for when using § 63.1256(g)(11) to comply, except as provided in paragraph (e)(2)(iii)(A)(*4*) of this section.

(B) *Noncombustion treatment process—concentration limits.* This paragraph applies to performance tests that are conducted to demonstrate compliance of a noncombustion treatment process with the ppmw wastewater stream concentration limits at the outlet of the treatment process. This compliance option is specified in § 63.1256(g)(8)(i) and (9)(i). Wastewater samples shall be collected using sampling procedures which minimize loss of organic compounds during sample collection and analysis and maintain sample integrity per paragraph (b)(10)(iii) of this section. Samples shall be collected and analyzed using the procedures specified in paragraphs (b)(10)(i), (ii), and (iii) of this section. Samples may be grab samples or composite samples. Samples shall be taken at approximately equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of three runs. Concentration measurements based on methods other than Method 305 may be adjusted by multiplying each concentration by the compound-specific Fm factor listed in Table 8 of this subpart. (For affected wastewater streams that contains both partially soluble and soluble HAP compounds, compliance is

demonstrated only if the sum of the concentrations of partially soluble HAP compounds is less than 50 ppmw, and the sum of the concentrations of soluble HAP compounds is less than 520 ppmw.)

(C) *Noncombustion, nonbiological treatment process: percent mass removal/destruction option.* This paragraph applies to performance tests that are conducted to demonstrate compliance of a noncombustion, nonbiological treatment process with the percent mass removal limits specified in § 63.1256(g)(8)(ii) and (9)(ii) for partially soluble and soluble HAP compounds, respectively. The owner or operator shall comply with the requirements specified in paragraphs (e)(2)(iii)(C)(*1*) through (*5*) of this section.

(*1*) *Concentration.* The concentration of partially soluble and/or soluble HAP compounds entering and exiting the treatment process shall be determined as provided in this paragraph. Wastewater samples shall be collected using sampling procedures which minimize loss of organic compounds during sample collection and analysis and maintain sample integrity per paragraph (b)(10)(v) of this section. The method shall be an analytical method for wastewater which has the compound of interest as a target analyte. Samples may be grab samples or composite samples. Samples shall be taken at approximately equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of three runs. Concentration measurements based on Method 305 shall be adjusted by dividing each concentration by the compound-specific Fm factor listed in Table 8 of this subpart. Concentration measurements based on methods other than Method 305 shall not be adjusted by the compound-specific Fm factor listed in Table 8 of this subpart.

(*2*) *Flow rate.* The flow rate of the entering and exiting wastewater streams shall be determined using inlet and outlet flow meters, respectively. Where the outlet flow is not greater than the inlet flow, a single flow meter may be used, and may be used at either the inlet or outlet. Flow rate measurements shall be taken at the same time as the concentration measurements.

(*3*) *Calculation of mass flow rate—for noncombustion, nonbiological treatment processes.* The mass flow rates of partially soluble and/or soluble HAP compounds entering and exiting the treatment process are calculated using Equations 44 and 45 of this subpart.

$$QMW_a = \frac{\rho}{p * 10^6}\left(\sum_{k=1}^{p}\left(Q_{a,k} * C_{T,a,k}\right)\right) \qquad \text{(Eq. 44)}$$

$$QMW_b = \frac{\rho}{p * 10^6}\left(\sum_{k=1}^{p}\left(Q_{b,k} * C_{T,b,k}\right)\right) \qquad \text{(Eq. 45)}$$

Where:

QMW_a, QMW_b = mass flow rate of partially soluble or soluble HAP compounds, average of all runs, in wastewater entering (QMW_a) or exiting (QMW_b) the treatment process, kg/hr

P = density of the wastewater, kg/m^3

$Q_{a,k}$, $Qb_{b,k}$ = volumetric flow rate of wastewater entering ($Q_{a,k}$) or exiting ($Q_{b,k}$) the treatment process during each run k, m^3/hr

$C_{T,a,k}$, $C_{T,b,k}$ = total concentration of partially soluble or soluble HAP compounds in wastewater entering ($C_{T,a,k}$) or exiting ($C_{T,b,k}$) the treatment process during each run k, ppmw

p = number of runs

k = identifier for a run

10^6 = conversion factor, mg/kg

(*4*) *Percent removal calculation for mass flow rate.* The percent mass removal across the treatment process shall be calculated as follows:

$$E = \frac{QMW_a - QMW_b}{QMW_a} \times 100 \qquad \text{(Eq. 46)}$$

Where:

E = removal or destruction efficiency of the treatment process, percent

QMW_a, QMW_b = mass flow rate of partially soluble or soluble HAP compounds in wastewater entering (QMW_a) and exiting (QMW_b) the treatment process, kg/hr (as calculated using Equations 44 and 45 of this subpart)

(*5*) *Compare mass removal efficiency to required efficiency.* Compare the mass removal efficiency (calculated in Equation 44 of this subpart) to the required efficiency as specified in § 63.1256(g)(8)(ii) or (9)(ii). If complying with § 63.1256(g)(8)(ii), compliance is demonstrated if the mass removal efficiency is 99 percent or greater. If complying with § 63.1256(g)(9)(ii), compliance is demonstrated if the mass removal efficiency is 90 percent or greater.

(D) *Combustion treatment processes: percent mass removal/destruction option.* This paragraph applies to performance tests that are conducted to demonstrate compliance of a combustion treatment process with the percent mass destruction limits specified in § 63.1256(g)(8)(ii) for partially soluble HAP compounds, and/or § 63.1256(g)(9)(ii) for soluble HAP compounds. The owner or operator shall comply with the requirements specified in paragraphs (e)(2)(iii)(D)(*1*) through (*8*) of this section.

(*1*) *Concentration in wastewater stream entering the combustion treatment process.* The concentration of partially soluble and/or soluble HAP compounds entering the treatment process shall be determined as provided in this paragraph. Wastewater samples shall be collected using sampling procedures which minimize loss of organic compounds during sample collection and analysis and maintain sample integrity per paragraph (b)(10)(v) of this section. The method shall be an analytical method for wastewater which has the compound of interest as a target analyte. Samples may be grab samples or composite samples. Samples shall be taken at approximately equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of three runs. Concentration measurements based on Method 305 of appendix A of this part shall be adjusted by dividing each concentration by the compound-specific Fm factor listed in Table 8 of this subpart. Concentration measurements based on methods other than Method 305 shall not be adjusted by the compound-specific Fm factor listed in Table 8 of this subpart.

(*2*) *Flow rate of wastewater entering the combustion treatment process.* The flow rate of the wastewater stream entering the combustion treatment process shall be determined using an inlet flow meter. Flow rate measurements shall be taken at the same time as the concentration measurements.

(*3*) *Calculation of mass flow rate in wastewater stream entering combustion treatment processes.* The mass flow rate of partially soluble and/or soluble HAP compounds entering the treatment process is calculated as follows:

$$QMW_a = \frac{\rho}{p * 10^6}\left(\sum_{k=1}^{p}\left(Q_{a,k} * C_{T,a,k}\right)\right) \qquad \text{(Eq. 47)}$$

Where:

QMW_a = mass flow rate of partially soluble or soluble HAP compounds entering the combustion unit, kg/hr

π= density of the wastewater stream, kg/m3

$Q_{a,k}$ = volumetric flow rate of wastewater entering the combustion unit during run k, m^3/hr

$C_{T,a,k}$ = total concentration of partially soluble or soluble HAP compounds in the wastewater stream entering the combustion unit during run k, ppmw

ρ = number of runs

k = identifier for a run

(*4*) *Concentration in vented gas stream exiting the combustion treatment process.* The concentration of partially soluble and/or soluble HAP compounds (or TOC) exiting the combustion treatment process in any vented gas stream shall be determined as provided in this paragraph. Samples may be grab samples or composite samples. Samples shall be taken at approximately equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of three runs. Concentration measurements shall be determined using Method 18 of 40 CFR part 60, appendix A. Alternatively, any other test method validated according to the procedures in Method 301 of appendix A of this part may be used.

(*5*) *Volumetric flow rate of vented gas stream exiting the combustion treatment process.* The volumetric flow rate of the vented gas stream exiting the combustion treatment process shall be determined using Method 2, 2A, 2C, or 2D of 40 CFR part 60, appendix A, as appropriate. Volumetric flow rate measurements shall be taken at the same time as the concentration measurements.

(*6*) *Calculation of mass flow rate of vented gas stream exiting combustion treatment processes.* The mass flow rate of partially soluble and/or soluble HAP compounds in a vented gas stream exiting the combustion treatment process shall be calculated as follows:

$$QMG_b = K_2 * \left(\sum_{i=1}^{n}\left(CG_{b,i} * MW_i\right)\right) * QG_b \qquad \text{(Eq. 48)}$$

where:

QMG_b = mass rate of TOC (minus methane and ethane) or total partially soluble and/or soluble HAP, in vented gas stream, exiting (QMG_b) the combustion device, dry basis, kg/hr

$CG_{b,i}$ = concentration of TOC (minus methane and ethane) or total partially soluble and/or soluble HAP, in vented gas stream, exiting ($CG_{b,i}$) the combustion device, dry basis, ppmv

MW_i = molecular weight of a component, kilogram/kilogram-mole

QG_b = flow rate of gas stream exiting (QG_b) the combustion device, dry standard cubic meters per hour

K_2 = constant, 41.57 x 10^{-9} (parts per million)$^{-1}$ (gram-mole per standard cubic meter) (kilogram/gram), where standard temperature (gram-mole per standard cubic meter) is 20°C

i = identifier for a compound

n = number of components in the sample

(*7*) *Destruction efficiency calculation.* The destruction efficiency of the combustion unit for partially soluble and/or soluble HAP compounds shall be calculated as follows:

$$E = \frac{QMW_a - QMG_b}{QMW_a} * 100 \qquad \text{(Eq. 49)}$$

Where:

E = destruction efficiency of partially soluble or soluble HAP compounds for the combustion unit, percent

QMW^{2a} = mass flow rate of partially soluble or soluble HAP compounds entering the combustion unit, kg/hr

QMG_b = mass flow rate of TOC (minus methane and ethane) or partially soluble and/or soluble HAP compounds in vented gas stream exiting the combustion treatment process, kg/hr

(*8*) *Compare mass destruction efficiency to required efficiency.* Compare the mass destruction efficiency (calculated in Equation 49 of this subpart) to the required efficiency as specified in § 63.1256(g)(8)(ii) or (g)(9)(ii). If complying with § 63.1256(g)(8)(ii), compliance is demonstrated if the mass destruction efficiency is 99 percent or greater. If complying with § 63.1256(g)(9)(ii), compliance is demonstrated if the mass destruction efficiency is 90 percent or greater.

(E) *Open or closed aerobic biological treatment processes: 95-percent mass destruction option.* This paragraph applies to performance tests that are conducted for open or closed aerobic biological treatment processes to demonstrate compliance with the 95-percent mass destruction provisions in § 63.1256(g)(11) for partially soluble and/or soluble HAP compounds.

(*1*) *Concentration in wastewater stream.* The concentration of partially soluble and/or soluble HAP as provided in this paragraph. Concentration measurements to determine E shall be taken as provided in paragraph (e)(2)(iii)(A)(*5*) of this section for a series of treatment processes. Wastewater samples shall be collected using sampling procedures which minimize loss of organic compounds during sample collection and analysis and maintain sample integrity per paragraph (b)(10)(v) of this section. The method shall be an analytical method for wastewater which has the compound of interest as a target analyte. Samples may

be grab samples or composite samples. Samples shall be taken at approximately equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of three runs. Concentration measurements based on Method 305 shall be adjusted by dividing each concentration by the compound-specific Fm factor listed in Table 8 of this subpart. Concentration measurements based on methods other than Method 305 shall not be adjusted by the compound-specific Fm factor listed in Table 8 of this subpart.

(*2*) *Flow rate.* Flow rate measurements to determine E shall be taken as provided in paragraph (e)(2)(iii)(A)(*5*) of this section for a series of treatment processes. Flow rate shall be determined using inlet and outlet flow measurement devices. Where the outlet flow is not greater than the inlet flow, a single flow measurement device may be used, and may be used at either the inlet or outlet. Flow rate measurements shall be taken at the same time as the concentration measurements.

(3) *Destruction efficiency.* The owner or operator shall comply with the provisions in either paragraph (e)(2)(iii)(E)(*3*)(*i*), (*ii*) or (*iii*) of this section. Compliance is demonstrated if the destruction efficiency, E, is equal to or greater than 95 percent.

(*i*) If the performance test is performed across the open or closed biological treatment system only, compliance is demonstrated if E is equal to F_{bio}, where E is the destruction efficiency of partially soluble and/or soluble HAP compounds and F_{bio} is the site-specific fraction of partially soluble and/or soluble HAP compounds biodegraded. F_{bio} shall be determined as specified in paragraph (e)(2)(iii)(E)(*4*) of this section and appendix C of subpart G of this part.

(*ii*) If compliance is being demonstrated in accordance with paragraphs (e)(2)(iii)(A)(*5*)(*i*) or (*ii*) of this section, the removal efficiency shall be calculated using Equation 49 of this subpart. When complying with paragraph (e)(2)(iii)(A)(*5*)(*i*) of this section, the series of nonbiological treatment processes comprise one treatment process segment. When complying with paragraph (e)(2)(iii)(A)(*5*)(*ii*) of this section, each nonbiological treatment process is a treatment process segment.

$$E = \frac{\text{Nonbiotreatment HAP load removal} + \text{Biotreatment HAP load removal}}{\text{Total influent HAP load}} = \frac{\left(\sum_{i=1}^{n}\left(QMW_{a,i} - QMW_{b,i}\right)\right) + QMW_{bio} * F_{bio}}{QMW_{all}} \quad \text{(Eq. 50)}$$

Where:

$QMW_{a,i}$ = the soluble and/or partially soluble HAP load entering a treatment process segment

$QMW_{b,i}$ = the soluble and/or partially soluble HAP load exiting a treatment process segment

n = the number of treatment process segments

i = identifier for a treatment process element

QMW_{bio} = the inlet load of soluble and/or partially soluble HAP to the biological treatment process. The inlet is defined in accordance with paragraph (e)(2)(iii)(A)(*6*) of this section. If complying with paragraph (e)(2)(iii)(A)(*6*)(*ii*) of this section, QMW_{bio} is equal to $QMW_{b,n}$

F_{bio} = site-specific fraction of soluble and/or partially soluble HAP compounds biodegraded. F_{bio} shall be determined as specified in paragraph (e)(2)(iii)(E)(*4*) of this section and Appendix C of subpart G of this part.

QMW_{all} = the total soluble and/or partially soluble HAP load to be treated.

(*4*) *Site-specific fraction biodegraded (F_{bio}).* The procedures used to determine the compound-specific kinetic parameters for use in calculating F_{bio} differ for the compounds listed in Tables 2 and 3 of this subpart. An owner or operator shall calculate F_{bio} as specified in either paragraph (e)(2)(iii)(E)(*4*)(*i*) or (*ii*) of this section.

(*i*) For biological treatment processes that do not meet the definition for enhanced biological treatment in § 63.1251, the owner or operator shall determine the F_{bio} for the compounds in Tables 2 and 3 of this subpart using any of the procedures in appendix C to part 63, except procedure 3 (inlet and outlet concentration measurements). (The symbol ''F_{bio}'' represents the site-specific fraction of an individual partially soluble or soluble HAP compound that is biodegraded.)

(*ii*) If the biological treatment process meets the definition of ''enhanced biological treatment process'' in § 63.1251, the owner or operator shall determine F_{bio} for the compounds in Table 2 of this subpart using any of the procedures specified in appendix C to part 63. The owner or operator shall calculate F_{bio} for the compounds in Table 3 of this subpart using the defaults for first order biodegradation rate constants (K_1) in Table 9 of this subpart and follow the procedure explained in Form III of appendix C, 40 CFR part 63, or any of the procedures specified in appendix C of 40 CFR part 63.

(F) *Open or closed aerobic biological treatment processes: percent removal for partially soluble or soluble HAP compounds.* This paragraph applies to the use of performance tests that are conducted for open or closed aerobic biological treatment processes to demonstrate compliance with the percent removal provisions for either partially soluble HAP compounds in § 63.1256(g)(8)(ii) or soluble HAP compounds in § 63.1256(g)(9)(ii) or (g)(12). The owner or operator shall comply with the provisions in paragraph (e)(2)(iii)(E) of this section, except that compliance with § 63.1256(g)(8)(ii) shall be demonstrated when E is equal to or greater than 99 percent, compliance with § 63.1256(g)(9)(ii) shall be demonstrated when E is equal to or greater than 90 percent, and compliance with § 63.1256(g)(12) shall be demonstrated when E is equal to or greater than 99 percent.

(G) *Closed biological treatment processes: percent mass removal option.* This paragraph applies to the use of performance tests that are conducted for closed biological treatment processes to demonstrate compliance with the percent removal provisions in §§ 63.1256(g)(8)(ii), (g)(9)(ii), (g)(11), or (g)(12). The owner or operator shall comply with the requirements specified in paragraphs (e)(2)(iii)(G) (*1*) through (*4*) of this section.

(*1*) Comply with the procedures specified in paragraphs (e)(2)(iii)(C) (*1*) through (*3*) of this section to determine characteristics of the wastewater entering the biological treatment unit, except that the term ''partially soluble and/or soluble HAP'' shall mean ''soluble HAP'' for the purposes of this section if the owner or operator is complying with § 63.1256(g)(9)(ii) or (g)(12), and it shall mean ''partially

soluble HAP'' if the owner or operator is complying with § 63.1256(g)(8)(ii).

(*2*) Comply with the procedures specified in paragraphs (e)(2)(iii)(D) (*4*) through (*6*) of this section to determine the characteristics of gas vent streams exiting a control device, with the differences noted in paragraphs (e)(2)(iii)(G)(*3*) (*i*) and (*ii*) of this section.

(*i*) The term ''partially soluble and/or soluble HAP'' shall mean ''soluble HAP'' for the purposes of this section if the owner or operator is complying with § 63.1256(g)(9)(ii) or (g)(12), and it shall mean ''partially soluble HAP'' if the owner or operator is complying with § 63.1256(g)(8)(ii).

(*ii*) The term ''combustion treatment process'' shall mean ''control device'' for the purposes of this section.

(*3*) *Percent removal/destruction calculation.* The percent removal and destruction across the treatment unit and any control device(s) shall be calculated using Equation 51 of this subpart:

$$E = \frac{\left(QMW_a - \left(QMW_b + QMG_b\right)\right)}{QMW_a} \qquad \text{(Eq. 51)}$$

Where:

E = removal and destruction efficiency of the treatment unit and control device(s), percent

QMW_a, QMW_b = mass flow rate of partially soluble or soluble HAP compounds in wastewater entering (QMW_a) and exiting (QMW_b) the treatment process, kilograms per hour (as calculated using Equations WW1 and WW2)

QMG_b = mass flow rate of partially soluble or soluble HAP compounds in vented gas stream exiting the combustion treatment process, kg/hr

(*4*) *Compare mass removal/destruction efficiency to required efficiency.* Compare the mass removal/destruction efficiency (calculated using Equation 51 of this subpart) to the required efficiency as specified in § 63.1256(g)(8)(ii), (g)(9)(ii), (g)(11), or (g)(12). If complying with § 63.1256(g)(8)(ii), compliance is demonstrated if the mass removal/destruction is 99 percent or greater. If complying with § 63.1256(g)(9)(ii), compliance is demonstrated if the mass removal/destruction efficiency is 90 percent or greater. If complying with § 63.1256(g)(11), compliance is demonstrated if the mass removal/destruction efficiency is 95 percent or greater. If complying with § 63.1256(g)(12), compliance is demonstrated if the mass removal/destruction efficiency is 99 percent or greater.

(3) *Compliance with control device provisions.* Except as provided in paragraph (e)(3)(iv) of this section, an owner or operator shall demonstrate that each control device or combination of control devices achieves the appropriate conditions specified in § 63.1256(h)(2) by using one or more of the methods specified in paragraphs (e)(3)(i), (ii), or (iii) of this section.

(i) *Performance test for control devices other than flares.* This paragraph applies to performance tests that are conducted to demonstrate compliance of a control device with the efficiency limits specified in § 63.1256(h)(2). If complying with the 95-percent reduction efficiency requirement, comply with the requirements specified in paragraphs (e)(3)(i) (A) through (J) of this section. If complying with the 20 ppm by volume requirement, comply with the requirements specified in paragraphs (e)(3)(i) (A) through (G) and (e)(3)(i)(J) of this section.

(A) *General.* The owner or operator shall comply with the general performance test provisions in paragraphs (e)(2)(iii)(A) (*1*) through (*4*) of this section, except that the term ''treatment unit'' shall mean ''control device'' for the purposes of this section.

(B) *Sampling sites.* Sampling sites shall be selected using Method 1 or 1A of 40 CFR part 60, appendix A, as appropriate. For determination of compliance with the 95 percent reduction requirement, sampling sites shall be located at the inlet and the outlet of the control device. For determination of compliance with the 20 ppmv limit, the sampling site shall be located at the outlet of the control device.

(C) *Concentration in gas stream entering or exiting the control device.* The concentration of total organic HAP or TOC in a gas stream shall be determined as provided in this paragraph. Samples may be grab samples or composite samples (i.e., integrated samples). Samples shall be taken at approximately equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of three runs. Concentration measurements shall be determined using Method 18 of 40 CFR part 60, appendix A. Alternatively, any other test method validated according to the procedures in Method 301 of appendix A of this part may be used.

(D) *Volumetric flow rate of gas stream entering or exiting the control device.* The volumetric flow rate of the gas stream shall be determined using Method 2, 2A, 2C, or 2D of 40 CFR part 60, appendix A, as appropriate. Volumetric flow rate measurements shall be taken at the same time as the concentration measurements.

(E) *Calculation of TOC concentration.* The owner or operator shall compute TOC in accordance with the procedures in paragraph (a)(2) of this section.

(F) *Calculation of total organic HAP concentration.* The owner or operator determining compliance based on total organic HAP concentration shall compute the total organic HAP concentration in accordance with the provisions in paragraph (a)(2) of this section.

(G) *Requirements for combustion control devices.* If the control device is a combustion device, the owner or operator shall correct TOC and organic HAP concentrations to 3 percent oxygen in accordance with the provisions in paragraph (a)(3) of this section, and demonstrate initial compliance with the requirements for halogenated streams in accordance with paragraph (a)(6) of this section.

(H) *Mass rate calculation.* The mass rate of either TOC (minus methane and ethane) or total organic HAP for each sample run shall be calculated using the following equations. Where the mass rate of TOC is being calculated, all organic compounds (minus methane and ethane) measured by methods specified in paragraph (e)(3)(i)(C) of this section are summed using Equations 52 and 53 of this subpart. Where the mass rate of total organic HAP is being calculated, only soluble and partially soluble HAP compounds shall be summed using Equations 52 and 53.

$$QMG_a = K_2 * \left(\sum_{i=1}^{n} \left(CG_{a,i} \right) * \left(MW_i \right) \right) * QG_a \qquad \text{(Eq. 52)}$$

$$QMG_b = K_2 * \left(\sum_{i=1}^{n} \left(CG_{b,i} \right) * \left(MW_i \right) \right) * QG_b \qquad \text{(Eq. 53)}$$

Where:

$CG_{a,i}$, $CG_{b,i}$ = concentration of TOC or total organic HAP, in vented gas stream, entering ($CG_{a,i}$) and exiting ($CG_{b,i}$) the control device, dry basis, ppmv

QMG_a, QMG_b = mass rate of TOC or total organic HAP, in vented gas stream, entering (QMG_a) and exiting (QMG_b) the control device, dry basis, kg/hr

M_{wi} = molecular weight of a component, kilogram/kilogram-mole

QG_a,QG_b = flow rate of gas stream entering (QG_a) and exiting (QG_b) the control device, dry standard cubic meters per hour

K_2 = constant, 41.57×10^{-9} (parts per million)$^{-1}$ (gram-mole per standard cubic meter) (kilogram/gram), where standard temperature (gram-mole per standard cubic meter) is 20°C

i = identifier for a compound

n = number of components in the sample

(I) *Percent reduction calculation.* The percent reduction in TOC or total organic HAP for each sample run shall be calculated using Equation 54 of this subpart:

$$E = \frac{QMG_a - QMG_b}{QMG_a} (100\%) \qquad \text{(Eq. 54)}$$

where:

E = destruction efficiency of control device, percent

QMG_a,QMG_b = mass rate of TOC or total organic HAP, in vented gas stream entering and exiting (QMG_b) the control device, dry basis, kilograms per hour

(J) *Compare mass destruction efficiency to required efficiency.* If complying with the 95-percent reduction efficiency requirement, compliance is demonstrated if the mass destruction efficiency (calculated in Equation 51 of this subpart) is 95 percent or greater. If complying with the 20 ppmv limit, compliance is demonstrated if the outlet TOC concentration is 20 ppmv, or less.

(ii) *Design evaluation.* A design evaluation conducted in accordance with the provisions in paragraph (a)(1) of this section. Compounds that meet the requirements specified in paragraph (e)(2)(iii)(A)(4) of this section are not required to be included in the design evaluation.

(iii) *Compliance demonstration for flares.* When a flare is used to comply with § 63.1256(h), the owner or operator shall comply with the flare provisions in § 63.11(b). An owner or operator is not required to conduct a performance test to determine percent emission reduction or outlet organic HAP or TOC concentration when a flare is used.

(iv) *Exemptions from compliance demonstrations.* An owner or operator using any control device specified in paragraph (a)(4) of this section is exempt from the requirements in paragraphs (e)(3)(i) through (e)(3)(iii) of this section and from the requirements in § 63.6(f).

(f) *Pollution prevention alternative standard.* The owner or operator shall demonstrate compliance with § 63.1252(e)(2) using the procedures described in paragraph (f)(1) and (f)(3) of this section. The owner or operator shall demonstrate compliance with § 63.1252(e)(3) using the procedures described in paragraphs (f)(2) and (f)(3) of this section.

(1) Compliance is demonstrated when the annual kg/kg factor, calculated according to the procedure in paragraphs (f)(1)(i) and (iii) of this section, is reduced by at least 75 percent as calculated according to the procedure in paragraph (f)(1)(i) and (ii) of this section.

(i) The production-indexed HAP consumption factors shall be calculated by dividing annual consumption of total HAP by the annual production rate, per process. The production-indexed total VOC consumption factor shall be calculated by dividing annual consumption of total VOC by the annual production rate, per process.

(ii) The baseline factor is calculated from yearly production and consumption data for the first 3-year period in which the PMPU was operational, beginning no earlier than the 1987 calendar year, or for a minimum period of 12 months from startup of the process until the present in which the PMPU was operational and data are available, beginning no earlier than the 1987 calendar year.

(iii) The annual factor is calculated on the following bases:

(A) For continuous processes, the annual factor shall be calculated every 30 days for the 12-month period preceding the 30th day (30-day rolling average).

(B) For batch processes, the annual factor shall be calculated every 10 batches for the 12-month period preceding the 10th batch (10-batch rolling average). The annual factor shall be calculated every 5 batches if the number of batches is less than 10 for the 12-month period preceding the 10th batch and shall be calculated every year if the number of batches is less than 5 for the 12-month period preceding the 5th batch.

(2) Compliance is demonstrated when the requirements of paragraphs (f)(2)(i) through (iv) of this section are met.

(i) The annual kg/kg factor, calculated according to the procedure in paragraphs (f)(1)(i) and (f)(1)(iii) of this section, is reduced to a value equal to or less than 50 percent of the baseline factor calculated according to the procedure in paragraphs (f)(1)(i) and (ii) of this section.

(ii) The yearly reductions associated with add-on controls that meet the criteria of §§ 63.1252(h)(3)(ii)(A) through (D) must be equal to or greater than the amounts calculated in paragraphs (f)(2)(ii)(A) and (B) of this section:

(A) The mass of HAP calculated using Equation 55 of this subpart:

$$[\text{kg reduced}]_a = [\text{kg/kg}]_b(0.75 - P_R)[\text{kg produced}]_a \quad \text{(Eq. 55)}$$

Where:

$[\text{kg/kg}]_b$ = the baseline production-indexed HAP consumption factor, in kg/kg

$[\text{kg produced}]_a$ = the annual HAP production rate, in kg/yr

$[\text{kg reduced}]_a$ = the annual reduction required by add-on controls, in kg/yr

P_R = the fractional reduction in the annual kg/kg factor achieved using pollution prevention where P_R is ≥0.5

(B) The mass of VOC calculated using Equation 56 of this subpart:

$$VOC_{reduced} = (VF_{base} - VF_P - VF_{annual}) \times M_{prod} \quad \text{(Eq. 56)}$$

Where:

$VOC_{reduced}$ = required VOC emission reduction from add-on controls, kg/yr

VF_{base} = baseline VOC factor, kg VOC emitted/kg production

VF_p = reduction in VOC factor achieved by pollution prevention, kg VOC emitted/kg production

VF_{annual} = target annual VOC factor, kg VOC emitted/kg production

M_{prod} = production rate, kg/yr

(iii) Demonstration that the criteria in § 63.1252(e)(3)(ii)(A) through (D) are met shall be accomplished through a description of the control device and of the material streams entering and exiting the control device.

(iv) The annual reduction achieved by the add-on control shall be quantified using the methods described in § 63.1257(d).

(3) Each owner or operator of a PMPU complying with the P2 standard shall prepare a P2 demonstration summary that shall contain, at a minimum, the following information:

(i) Descriptions of the methodologies and forms used to measure and record daily consumption of HAP compounds reduced as part of the P2 standard.

(ii) Descriptions of the methodologies and forms used to measure and record daily production of products which are included in the P2 standard.

(iii) Supporting documentation for the descriptions provided in paragraphs (f)(3)(i) and (ii) including, but not limited to, operator log sheets and copies of daily, monthly, and annual inventories of materials and products.

(g) *Compliance with storage tank provisions by using emissions averaging.* An owner or operator with two or more affected storage tanks may demonstrate compliance with § 63.1253, as applicable, by fulfilling the requirements of paragraphs (g)(1) through (4) of this section.

(1) The owner or operator shall develop and submit for approval an Implementation Plan containing all the information required in § 63.1259(e) 6 months prior to the compliance date of the standard. The Administrator shall have 90 days to approve or disapprove the emissions averaging plan after which time the plan shall be considered approved.

(2) The annual mass rate of total organic HAP (E^{Ti}, E^{To}) shall be calculated for each storage tank included in the emissions average using the procedures specified in paragraph (c)(1), (2), or (3) of this section.

(3) Equations 57 and 58 of this subpart shall be used to calculate total HAP emissions for those tanks subject to § 63.1253(b) or (c):

$$E_{Ti} = \sum_{j=1}^{n} E_{ij} \quad \text{(Eq. 57)}$$

$$E_{To} = \sum_{j=1}^{n} E_{oj} \quad \text{(Eq. 58)}$$

Where:

E_{ij} = yearly mass rate of total HAP at the inlet of the control device for tank j

E_{oj} = yearly mass rate of total HAP at the outlet of the control device for tank j

ET_i = total yearly uncontrolled HAP emissions

E_{To} = total yearly actual HAP emissions

$_n$ = number of tanks included in the emissions average

(4) The overall percent reduction efficiency shall be calculated as follows:

$$R = \frac{E_{Ti} - D\,E_{To}}{E_{Ti}} 100\% \quad \text{(Eq. 59)}$$

where:

R = overall percent reduction efficiency

D = discount factor = 1.1 for all controlled storage tanks

(h) *Compliance with process vent provisions by using emissions averaging.* An owner or operator with two or more affected processes complying with § 63.1254 by using emissions averaging shall demonstrate compliance with paragraphs (h)(1), (2) and (3) of this section.

(1) The owner or operator shall develop and submit for approval an Implementation Plan at least 6 months prior to the compliance date of the standard containing all the information required in § 63.1259(e). The Administrator shall have 90 days to approve or disapprove the emissions averaging plan. The plan shall be considered approved if the Administrator either approves the plan in writing, or fails to disapprove the plan in writing. The 90-day period shall begin when the Administrator receives the request. If the request is denied, the owner or operator must still be in compliance with the standard by the compliance date.

(2) Owners or operators shall calculate uncontrolled and controlled emissions of HAP by using the methods specified in paragraph (d)(2) and (3) of this section for each process included in the emissions average.

(i) Equations 60 and 61 of this subpart shall be used to calculate total HAP emissions:

$$E_{TU} = \sum_{j=1}^{n} E_{Ui} \quad \text{(Eq. 60)}$$

where:

E_{Ui} = yearly uncontrolled emissions from process I

E_{Ci} = yearly actual emissions for process I

E_{TU} = total yearly uncontrolled emissions

E_{TC} = total yearly actual emissions

n = number of processes included in the emissions average

(3) The overall percent reduction efficiency shall be calculated using Equation 62 of this subpart:

$$E_{TC} = \sum_{j=1}^{n} E_{Ci} \qquad \text{(Eq. 61)}$$

$$R = \frac{E_{TU} - D\,E_{TC}}{E_{TU}}\,(100\%) \qquad \text{(Eq. 62)}$$

where:
R = overall percent reduction efficiency
D = discount factor = 1.1 for all controlled emission points

§ 63.1258 Monitoring Requirements.

(a) The owner or operator of any existing, new, or reconstructed affected source shall provide evidence of continued compliance with the standard as specified in this section. During the initial compliance demonstration, maximum or minimum operating parameter levels, as appropriate, shall be established for emission sources that will indicate the source is in compliance. Test data, calculations, or information from the evaluation of the control device design shall be used to establish the operating parameter level.

(b) *Monitoring for control devices.* (1) *Parameters to monitor.* Except as specified in paragraph (b)(1)(i) of this section, for each control device, the owner or operator shall install and operate monitoring devices and operate within the established parameter levels to ensure continued compliance with the standard. Monitoring parameters are specified for control scenarios in Table 4 of this subpart and in paragraphs (b)(1)(ii) through (xi) of this section.

(i) *Periodic verification.* For control devices that control vent streams totaling less than 1 ton/yr HAP emissions, before control, monitoring shall consist of a daily verification that the device is operating properly. If the control device is used to control batch process vents alone or in combination with other streams, the verification may be on a per batch basis. This verification shall include, but not be limited to, a daily or per batch demonstration that the unit is working as designed and may include the daily measurements of the parameters described in (b)(1)(ii) through (x) of this section. This demonstration shall be included in the Precompliance report, to be submitted 6 months prior to the compliance date of the standard.

(ii) *Scrubbers.* For affected sources using liquid scrubbers, the owner or operator shall establish a minimum scrubber liquid flow rate or pressure drop as a site-specific operating parameter which must be measured and recorded every 15 minutes during the period in which the scrubber is functioning in achieving the HAP removal required by this subpart. If the scrubber uses a caustic solution to remove acid emissions, the owner or operator shall establish a minimum pH of the effluent scrubber liquid as a site-specific operating parameter which must be monitored at least once a day. The minimum scrubber flowrate or pressure drop shall be based on the conditions anticipated under worst-case conditions, as defined in § 63.1257(b)(8)(i).

(A) The monitoring device used to determine the pressure drop shall be certified by the manufacturer to be accurate to within a gage pressure of ±10 percent of the maximum pressure drop measured.

(B) The monitoring device used for measurement of scrubber liquid flowrate shall be certified by the manufacturer to be accurate within ±10 percent of the design scrubber liquid flowrate.

(C) The monitoring device shall be calibrated annually.

(iii) *Condensers.* For each condenser, the owner or operator shall establish the maximum condenser outlet gas temperature as a site-specific operating parameter which must be measured and recorded at least every 15 minutes during the period in which the condenser is functioning in achieving the HAP removal required by this subpart.

(A) The temperature monitoring device must be accurate to within ±2 percent of the temperature measured in degrees Celsius or ±2.5°C, whichever is greater.

(B) The temperature monitoring device must be calibrated annually.

(iv) *Regenerative carbon adsorbers.* For each regenerative carbon adsorber, the owner or operator shall comply with the provisions in paragraphs (b)(1)(iv)(A) through (F) of this section.

(A) Establish the regeneration cycle characteristics specified in paragraphs (b)(1)(iv)(A)(*1*) through (*4*) of this section under worst-case conditions, as defined in § 63.1257(b)(8)(i).

(*1*) Minimum regeneration frequency (i.e., operating time since last regeneration);

(*2*) Minimum temperature to which the bed is heated during regeneration;

(*3*) Maximum temperature to which the bed is cooled, measured within 15 minutes of completing the cooling phase; and

(*4*) Minimum regeneration stream flow.

(B) Monitor and record the regeneration cycle characteristics specified in paragraphs (b)(1)(iv)(B)(*1*) through (*4*) of this section for each regeneration cycle.

(*1*) Regeneration frequency (operating time since end of last regeneration);

(*2*) Temperature to which the bed is heated during regeneration;

(*3*) Temperature to which the bed is cooled, measured within 15 minutes of the completion of the cooling phase; and

(*4*) Regeneration stream flow.

(C) Use a temperature monitoring device that is accurate to within ±2 percent of the temperature measured in degrees Celsius or ± 2.5 °C, whichever is greater.

(D) Use a regeneration stream flow monitoring device capable of recording the total regeneration stream flow to within ± 10 percent of the established value (i.e., accurate to within ± 10 percent of the reading).

(E) Calibrate the temperature and flow monitoring devices annually.

(F) Conduct an annual check for bed poisoning in accordance with manufacturer's specifications.

(v) *Nonregenerative carbon adsorbers.* For each nonregenerative carbon adsorber, the owner or operator shall establish and monitor the maximum time interval between replacement based on the conditions anticipated under worst-case, as defined in § 63.1257(b)(8)(i).

(vi) *Flares.* For each flare, the presence of the pilot flame shall be monitored every 15 minutes during the period in which the flare is functioning in achieving the HAP removal required by this subpart.

(vii) *Thermal incinerators.* For each thermal incinerator, the owner or operator shall establish the minimum temperature of the gases exiting the combustion chamber as the site-specific operating parameter which must be measured and recorded at least once every 15 minutes during the period in which the combustion device is functioning in achieving the HAP removal required by this subpart.

(A) The temperature monitoring device must be accurate to within ± 0.75 percent of the temperature measured in degrees Celsius or ± 2.5 °C, whichever is greater.

(B) The monitoring device must be calibrated annually.

(viii) *Catalytic incinerators.* For each catalytic incinerator, the owner or operator shall monitor the temperature of the gas stream immediately before and after the catalyst bed. The owner or operator shall establish the minimum temperature of the gas stream immediately before the catalyst bed and the minimum temperature difference across the catalyst bed as the site-specific operating parameter which must be monitored and recorded at least

once every 15 minutes during the period in which the catalytic incinerator is functioning in achieving the HAP removal required by this subpart.

(A) The temperature monitoring devices must be accurate to within ± 0.75 percent of the temperature measured in degrees Celsius or ± 2.5 °C, whichever is greater.

(B) The temperature monitoring devices must be calibrated annually.

(ix) *Process heaters and boilers.* (A) Except as specified in paragraph (b)(1)(ix)(B) of this section, for each boiler or process heater, the owner or operator shall establish the minimum temperature of the gases exiting the combustion chamber as the site-specific operating parameter which must be monitored and recorded at least once every 15 minutes during the period in which the boiler or process heater is functioning in achieving the HAP removal required by this subpart.

(*1*) The temperature monitoring device must be accurate to within ±0.75 percent of the temperature measured in degrees Celsius or ±2.5°C, whichever is greater.

(*2*) The temperature monitoring device must be calibrated annually.

(B) The owner or operator is exempt from the monitoring requirements specified in paragraph (b)(1)(ix)(A) of this section if either:

(*1*) All vent streams are introduced with primary fuel; or

(*2*) The design heat input capacity of the boiler or process heater is 44 megawatts or greater.

(x) *Continuous emission monitor.* As an alternative to the parameters specified in paragraphs (b)(1)(ii) through (ix) of this section, an owner or operator may monitor and record the outlet HAP concentration or both the outlet TOC concentration and outlet hydrogen halide and halogen concentration every 15 minutes during the period in which the control device is functioning in achieving the HAP removal required by this subpart. The owner or operator need not monitor the hydrogen halide and halogen concentration if, based on process knowledge, the owner or operator determines that the emission stream does not contain hydrogen halides or halogens. The HAP or TOC monitor must meet the requirements of Performance Specification 8 or 9 of appendix B of part 60 and must be installed, calibrated, and maintained, according to § 63.8. As part of the QA/QC Plan, calibration of the device must include, at a minimum, quarterly cylinder gas audits.

(xi) *CVS visual inspections.* The owner or operator shall perform monthly visual inspections of each closed vent system as specified in § 63.1252(b).

(2) *Averaging periods.* Averaging periods for parametric monitoring levels shall be established according to paragraphs (b)(2)(i) through (iii) of this section.

(i) Except as provided in paragraph (b)(2)(iii) of this section, a daily (24-hour) or block average shall be calculated as the average of all values for a monitored parameter level set according to the procedures in (b)(3)(iii) of this section recorded during the operating day or block.

(ii) The operating day or block shall be defined in the Notification of Compliance Status report. The daily average may be from midnight to midnight or another continuous 24-hour period. The block average is limited to a period of time that is, at a maximum, equal to the time from the beginning to end of a batch process.

(iii) Monitoring values taken during periods in which the control devices are not functioning in controlling emissions, as indicated by periods of no flow, shall not be considered in the averages. Where flow to the device could be intermittent, the owner or operator shall install, calibrate and operate a flow indicator at the inlet or outlet of the control device to identify periods of no flow.

(3) *Procedures for setting parameter levels for control devices used to control emissions from process vents.* (i) *Small control devices.* Except as provided in paragraph (b)(1)(i) of this section, for devices controlling less than 10 tons per year of HAP for which a performance test is not required, the parametric levels shall be set based on the design evaluation required in § 63.1257(d)(3)(i). If a performance test is conducted, the monitoring parameter level shall be established according to the procedures in (b)(3)(ii) of this section.

(ii) *Large control devices.* For devices controlling greater than 10 tons per year of HAP for which a performance test is required, the parameter level must be established as follows:

(A) If the operating parameter level to be established is a maximum, it must be based on the average of the values from each of the three test runs.

(B) If the operating parameter level to be established is a minimum, it must be based on the average of the values from each of the three test runs.

(C) The owner or operator may establish the parametric monitoring level(s) based on the performance test supplemented by engineering assessments and manufacturer's recommendations. Performance testing is not required to be conducted over the entire range of expected parameter values. The rationale for the specific level for each parameter, including any data and calculations used to develop the level(s) and a description of why the level indicates proper operation of the control device shall be provided in the Precompliance report. The procedures specified in this section have not been approved by the Administrator and determination of the parametric monitoring level using these procedures is subject to review and approval by the Administrator.

(iii) *Parameters for control devices controlling batch process vents.* For devices controlling batch process vents alone or in combination with other streams, the parameter level(s) shall be established in accordance with paragraph (b)(3)(iii)(A) or (B) of this section.

(A) If more than one batch emission episode has been selected to be controlled, a single level for the batch process(es) shall be determined from the initial compliance demonstration.

(B) Instead of establishing a single level for the batch process(es), as described in paragraph (b)(3)(iii)(A) of this section, an owner or operator may establish separate levels for each batch emission episode, selected to be controlled. If separate monitoring levels are established, the owner or operator must provide a record indicating at what point in the daily schedule or log of processes required to be recorded per the requirements of § 63.1259(b)(9) the parameter being monitored changes levels and must record at least one reading of the new parameter level, even if the duration of monitoring for the new parameter is less than 15-minutes.

(4) *Request approval to monitor alternative parameters.* An owner or operator may request approval to monitor parameters other than those required by paragraphs (b)(1)(ii) through (ix) of this section. The request shall be submitted according to the procedures specified in § 63.8(f) or included in the Precompliance report.

(5) *Monitoring for the alternative standards.* For control devices that are used to comply with the provisions of § 63.1253(d) or 63.1254(c), the owner or operator shall monitor and record the outlet TOC concentration and the outlet hydrogen halide and halogen concentration every 15 minutes during the period in which the device is functioning in achieving the HAP removal required by this subpart. A TOC monitor meeting the requirements of Performance Specification 8 or 9 of appendix B of part 60 shall be installed, calibrated, and maintained, according to § 63.8. The owner or operator need not

monitor the hydrogen halide and halogen concentration if, based on process knowledge, the owner or operator determines that the emission stream does not contain hydrogen halides or halogens.

(6) *Exceedances of operating parameters.* An exceedance of an operating parameter is defined as one of the following:

(i) If the parameter, averaged over the operating day or block, is below a minimum value established during the initial compliance demonstration.

(ii) If the parameter, averaged over the operating day or block, is above the maximum value established during the initial compliance demonstration.

(iii) Each loss of pilot flame for flares.

(7) *Excursions.* Excursions are defined by either of the two cases listed in paragraphs (b)(7)(i) or (ii) of this section.

(i) When the period of control device operation is 4 hours or greater in an operating day and monitoring data are insufficient to constitute a valid hour of data, as defined in paragraph (b)(7)(iii) of this section, for at least 75 percent of the operating hours.

(ii) When the period of control device operation is less than 4 hours in an operating day and more than one of the hours during the period of operation does not constitute a valid hour of data due to insufficient monitoring data.

(iii) Monitoring data are insufficient to constitute a valid hour of data, as used in paragraphs (b)(7)(i) and (ii) of this section, if measured values are unavailable for any of the required 15-minute periods within the hour.

(8) *Violations.* Exceedances of parameters monitored according to the provisions of paragraphs (b)(1)(ii) and (iv) through (ix) of this section or excursions as defined by paragraphs (b)(7)(i) through (iii) of this section constitute violations of the operating limit according to paragraphs (b)(8)(i), (ii), and (iv) of this section. Exceedances of the temperature limit monitored according to the provisions of paragraph (b)(1)(iii) of this section or exceedances of the outlet concentrations monitored according to the provisions of paragraph (b)(1)(x) of this section constitute violations of the emission limit according to paragraphs (b)(8)(i), (ii), and (iv) of this section. Exceedances of the outlet concentrations monitored according to the provisions of paragraph (b)(5) of this section constitute violations of the emission limit according to the provisions of paragraphs (b)(8)(iii) and (iv) of this section.

(i) Except as provided in paragraph (b)(8)(iv) of this section, for episodes occurring more than once per day, exceedances of established parameter limits or excursions will result in no more than one violation per operating day for each monitored item of equipment utilized in the process.

(ii) Except as provided in paragraph (b)(8)(iv) of this section, for control devices used for more than one process in the course of an operating day, exceedances or excursions will result in no more than one violation per operating day, per control device, for each process for which the control device is in service.

(iii) Except as provided in paragraph (b)(8)(iv) of this section, exceedances of the 20 ppmv TOC outlet emission limit, averaged over the operating day, will result in no more than one violation per day per control device. Except as provided in paragraph (b)(8)(iv) of this section, exceedances of the 20 ppmv hydrogen halide or halogen outlet emission limit, averaged over the operating day, will result in no more than one violation per day per control device.

(iv) Periods of time when monitoring measurements exceed the parameter values as well as periods of inadequate monitoring data do not constitute a violation if they occur during a startup, shutdown, or malfunction, and the facility follows its startup, shutdown, and malfunction plan.

(c) *Monitoring for emission limits.* The owner or operator of any affected source complying with the provisions of § 63.1254(a)(1) shall demonstrate continuous compliance with the 2,000 lb/yr emission limits by calculating daily a 365-day rolling summation of emissions. For owners and operators opting to switch compliance strategy from the 93 percent control requirement to the 2,000 lb/yr compliance method, as decribed in § 63.1254(a), the rolling average must include emissions from the past 365 days. Each day that the total emissions per process exceeds 2,000 lb/yr will be considered a violation of the emission limit.

(d) *Monitoring for equipment leaks.* The owner or operator of any affected source complying with the requirements of § 63.1255 of this subpart shall meet the monitoring requirements described § 63.1255 of this subpart.

(e) *Pollution prevention.* The owner or operator of any affected source that chooses to comply with the requirements of §§ 63.1252(e)(2) and (3) shall calculate a yearly rolling average of kg HAP consumption per kg production and kg VOC consumption per kg production every month or every 10 batches. Each rolling average kg/kg factor that exceeds the value established in § 63.1257(f)(1)(ii) will be considered a violation of the emission limit.

(f) *Emissions averaging.* The owner or operator of any affected source that chooses to comply with the requirements of § 63.1252(d) shall meet all monitoring requirements specified in paragraphs (b)(1) and (3) of this section, as applicable, for all processes and storage tanks included in the emissions average.

(g) *Inspection and monitoring of waste management units and treatment processes.* (1) For each wastewater tank, surface impoundment, container, individual drain system, and oil-water separator that receives, manages, or treats wastewater, a residual removed from wastewater, a recycled wastewater, or a recycled residual removed from wastewater, the owner or operator shall comply with the inspection requirements specified in Table 7 of this subpart.

(2) For each biological treatment unit used to comply with § 63.1256(g), the owner or operator shall monitor TSS, BOD, and the biomass concentration at a frequency approved by the permitting authority and using methods approved by the permitting authority. The owner or operator may request approval to monitor other parameters. The request shall be submitted in the Precompliance report according to the procedures specified in § 63.1260(e), and shall include a description of planned reporting and recordkeeping procedures. The owner or operator shall include as part of the submittal the basis for the selected monitoring frequencies and the methods that will be used. The Administrator will specify appropriate reporting and recordkeeping requirements as part of the review of the permit application or by other appropriate means.

(3) For nonbiological treatment units, the owner or operator shall request approval to monitor appropriate parameters that demonstrate proper operation of the selected treatment process. The request shall be submitted in the Precompliance report according to the procedures specified in § 63.1260(e), and shall include a description of planned reporting and recordkeeping procedures. The Administrator will specify appropriate reporting and recordkeeping requirements as part of the review of the permit application or by other appropriate means.

(h) *Leak inspection provisions for vapor suppression equipment.* (1) Except as provided in paragraph (h)(9) of this section, for each vapor collection system, closed-vent system, fixed roof, cover, or enclosure required to comply

with this section, the owner or operator shall comply with the requirements of paragraphs (h)(2) through (8) of this section.

(2) Except as provided in paragraphs (h)(6) and (7) of this section, each vapor collection system and closed-vent system shall be inspected according to the procedures and schedule specified in paragraphs (h)(2)(i) and (ii) of this section and each fixed roof, cover, and enclosure shall be inspected according to the procedures and schedule specified in paragraph (h)(2)(iii) of this section.

(i) If the vapor collection system or closed-vent system is constructed of hard-piping, the owner or operator shall:

(A) Conduct an initial inspection according to the procedures in paragraph (h)(3) of this section, and

(B) Conduct annual visual inspections for visible, audible, or olfactory indications of leaks.

(ii) If the vapor collection system or closed-vent system is constructed of ductwork, the owner or operator shall:

(A) Conduct an initial inspection according to the procedures in paragraph (h)(3) of this section, and

(B) Conduct annual inspections according to the procedures in paragraph (h)(3) of this section.

(C) Conduct annual visual inspections for visible, audible, or olfactory indications of leaks.

(iii) For each fixed roof, cover, and enclosure, the owner or operator shall:

(A) Conduct an initial inspection according to the procedures in paragraph (h)(3) of this section, and

(B) Conduct semiannual visual inspections for visible, audible, or olfactory indications of leaks.

(3) Each vapor collection system, closed-vent system, fixed roof, cover, and enclosure shall be inspected according to the procedures specified in paragraphs (h)(3)(i) through (v) of this section.

(i) Inspections shall be conducted in accordance with Method 21 of 40 CFR part 60, appendix A.

(ii) *Detection instrument performance criteria.* (A) Except as provided in paragraph (h)(3)(ii)(B) of this section, the detection instrument shall meet the performance criteria of Method 21 of 40 CFR part 60, appendix A, except the instrument response factor criteria in section 3.1.2(a) of Method 21 shall be for the average composition of the process fluid not each individual VOC in the stream. For process streams that contain nitrogen, air, or other inerts which are not organic HAP or VOC, the average stream response factor shall be calculated on an inert-free basis.

(B) If no instrument is available at the plant site that will meet the performance criteria specified in paragraph (h)(3)(ii)(A) of this section, the instrument readings may be adjusted by multiplying by the average response factor of the process fluid, calculated on an inert-free basis as described in paragraph (h)(3)(ii)(A) of this section.

(iii) The detection instrument shall be calibrated before use on each day of its use by the procedures specified in Method 21 of 40 CFR part 60, appendix A.

(iv) Calibration gases shall be as follows:

(A) Zero air (less than 10 parts per million hydrocarbon in air); and

(B) Mixtures of methane in air at a concentration less than 10,000 parts per million. A calibration gas other than methane in air may be used if the instrument does not respond to methane or if the instrument does not meet the performance criteria specified in paragraph (h)(2)(ii)(A) of this section. In such cases, the calibration gas may be a mixture of one or more of the compounds to be measured in air.

(v) An owner or operator may elect to adjust or not adjust instrument readings for background. If an owner or operator elects to not adjust readings for background, all such instrument readings shall be compared directly to the applicable leak definition to determine whether there is a leak. If an owner or operator elects to adjust instrument readings for background, the owner or operator shall measure background concentration using the procedures in § 63.180(b) and (c). The owner or operator shall subtract background reading from the maximum concentration indicated by the instrument.

(vi) The background level shall be determined according to the procedures in Method 21 of 40 CFR part 60 appendix A.

(vii) The arithmetic difference between the maximum concentration indicated by the instrument and the background level shall be compared with 500 parts per million for determining compliance.

(4) Leaks, as indicated by an instrument reading greater than 500 parts per million above background or by visual inspections, shall be repaired as soon as practicable, except as provided in paragraph (h)(5) of this section.

(i) A first attempt at repair shall be made no later than 5 calendar days after the leak is detected.

(ii) Repair shall be completed no later than 15 calendar days after the leak is detected, except as provided in paragraph (h)(4)(iii) of this section.

(iii) For leaks found in vapor collection systems used for transfer operations, repairs shall be completed no later than 15 calendar days after the leak is detected or at the beginning of the next transfer loading operation, whichever is later.

(5) Delay of repair of a vapor collection system, closed-vent system, fixed roof, cover, or enclosure for which leaks have been detected is allowed if the repair is technically infeasible without a shutdown, as defined in § 63.1251, or if the owner or operator determines that emissions resulting from immediate repair would be greater than the fugitive emissions likely to result from delay of repair. Repair of such equipment shall be complete by the end of the next shutdown.

(6) Any parts of the vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated, as described in paragraph (h)(8)(i) of this section, as unsafe to inspect are exempt from the inspection requirements of paragraphs (h)(2)(i), (ii), and (iii) of this section if:

(i) The owner or operator determines that the equipment is unsafe to inspect because inspecting personnel would be exposed to an imminent or potential danger as a consequence of complying with paragraphs (h)(2)(i), (ii), or (iii) of this section; and

(ii) The owner or operator has a written plan that requires inspection of the equipment as frequently as practicable during safe-to-inspect times.

(7) Any parts of the vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated, as described in paragraph (h)(8)(ii) of this section, as difficult to inspect are exempt from the inspection requirements of paragraphs (h)(2)(i), (ii), and (iii)(A) of this section if:

(i) The owner or operator determines that the equipment cannot be inspected without elevating the inspecting personnel more than 2 meters above a support surface; and

(ii) The owner or operator has a written plan that requires inspection of the equipment at least once every 5 years.

(8) Records shall be maintained as specified in § 63.1259(i) (4) through (9).

(9) If a closed-vent system subject to this section is also subject to the equipment leak provisions of § 63.1255, the owner or operator shall comply with the provisions of § 63.1255 and is exempt from the requirements of this section.

§ 63.1259 Recordkeeping requirements.

(a) *Requirements of subpart A of this part.* The owner or operator of an affected source shall comply with the recordkeeping requirements in subpart A of this part as specified in Table 1 of this subpart and in paragraphs (a)(1) through (5) of this section.

(1) *Data retention.* Each owner or operator of an affected source shall keep copies of all records and reports required by this subpart for at least 5 years, as specified in § 63.10(b)(1).

(2) *Records of applicability determinations.* The owner or operator of a stationary source that is not subject to this subpart shall keep a record of the applicability determination, as specified in § 63.10(b)(3).

(3) *Startup, shutdown, and malfunction plan.* The owner or operator of an affected source shall develop and implement a written startup, shutdown, and malfunction plan as specified in § 63.6(e)(3). This plan shall describe, in detail, procedures for operating and maintaining the affected source during periods of startup, shutdown, and malfunction and a program for corrective action for malfunctioning process, air pollution control, and monitoring equipment used to comply with this subpart. The owner or operator of an affected source shall keep the current and superseded versions of this plan onsite, as specified in § 63.6(e)(3)(v). The owner or operator shall keep the startup, shutdown, and malfunction records specified in paragraphs (b)(3)(i) through (iii) of this section. Reports related to the plan shall be submitted as specified in § 63.1260(i).

(i) The owner or operator shall record the occurrence and duration of each malfunction of air pollution control equipment used to comply with this subpart, as specified in § 63.6(e)(3)(iii).

(ii) The owner or operator shall record the occurrence and duration of each malfunction of continuous monitoring systems used to comply with this subpart.

(iii) For each startup, shutdown, or malfunction, the owner or operator shall record all information necessary to demonstrate that the procedures specified in the affected source's startup, shutdown, and malfunction plan were followed, as specified in § 63.6(e)(3)(iii); alternatively, the owner or operator shall record any actions taken that are not consistent with the plan, as specified in § 63.6(e)(3)(iv).

(4) *Recordkeeping requirements for sources with continuous monitoring systems.* The owner or operator of an affected source who elects to install a continuous monitoring system shall maintain records specified in § 63.10(c)(1) through (14).

(5) *Application for approval of construction or reconstruction.* For new affected sources, each owner or operator shall comply with the provisions in § 63.5 regarding construction and reconstruction, excluding the provisions specified in § 63.5(d)(1)(ii)(H), (d)(2), and (d)(3)(ii).

(b) *Records of equipment operation.* The owner or operator must keep the following records up-to-date and readily accessible:

(1) Each measurement of a control device operating parameter monitored in accordance with § 63.1258 and each measurement of a treatment process parameter monitored in accordance with § 63.1258(g)(2) and (3).

(2) For processes subject to § 63.1252(e), records of consumption, production, and the rolling average values of the production-indexed HAP and VOC consumption factors.

(3) For each continuous monitoring system used to comply with this subpart, records documenting the completion of calibration checks and maintenance of continuous monitoring systems.

(4) For processes in compliance with the 2,000 lb/yr emission limit of § 63.1254(a)(1), records of the rolling annual total emissions.

(5) Records of the following, as appropriate:

(i) The number of batches per year for each batch process.

(ii) The operating hours per year for continuous processes.

(6) Uncontrolled and controlled emissions per batch for each process.

(7) Wastewater concentration per POD or process.

(8) Number of storage tank turnovers per year, if used in an emissions average.

(9) Daily schedule or log of each operating scenario prior to its operation.

(10) Description of worst-case operating conditions as determined using the procedures described in § 63.1257(b)(8) for control devices.

(11) Periods of planned routine maintenance as described in § 63.1257 (c)(5).

(c) *Records of operating scenarios.* The owner or operator of an affected source shall keep records of each operating scenario which demonstrates compliance with this subpart.

(d) *Records of equipment leak detection and repair programs.* The owner or operator of any affected source implementing the leak detection and repair (LDAR) program specified in § 63.1255 of this subpart, shall implement the recordkeeping requirements in § 63.1255 of this subpart.

(e) *Records of emissions averaging.* The owner or operator of any affected source that chooses to comply with the requirements of § 63.1252(d) shall maintain up-to-date records of the following information:

(1) An Implementation Plan which shall include in the plan, for all process vents and storage tanks included in each of the averages, the information listed in paragraphs (e)(1)(i) through (v) of this section.

(i) The identification of all process vents and storage tanks in each emissions average.

(ii) The uncontrolled and controlled emissions of HAP and the overall percent reduction efficiency as determined in §§ 63.1257(g)(1) through (4) or 63.1257(h)(1) through (3) as applicable.

(iii) The calculations used to obtain the uncontrolled and controlled HAP emissions and the overall percent reduction efficiency.

(iv) The estimated values for all parameters required to be monitored under § 63.1258(f) for each process and storage tank included in an average.

(v) A statement that the compliance demonstration, monitoring, inspection, recordkeeping and reporting provisions in §§ 63.1257(g) and (h), 63.1258(f), and 63.1260(k) that are applicable to each emission point in the emissions average will be implemented beginning on the date of compliance.

(2) The Implementation Plan must demonstrate that the emissions from the processes and storage tanks proposed to be included in the average will not result in greater hazard or, at the option of the operating permit authority, greater risk to human health or the environment than if the storage tanks and process vents were controlled according to the provisions in §§ 63.1253 and 63.1254, respectively.

(i) This demonstration of hazard or risk equivalency shall be made to the satisfaction of the operating permit authority.

(A) The Administrator may require owners and operators to use specific methodologies and procedures for making a hazard or risk determination.

(B) The demonstration and approval of hazard or risk equivalency shall be made according to any guidance that the Administrator makes available for use or any other technically sound information or methods.

(ii) An emissions averaging plan that does not demonstrate hazard or risk equivalency to the satisfaction of the Administrator shall not be approved.

The Administrator may require such adjustments to the emissions averaging plan as are necessary in order to ensure that the average will not result in greater hazard or risk to human health or the environment than would result if the emission points were controlled according to §§ 63.1253 and 63.1254.

(iii) A hazard or risk equivalency demonstration must:

(A) Be a quantitative, comparative chemical hazard or risk assessment;

(B) Account for differences between averaging and non-averaging options in chemical hazard or risk to human health or the environment; and

(C) Meet any requirements set by the Administrator for such demonstrations.

(3) Records as specified in paragraphs (a), (b) and (d) of this section.

(4) A rolling quarterly calculation of the annual percent reduction efficiency as specified in § 63.1257(g) and (h).

(f) *Records of delay of repair.* Documentation of a decision to use a delay of repair due to unavailability of parts, as specified in § 63.1256(i), shall include a description of the failure, the reason additional time was necessary (including a statement of why replacement parts were not kept onsite and when delivery from the manufacturer is scheduled), and the date when the repair was completed.

(g) *Record of wastewater stream or residual transfer.* The owner or operator transferring an affected wastewater stream or residual removed from an affected wastewater stream in accordance with § 63.1256(a)(5) shall keep a record of the notice sent to the treatment operator stating that the wastewater stream or residual contains organic HAP which are required to be managed and treated in accordance with the provisions of this subpart.

(h) *Records of extensions.* The owner or operator shall keep documentation of a decision to use an extension, as specified in § 63.1256(b)(6)(ii) or (b)(9), in a readily accessible location. The documentation shall include a description of the failure, documentation that alternate storage capacity is unavailable, and specification of a schedule of actions that will ensure that the control equipment will be repaired and the tank will be emptied as soon as practical.

(i) *Records of inspections.* The owner or operator shall keep records specified in paragraphs (i)(1) through (9) of this section.

(1) A record that each waste management unit inspection required by § 63.1256(b) through (f) was performed.

(2) A record that each inspection for control devices required by § 63.1256(h) was performed.

(3) A record of the results of each seal gap measurement required by § 63.1256(b)(5) and (f)(3). The records shall include the date of measurement, the raw data obtained in the measurement, and the calculations described in § 63.120(b)(2) through (4).

(4) Records identifying all parts of the vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated as unsafe to inspect in accordance with § 63.1258(h)(6), an explanation of why the equipment is unsafe to inspect, and the plan for inspecting the equipment.

(5) Records identifying all parts of the vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated as difficult to inspect in accordance with § 63.1258(h)(7), an explanation of why the equipment is difficult to inspect, and the plan for inspecting the equipment.

(6) For each vapor collection system or closed-vent system that contains bypass lines that could divert a vent stream away from the control device and to the atmosphere, the owner or operator shall keep a record of the information specified in either paragraph (i)(6)(i) or (ii) of this section.

(i) Hourly records of whether the flow indicator specified under § 63.1252(b)(1) was operating and whether a diversion was detected at any time during the hour, as well as records of the times and durations of all periods when the vent stream is diverted from the control device or the flow indicator is not operating.

(ii) Where a seal mechanism is used to comply with § 63.1252(b)(2), hourly records of flow are not required. In such cases, the owner or operator shall record that the monthly visual inspection of the seals or closure mechanisms has been done, and shall record the occurrence of all periods when the seal mechanism is broken, the bypass line valve position has changed, or the key for a lock-and-key type lock has been checked out, and records of any car-seal that has broken.

(7) For each inspection conducted in accordance with § 63.1258(h)(2) and (3) during which a leak is detected, a record of the information specified in paragraphs (i)(7)(i) through (viii) of this section.

(i) The instrument identification numbers; operator name or initials; and identification of the equipment.

(ii) The date the leak was detected and the date of the first attempt to repair the leak.

(iii) Maximum instrument reading measured by the method specified in § 63.1258(h)(4) after the leak is successfully repaired or determined to be nonrepairable.

(iv) ''Repair delayed'' and the reason for the delay if a leak is not repaired within 15 calendar days after discovery of the leak.

(v) The name, initials, or other form of identification of the owner or operator (or designee) whose decision it was that repair could not be effected without a shutdown.

(vi) The expected date of successful repair of the leak if a leak is not repaired within 15 calendar days.

(vii) Dates of shutdowns that occur while the equipment is unrepaired.

(viii) The date of successful repair of the leak.

(8) For each inspection conducted in accordance with § 63.1258(h)(3) during which no leaks are detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected.

(9) For each visual inspection conducted in accordance with § 63.1258(h)(2)(i)(B) or (h)(2)(iii)(B) of this section during which no leaks are detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected.

§ 63.1260 Reporting requirements.

(a) The owner or operator of an affected source shall comply with the reporting requirements of paragraphs (b) through (l) of this section. Applicable reporting requirements of §§ 63.9 and 63.10 are also summarized in Table 1 of this subpart.

(b) *Initial notification.* The owner or operator shall submit the applicable initial notification in accordance with § 63.9(b) or (d).

(c) *Application for approval of construction or reconstruction.* An owner or operator who is subject to § 63.5(b)(3) shall submit to the Administrator an application for approval of the construction of a new major affected source, the reconstruction of a major affected source, or the reconstruction of a major source such that the source becomes a major affected source subject to the standards. The application shall be prepared in accordance with § 63.5(d).

(d) *Notification of CMS performance evaluation.* An owner or operator who is required by the Administrator to conduct a performance evaluation for a continuous monitoring system shall notify the Administrator of the date of the performance evaluation as specified in § 63.8(e)(2).

(e) *Precompliance report.* The Precompliance report shall be submitted at least 6 months prior to the

compliance date of the standard. For new sources, the Precompliance report shall be submitted to the Administrator with the application for approval of construction or reconstruction. The Administrator shall have 90 days to approve or disapprove the plan. The plan shall be considered approved if the Administrator either approves the plan in writing, or fails to disapprove the plan in writing. The 90 day period shall begin when the Administrator receives the request. If the request is denied, the owner or operator must still be in compliance with the standard by the compliance date. To change any of the information submitted in the report, the owner or operator shall notify the Administrator 90 days before the planned change is to be implemented; the change shall be considered approved if the Administrator either approves the change in writing, or fails to disapprove the change in writing. The Precompliance report shall include:

(1) Requests for approval to use alternative monitoring parameters or requests to set monitoring parameters according to § 63.1258(b)(4).

(2) Descriptions of the daily or per batch demonstrations to verify that control devices subject to § 63.1258(b)(1)(i) are operating as designed.

(3) A description of test conditions, and the corresponding monitoring parameter values for parameters that are set according to § 63.1258(b)(3)(ii)(C).

(4) For owners and operators complying with the requirements of § 63.1252(e), the P2 demonstration summary required in § 63.1257(f).

(5) Data and rationale used to support an engineering assessment to calculate uncontrolled emissions from process vents as required in § 63.1257(d)(2)(ii).

(f) *Notification of Compliance Status report.* The Notification of Compliance Status report required under § 63.9 shall be submitted no later than 150 days after the compliance date and shall include:

(1) The results of any applicability determinations, emission calculations, or analyses used to identify and quantify HAP emissions from the affected source.

(2) The results of emissions profiles, performance tests, engineering analyses, design evaluations, or calculations used to demonstrate compliance. For performance tests, results should include descriptions of sampling and analysis procedures and quality assurance procedures.

(3) Descriptions of monitoring devices, monitoring frequencies, and the values of monitored parameters established during the initial compliance determinations, including data and calculations to support the levels established.

(4) Listing of all operating scenarios.

(5) Descriptions of worst-case operating and/or testing conditions for control devices.

(6) Identification of emission points subject to overlapping requirements described in § 63.1250(h) and the authority under which the owner or operator will comply.

(g) *Periodic reports.* An owner or operator shall prepare Periodic reports in accordance with paragraphs (g)(1) and (2) of this section and submit them to the Administrator.

(1) *Submittal schedule.* Except as provided in (g)(1) (i), (ii) and (iii) of this section, an owner or operator shall submit Periodic reports semiannually, beginning 60 operating days after the end of the applicable reporting period. The first report shall be submitted no later than 240 days after the date the Notification of Compliance Status is due and shall cover the 6-month period beginning on the date the Notification of Compliance Status is due.

(i) When the Administrator determines on a case-by-case basis that more frequent reporting is necessary to accurately assess the compliance status of the affected source; or

(ii) When the monitoring data are used directly for compliance determination and the source experience excess emissions, in which case quarterly reports shall be submitted. Once an affected source reports excess emissions, the affected source shall follow a quarterly reporting format until a request to reduce reporting frequency is approved. If an owner or operator submits a request to reduce the frequency of reporting, the provisions in § 63.10(e)(3)(ii) and (iii) shall apply, except that the term ''excess emissions and continuous monitoring system performance report and/or summary report'' shall mean ''Periodic report'' for the purposes of this section.

(iii) When a new operating scenario has been operated since the last report, in which case quarterly reports shall be submitted.

(2) *Content of Periodic report.* The owner or operator shall include the information in paragraphs (g)(2)(i) through (vii) of this section, as applicable.

(i) Each Periodic report must include the information in § 63.10(e)(3)(vi)(A) through (I) and (K) through (M). For each continuous monitoring system, the Periodic report must also include the information in § 63.10(e)(3)(vi)(J).

(ii) If the total duration of excess emissions, parameter exceedances, or excursions for the reporting period is 1 percent or greater of the total operating time for the reporting period, or the total continuous monitoring system downtime for the reporting period is 5 percent or greater of the total operating time for the reporting period, the Periodic report must include the information in paragraphs (g)(2)(ii)(A) through (D) of this section.

(A) Monitoring data, including 15-minute monitoring values as well as daily average values of monitored parameters, for all operating days when the average values were outside the ranges established in the Notification of Compliance Status report or operating permit.

(B) Duration of excursions, as defined in § 63.1258(b)(7).

(C) Operating logs and operating scenarios for all operating scenarios for all operating days when the values are outside the levels established in the Notification of Compliance Status report or operating permit.

(D) When a continuous monitoring system is used, the information required in § 63.10(c)(5) through (13).

(iii) For each inspection conducted in accordance with § 63.1258(h)(2) or (3) during which a leak is detected, the records specified in § 63.1259(i)(7) must be included in the next Periodic report.

(iv) For each vapor collection system or closed vent system with a bypass line subject to § 63.1252(b)(1), records required under § 63.1259(i)(6)(i) of all periods when the vent stream is diverted from the control device through a bypass line. For each vapor collection system or closed vent system with a bypass line subject to § 63.1252(b)(2), records required under § 63.1259(i)(6)(ii) of all periods in which the seal mechanism is broken, the bypass valve position has changed, or the key to unlock the bypass line valve was checked out.

(v) The information in paragraphs (g)(2)(iv)(A) through (D) of this section shall be stated in the Periodic report, when applicable.

(A) No excess emissions.

(B) No exceedances of a parameter.

(C) No excursions.

(D) No continuous monitoring system has been inoperative, out of control, repaired, or adjusted.

(vi) For each tank subject to control requirements, periods of planned routine maintenance during which the control device does not meet the specifications of § 63.1253(b) through (d).

(vii) Each new operating scenario which has been operated since the time period covered by the last Periodic report. For the initial Periodic report,

each operating scenario for each process operated since the compliance date shall be submitted.

(h) *Notification of process change.*

(1) Except as specified in paragraph (h)(2) of this section, whenever a process change is made, or a change in any of the information submitted in the Notification of Compliance Status Report, the owner or operator shall submit a report quarterly. The report may be submitted as part of the next Periodic report required under paragraph (g) of this section. The report shall include:

(i) A brief description of the process change.

(ii) A description of any modifications to standard procedures or quality assurance procedures.

(iii) Revisions to any of the information reported in the original Notification of Compliance Status Report under paragraph (f) of this section.

(iv) Information required by the Notification of Compliance Status Report under paragraph (f) of this section for changes involving the addition of processes or equipment.

(2) An owner or operator must submit a report 60 days before the scheduled implementation date of either of the following:

(i) Any change in the activity covered by the Precompliance report.

(ii) A change in the status of a control device from small to large.

(i) *Reports of startup, shutdown, and malfunction.* For the purposes of this subpart, the startup, shutdown, and malfunction reports shall be submitted on the same schedule as the periodic reports required under paragraph (g) of this section instead of the schedule specified in § 63.10(d)(5)(i). These reports shall include the information specified in § 63.1259(a)(3)(i) through (iii) and shall contain the name, title, and signature of the owner or operator or other responsible official who is certifying its accuracy. Reports are only required if a startup, shutdown, or malfunction occurred during the reporting period. Any time an owner or operator takes an action that is not consistent with the procedures specified in the affected source's startup, shutdown, and malfunction plan, the owner or operator shall submit an immediate startup, shutdown, and malfunction report as specified in § 63.10(d)(4)(ii).

(j) *Reports of LDAR programs.* The owner or operator of any affected source implementing the LDAR program specified in § 63.1255 of this subpart shall implement the reporting requirements in § 63.1255 of this subpart. Copies of all reports shall be retained as records for a period of 5 years, in accordance with the requirements of § 63.10(b)(1).

(k) *Reports of emissions averaging.* The owner or operator of any affected source that chooses to comply with the requirements of § 63.1252(d) shall submit the implementation plan described in § 63.1259(e) 6 months prior to the compliance date of the standard and the following information in the periodic reports:

(1) The records specified in § 63.1259(e) for each process or storage tank included in the emissions average;

(2) All information as specified in paragraph (g) of this section for each process or storage tank included in the emissions average;

(3) Any changes of the processes or storage tanks included in the average.

(4) The calculation of the overall percent reduction efficiency for the reporting period.

(5) Changes to the Implementation Plan which affect the calculation methodology of uncontrolled or controlled emissions or the hazard or risk equivalency determination.

(6) Every second semiannual or fourth quarterly report, as appropriate, shall include the results according to § 63.1259(e)(4) to demonstrate the emissions averaging provisions of §§ 63.1252(d), 63.1257(g) and (h), 63.1258(f), and 63.1259(f) are satisfied.

(l) *Notification of performance test and test plan.* The owner or operator of an affected source shall notify the Administrator of the planned date of a performance test at least 60 days before the test in accordance with § 63.7(b). The owner or operator also must submit the test plan required by § 63.7(c) and the emission profile required by 63.1257(b)(8)(ii) with the notification of the performance test.

(m) *Request for extension of compliance.* An owner or operator may submit to the Administrator a request for an extension of compliance in accordance with § 63.1250(f)(4).

§ 63.1261 Delegation of authority.

(a) In delegating implementation and enforcement authority to a State under § 112(d) of the Clean Air Act, the authorities contained in paragraph (b) of this section shall be retained by the Administrator and not transferred to a State.

(b) The authority conferred in § 63.177; the authority to approve applications for determination of equivalent means of emission limitation; and the authority to approve alternative test methods shall not be delegated to any State.

TABLE 1 TO SUBPART GGG.—GENERAL PROVISIONS APPLICABILITY TO SUBPART GGG

General provisions reference	Summary of requirements	Applies to subpart GGG	Comments
63.1(a)(1)	General applicability of the General Provisions	Yes	Additional terms defined in § 63.1251; when overlap between subparts A and GGG of this part, subpart GGG takes precedence.
63.1(a)(2–7)		Yes	
63.1(a)(8)		No	Discusses state programs.
63.1(a)(9–14)		Yes	
63.1(b)(1)	Initial applicability determination	Yes	Subpart GGG clarifies the applicability in § 63.1250.
63.1(b)(2)	Title V operating permit—see part 70	Yes	All major affected sources are required to obtain a title V permit.
63.1(b)(3)	Record of the applicability determination	Yes	All affected sources are subject to subpart GGG according to the applicability definition of subpart GGG.
63.1(c)(1)	Applicability after standards are set	Yes	Subpart GGG clarifies the applicability of each paragraph of subpart A to sources subject to subpart GGG.
63.1(c)(2)	Title V permit requirement	No	All major affected sources are required to obtain a title V permit. Area sources are not subject to subpart GGG.

TABLE 1 TO SUBPART GGG.—GENERAL PROVISIONS APPLICABILITY TO SUBPART GGG—Continued

General provisions reference	Summary of requirements	Applies to subpart GGG	Comments
63.1(c)(3)	Reserved		
63.1(c)(4)	Requirements for existing source that obtains an extension of compliance.	Yes	
63.1(c)(5)	No	Notification requirements for an area source that increases HAP emissions to major source levels.	Yes
63.1(d)	[Reserved]	NA	
63.1(e)	Applicability of permit program before a relevant standard has been set.	Yes	
63.2	Definitions.	Yes	Additional terms defined in § 63.1251; when overlap between subparts A and GGG of this part occurs, subpart GGG takes precedence.
63.3	Units and abbreviations.	Yes	Other units used in subpart GGG are defined in that subpart.
63.4	Prohibited activities.	Yes	
63.5(a)	Construction and reconstruction—applicability	Yes	Except replace the terms ''source'' and ''stationary source'' with ''affected source''.
63.5(b)(1)	Upon construction, relevant standards for new sources.	Yes	
63.5(b)(2)	[Reserved]	NA	
63.5(b)(3)	New construction/reconstruction	Yes	
63.5(b)(4)	Construction/reconstruction notification	Yes	
63.5(b)(5)	Construction/reconstruction compliance	Yes	
63.5(b)(6)	Equipment addition or process change	Yes	
63.5(c)	[Reserved]	NA	
63.5(d)	Application for approval of construction/reconstruction	Yes	Except for certain provisions identified in 63.1259(a)(5)
63.5(e)		Construction/reconstruction approval..	Yes
63.5(f)	Construction/reconstruction approval based on prior State review..	Yes	Except replace ''source'' with ''affected source''.
63.6(a)(1)	Compliance with standards and maintenance requirements.	Yes	
63.6(a)(2)	Requirements for area source that increases emissions to become major.	Yes	
63.6(b)(1–2)	Compliance dates for new and reconstructed sources	No	Subpart GGG specifies compliance dates.
63.6(b)(3–6)	Compliance dates for area sources that become major sources.	Yes	
63.6 (b)(7)	Compliance dates for new sources resulting from new unaffected area sources becoming subject to standards.	No	Subpart GGG specifies NS applicability and compliance dates
63.6(c)	Compliance dates for existing sources	Yes	Except replace ''source'' with ''affected source''. Subpart GGG specifies compliance dates.
63.6(e)	Operation and maintenance requirements	Yes	Startup, Shutdown, Malfunction Plan requirements specifically include malfunction process, control and monitoring equipment.
63.6(f)–(g)	Compliance with nonopacity and alternative nonopacity emission standards.	Yes	Except that subpart GGG specifies performance test conditions.
63.6(h)	Opacity and visible emission standards	No	Subpart GGG does not contain any opacity or visible emission standards.
63.6(i)	Extension of compliance with emission standards	No	§ 63.1250(f)(4) specifies provisions for compliance extensions.
63.6(j)	Exemption from compliance with emission standards	Yes	
63.7(a)(1)	Performance testing requirements.	Yes	Subpart GGG specifies required testing and compliance procedures.
63.7(a)(2)(I-ix)		Yes	
63.7(a)(3)		Yes	
63.7(b)(1)	Notification of performance test	Yes	
63.7(b)(2)	Notification of delay in conducting a scheduled performance test.	Yes	

TABLE 1 TO SUBPART GGG.—GENERAL PROVISIONS APPLICABILITY TO SUBPART GGG—Continued

General provisions reference	Summary of requirements	Applies to subpart GGG	Comments
63.7(c)	Quality assurance program	Yes	Except that the test plan must be submitted with the notification of the performance test.
63.7(d)	Performance testing facilities.	Yes	Except replace ''source'' with ''affected source''.
63.7(e)	Conduct of performance tests.	Yes	Subpart GGG also contains test methods and procedures specific to pharmaceutical sources.
63.7(f)	Use of alternative test method	Yes	
63.7(g)	Data analysis, recordkeeping, and reporting	Yes	
63.7(h)	Waiver of performance tests	Yes	
63.8(a)	Monitoring requirements	Yes	See § 63.1258.
63.8(b)(1)	Conduct of monitoring	Yes	
63.8(b)(2)	CMS and combined effluents	No	§ 63.1258 of subpart GGG provides specific CMS requirements.
63.8(b)(3)–(c)(3)	CMS requirements	Yes	
63.8(c)(4–5)	CMS operation requirements	Yes	
63.8 (c)6–8)	CMS calibration and malfunction provisions	Yes	
63.8(d)	CMS quality control program	Yes	
63.8(e)(1)	Performance evaluations of CMS	Yes	
63.8(e)(2)	Notification of performance evaluation	Yes	
63.8(e)(3–4)	CMS requirements/alternatives	Yes	
63.8(e)(5)(i)	Reporting performance evaluation results	Yes	See § 63.1260 (a)..
63.8(e)(5)(ii)	Results of COMS performance evaluation	No	Subpart GGG does not contain any opacity or visible emission standards.
63.8(f)–(g)	Alternative monitoring method/reduction of monitoring data.	Yes	
63.9(a)–(d)	Notification requirements—Applicability and general information.	Yes	
63.9(e)	Notification of performance test	Yes	
63.9(f)	Notification of opacity and visible emissions observations.	No	Subpart GGG does not contain any opacity or visible emission standards.
63.9(g)(1)	Additional notification requirements for sources with CMS.	Yes	
63.9(g)(2)	Notification of compliance with opacity emission standard.	No	Subpart GGG does not contain any opacity or visible emission standards.
63.9(g)(3)	Notification that criterion to continue use of alternative to relative accuracy testing has been exceeded.	Yes	
63.9(h)	Notification of compliance status.	Yes	Due 150 days after compliance date.
63.9(i)	Adjustment to time periods or postmark deadlines for submittal and review of required communications.	Yes	
63.9(j)	Change in information provided	Yes	
63.10(a)	Recordkeeping requirements	Yes	See § 63.1259..
63.10(b)(1)	Records retention	Yes	
63.10(b)(2)	Information and documentation to support notifications.	No	Subpart GGG specifies recordkeeping requirements.
63.10(b)(3)	Records retention for sources not subject to relevant standard.	Yes	Applicability requirements are given in § 63.1250.
63.10(c)-(d)(2)	Other recordkeeping and reporting provisions	Yes.	
63.10(d)(3)	Reporting results of opacity or visible emissions observations.	No	Subpart GGG does not include any opacity or visible emission standards.
63.10(d)(4-5)	Other recordkeeping and reporting provisions	Yes.	
63.10(e)	Additional CMS reporting requirements	Yes.	
63.10(f)	Waiver of recordkeeping or reporting requirements. ..	Yes.	
63.11	Control device requirements for flares	Yes.	
63.12	State authority and delegations	Yes	See § 63.1261.
63.13	Addresses of State air pollution control agencies	Yes.	
63.14	Incorporations by reference	Yes.	
63.15	Availability of information and confidentiality	Yes.	

TABLE 2 TO SUBPART GGG.—PARTIALLY SOLUBLE HAP

1,1,1-Trichloroethane (methyl chloroform)
1,1,2,2-Tetrachloroethane
1,1,2-Trichloroethane
1,1-Dichloroethylene (vinylidene chloride)
1,2-Dibromoethane
1,2-Dichloroethane (ethylene dichloride)

TABLE 2 TO SUBPART GGG.—PARTIALLY SOLUBLE HAP—Continued

1,2-Dichloropropane
1,3-Dichloropropene
2,4,5-Trichlorophenol
2-Butanone (mek)
1,4-Dichlorobenzene
2-Nitropropane
4-Methyl-2-pentanone (mibk)

TABLE 2 TO SUBPART GGG.—PARTIALLY SOLUBLE HAP—Continued

Acetaldehyde
Acrolein
Acrylonitrile
Allyl chloride
Benzene
Benzyl chloride
Biphenyl

TABLE 2 TO SUBPART GGG.—PARTIALLY SOLUBLE HAP—Continued

Bromoform (tribromomethane)
Bromomethane
Butadiene
Carbon disulfide
Chlorobenzene
Chloroethane (ethyl chloride)
Chloroform
Chloromethane
Chloroprene
Cumene
Dichloroethyl ether
Dinitrophenol
Epichlorohydrin

TABLE 2 TO SUBPART GGG.—PARTIALLY SOLUBLE HAP—Continued

Ethyl acrylate
Ethylbenzene
Ethylene oxide
Hexachlorobenzene
Hexachlorobutadiene
Hexachloroethane
Methyl methacrylate
Methyl-t-butyl ether
Methylene chloride
N,N-dimethylaniline
Propionaldehyde.
Propylene oxide
Styrene

TABLE 2 TO SUBPART GGG.—PARTIALLY SOLUBLE HAP—Continued

Tetrachloroethene (perchloroethylene)
Tetrachloromethane (carbon tetrachloride
Toluene
Trichlorobenzene (1,2,4-)
Trichloroethylene
Triethylamine
Trimethylpentane
Vinyl acetate
Vinyl chloride
Xylene (m)
Xylene (o)
Xylene (p)
N-hexane

TABLE 3 TO SUBPART GGG.—SOLUBLE HAP

Compound
1,1-Dimethylhydrazine.
1,4-Dioxane.
Acetonitrile.
Acetophenone.
Diethyl sulfate.
Dimethyl sulfate.
Dinitrotoluene.
Ethylene glycol dimethyl ether.
Ethylene glycol monobutyl ether acetate.
Ethylene glycol monomethyl ether acetate.
Isophorone.
Methanol (methyl alcohol).
Nitrobenzene.
Toluidene.

TABLE 4 TO SUBPART GGG.—MONITORING REQUIREMENTS FOR CONTROL DEVICES [a]

Control device	Monitoring equipment required	Parameters to be monitored	Frequency
All control devices	1. Flow indicator installed at all bypass lines to the atmosphere and equipped with continuous recorder *or*.	1. Presence of flow diverted from the control device to the atmosphere *or*.	Hourly records of whether the flow indicator was operating and whether a diversion was detected at any time during each hour.
	2. Valves sealed closed with car-seal or lock-and-key configuration.	2. Monthly inspections of sealed valves.	Monthly.
Scrubber	Liquid flow rate or pressure drop mounting device. Also a pH monitor if the scrubber is used to control acid emissions.	1. Liquid flow rate into or out of the scrubber or the pressure drop across the scrubber.	1. Every 15 minutes.
		2. pH of effluent scrubber liquid	2. Once a day.
Thermal incinerator	Temperature monitoring device installed in firebox or in ductwork immediately downstream of firebox [b].	Firebox temperature	Every 15 minutes.
Catalytic incinerator	Temperature monitoring device installed in gas stream immediately before and after catalyst bed.	Temperature difference across catalyst bed.	Every 15 minutes.
Flare	Heat sensing device installed at the pilot light.	Presence of a flame at the pilot light.	Every 15 minutes.
Boiler or process heater <44 mega watts and vent stream is not mixed with the primary fuel.	Temperature monitoring device installed in firebox [b].	Combustion temperature	Every 15 minutes.
Condenser	Temperature monitoring device installed at condenser exit.	Condenser exit (product side) temperature.	Every 15 minutes.
Carbon adsorber (nonregenerative).	None	Operating time since last replacement.	N/A.
Carbon adsorber (regenerative)	Stream flow monitoring device, *and*.	1. Total regeneration stream mass or volumetric flow during carbon bed regeneration cycle(s).	1. For each regeneration cycle, record the total regeneration stream mass or volumetric flow.

TABLE 4 TO SUBPART GGG.—MONITORING REQUIREMENTS FOR CONTROL DEVICES [a]—Continued

Control device	Monitoring equipment required	Parameters to be monitored	Frequency
	Carbon bed temperature monitoring device.	2. Temperature of carbon bed after regeneration.	2. For each regeneration cycle, record the maximum carbon bed-temperature.
		3. Temperature of carbon bed within 15 minutes of completing any cooling cycle(s).	3. Within 15 minutes of completing any cooling cycle, record the carbon bed temperature.
		4. Operating time since end of last regeneration.	4. Operating time to be based on worst-case conditions.
		5. Check for bed poisoning	5. Yearly.

[a] As an alternative to the monitoring requirements specified in this table, the owner or operator may use a CEM meeting the requirements of Performance Specifications 8 or 9 of appendix B of part 60 to monitor TOC every 15 minutes.

[b] Monitor may be installed in the firebox or in the ductwork immediately downstream of the firebox before any substantial heat exchange is encountered.

TABLE 5 TO SUBPART GGG.—CONTROL REQUIREMENTS FOR ITEMS OF EQUIPMENT THAT MEET THE CRITERIA OF § 63.1252(f)

Item of equipment	Control requirement [a]
Drain or drain hub	(a) Tightly fitting solid cover (TFSC); or (b) TFSC with a vent to either a process, or to a fuel gas system, or to a control device meeting the requirements of § 63.1256(h)(2); or (c) Water seal with submerged discharge or barrier to protect discharge from wind.
Manhole [b]	(a) TFSC; or (b) TFSC with a vent to either a process, or to a fuel gas system, or to a control device meeting the requirements of § 63.1256(h)(2); or (c) If the item is vented to the atmosphere, use a TFSC with a properly operating water seal at the entrance or exit to the item to restrict ventilation in the collection system. The vent pipe shall be at least 90 cm in length and not exceeding 10.2 cm in nominal inside diameter.
Lift station	(a) TFSC; or (b) TFSC with a vent to either a process, or to a fuel gas system, or to a control device meeting the requirements of § 63.1256(h)(2); or (c) If the lift station is vented to the atmosphere, use a TFSC with a properly operating water seal at the entrance or exit to the item to restrict ventilation in the collection system. The vent pipe shall be at least 90 cm in length and not exceeding 10.2 cm in nominal inside diameter. The lift station shall be level controlled to minimize changes in the liquid level.
Trench	(a) TFSC; or (b) TFSC with a vent to either a process, or to a fuel gas system, or to a control device meeting the requirements of § 63.1256(h)(2); or (c) If the item is vented to the atmosphere, use a TFSC with a properly operating water seal at the entrance or exit to the item to restrict ventilation in the collection system. The vent pipe shall be at least 90 cm in length and not exceeding 10.2 cm in nominal inside diameter.
Pipe	Each pipe shall have no visible gaps in joints, seals, or other emission interfaces
Oil/Water separator	(a) Equip with a fixed roof and route vapors to a process or to a fuel gas system, or equip with a closed-vent system that routes vapors to a control device meeting the requirements of § 63.1256(h)(2); or (b) Equip with a floating roof that meets the equipment specifications of § 60.693 (a)(1)(i), (a)(1)(ii), (a)(2), (a)(3), and (a)(4).
Tank	Maintain a fixed roof.[c] If the tank is sparged[d] or used for heating or treating by means of an exothermic reaction, a fixed roof and a system shall be maintained that routes the organic hazardous air pollutants vapors to other process equipment or a fuel gas system, or a closed-vent system that routes vapors to a control device that meets the requirements of 40 CFR § 63.119 (e)(1) or (e)(2).

AAA[a] Where a tightly fitting solid cover is required, it shall be maintained with no visible gaps or openings, except during periods of sampling, inspection, or maintenance.

AAA[b] Manhole includes sumps and other points of access to a conveyance system.

AAA[c] A fixed roof may have openings necessary for proper venting of the tank, such as pressure/vacuum vent, j-pipe vent.

AAA[d] The liquid in the tank is agitated by injecting compressed air or gas.

TABLE 6 TO SUBPART GGG.—WASTEWATER—COMPLIANCE OPTIONS FOR WASTEWASTER TANKS

Capacity, m^3	Maximum true vapor pressure, kPa	Control requirements
<75	.....	§ 63.1256(b)(1).
≥75 and <151	<13.1	§ 63.1256(b)(1).
	≥13.1	§ 63.1256(b)(2).
≥151	<5.2	§ 63.1256(b)(1).
	≥5.2	§ 63.1256(b)(2).

TABLE 7 TO SUBPART GGG.—WASTEWATER—INSPECTION AND MONITORING REQUIREMENTS FOR WASTE MANAGEMENT UNITS

To comply with	Inspection or monitoring requirement	Frequency of inspection or monitoring	Method
TANKS:			
63.1256(b)(3)(i)	Inspect fixed roof and all openings for leaks.	Initially Semiannually	Visual.
63.1256(b)(4)	Inspect floating roof in accordance with §§ 63.120(a)(2) and (a)(3).	See §§ 63.120(a)(2) and (a)(3)	Visual.
63.1256(b)(5)	Measure floating roof seal gaps in accordance with §§ 63.120(b)(2)(i) through (b)(4).		See § 63.120(b)(2)(i) through (b)(4).
	—Primary seal gaps	Initially Once every 5 years (annually if no secondary seal).	
	—Secondary seal gaps	Initially Semiannually	
63.1256(b)(7)	Inspect wastewater tank for control equipment failures and improper work practices.	Initially Semiannually	Visual.
63.1256(b)(8)			
SURFACE IMPOUNDMENTS:			
63.1256(c)(1)(i)	Inspect cover and all openings for leaks.	Initially Semiannually	Visual.
63.1256(c)(2)	Inspect surface impoundment for control equipment failures and improper work practices.	Initially Semiannually	Visual.
CONTAINERS:			
63.1256(d)(1)(i)	Inspect cover and all openings for leaks.	Initially Semiannually	Visual.
63.1256(d)(1)(ii)			
63.1256(d)(3)(i)	Inspect enclosure and all openings for leaks.	Initially Semiannually	Visual.
63.1256(d)(4)	Inspect container for control equipment failures and improper work practices.	Initially Semiannually	Visual.
INDIVIDUAL DRAIN SYSTEMS [a]:			
63.1256(e)(1)(i)	Inspect cover and all openings to ensure there are no gaps, cracks, or holes.	Initially Semiannually	Visual.
63.1256(e)(2)	Inspect individual drain system for control equipment failures and improper work practices.	Initially Semiannually	Visual.
63.1256(e)(4)(i)	Verify that sufficient water is present to properly maintain integrity of water seals.	Initially Semiannually	Visual.
63.1256(e)(4)(ii)	Inspect all drains using tightly-fitted caps or plugs to ensure caps and plugs are in place and properly installed.	Initially Semiannually	Visual.
63.1256(e)(5)(i)			
63.1256(e)(5)(ii)	Inspect all junction boxes to ensure covers are in place and have no visible gaps, cracks, or holes.	Initially Semiannually	Visual or smoke test or other means as specified.
63.1256(e)(5)(iii)	Inspect unburied portion of all sewer lines for cracks and gaps.	Initially Semiannually	Visual.
OIL-WATER SEPARATORS:			
63.1256(f)(2)(i)	Inspect fixed roof and all openings for leaks.	Initially Semiannually	Visual.
63.1256(f)(3)	Measure floating roof seal gaps in accordance with 40 CFR 60.696(d)(1).	Initially [b]	See 40 CFR 60.696(d)(1).
	—Primary seal gaps	Once every 5 years.	
63.1256(f)(3)	—Secondary seal gaps	Initially [b] Annually.	
63.1256(f)(4)	Inspect oil-water separator for control equipment failures and improper work practices.	Initially Semiannually	Visual.

[a] As specified in § 63.1256(e), the owner or operator shall comply with either the requirements of § 63.1256(e)(1) and (2) or § 63.1256(e)(4) and (5).

[b] Within 60 days of installation as specified in § 63.1256(f)(3).

TABLE 8 TO SUBPART GGG.—FRACTION MEASURED (F_m) for HAP Compounds in Wastewater Streams

Chemical name	CAS No. [a]	F_m
Acetaldehyde	75070	1.00
Acetonitrile	75058	0.99
Acetophenone	98862	0.31
Acrolein	107028	1.00
Acrylonitrile	107131	1.00
Allyl chloride	107051	1.00
Benzene	71432	1.00
Benzyl chloride	100447	1.00
Biphenyl	92524	0.86
Bromoform	75252	1.00
Butadiene (1,3-)	106990	1.00
Carbon disulfide	75150	1.00
Carbon tetrachloride	56235	1.00
Chlorobenzene	108907	0.96
Chloroform	67663	1.00
Chloroprene (2-Chloro-1,3-butadiene)	126998	1.00
Cumene	98828	1.00
Dichlorobenzene (p-1,4-)	106467	1.00
Dichloroethane (1,2-) (Ethylene dichloride)	107062	1.00
Dichloroethylether (Bis(2-Chloroethyl ether))	111444	0.76
Dichloropropene (1,3-)	542756	1.00
Diethyl sulfate	64675	0.0025
Dimethyl sulfate	77781	0.086
Dimethylaniline (N,N-)	121697	0.00080
Dimethylhydrazine (1,1-)	57147	0.38
Dinitrophenol (2,4-)	51285	0.0077
Dinitrotoluene (2,4-)	121142	0.085
Dioxane (1,4-) (1,4-Diethyleneoxide)	123911	0.87
Epichlorohydrin(1-Chloro-2,3-epoxypropane)	106898	0.94
Ethyl acrylate	140885	1.00
Ethylbenzene	100414	1.00
Ethyl chloride (Chloroethane)	75003	1.00
Ethylene dibromide (Dibromomethane)	106934	1.00
Ethylene glycol dimethyl ether	110714	0.86
Ethylene glycol monobutyl ether acetate	112072	0.043
Ethylene glycol monomethyl ether acetate	110496	0.093
Ethylene oxide	75218	1.00
Ethylidene dichloride (1,1-Dichloroethane)	75343	1.00
Hexachlorobenzene	118741	0.97
Hexachlorobutadiene	87683	0.88
Hexachloroethane	67721	0.50
Hexane	110543	1.00
Isophorone	78591	0.47
Methanol	67561	0.85
Methyl bromide (Bromomethane)	74839	1.00
Methyl chloride (Chloromethane)	74873	1.00
Methyl ethyl ketone (2-Butanone)	78933	0.99
Methyl isobutyl ketone (Hexone)	108101	0.98
Methyl methacrylate	80626	1.00
Methyl tert-butyl ether	1634044	1.00
Methylene chloride (Dichloromethane)	75092	1.00
Naphthalene	91203	0.99
Nitrobenzene	98953	0.39
Nitropropane (2-)	79469	0.99
Phosgene	75445	1.00
Propionaldehyde	123386	1.00
Propylene dichloride (1,2-Dichloropropane)	78875	1.00
Propylene oxide	75569	1.00
Styrene	100425	1.00
Tetrachloroethane (1,1,2,2-)	79345	1.00
Tetrachloroethylene (Perchloroethylene)	127184	1.00
Toluene	108883	1.00
Toluidine (o-)	95534	0.15
Trichlorobenzene (1,2,4-)	120821	1.00
Trichloroethane (1,1,1-) (Methyl chloroform)	71556	1.00
Trichloroethane (1,1,2-) (Vinyl Trichloride)	79005	0.98
Trichloroethylene	79016	1.00
Trichlorophenol (2,4,5-)	95954	1.00
Triethylamine	121448	1.00
Trimethylpentane (2,2,4-)	540841	1.00
Vinyl acetate	108054	1.00
Vinyl chloride (Chloroethylene)	75014	1.00

TABLE 8 TO SUBPART GGG.—FRACTION MEASURED (F_m) for HAP Compounds in Wastewater Streams—Continued

Chemical name	CAS No. [a]	F_m
Vinylidene chloride (1,1-Dichloroethylene)	75354	1.00
Xylene (m-)	108383	1.00
Xylene (o-)	95476	1.00
Xylene (p-)	106423	1.00

[a] CAS numbers refer to the Chemical Abstracts Service registry number assigned to specific compounds, isomers, or mixtures of compounds.

TABLE 9 TO SUBPART GGG.—DEFAULT BIORATES FOR LIST 1 COMPOUNDS

Compound name	Biorate (K1), L/g MLVSS-hr
Acetonitrile	0.100
Acetophenone	0.538
Diethyl sulfate	0.105
Dimethyl hydrazine(1,1)	0.227
Dimethyl sulfate	0.178
Dinitrotoluene(2,4)	0.784
Dioxane(1,4)	0.393
Ethylene glycol dimethyl ether	0.364
Ethylene glycol monomethyl ether acetate	0.159
Ethylene glycol monobutyl ether acetate	0.496
Isophorone	0.598
Methanol	([a])
Nitrobenzene	2.300
Toluidine (-0)	0.859

[a] For direct dischargers, the default biorate for methanol is 3.5 L/g MLVSS-hr; for indirect dischargers, the default biorate for methanol is 0.2 L/g MLVSS-hr.

[FR Doc. 98–23168 Filed 9–18–98; 8:45 am]

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Federal Register

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Part III

Environmental Protection Agency

40 CFR Parts 136 and 439

Pharmaceutical Manufacturing Category Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 136 and 439

[FRL–6135–7]

RIN 2040–AA13

Pharmaceutical Manufacturing Category Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards; Final Rule

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This final regulation limits the discharge of pollutants into navigable waters of the United States and into publicly owned treatment works (POTWs) by existing and new pharmaceutical manufacturing facilities. This regulation revises limitations and standards for four subcategories of the pharmaceutical manufacturing Point Source Category: Subcategory A (Fermentation), Subcategory B (Extraction), Subcategory C (Chemical Synthesis): and Subcategory D (Mixing, Compounding, and Formulating); and reformats and clarifies language without revision to certain specified provisions of these four subcategories and a fifth subcategory: Subcategory E (Research). This regulation establishes effluent limitations guidelines and standards under the Clean Water Act including ''best conventional pollutant control technology (BCT) and ''best available technology economically achievable (BAT)'' for existing direct dischargers, ''new source performance standards (NSPS)'' for new direct dischargers and pretreatment standards for existing and new indirect dischargers (PSES and PSNS). This regulation also amends and clarifies some of the limitations based on ''best practicable control technology (BPT)'' for pharmaceutical manufacturing facilities and establishes analytical methods for certain organic pollutants contained in this regulation. EPA is today also publishing final Maximum Available Control Technology (MACT) standards under the Clean Air Act (CAA) for the pharmaceutical manufacturing industry elsewhere in today's **Federal Register**. The MACT standards final rule will control emissions of hazardous air pollutants (HAPs) from pharmaceutical manufacturing emission sources including wastewater collection and treatment systems. The Offices of Water and Air and Radiation have coordinated the development of these regulations and have used a common technology basis in developing limitations and standards for the volatile organic compounds (VOCs).

The final MACT standards and effluent limitations guidelines and standards rules will benefit the environment by removing a total of 85.4 million pounds per year of conventional, nonconventional and toxic (priority) pollutants from water discharges. The effluent limitations guidelines and standards portion of those removals is 13.9 million pounds per year of nonconventional and 16.0 million pounds per year of organic pollutants including VOCs.

DATES: This regulation shall become effective November 20, 1998. The incorporation by reference of certain publications listed in Part 136 is approved by the Director of the Federal Register as of November 20, 1998.

ADDRESSES: For additional technical information write to Dr. Frank H. Hund, Engineering and Analysis Division (4303), U.S. EPA, East Tower, 401 M Street SW, Washington, D.C. 20460 or send E-mail to: hund.frank@epamail.epa.gov or call at (202) 260-7182. For additional economic information contact Mr. William Anderson at the address above or by calling (202) 260–5131 or send E-mail to: anderson.william@epamail.epa.gov.

The complete record (excluding confidential business information) for this Clean Water Act rulemaking is available for review at EPA's Water Docket, Room EB57; 401 M Street, SW, Washington, DC 20460. For access to Docket materials, call (202) 260–3027 between 9 a.m. and 3:30 p.m. for an appointment. The EPA public information regulation (40 CFR part 2) provides that a reasonable fee may be charged for copying.

The Technical Development Document and Economic Impact Analysis supporting today's final water rule may be obtained by writing to the EPA Office of Water Resource Center (RC–4100), 401 M Street SW., Washington, DC 20460, or calling (202) 260–7786.

FOR FURTHER INFORMATION CONTACT: For additional technical information call Dr. Frank H. Hund at (202) 260–7182. For additional information on the economic impact analyses contact Mr. William Anderson at (202) 260–5131.

SUPPLEMENTARY INFORMATION:

Judicial Review

In accordance with 40 CFR 23.2, the rule will be considered promulgated for purposes of judicial review at 1:00 p.m. Eastern time on October 5, 1998. Under section 509(b)(1) of the Act, judicial review of this regulation can be obtained only by filing a petition for review in the United States Court of Appeals within 120 days after the regulation is considered promulgated for purposes of judicial review. Under section 509 (b)(2) of the Act, the requirements in this regulation may not be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements.

Regulated Entities

Entities potentially regulated by this action include:

Category	Examples of regulated entities
Industry	Facilities that generate process wastewater from the manufacture of pharmaceutical products and/or pharmaceutical intermediates by fermentation, extraction, chemical synthesis and/or mixing, compounding and formulating.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in §§ 439.1, 439.10, 439.20, 439.30, 439.40 and 439.50 of this final rule. If you have questions regarding the applicability of this action to a particular entity, consult the technical information person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Compliance Dates

The compliance date for PSES is as soon as possible, but no later than September 21, 2001. The compliance dates for NSPS and PSNS are the dates the new source commences discharging.

Deadlines for compliance with BPT, BCT, and BAT are established in the National Pollutant Discharge Elimination System (NPDES) permits.

Organization of This Document

I. Legal Authority

This final regulation establishes effluent limitations guidelines and standards of performance and analytical methods for the pharmaceutical manufacturing point source category under the authorities of sections 301, 304, 306, 307, 308, 402 and 501 of the Clean Water Act (''the Act''), 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

II. Background

A. Clean Water Act

The Federal Water Pollution Control Act Amendments of 1972 established a comprehensive program to ''restore and maintain the chemical, physical, and biological integrity of the Nation's waters,'' (section 101(a)). To implement the Act, EPA is to issue effluent limitations guidelines, pretreatment standards and new source performance standards for industrial dischargers.

These guidelines and standards are summarized briefly below:

1. Best Practicable Control Technology Currently Available (BPT) (Section 304(b)(1) of the Act)

BPT effluent limitations apply to all discharges from existing direct dischargers. BPT effluent limitations guidelines are generally based on the average of the best existing performance by plants of various sizes, ages, and unit processes within the category or subcategory for control of pollutants.

In establishing BPT effluent limitations guidelines, EPA considers the total cost of achieving effluent reductions in relation to the effluent reduction benefits, the age of equipment and facilities involved, 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 Act). The Agency considers the category or subcategory-wide cost of applying the technology in relation to the effluent reduction benefits. Where existing performance is uniformly inadequate within a category or subcategory, BPT may be transferred from a different subcategory or category.

2. Best Available Technology Economically Achievable (BAT) (Section 304(b)(2) of the Act)

In general, BAT effluent limitations represent the best existing economically achievable performance of plants in the industrial subcategory or category, based upon available technology. The Act establishes BAT as the principal national means of controlling the direct discharge of toxic and nonconventional pollutants to navigable waters. 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) (Section 304(b)(2)(B)). 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 subcategory or category. BAT may include process changes or internal controls, even when these technologies are not common industry practice.

3. Best Conventional Pollutant Control Technology (BCT) (Section 304(b)(4) of the Act)

The 1977 Amendments to the Act established BCT for discharges of conventional pollutants from existing industrial point sources. Section 304(a)(4) designated the following as conventional pollutants: Biochemical oxygen demanding pollutants (BOD_5), 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).

BCT is not an additional limitation, but replaces BAT for the control of conventional pollutants. In addition to other factors specified in Section 304(b)(4)(B), the Act requires that BCT limitations be established in light of a two part ''cost-reasonableness'' test. *American Paper Institute* v. *EPA*, 660 F.2d 954 (4th Cir. 1981). EPA's current methodology for the general development of BCT limitations was issued in 1986 (51 FR 24974; July 9, 1986).

4. New Source Performance Standards (NSPS) (Section 306 of the Act)

NSPS are based on the best available demonstrated control 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 numerical values attainable through the application of the best available control technology for all pollutants (e.g., 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.

5. Pretreatment Standards for Existing Sources (PSES) (Section 307(b) of the Act)

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 Act authorizes EPA to establish pretreatment standards for pollutants that pass through POTWs or interfere with POTWs' treatment processes or sludge disposal methods. The legislative history of the 1977 Act indicates that pretreatment standards are to be technology-based and analogous to the BAT effluent limitations guidelines for removal of toxic pollutants. For the purpose of determining whether to promulgate national category-wide pretreatment standards, EPA generally determines that there is pass through of a pollutant and thus a need for categorical standards if the nation-wide average percent removal of a pollutant removed by well-operated POTWs achieving secondary treatment is less than the percent removed by the BAT model treatment system.

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 does not use the percent removal comparison test described above. See 52 FR 1586, January 14, 1987.)

6. Pretreatment Standards for New Sources (PSNS) (Section 307(b) of the Act)

Like PSES, PSNS are designed to prevent the discharges of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of POTWs. PSNS are to be issued at the same time as NSPS. New indirect dischargers, like new direct dischargers, have the opportunity to incorporate into their plants the best available demonstrated technologies. The Agency considers the same factors in promulgating PSNS as it considers in promulgating NSPS.

B. Section 304(m) Requirements and the Pollution Prevention Act

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 (''effluent guidelines''), 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). The plaintiffs charged that EPA's plan did not meet the requirements of sec. 304(m). A Consent Decree in this litigation was entered by the Court on January 31, 1992. The terms of the Consent Decree are reflected in the Effluent Guidelines Plan published on September 8, 1992 (57 FR 41000). This plan, as modified, required, among other things, that EPA propose effluent guidelines for the pharmaceutical manufacturing category by February, 1995 and take final action on these effluent guidelines by April, 1998. Recently EPA filed an unopposed motion requesting an extension of time until July 30, 1998 for the Administrator to sign the final rule.

The Pollution Prevention Act of 1990 (PPA) (42 U.S.C. 13101 *et seq.*, Pub. L. 101–508, November 5, 1990) ''declares it to be the national policy of the United States that pollution should be prevented or reduced whenever feasible; pollution that cannot be prevented should be recycled 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 release into the environment should be employed only as a last resort...'' (Sec. 6602; 42 U.S.C. 13101(b). In short, preventing pollution before it is created is preferable to trying to manage, treat or dispose of it after it is created. This effluent guideline was reviewed for its incorporation of pollution prevention as part of this Agency effort.

According to the PPA, source reduction reduces the generation and release of hazardous substances, pollutants, wastes, contaminants or residuals at the source, usually within a process. The term source reduction ''include[s] equipment or technology modifications, process or procedure modifications, reformulation or redesign of products, substitution of raw materials, and improvements in housekeeping, maintenance, training, or inventory control.'' The term ''source reduction'' does not include any practice which alters the physical, chemical, or biological characteristics or the volume of a hazardous substance, pollutant, or contaminant through a process or activity which itself is not integral to or necessary for the production of a product or the providing of a service.'' 42 U.S.C. 13102(5) In effect, source reduction means reducing the amount of a pollutant that enters a waste stream or that is otherwise released into the environment prior to out-of-process recycling, treatment, or disposal.

The PPA directs the Agency to, among other things, ''review regulations of the Agency prior and subsequent to their proposal to determine their effect on

source reduction'' (Sec. 6604; 42 U.S.C. 13103(b)(2). This directive led the Agency to implement a pilot project called the Source Reduction Review Project that would facilitate the integration of source reduction in the Agency's regulations, including the technology-based effluent guidelines and standards.

In the preamble to the proposed regulations, EPA discussed the possible pollution prevention alternatives available in pharmaceutical manufacturing. At that time, EPA indicated that pollution prevention opportunities were limited in the active ingredient manufacturing subcategories (namely, fermentation, natural extraction and chemical synthesis) but the use of water-based coatings in the formulation subcategory operations was a viable pollution prevention approach which eliminates the need for solvents in tablet coating operations. This approach may only be applicable to some and not most tablet coating operations, however. Since the proposal, EPA has received two suggestions for incorporating pollution prevention into the final regulations which were discussed in the August 8, 1997 Notice of Availability at 62 FR 42720. One suggestion presented to the Agency was that Subcategories B and D dischargers that incorporate best management practices (BMPs), which reduce their discharge of any of the regulated pollutants should not have to monitor for the specific regulated pollutants, and possibly only monitor for the conventional pollutants and COD. This pollution prevention approach is similar to the one adopted in the Pesticide Formulators, Packagers and Repackagers (PFPR) final regulation which was published in the **Federal Register** on November 6, 1996 at 61 FR 57518. (It should be noted that PFPR facilities that use the promulgated pollution prevention option have to assess their wastewater and may be required to treat wastewater prior to discharge.) EPA evaluated this suggestion and decided that since EPA is not promulgating BAT limitations for specific organic pollutants, this pollution prevention suggestion was not relevant to compliance by subcategory B and D direct dischargers with final BAT limitations. For PSES, EPA believes the suggestion may be workable for indirect dischargers, since standards for specific organic pollutants are contained in the final rule; however, no information was submitted to identify the pollution prevention practices that would be incorporated into the rule, and EPA has been unable to identify any.

Another pollution prevention approach suggested to EPA was that Subcategories A and C facilities that can demonstrate a reduction in the use of a regulated pollutant and resultant lowered air emissions or water discharges should receive a higher effluent discharge limitation. As suggested, the higher effluent discharge limitation would be directly proportional to the amount of reduction achieved in the use of the regulated pollutant. Along with this suggestion, the commenters provided examples of how this pollution prevention suggestion could work in individual instances.

In evaluating this suggestion including the examples provided, EPA was concerned about the amount and type of process information that would have to be obtained from facilities and the methodology for estimating the pollutant reductions as the result of any pollution prevention practices. Another concern of the Agency had to do with the determination of when, in the new product development phase of work, the practice represents a pollution prevention activity or is just part of normal process development work in bringing a new product process to full scale production. EPA was also concerned that pollutant discharge or emission reductions achieved in the bench scale or pilot scale product development activities may not be realized during full scale production operations. In the period following publication of the NOA, the Agency did not receive sufficient information relative to these concerns to enable it to develop a viable pollution prevention alternative based on this suggestion.

C. Updated Profile of the Industry

The pharmaceutical manufacturing industry covered by this rulemaking is made up of 566 facilities located in 39 states, Puerto Rico and the Virgin Islands. EPA estimates that 304 of these facilities could be affected by today's final rule. The major concentrations of manufacturing facilities are located in the Northeast, the Midwest and Puerto Rico.

The pharmaceutical manufacturing industry is defined by four types of manufacturing operations or processes. These activities result in subcategorization for purposes of this rulemaking. The four subcategories are referred to as:

- Subcategory A: Fermentation
- Subcategory B: Natural Extraction
- Subcategory C: Chemical Synthesis
- Subcategory D: Formulating, Mixing and Compounding

A complete discussion of each subcategory's manufacturing operations and wastewater characteristics may be found in Sections 3 and 5 of the final Technical Development Document (TDD), ''Development Document for Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category'' (EPA 821–R–98–005).

A fifth subcategory, Subcategory E: Research, was excluded from regulation beyond the existing BPT regulation promulgated on October 27, 1983 at 48 FR 49808. The Research subcategory is defined by bench-scale activities or operations related to the research on and development of pharmaceutical products. BAT/BCT limitations for this subcategory are determined on a case by case best professional judgment (BPJ) basis. For indirect dischargers, the general prohibition in 40 CFR part 403 apply; in addition POTWs will establish local pretreatment limits on a case by case basis as necessary.

D. Existing and Proposed Rules

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 through E). The five subcategories of the pharmaceutical manufacturing industry (40 CFR part 439) were defined at that time as:

- 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 biochemical oxygen demand (BOD_5) and chemical oxygen demand (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 concentration-based limitations for total suspended solids (TSS) 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 revised the subcategory names to those currently applicable and promulgated revised BPT, BAT, PSES and PSNS for Subparts A thru D to cover the toxic pollutant cyanide, conventional pollutants BOD_5, 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, D and E. The revisions for TSS consisted of deriving the limitations by the use of a multiplication factor of 1.7 times each plant's BOD_5 discharge. EPA also promulgated BPT, BAT, PSES and PSNS for pH (6.0–9.0) and BAT concentration-based limitations controlling the discharge of cyanide for subcategory A through D. The Agency also proposed NSPS for BOD_5, TSS and pH in the October 1983 notice, but did not publish final NSPS for these parameters.

On December 16, 1986, at 51 FR 45094, EPA promulgated BCT effluent limitations guidelines for BOD_5, TSS and pH for subcategories A thru D. That final rule set BCT effluent limitations equal to the existing BPT effluent limitations guidelines for BOD_5, TSS, and pH.

1. Clean Water Act Proposal

On May 2, 1995 at 60 FR 21592, EPA proposed revised BPT concentration based limitations for BO_5, COD and TSS based on advanced biological treatment for all subcategories and cyanide limitations based on hydrogen peroxide oxidation technology for the A (Fermentation) and C (Chemical Synthesis) subcategories. For BAT, EPA proposed end-of-pipe limitations for 53 organic pollutants plus ammonia, cyanide and COD for subcategories A and C. For subcategories B (Natural Extraction) and D (Formulating, Mixing and Compounding), EPA proposed BAT limitations for 53 organic pollutants and COD. The technology basis for the volatile organic compounds (VOCs) limitations was steam stripping plus advanced biological treatment for subcategories A and C and advanced biological treatment for subcategories B and D. The technology basis for the non-volatile organics was advanced biological treatment only, and the proposed ammonia limitations were based on nitrification. The proposed BAT cyanide limitations were equivalent to the BPT limitations, and the BCT limitations were also proposed equal to BPT for all manufacturing subcategories.

For NSPS, EPA proposed end-of-pipe standards for 53 organic pollutants plus ammonia, BO_5, TSS, cyanide and COD for subcategories A and C and end-of-pipe standards for 53 organic pollutants plus BO_5, TSS, and COD for subcategories B and D. The BO_5, COD, and TSS standards were based on two sets of performance data from the best performing plants in each of the A or C and B or D subcategories. The end-of-pipe VOC limitations were based on steam stripping with distillation and advanced biological treatment.

For PSES EPA detailed two coproposals (A and B) to control VOCs in all subcategories. Coproposal A had pretreatment standards for 12 highly volatile organic compounds and 33 less volatile organic compounds. To show compliance with the pretreatment standards, monitoring for the 12 highly volatile compounds would have been required in-plant. Coproposal B had only the pretreatment standards for the 12 highly volatile compounds. In addition, EPA proposed cyanide (identical to BPT) and ammonia standards (based on steam stripping) for subcategories A and C. The proposed PSNS differed from PSES in that the standards for all volatile organic compounds were based on steam stripping plus distillation technologies.

Finally, EPA proposed that pilot plant wastewater would not be regulated by Subcategory E (Research) limitations but under appropriate manufacturing subcategory limitations.

2. Clean Air Act Proposal

On April 2, 1997 at 62 FR 15753, EPA proposed National Emission Standards for Hazardous Air Pollutants (NESHAPs) for the Pharmaceuticals Production Source Category. In that proposed rule, the Agency proposed Maximum Available Control Technology (MACT) standards for controlling emissions of hazardous air pollutants (HAPs) from process vents, storage tanks, equipment leaks, wastewater collection and treatment systems and heat exchange systems at pharmaceutical manufacturing facilities that are determined to be major sources of HAPs.

The proposed MACT standards for wastewater emission sources contained two alternative formats for achieving compliance, a percent removal and a reference control technology. Applicability determination, definitions, and control requirements were similar to the Hazardous Organic NESHAPs (HON) MACT standards for wastewater. The proposed standard required facilities to control wastewater streams that exceed the concentration cutoff where the process wastewater stream exits the pharmaceutical process equipment identified as the point of determination (POD). The proposed concentration cutoffs were 1,300 parts per million by weight (ppmw) for partially soluble HAPs and 5,200 ppmw for total HAPs at processes or PODs with annual HAP loads of 1 megagram per year or metric ton per year (Mg/yr).

Also, the proposed standard required all streams having a HAP concentration of 10,000 ppmw to be controlled at facilities with annual HAP loads of 1 Mg/yr or greater.

The proposed standards required that the control of wastewater emissions be accomplished in one of the following manners: (1) Using a design biotreatment system for soluble HAPs; (2) Demonstrating removals achieving 99 percent by weight of partially soluble HAPs and 90 percent by weight of soluble HAPs from treatment systems; or (3) Demonstrating a removal of 95 percent by weight of total organic HAP from the treatment system. The MACT standard proposal also discussed options for CWA controls in light of the CAA MACT standard proposal for controlling emissions from wastewater streams at pharmaceutical facilities being covered by the proposed effluent limitations guidelines and standards. EPA's intent was that the effluent limitations guidelines and standards build on the MACT standards, and the discussion suggested several options to accomplish this.

3. Clean Water Act **Federal Register** Notice of Availability

EPA published a Notice of Availability (NOA) in the **Federal Register** on August 8, 1997 at 62 FR 42720. EPA published this Notice in order to: allow public comment on the data received since the May 2, 1995 CWA proposal, further develop and revise options for the control of the VOCs that were presented in the April 2, 1997 CAA MACT proposal, and suggest responses to some comments on the 1995 CWA proposal.

In section II of the NOA, EPA provided the results of an EPA sampling study designed to provide information concerning the pass through analysis for water soluble organic pollutants such as methanol and discussed the pass through analysis that EPA would be performing with respect to these and other pollutants.

In section III, EPA presented revisions of the pretreatment options which were earlier described in the MACT proposal, and presented options for reducing the discharge loadings of VOCs not controlled by the proposed MACT

standards. One option was compliance with the proposed MACT standards together with additional PSES requirements for all VOCs except alcohols and related compounds based on the performance database used in the 1995 proposal. A second option included coverage of additional pollutants including alcohols and related compounds. EPA also presented costs and loadings for two scenarios involving these two options. One scenario would exclude facilities that discharged less than 10,000 pounds per year of pollutants of concern, while the other scenario would not exclude them.

In section IV, EPA presented the results of analyses with respect to the proposed data base for NSPS requirements for the conventional pollutants, COD and ammonia, pollutant exclusions, use of surrogate pollutants for compliance monitoring, small facility exclusion and changes to engineering costs and loadings removal estimates. In addition, EPA presented data editing criteria and methodologies for deriving BPT and BAT effluent limitations and PSES. On pages 42722–42724 of the NOA, EPA presented BPT, BAT limitations and PSES being considered.

E. Discussion of Final Clean Air Act Rule Published Elsewhere in Today's Federal Register

EPA received a number of comments on the proposed MACT standards for wastewater streams. While certain changes were made (see the final MACT rule published elsewhere in today's **Federal Register**) the controls required by the proposed MACT standards have not changed. As proposed, the final MACT incorporates the HON wastewater standards, thereby clarifying the MACT requirements for off-site treatment of wastewater. Under specified conditions, a source can transfer affected wastewater streams containing soluble HAPs and less than 50 ppmw partially soluble HAPs off-site for treatment. In addition, if the off-site treatment facility is a POTW with uncovered headworks (grit chamber, primary settling tanks, etc.) a demonstration that less than five percent of the total soluble HAPs are emitted is required. For POTWs with completely covered headworks, the final rule does not require a demonstration that less than five percent of the total soluble HAPs are emitted.

F. Relationship Between the MACT and CWA Rules

As noted above, the CAA MACT rule being promulgated today sets emission standards for HAPs from wastewater collection and treatment systems at major source pharmaceutical manufacturing facilities. The CWA final effluent limitations guidelines and standards control the discharge of toxic, conventional and nonconventional pollutants in wastewater discharges from pharmaceutical manufacturing facilities. Some of the water pollutants being controlled by today's effluent guidelines and standards are also HAPs and thus these pollutants are being controlled by both the MACT and CWA final rules. The extent of the coverage of waterborne HAPs by the air and water rules will be discussed in subsequent sections, as will the joint economic analysis and environmental benefits assessment that were conducted for the two rules.

G. Final Clean Water Act Effluent Guidelines Limitations and Standards Rule

Today EPA is promulgating revised BPT limitations only for COD based on advanced biological treatment for all four subcategories.

For subcategories A and C, EPA is promulgating BAT limitations for COD equal to the revised BPT limitations and for 30 organic pollutants, including 28 VOCs (of which 13 are HAPS) based on advanced biological treatment identified as a basis for the revised COD limitations. In addition, for subcategories A and C, EPA is promulgating BAT ammonia limitations based on nitrification technology, and is modifying the BAT compliance monitoring requirements for the existing cyanide limitations.

For subcategories B and D, EPA is adding BAT limitations for COD equal to the revised BPT requirements, and is withdrawing the existing BPT and BAT cyanide limitations since the facilities in these subcategories do not generate cyanide in their wastewaters.

The Agency is promulgating PSES for 23 VOCs (10 of which are HAPs) plus ammonia for subcategories A and C, and is also clarifying the compliance requirements for the existing cyanide pretreatment standards. For subcategories B and D, EPA is promulgating PSES for the 5 VOCs (1 of which is a HAP) and, for the same reason given above, is withdrawing the existing cyanide standards. Subcategories A and C facilities must continue to comply with the cyanide standards, and achieve compliance with the standards for ammonia and the 23 organic pollutants within three years. Subcategories B and D facilities must achieve compliance with the 5 organic pollutant standards within three years. The compliance times of up to three years is being given because of the design and installation of technologies used as a basis for the standards, such as steam stripping and nitrification require sufficient lead times for implementation.

EPA is promulgating NSPS for subcategories A and C equal to the BAT limitations for COD, ammonia and the organic pollutants, including the VOCs, and revised limitations for BOD_5 and TSS based on advanced biological treatment. EPA is also promulgating NSPS for subcategories B and D equal to BAT for COD and revised limitations for BOD_5 and TSS based on advanced biological treatment, and is withdrawing the existing cyanide NSPS for these two subcategories.

For PSNS EPA is promulgating standards equal to PSES for all pollutants and subcategories and is withdrawing the existing cyanide PSNS for subcategories B and D. Finally, EPA is promulgating BCT limitations equal to the existing BPT limitations for BOD_5, TSS and pH.

In today's rule, EPA has republished many parts of the existing guideline in Part 439 to make the changes made today easier to understand, and also reformated the guideline to make it more clear and easier to use. The republication or reformatting of existing requirements is not intended to introduce substantive changes to these regulatory provisions. For that reason, EPA believes prior notice and comment on these provisions is unnecessary.

III. Summary of Most Significant Changes to Water Rules From Proposal

This section describes the most significant changes to the rule since proposal. Many of these changes have resulted from the comments that are discussed below (see section X). This section will discuss the major changes in the rule concerning revisions to the limitations and standards for VOCs, changes in the BAT technology basis and changes in the BPT and BAT limitations for pollutants other than the VOCs. More detailed explanations for changes may be found in the comment response document in the record of the final rule.

A. Limitations and Standards for Volatile Compounds

In today's final rule, EPA is not requiring that the limitations for VOCs be measured in-plant as proposed. For all four subcategories, BAT, NSPS, PSES, and PSNS limitations and standards, except for cyanide limitations and standards in subcategories A and C, this rule does not alter the generally applicable rule

(122.45(h) or 403.6(e)) that limitations generally are measured at the end-of-pipe discharge point. This rule provides clarification of the existing in-plant monitoring for cyanide as discussed in the Implementation Section of this preamble (see section VIII A).

At proposal, EPA proposed PSES for 13 alcohols and related pollutants (compounds) under coproposal B. These pollutants were methanol, ethanol, n-propanol, isopropanol, n-butyl alcohol, tert-butyl alcohol, amyl alcohol, formamide, N,N-dimethylaniline, pyridine, 1,4-dioxane, aniline, and petroleum naphtha. No PSES/PSNS are being promulgated for these pollutants today because EPA determined these pollutants do not pass through POTWs or interfere with the treatment works. (See section IV.E for a discussion of the passthrough analysis for these pollutants).

B. Change in BAT Technology Basis for Organic Pollutants

In the August 8, 1997 NOA, EPA discussed changing the technology basis for BAT organic pollutant limitations for subcategories A and C facilities from in-plant steam stripping and advanced biological treatment to advanced biological treatment only. EPA received comments supporting this change in technology basis. The final MACT standards being promulgated today will control most emissions of VOCs from wastewaters at subcategories A and C direct discharging facilities based on the use of steam stripping technology. Accordingly, EPA believes that it is not necessary or appropriate to include this technology in the BAT technology basis; the CWA limitations and standards are calculated from a data base representing advanced biological treatment only. Thus, EPA is promulgating BAT limitations for all of the 30 organic pollutants for subcategories A and C facilities based on advanced biological treatment only. EPA notes that one facility not covered by the MACT standards would need to install steam stripping technology in order to achieve the effluent limitations following the biological treatment system.

C. BPT and BAT/BCT Limitation Changes

Based on the receipt of new data from commenters, proposed limitations were revised for the nonconventional pollutants COD and ammonia and a number of the organic pollutants. In addition, commenters on the proposed limitations for the conventional pollutants BOD5 and TSS, as well as COD, indicated that EPA should eliminate all non-process wastewater in the calculation of limitations for these parameters. In developing limitations for the proposal, EPA did not back out the estimated non-process wastewater from the total wastewater flow and adjust the concentration accordingly because the non-process flow data provided by facilities in the data sets were only gross estimates and were not based on daily measurements of non-process flow. Despite requesting more precise information (such as daily non-process flow data) from facilities that generated the data sets used to calculate the proposed limitations for BOD5, TSS and COD, EPA did not obtain this information. However, in the NOA, EPA presented revised proposed limitations for BOD5 and TSS and COD that were calculated from the existing plant data sets using the gross estimates of non-process flow, as described below, to adjust the concentrations in addition to several new data sets from plants other than those used for the proposal.

In a previous EPA effluent limitations guidelines and standards rulemaking for the Organic Chemicals, Plastics and Synthetic Fibers (OCPSF) industry (52 FR 42522), only plant data sets that contained less than 25 percent non-process wastewater through treatment were used in calculating limitations. Thus, the 25 percent level of non-process wastewater dilution was determined as a benchmark in order to evaluate biological treatment performance. For the purposes of the NOA, in cases where the non-process flow was estimated to be more than 25 percent of the total flow, the non-process wastewater was backed out of the total flow volume and the parameters corrected for the absence of this non-process wastewater. However, for the final rule, limitations for COD are developed from data sets in which the reported flow volume contains less than 25 percent non-process wastewater and the limitations are calculated without correcting the data sets for the non-process flow dilution. This change is discussed further in section IV.D below. As further discussed below, limitations for BOD5 and some of the remaining TSS are not being revised at this time since the revised COD limits requiring advanced biological treatment will incidentally remove a large portion of the remaining BOD5 and TSS.

Another change to the proposal involved the limitations and standards proposed for cyanide. EPA proposed BPT, BAT, NSPS, PSES and PSNS limitations and standards for cyanide based on the performance of hydrogen peroxide oxidation technology. Following the proposal, EPA received comments indicating that the use of the hydrogen peroxide technology to destroy cyanide could possibly result in equipment explosions with certain types of wastewater. Other commenters indicated that hydrogen peroxide technology may not be an appropriate cyanide destruction technology for all treatment situations. Along with these comments, EPA received additional data on the performance of alkaline chlorination technology in destroying cyanide. Based on these comments and the new performance data, EPA indicated in the NOA that it was considering promulgating two sets of cyanide limitations, one based on the performance of hydrogen peroxide technology and the other based on the performance of alkaline chlorination technology. In the NOA, EPA indicated that only those facilities that could demonstrate that a potential safety hazard could result from their use of hydrogen peroxide technology would be subject to the alkaline chlorination limitations and standards. EPA also solicited information and comments regarding wastestreams with high organic content as evidenced by high COD or total organic carbon (TOC) levels, and at what levels these pollutants would indicate that the wastestream(s) high organic content would present a safety concern and would more appropriately be controlled by limitations based on alkaline chlorination. After consideration of the information provided in response to the solicitation in the NOA, particularly new performance data representing current (post 1990 base year) loadings, EPA has decided not to revise the existing limitations and standards for cyanide based on the small amount of cyanide discharge loadings that would be removed. However, the final rule continues to require compliance with the cyanide limitations be established in-plant, prior to commingling the cyanide bearing wastestreams with non-cyanide wastestreams for those facilities where the cyanide levels would be below the level of detection at the end-of-pipe monitoring location.

Along with comments on its proposed numerical limitations and standards for ammonia and organic pollutants, EPA received data concerning the performance of steam strippers, advanced biological treatment and nitrification in connection with these proposed limitations. EPA evaluated these data, and provided revised numerical limitations and standards in the NOA for ammonia, several organic pollutants controlled by BAT technology (advanced biological treatment) and several VOCs controlled

by steam stripping technology for PSES. As the result of the data received and evaluated, along with comments on the NOA, EPA has changed the numerical BAT limitations for ammonia. In response to comments in the NOA indicating that indirect dischargers should be able to achieve the PSES ammonia limitations using either two-step nitrification technology or steam stripping, EPA has decided to set the PSES ammonia limitations equal to the BAT ammonia limitations, and to provide that indirect discharging subcategories A and C facilities discharging to POTWs with nitrification capability need not comply with the categorical limit for ammonia. EPA has also changed the numerical BAT limitations and PSES for several organic pollutants based on its analysis of data received in response to the proposal.

D. Pollutant Selection

EPA received several comments concerning the reasoning behind the regulation of certain pollutants as well as the overall rationale for selecting pollutants for regulation. In the NOA, EPA indicated that it had reviewed the loadings bases of all the pollutants selected for regulation and had determined that in the case of eight pollutants, insufficient amounts of the pollutants are being discharged to justify national regulation. These pollutants are diethyl ether, cyclohexane, chloromethane, dimethylamine, methylamine, furfural, 2-methylpyridine and trichlorofluoromethane. Since the NOA, EPA has reevaluated its final loadings database and has determined that the exclusion of these pollutants along with an additional 15 pollutants is appropriate. The additional 15 pollutants are excluded from the BAT regulation based on the lack of removals from current discharge or the control of discharges of the pollutant by other regulated pollutant parameters. These pollutants are butanone, formaldehyde, n-butanol, tertiary butanol, n-propanol, ethylene glycol, polyethylene glycol 600, aniline, petroleum naphtha, 1,4-dioxane, formamide and dimethyl formamide, dimethylaniline, dimethylacetamide and pyridine.

EPA proposed PSES for 45 organic pollutants, 37 of which are VOCs, under co-proposal A with compliance for the standards for 12 of the VOCs to be monitored in-plant, and compliance for the standards for the remaining 33 organics to be monitored at the end-of-pipe. In the NOA, EPA presented two revised PSES options, under which EPA would promulgate pretreatment standards for VOCs with end-of-pipe monitoring. The pollutants not regulated under one of these PSES options include water soluble alcohols such as methanol and related compounds. After consideration of comments and evaluating the results of the Barcelonetta POTW study and its implications on the final pass through analysis (see further discussion of pass through analysis in section IV E below) and further evaluation of incidental removals and the amount of or discharge removals for the pollutants, EPA is promulgating PSES and PSNS for 23 VOCs for subcategories A and C and 5 VOCs for subcategories B and D. The PSES and PSNS do not include the alcohols and related compounds, and are based on monitoring at the end-of-pipe unless the POTW determines it to be impractical per 40 CFR 403.6(e).

IV. The Final Clean Water Act Regulation

This section discusses the applicability of the final rule, regulatory options considered and the rationale for the selected options for BPT, BCT, BAT, PSES, PSNS and NSPS.

A. Applicability and Scope of the Final Rule

Today's final effluent limitations guidelines and standards are intended to cover pollutants in process wastewater discharges from existing and new pharmaceutical manufacturing facilities. Based on comments, EPA has revised the proposed scope of the rule. This final rule contains revisions to the effluent limitations guidelines and standards in four subcategories (A thru D) of the pharmaceutical manufacturing point source category, EPA is not revising the scope of the applicability for the fifth subcategory (Subcategory E-Research).

With regard to subcategory E facilities, EPA proposed to revise the description of the research subcategory in the applicability section of the existing subcategory E regulations to exclude pilot or full-scale operations that generate wastewater using fermentation, extraction, chemical synthesis or mixing, compounding and formulating from the scope of subpart E, and these operations were proposed to be covered by the appropriate subcategory A through D. After considering the comments received concerning the regulation of wastewaters from pilot-scale operations, EPA has decided not to change the existing description of the research subcategory in the applicability section. EPA believes that it does not have sufficient information concerning subcategory E generated wastewaters to change the existing description. Subpart E facilities remain subject to the BPT limitations in the existing guidelines. If pilot scale operations occur at either stand alone research facilities or during operations at manufacturing facilities, then BAT and BCT limits for these wastewaters can be determined by permit writers on a best professional judgment (BPJ) basis, or similarly, such wastewater generated at indirect discharging facilities may be addressed by the regulations found at 40 CFR 403.5 and by local limits on a case-by-case basis.

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 the manufacturing subcategories in this final regulation include, but are not limited to:

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 or other categorical limitations and standards if they are manufactured by a pharmaceutical manufacturer by processes that generate wastewaters that in turn closely correspond to those of pharmaceutical products. (An example of such a product is citric acid.)

g. Cosmetic preparations covered by SIC Code No. 2844 that contain pharmaceutically active ingredients or

ingredients intended for treatment of some skin condition. (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, shaving preparations and non-medicated shampoos that do not function primarily as a skin treatment.)

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 pharmaceutical manufacturing category are contained in the applicability provision of the final rule and in sections 2 and 3 of the final TDD.

In the NOA, EPA indicated that it was considering excluding from the scope of the regulation organic chemical manufacturers covered by the OCPSF regulation (40 CFR, Part 414) that manufacture pharmaceutical intermediates and active ingredients provided that the pharmaceutical portion of the process wastewater is less than 50 percent of the total process wastewater. EPA received no adverse comments concerning this, and has decided to promulgate this exclusion as described in the NOA. Thus facilities will be covered by the existing OCPSF regulation for both their OCPSF and pharmaceutical manufacturing process wastewaters provided that the pharmaceutical portion of the process wastewater at the facility is less than 50 percent of the total.

B. Options Selection

EPA evaluated final technology options for BPT, BAT, BCT, NSPS, PSES and PSNS limitations and standards for all four subcategories A thru D. The options considered for each level of control are discussed below in sections IV.C thru H.

C. Best Practicable Control Technology Currently Available (BPT)

EPA proposed to revise BPT for the conventional pollutants BOD_5 and TSS, the nonconventional pollutant COD, and the toxic pollutant cyanide for subcategories A and C, and for subcategories B and D, proposed to revise BPT limitations for BOD_5, TSS, and COD and to withdraw the cyanide limitations. In response to this proposal, EPA received comments claiming that EPA lacks the legal authority to revise BPT for the conventional pollutants since the proposed revised BPT limitations did not pass the BCT cost-reasonableness test. EPA also received comments claiming that COD and cyanide should not be regulated at BPT but only at the BAT level.

In today's rulemaking, EPA is revising BPT limitations only as to COD. The current BPT limitations for BOD_5, TSS and cyanide will continue to apply (except for subcategories B and D where EPA is withdrawing the BPT limitations for cyanide). Accordingly, issues raised by commenters regarding EPA's legal authority to revise BPT for BOD_5, TSS, or cyanide do not need to be addressed in this rulemaking. Nonetheless, EPA continues to believe that it has the legal authority to revise BPT limitations as appropriate. EPA further believes it can do so for conventional pollutants without having to apply the BCT cost-reasonableness test. Because EPA's authority to revise BPT limitations for conventional pollutants or cyanide is no longer an issue in this rulemaking, EPA is providing only a general statement of its statutory authority to revise BPT. For example, section 304(b) of the CWA directs EPA to revise all effluent limitation guidelines, including those based on BPT, at least annually if appropriate. Similarly, section 304(m) directs EPA to establish a schedule ''for the annual review and revision of promulgated effluent guidelines, in accordance with subsection (b) of this section.'' EPA does not believe that the addition of the BCT provisions to the CWA supplanted the BPT provisions. When enacting the more recent BCT provisions, Congress did not strip EPA of its explicit authority to revise or update BPT as necessary and appropriate. Moreover, the different purposes of BPT and BCT limitations would support an EPA decision to promulgate best ''practicable'' control technology for conventional pollutant control (represented by BPT), rather than the higher ''best available'' standard (represented by BCT).

Similarly, it is the Agency's position that it is not required to regulate COD or cyanide only at the BAT level. As noted above, section 304(b) of the CWA as well as section 304(m) directs EPA to revise all effluent limitations guidelines, including those based on BPT, at least annually if necessary and appropriate. It is EPA's view that the addition of BAT provisions to the CWA did not supplant the BPT provisions. When enacting the more recent BAT provisions, Congress did not strip EPA of its authority to revise or update BPT as necessary and appropriate. Further, the different purposes of BPT and BAT limitations would support an EPA decision to promulgate revised effluent limitation guidelines for nonconventional or toxic pollutants that reflect simply the next generation of best ''practicable'' control technology (represented by BPT), rather than the higher ''best available'' standard (represented by BAT).

Since EPA is not revising BPT limitations for cyanide (but rather is modifying the compliance monitoring requirements for cyanide for subcategories A and C, and withdrawing the limitations as to subcategories B and D), the issue need not be addressed further in this rulemaking.

EPA believes that the decision of whether or not to revise BPT for nonconventional pollutants should be made based upon consideration of a number of factors, including, but not necessarily limited to, cost, the technology being considered and the relative performance being achieved (best ''practicable'' versus best ''available''), the anticipated pollutant reductions, and implementation burden on permit writers.

In this case, EPA has made a determination that the costs and removals associated with the implementation of advanced biological treatment at a best ''practicable'' level warrant revision of COD at BPT. This is in part due to the relatively high concentrations of COD in the effluent that are allowed under the existing percent removal BPT limitations which are unique to this industry. In other cases, the Agency has decided not to revise BPT (see, for example, Effluent Limitation Guidelines for the Pulp, Paper, and Paperboard Category, subparts B and E, 63 FR 18534, April 15, 1998).

As noted above, EPA proposed to revise BPT for the conventional pollutants BOD_5 and TSS, the nonconventional pollutant COD, and the toxic pollutant cyanide for subcategories A and D, and for subcategories B and D, to revise BPT limitations for BOD_5, TSS, and COD and to withdraw the existing cyanide limitations. The technology basis of the proposed BPT limitations was advanced biological treatment. EPA also determined that the level of performance necessary for a plant to be considered as a best performer at the best ''practicable'' level was full compliance with the existing BPT limitations. Of the plants considered as best performers at proposal, EPA selected five A and C subcategory plants and two B and D subcategory plants. The Agency then calculated long-term average performance concentrations for regulated pollutants from the best performing A and C and B and D plants.

In developing the final BPT limitations, EPA has essentially

followed the proposal methodology except that EPA used only data sets representing less than 25 percent non-process wastewater through treatment and included the additional data sets received since proposal in its final limitations determinations. Except for one facility which adds non-process wastewater after treatment but before the end-of-pipe sample point, the BPT data sets were not corrected for non-process wastewater and the final limitations were calculated using the plant flow that included some non-process wastewater.

EPA did not back out the estimated non-process wastewater in developing the proposed BPT concentration based limitations because non-process flow data available at that time were only gross estimates not identified in sufficient detail and were not based on daily measurements of non-process flow. Regarding the proposed BPT limitations, commenters indicated that EPA should eliminate all non-process wastewater from the calculation of BPT limitations. EPA did not have information such as daily non-process flow data from facilities that generated the data sets used in the calculation of BPT and BAT limitations for BOD_5, TSS and COD to allow adjustment. In the recent NOA, EPA presented BPT limitations for BOD_5 and TSS and BAT COD limitations that were calculated from plant data sets which included the additional data submissions obtained since proposal from which the non-process wastewater had been backed out. In cases where the non-process flow was estimated by EPA to be more than 25 percent of the total flow using the available data, the fraction of the non-process to process flow volume was used to calculate a correction factor and the long-term average concentration values for each of the BPT parameters were adjusted to reflect the parameters absence of this non-process wastewater. No corrections were made to data sets where the non-process flow was estimated to be less than 25 percent of the total flow.

EPA received no adverse comments regarding these adjusted limitations. However, based on further analysis, EPA believes that it is more appropriate to follow the methodology used in developing the final Organic Chemicals, Plastics, and Synthetic Fibers (OCPSF) regulation (52 FR 52522) final BPT limitations. In that rule, only plant data sets that contained less than 25 percent non-process wastewater through treatment were used in the calculation of BPT limits, and the effluent data were not adjusted to take into account plant data sets that contained more than 25 percent non-process wastewater through treatment. EPA selected this approach in calculating the final BPT limitations in this rule for the same two reasons used during development of the OCPSF rule. (See 52 FR 42522). First, using data sets with greater than 25 percent non-process wastewater through treatment introduces considerable uncertainty into the limitation calculations because the flow data that would be used are only in part based on daily flow measurements whereas the concentration-based limitations are calculated from the long term average of daily measurements over long periods of time (12–24 months). Second, the final limitations should represent as much as possible the performance of treatment technology on process wastewater. In determining permit mass limits, permit writers and, where applicable, pretreatment control authorities should identify the amount of non-process wastewater being treated. The flow volume representing 25 percent or less of the total flow should be included in the volume used to calculate allowable mass discharges. Any additional volume would have to be evaluated on a case-by-case basis to determine what, if any, mass allowances are appropriate.

EPA considered four options for the final BPT limitations. Under the first option, EPA would not revise the existing BPT limitations for BOD_5, TSS, COD and cyanide. No costs or removals are associated with this option. Under the second option, EPA would revise the BPT limitations based on advanced biological treatment only for COD, and revise the monitoring requirements for the existing cyanide limitations. Under option three, EPA would revise BPT limitations for BOD_5 and TSS based on advanced biological treatment and revise the monitoring requirements for the existing cyanide limitations. Under the fourth option, EPA would revise BPT limitations for BOD_5, TSS, and COD based on advanced biological treatment, and revise the monitoring requirements for the existing cyanide limitations. The options for all subcategories are the same, except as to cyanide where the option for subcategories B and D contains the option to withdraw the cyanide limitations rather than just modify the monitoring requirements.

The pretax total annualized costs, pollutant removals, and costs per pound removed associated with the options, except the ''no action'' option, are shown below in Table IV.C.1.

TABLE IV.C.1.—BPT PRETAX OPTION COSTS, POLLUTANT REMOVALS AND COST PER POUND REMOVED

Treatment option	Total annualized cost ($ million 1997)	Pollutant removals (lbs)	Cost per pound ($1996/lb)
A/C Subcategory			
Clarify cyanide monitoring, revise COD only	$2.48	14,352,000	$0.17
Clarify cyanide monitoring, revise BOD_5 & TSS	2.61	4,692,000	0.56
Clarify cyanide monitoring, revise BOD_5, TSS, & COD	3.10	15,731,000	0.20
B/D Subcategory			
Withdraw cyanide, revise COD only	$1.38	539,000	$2.56
Withdraw cyanide, revise BOD_5 & TSS	1.89	588,000	3.21
Withdraw cyanide, revise BOD_5, TSS, & COD	2.16	598,000	3.62

In selecting these treatment options, EPA considered the total cost in relation to the effluent reduction benefits, the age of equipment and facilities involved, the processes employed, process changes required, engineering aspects of the control technologies, non-water quality environmental impacts (including energy requirements) and

other factors in accordance with section 304(b)(1)(B) of the CWA.

EPA has determined to revise BPT effluent limitations only for COD. EPA is also clarifying the compliance monitoring requirements for the existing BPT limitations for cyanide for subcategories A and C, and withdrawing the existing cyanide limitations for subcategories B and D. As discussed above, EPA believes that it has the statutory authority to revise BPT and that it has the discretion to determine whether to revise BPT effluent limitations guidelines in particular circumstances. The CWA requires EPA, when setting BPT, to examine the total cost of treatment technologies in relation to the effluent reduction benefits achieved. In addition, in determining whether to set BCT limitations, the Agency needs to consider the reasonableness of the cost of reducing conventional pollutants and compare the cost of removing those pollutants by regulated plants and by POTWs. Accordingly, EPA examined the use of advanced biological treatment as a basis for both BPT and BCT limitations for BOD_5 and TSS. The Agency found that the reductions in these conventional contaminants achieved by this technology were not commensurate with the costs, largely because of the large operational costs associated with the removal of TSS. While it is EPA's view that it can revise BPT limitations for conventional pollutants without passing the BCT cost test (where the BPT effluent reduction ratio is favorable), the Agency is not generally inclined to do so unless the removals achieved by the existing BPT limitations are significantly fewer than would be achieved through revision of BPT. That was not the case here. Revising BPT (and BAT) for COD plants will not only remove large amounts of COD, but also achieve significant incidental removals of BOD_5 and TSS. For this reason, EPA has determined that it is not necessary to separately revise the BPT limits for BOD_5 and TSS in this case.

EPA has determined to revise BPT for COD because the biological treatment technology used as a basis for the limitations really represents BPT technology and is widely used in the industry.

The bulk parameter and nonconventional pollutant COD is an indicator of organic matter in the wastestream that is susceptible to strong oxidation, and as such would also measure organic material susceptible to biochemical oxidation, as well as some that is more difficult to oxidize biochemically. In addition, limited studies and discharge monitoring data have identified toxicity associated with the COD levels contained in effluents from pharmaceutical manufacturing facilities. Further discussion of the toxicity levels measured in the effluents from pharmaceutical manufacturing facilities is contained in Section 6 of the TDD. The revised COD limitations are estimated to remove approximately 14.9 million pounds annually, including incidental removal of 2.7 million pounds of BOD at an annualized cost of $2.48 million ($1997).

The revised COD provisions require the use of either the new effluent concentration limitations or the existing 74 percent reduction requirement, depending upon which method determines the more stringent plant permit limitation. This is being done in order to avoid back-sliding issues for existing plants that because of low influent concentration already meet lower effluent limits for COD.

With regard to cyanide, EPA is retaining the existing BPT limitations for the A and C subcategories. Further revision of the BPT cyanide limitations was not selected since the removals were estimated to be less than 42 pounds per year, thus, determined not to be beneficial in relation to the annualized costs of over $200,000 ($1997).

However, EPA is modifying the requirements for compliance monitoring (for subcategories A and C). The current limitations require compliance monitoring after cyanide treatment and before dilution with other wastestreams, or in the alternative, monitoring after mixing with other wastestreams based on a standard dilution factor. Today's rule does not change the prohibition on dilution to meet the effluent limitations for cyanide. The rule continues to require monitoring for compliance with the existing limitations in-plant, prior to the commingling of cyanide-bearing wastestreams with non-cyanide bearing wastestreams for those facilities where the cyanide levels would be below the level of detection at the end-of-pipe monitoring location. The only change in the monitoring requirements is to eliminate the current dilution standard that applied industry-wide, and to allow individual facilities to demonstrate that end-of-pipe monitoring for cyanide is feasible (i.e., cyanide is detectable); those facilities may continue to monitor at the end of pipe.

The ability of EPA to require in-plant monitoring has recently been questioned in connection with the Great Lakes water quality guidance program. *American Iron and Steel Institute (AISI)* v. *EPA,* 115 F.3d 979 (D.C. Cir. 1997). The Court held that although EPA has the authority to require monitoring of internal wastestreams, *see AISI,* 115 F.3d at 995, the CWA does not authorize EPA to require compliance with water quality based effluent limitations at a point inside the facility and thereby deprive a permittee of the ability to choose its own control system to meet the limitations, see *id.* at 966. EPA does not believe that decision controls here. The *AISI* court did not consider the question whether EPA has authority to regulate internal wastestreams in the context of technology-based controls such as BPT/BAT, PSES and NSPS/PSNS. Unlike water quality-based effluent limitations, which are calculated to ensure that water quality standards for the receiving water are attained, technology-based limitations and standards are derived to measure the performance of specific model technologies that EPA is required by statute to identify. In identifying these technologies, EPA is directed to consider precisely the type of internal controls that are irrelevant to the development of water quality-based effluent limitations, such as the processes employed, process changes, and the engineering aspects of various types of control techniques. EPA's technology-based effluent limitations are intended to reflect, for each industrial category or subcategory, the ''base level'' of technology (including process changes) and to ensure that ''in no case * * * should any plant be allowed to discharge more pollutants per unit of production than is defined by that base level.'' *E.I. du Pont de Nemours & Co.* v. *Train,* 430 U.S. at 129 (1973).

EPA believes that it can require in-plant monitoring to demonstrate compliance with technology-based effluent limitations in accordance with the CWA and its regulations at 40 CFR 122.44(i), 122.45(h), 125.3(e) and 403.6(e). In today's rule, EPA is continuing to require in-plant monitoring for cyanide except where cyanide can be detected in the final effluent. Were EPA to require compliance monitoring of the final effluent without adjustment for the amount of dilution in cyanide-bearing waste streams, there would be no way to determine whether the facility had adequately controlled for cyanide or whether the effluent has simply been diluted below the analytical detection level. Diluting pollutants in this manner rather than preventing their discharge is inconsistent with achieving the removals represented by the technology-based levels of control and hence with

the purposes of the limitations. It is also inconsistent with the goals of the CWA in general.

D. Best Available Technology Economically Achievable

EPA proposed adding new end-of-pipe BAT limitations for 53 organic pollutants plus ammonia, revising the existing cyanide limitations and adding the BPT revised COD limitations for subcategories A and C. For subcategories B and D, EPA proposed adding new end-of-pipe BAT limitations for 53 organics, BPT revised COD limitations and withdrawing the existing cyanide limitations. The technology basis for the limitations for VOCs was steam stripping plus advanced biological treatment for subcategories A and C and advanced biological treatment for subcategories B and D. The technology basis for the ammonia limitations was nitrification. The revised cyanide limitations for the A and C subcategories were the same as the revised BPT proposed limitations. For subcategories B and D cyanide limitations were proposed to be withdrawn since facilities in these subcategories do not use or generate cyanide in their wastewaters.

EPA received a number of comments indicating that steam stripping technology was not appropriate for the treatment of VOCs and that emissions of these pollutants from wastewater should be controlled by CAA regulations. In the preamble to the proposed MACT standards, EPA indicated that, in view of the MACT proposed wastewater standards, that it was considering changing the BAT technology basis for subcategory A and C VOCs limitations to end-of-pipe advanced biological treatment. In the NOA, EPA reiterated this option and provided cost information which compared the original proposal technology basis (steam stripping and advanced biological treatment) to the advanced biological treatment technology basis.

EPA also received comments on its proposed ammonia limitations. Commenters indicated that the ammonia limitations were inadequately supported by nitrification data. In the NOA, EPA indicated that after reevaluating its nitrification data base, it intended to base the BAT ammonia limitations on both one or two stage nitrification technology, presented compliance costs estimates based on two stage nitrification technology and revised limitations based on incorporating additional data, including data representing two stage nitrification, into the data base. In comments on the NOA, commenters indicated that some plants employing the proposed technology basis did not believe that they could achieve consistent compliance with the revised limitations.

In order to respond to these commenters, EPA evaluated additional nitrification data received from facilities after the August 8, 1997 publication of the NOA. As a result of this evaluation, EPA has recalculated the ammonia limitations that were presented in the NOA. In doing so, EPA used only data that showed evidence that nitrification was occurring and compared separate sets of limitations developed using single-stage and two-stage nitrification data sets, respectively. The results of this comparison gave final limitations less stringent than those calculated for the NOA, but reflective of systems that nitrify continuously whether they are one or two stage systems.

EPA considered three regulatory options as the basis for BAT limitations for subcategory A and C facilities. All three options modify the existing BAT regulations to parallel the BPT regulations and to clarify the compliance monitoring point for the existing cyanide limitations. The first option is a no cost revision which incorporates the BPT clarification for cyanide and revised BPT limitations for COD. The second option adds limitations for 30 organic pollutants based on advanced biological treatment and revised limitations for COD equal to the final BPT limitations and clarifies the compliance monitoring point for cyanide. The third option adds limitations for 30 organic pollutants based on advanced biological treatment, ammonia limitations based on one or two stage biological nitrification technology, incorporates the revised COD limitations and clarifies the compliance monitoring point for cyanide. The pretax total annualized compliance costs and pollutant removals associated with the second and third options (only options incurring costs) are shown below in Table IV.D.1 for subcategories A and C:

TABLE IV.D.1—BAT PRETAX OPTIONS COSTS, AND POLLUTANT REMOVALS FOR SUBCATEGORY A AND C DIRECT DISCHARGERS

Regulatory option	Total annualized cost ($ million 1997)	Pollutant removals (million lbs per yr)
Add Organics and COD and clarify cyanide	$2.3	1.4
Add Organics, Ammonia and COD and clarify cyanide	3.6	2.2

EPA evaluated the costs and economic impacts associated with each option and determined that all the options were economically achievable. After considering the pollutant load removals, the costs, as well as the non-water quality environmental impacts associated with the options, EPA selected the third option which adds effluent limitations for 30 organic pollutants, ammonia and COD and modifies the cyanide monitoring requirements. EPA believes that this option is economically achievable and there are no significant adverse non-water quality impacts associated with it. In addition, EPA believes the discharge loadings of ammonia, COD and the organic pollutants are significant from subcategory A and C facilities, and that limitations on these discharges are appropriate. EPA has also evaluated the technology bases of the final BAT limitations in the context of the BAT statutory factors, i.e., the age of equipment and facilities involved, the process(s) employed, potential process changes and non-water quality impacts such as energy requirements. EPA believes the final BAT limitations are appropriate based on its assessment of these factors in relation to A and C subcategory facilities.

For facilities with subcategories B and D operations, EPA has identified only the pollutant COD for control by BAT limitations based on advanced biological treatment (the technology selected as the basis for the BPT limitations). As discussed under BPT, cyanide is not a pollutant of concern for subcategories B and D operations and EPA is withdrawing the current BAT cyanide limitations for facilities with subcategories B and D operations. EPA

also has determined that ammonia is not a pollutant of concern for these subcategories since ammonia is not found in significant amounts in wastewaters from these operations.

Thus, for subcategories B and D, EPA considered two final BAT regulatory options. The first option is a no cost option consisting of the withdrawal of the existing cyanide limitations, the same as the final BPT withdrawal of cyanide control and the addition of the BPT revised COD limitations. The second option includes the withdrawal of the existing cyanide limitations and the addition of the BPT revised COD limitations and limitations based only on advanced biological treatment for 30 of the same organic pollutants selected for regulation at the subcategories A and C facilities.

The total annualized cost and annual pollutant removal associated with the second option are $0.410 million ($1997) and 22,300 pounds per year.

EPA has evaluated the discharge loadings of organic pollutants from subcategories B and D facilities and has determined that 95 percent of the discharge of organic pollutants is from two facilities. Most direct discharging subcategories B and D facilities do not discharge any organic pollutants. EPA believes these organic pollutant discharges are not sufficient to justify national regulations for these subcategories. If permit writers determine the need to further control the organic pollutants from the two facilities, the appropriate limits contained in the subcategories A and C BAT regulations may be used. For this final rule, EPA has selected the first option, which is to only add the BPT revised COD limitations to BAT for subcategories B and D facilities, and to withdraw the existing cyanide limitations.

E. Pretreatment Standards for Existing Sources (PSES)

EPA proposed pretreatment standards for 45 organic pollutants (including 37 VOCs), with in-plant monitoring for 12 VOCs and end-of-pipe monitoring for the remaining 33 organics (25 of which are VOCs) under coproposal A; and in-plant monitoring only for the 12 VOCs under coproposal B. EPA received considerable comment on its proposal pass through analysis which indicated that the 45 organic pollutants passed through POTW treatment works. Thirty-seven of the organic pollutants, including 13 alcohols and related compounds had Henry's Law Constants greater than 10^{-6} atm m^3/gmole, which was the physical property used to consider a pollutant to be too volatile to be treated properly at POTWs. The other eight organic pollutants were determined to pass through based on the BAT technology percent removal exceeding that of well operated activated sludge treatment represented by EPA's 50 POTW data base.

Many commenters objected to the assumption that pollutants with Henry's Law constants greater than 10^{-6} atm m^3/gmole would be considered to pass through based on their volatility. The pollutants commenters identified as being insufficiently volatile and highly biodegradable included: methanol, ethanol and other pollutants with Henry's Law constants lower than 1×10^{-5} atm m^3/gmole. Commenters indicated that many of the alcohols and related compounds were easily biodegraded by POTWs and did not pass through.

EPA also received a number of comments concerning the proposed in-plant monitoring point for the 12 VOCs. Commenters indicated that CAA MACT standards not CWA pretreatment standards should control in-plant emissions of these pollutants from internal wastestreams.

In order to address these and other comments related to controlling the alcohols and related compounds, EPA conducted a sampling study in August 1996 at a POTW in Barceloneta, Puerto Rico. This POTW treats pharmaceutical industry wastewaters containing measurable amounts of the predominant alcohols and related compounds, such as methanol, ethanol and isopropanol. The purpose of the sampling study was to determine the extent to which methanol and other compounds with similar Henry's Law Constants volatilize in the primary treatment works (aerated grit chambers and primary clarifiers) prior to the biodegradation unit process. Amounts volatilized prior to the biodegradation unit are not considered to be treated.

In the NOA, EPA published the preliminary results of the study along with those of a separate bench-scale study of anaerobic degradation in the Barceloneta primary clarifiers conducted by industry. EPA indicated in the NOA that it was considering a finding of no pass through for 13 of the organic pollutants (methanol and other alcohols and related compounds) based on the belief that the volatization of these pollutants in the primary works of POTWs is roughly equivalent to that observed in the primary works of direct discharging BAT level facilities. Thus, the treatment of these pollutants by a well operated POTW is roughly equivalent to that achieved by industrial facilities meeting BAT. As noted earlier in section III.D. EPA proposed PSES for 45 organic pollutants, and subsequently removed eight pollutants based on no pass through at the POTWs, thus making a total of 21 (with the alcohols and related compounds) not passing through POTWs.

In addition to discussing results of its pass through analyses in the NOA, EPA presented two revised pretreatment options for all four subcategories, with end-of-pipe monitoring for all VOCs including the 12 volatile pollutants for which in-plant monitoring for PSES/PSNS had been proposed. In the NOA, EPA indicated that PSES for these 12 pollutants were unnecessary because they would be controlled by the MACT wastewater standards which require an in-plant compliance demonstration for 10 of the 12 VOCs which are HAPs. The remaining 12 VOCs, in addition to the two non-HAPs that are part of the 12 VOCs discussed above, are controlled by end-of-pipe limits based on steam stripping, with removals incidental to controlling HAPs either directly by the MACT standards or separately from the MACT standards at smaller facilities not covered by the MACT rule but controlled by this CWA final rule.

In finalizing the methodology for the pass through analysis discussed above, EPA relied on three criteria that had to be met before a pollutant was deemed to pass through. These criteria included volatility, solubility in water, and the BAT and POTW technologies percent removal comparison. With regard to volatility, EPA raised its Henry's Law Constant threshold for volatility from 1×10^{-6} atm/gmole/m^3 to 1×10^{-5} atm/gmole/m^3 based on comments that the Henry's Law Constant used at proposal was not consistent with what was used for the OCPSF final rule. Pollutants with Henry Law Constants greater than 1×10^{-5} atm/gmole/m^3 were believed to volatilize significantly before reaching treatment at a POTW. In connection with volatility, in order to be consistent with the MACT standards approved for controlling water soluble HAPs, EPA also considered whether a pollutant was water soluble because water soluble compounds are less likely to volatilize than compounds that are partially soluble. Finally, EPA considered differences in removal percentages for organic pollutants obtained by comparing the BAT model treatment system percentage removal to the average pollutant removal percentage achieved by well-operated POTWs achieving secondary treatment performance standards.

In developing BAT pollutant removal percentages, EPA only used pollutant data pairs where the influent

concentrations were greater than ten times the pollutant method detection limits which was the approach used in developing the supporting information for the NOA. In developing the final POTW pollutant removal percentages, EPA utilized the acclimated data from the same sources used to develop these percentages for the NOA. These removal percentages are the POTW removal percentages used in the final comparison. Thus, in order for a pollutant to be deemed to pass through, it had to have a Henry's Law Constant greater than 1×10^{-5} atm/gmole/m^3, be less than totally soluble in water, and have a BAT removal percentage greater than its POTW removal percentage. Based on this analysis, EPA has determined that 23 organic pollutants in subcategories A and C and 5 organic pollutants in subcategories B and D, that pass through POTWs are regulated by pretreatment standards in today's rule. A more detailed description of this analysis may be found in section 17 of the final TDD.

In addition to pretreatment standards for VOCs, EPA proposed ammonia standards based on either steam stripping or two-stage nitrification. In May 1995 EPA proposed ammonia pretreatment standards based only on steam stripping technology. The Agency received a number of comments concerning the proposed ammonia pretreatment standards. Some commenters indicated that steam stripping may not be a reliable treatment technology. Others questioned the need for national ammonia standards because many POTWs have imposed local limits for ammonia and others have nitrification capability. EPA discussed both of these concerns in the NOA. EPA suggested in the NOA that ammonia does not pass through POTWs with nitrification, and requested comments on the preliminary discussion not to set pretreatment standards for industrial users which discharge to POTWs with this technology. Comments from POTW control authorities and industry supported this approach to developing PSES ammonia standards. The final rule contains ammonia pretreatment standards only for subcategories A and C, based on the BAT technology of nitrification and is applicable to those facilities discharging to POTWs without nitrification capability.

EPA determined that cyanide passes through POTWs based on the percent removal comparison with the hydrogen peroxide (BAT) technology. Thus, EPA proposed revised cyanide pretreatment standards based on hydrogen peroxide technology but maintaining that the standards based on in-plant monitoring for the requirements. EPA received comments raising safety concerns using this technology for high organic strength wastes. Based on these comments and additional data submitted by facilities, in the NOA, EPA proposed establishing two sets of cyanide standards. One standard would be identical to the proposed standards based on hydrogen peroxide technology, while the other standard would be based on alkaline chlorination technology and applicable only to those facilities that could demonstrate, due to safety concerns, that hydrogen peroxide technology was not an appropriate technology to use with their wastewater. EPA estimated compliance costs and loadings removals to be the same for both sets of standards because it was assumed that the vast majority of facilities would meet these standards based on the use of the more expensive and efficient hydrogen peroxide technology.

In developing the final PSES for subcategories A and C, EPA considered three options. The first option was not to develop pretreatment standards for ammonia or any of the VOC pollutants, and to modify the monitoring requirements for the existing cyanide standards. The second option would build on compliance with the MACT standard with additional pretreatment standards for 23 VOCS based on steam stripping technology and ammonia based on steam stripping or nitrification and modify the cyanide monitoring requirements. The third option would be the same as the second option, with the addition of revised pretreatment standards for cyanide.

The annualized compliance costs (1997 dollars) and pollutant removals for the second and third options (the only ones incurring costs) are shown below in Table IV.E.1. EPA did not consider additional options involving small facility exclusions because results of the economic analyses for the small facilities using the costs for both options described above showed that both options are economically achievable (see section V of this preamble for more discussion).

TABLE IV.E.1—PSES PRETAX OPTIONS COSTS AND POLLUTANT REMOVALS FOR SUBCATEGORIES A AND C INDIRECT DISCHARGERS

Treatment option	Total annualized cost ($ million 1996)	Pollutant removals (million lbs)
Add organics and ammonia and modify cyanide monitoring requirements	$44.5	10.653
Add organics and ammonia and revise cyanide limits	44.8	10.654

Due to the low pollutant removals achievable by the revised cyanide standards (approximately 1000 lbs per year with 97 percent of the removals coming from one facility) in relation to the compliance costs, EPA has decided not to revise the existing cyanide standards, and has selected the option to add organics and ammonia only and modify the current cyanide monitoring requirements. The selected option adds standards for ammonia and the 23 organic pollutants determined to pass through (see previous discussion in this section), and modifies the monitoring point for the current cyanide pretreatment standards for subcategories A and C.

EPA is setting pretreatment standards for ammonia for subcategories A and C because of the high loads of ammonia currently being discharged by a number of pharmaceutical facilities to POTWs that do not have nitrification capability and receive wastewaters from subcategories A and C facilities. However, EPA is aware that some POTWs treating pharmaceutical wastewaters from these subcategories have nitrification capability, and EPA has made a determination of no passthrough for ammonia at these POTWS. Thus, PSES ammonia limitations will not apply to subcategory A and C facilities discharging to POTWs with nitrification capability. POTWs with nitrification capability oxidize ammonium salts to nitrites (via Nitrosomonas bacteria) and the further oxidize nitrites to nitrates via Nitrobacter bacteria and achieve greater removals of ammonia than POTWs

without nitrification. Nitrification can be accomplished in either a single or two-stage activated sludge system. In addition, POTWs that have wetlands which are developed and maintained for the expressed purpose of removing ammonia with a marsh/pond configuration are also examples of having nitrification capability. Indicators of nitrification capability are: (1) biological monitoring for ammonia oxidizing bacteria (AOB) and nitrite oxidizing bacteria (NOB) to determine if nitrification is occurring, and (2) analysis of the nitrogen balance to determine if nitrifying bacteria reduce the amount of ammonia and increase the amount of nitrite and nitrate.

For subcategories B and D, EPA considered two options. The first option was not to add regulated pollutants to the existing PSES and, since cyanide is not present in wastewaters for these subcategories facilities, to withdraw the existing cyanide standards. Thus, compliance with the MACT standard would be the only requirement for controlling VOC pollutants. The second option was to add pretreatment standards for 5 VOCs (not including the alcohols and related compounds and 19 pollutants determined not to be present in subcategory B and D wastewaters) based on steam stripping in addition to withdrawing the existing cyanide standards. No ammonia standards were considered since facilities in these subcategories do not generate significant levels of ammonia in their wastewaters. The pretax annualized compliance cost for this second option is $8.8 million ($1997) and annual pollutant removals are 3.35 million pounds.

For PSES for subcategories B and D, EPA has selected the second option. EPA is basing this selection on the fact that the 5 pollutants (VOCs) have been determined to passthrough, and the pollutant removals are relatively high with respect to the compliance costs. The costs are economically achievable and the nonwater quality environmental impacts are acceptable.

F. New Source Performance Standards (NSPS)

EPA proposed NSPS for 53 organic pollutants, BOD_5, TSS and COD based on steam stripping or distillation and advanced biological treatment for subcategories A and C. EPA also proposed NSPS for ammonia and cyanide based on nitrification and hydrogen peroxide oxidation technologies, respectively for these two subcategories. EPA received comments indicating that distillation technology was not a demonstrated technology for removing soluble VOCs (such as methanol), and therefore, should not be part of the technology basis of NSPS. EPA has reevaluated its steam stripping and distillation database and has concluded that distillation technology is sufficiently demonstrated to be considered BADT (Best Available Demonstrated Technology). However, after taking into account the high removal of these pollutants achievable by steam stripping and advanced biological treatment, the addition of distillation technology is unnecessary. Consequently EPA did not consider distillation technology as part of final NSPS model technology.

EPA evaluated technology options capable of achieving greater pollutant removal of conventional pollutants (BOD_5 and TSS), COD, Organics, Cyanide and Ammonia than those selected as the basis for existing source limitations (BPT, BCT and BAT). The only option potentially capable of achieving additional removals involves the use of granular activated carbon (GAC) adsorption technology. This technology is capable of reducing the COD from some direct discharging A and C subcategory facilities. However, there is only limited GAC performance data available, from one pilot study.

For subcategories B and D, EPA proposed NSPS for 53 organic pollutants, BOD_5, TSS and COD based on in-plant steam stripping with distillation and end-of-pipe advanced biological treatment. As was the case with the proposed NSPS for subcategories A and C, EPA received comments stating that use of distillation technology as BADT for new sources is inappropriate because its ability to remove methanol and other water soluble organic pollutants has not been demonstrated with respect to representative wastestreams.

For subcategories A and C, EPA is promulgating NSPS equal to the final BAT effluent limitations for 30 organic pollutants, cyanide and ammonia. For subcategories B and D, EPA is promulgating NSPS equal to BAT (including withdrawal of the existing cyanide standards). EPA is also promulgating revised NSPS for BOD_5, COD and TSS for all four subcategories at a level equal to the discharge characteristics of the best performing BPT plants which for COD is also the BAT/BPT level of control. These final standards are based on the best available demonstrated control technologies, which include advanced biological treatment, cyanide destruct and nitrification. In developing these final standards, the Agency considered factors including the cost of achieving effluent reductions, non-water quality environmental impacts, and energy requirements. EPA finds that the final standards represent the best available demonstrated control technologies, are economically achievable and do not present a barrier to entry and have acceptable non-water quality environmental impacts.

G. Pretreatment Standards for New Sources (PSNS)

EPA proposed PSNS for 45 organic pollutants, cyanide and ammonia for subcategories A and C, and the same 45 organic pollutants only, for subcategories B and D. The technology basis for the proposed organic pollutant standards was steam stripping with distillation, and the technology bases for the proposed cyanide and ammonia standards were hydrogen peroxide oxidation and steam stripping technologies, respectively.

The proposed pretreatment standards for new sources were more stringent than the proposed PSES. However, for the final rule, EPA was unable to identify a technology that would achieve greater removal of the pollutants to be controlled by the PSES being promulgated today and is therefore promulgating PSNS equal to PSES for all four subcategories.

H. Best Conventional Pollutant Control Technology (BCT)

EPA proposed BCT equal to BPT for the conventional pollutants BOD_5 and TSS for all four subcategories. The Agency indicated that it had not identified technologies that achieve greater removals of conventional pollutants other than those associated with the proposed revision of BPT limits, and that these technologies did not pass the two-part BCT cost reasonable test. EPA has not received any comments concerning its proposal BCT cost test analysis. The Agency has repeated the cost test with the postproposal data, with the same results. Based on the failure to identify any incremental conventional pollutant removal technology options that pass the BCT cost reasonable test, EPA is promulgating BCT limitations equal to the existing BPT limitations for BOD_5 and TSS for all subcategories.

V. Assessment of Costs and Impacts for the Final Pharmaceutical Regulations

A. Introduction

The economic analysis for the final pharmaceutical effluent limitations guidelines and standards assesses the costs and impacts of these guidelines. The results of this analysis are contained in the record for this final

rule and are summarized in a document entitled Economic Analysis for Final Effluent Guidelines and Standards for the Pharmaceutical Industry (EPA–821–B–98–009). Included in the Economic Analysis (EA) and summarized below are (1) the annualized costs of the rule by subcategory, separately and together with the costs of the MACT standards rule discussed previously; (2) the impacts of the rule both separately and together with the MACT standards on pharmaceutical facilities, both existing and new sources; (3) the impacts of these rules on pharmaceutical firms; (4) the impacts of these rules on employment and communities; and (5) other secondary impacts on trade, inflation, POTWs, environmental justice, and distributional equity. Also included in the EA are a Final Regulatory Flexibility Analysis as required under the Regulatory Flexibility Act and a Cost-Benefit Analysis, as required under the Unfunded Mandates Reform Act (UMRA) and Executive Order 12866, which are summarized in Sections V.E and V.F of this preamble. An additional document, Cost Effectiveness Analysis for Effluent Limitations Guidelines and Standards for the Pharmaceutical Industry (EPA–821–B–98–010), assesses the cost-effectiveness of the rule. The results of this analysis are summarized below in Section V.G.

B. Summary of the Economic Analysis Methodology and Data

EPA determined the annualized costs of compliance in exactly the same way as was done for proposal, with the exception of the choice of discount rate (discussed in V.C). Costs are annualized at seven percent over 16 years (a 1-year installation period a 15-year project life is assumed). The cost annualization also accounts for tax shields on both O&M and depreciation (calculated using the modified accelerated cost recovery system allowed by IRS rules) to develop a posttax estimate of annual costs (see Section 4 of the Economic Analysis for a detailed discussion). For analytical consistency, MACT standards costs are also annualized in the same way, both pretax and posttax. This is slightly different from the way EPA annualized the MACT standards costs in the preamble to the MACT standards rule, where costs are annualized at seven percent over ten years (with no delay for installation) to create a pretax annual cost (i.e., without accounting for tax shields). Additionally, the MACT standards costs presented in the preamble to the MACT standards rule include costs for new sources, which are not included in this preamble. Despite the differences in annualization method, the current cost annualization approach in no way conflicts with the alternative analysis.

To assess impacts on firms and facilities, EPA has set up three baselines in the analysis. Baseline 1 is the usual baseline analyzed in all effluent guidelines. It is a scenario that reflects a baseline condition without additional regulation, that is, no additional effluent limitations guidelines and standards or MACT standards costs are considered. This baseline is taken from the current (i.e., 1990 Survey) financial data. Baseline 2 incorporates certain MACT standards costs pertaining only to wastewater emission controls, and does not include costs for controlling emissions from process vents, equipment leaks and storage tanks. This baseline is presented in the EA, but results of this baseline (which are not appreciably different from those for Baseline 1) are not discussed at length in this preamble. Baseline 3 incorporates costs for all components associated with the MACT standards rule. EPA estimated the capital and operating costs for MACT standards cost components for emission controls on wastewater streams (on which Baseline 2 is based), as well as the capital and operating costs for all MACT components (on which Baseline 3 is based) as a part of the Agency's MACT standards rulemaking process.

To model Baseline 2, EPA used the capital and operating costs associated with the wastewater emission controls for all facilities in the MACT analysis for which costs were developed and matched them to the facilities that are also in the effluent guidelines analysis. However, a number of facilities in the effluent guidelines analysis are not covered by the MACT standards and were not assigned MACT costs.

EPA annualized the costs at seven percent over 16 years in the cost annualization model and also developed a present value of posttax compliance costs over this same time frame. EPA subtracted the present value posttax compliance costs from the Baseline 1 present value posttax facility earnings (derived from the Survey data) to determine Baseline 2 posttax earnings for each facility in the effluent guidelines analysis. EPA used this same approach to derive Baseline 3 posttax earnings (for those facilities without MACT standards costs, earnings are the same in all three baselines).

A facility whose posttax earnings are zero or negative in Baseline 1 is counted as a Baseline 1 closure; a facility whose posttax earnings are zero or negative in Baseline 2 is counted as a Baseline 2 closure; and a facility whose posttax earnings are zero or negative in Baseline 3 is counted as a Baseline 3 closure.

EPA then incorporated the present value posttax costs of the effluent guidelines into each of the baselines in the same way as MACT standards costs were incorporated to calculate postcompliance, posttax earnings. EPA then tallied the closure results (in terms of whether postcompliance, posttax earnings are zero or negative) by counting postcompliance closures incrementally from each baseline. In other words, EPA considered any closures that occurred additional to those occurring in each of the baselines as postcompliance closures under the three baseline scenarios. Any facilities that certified that the effluent guidelines would have no impact on them were assumed not to close under any baseline or in postcompliance. Note that as in the proposal Economic Impact Analysis (EIA), impacts on single-facility firms were assessed at the firm level.

MACT standards costs were also incorporated into firm-level data under the same three baseline scenarios. In the firm-level analysis, however, the key data that could change were assets, liabilities, and earnings before interest and taxes, which were used in an equation called Altman's Z, a multi-discriminant ratio analysis approach to identifying relative firm health. This equation is composed of several common financial ratios that are weighted according to their relative ability to predict bankruptcy based on empirical industry data. The result of this equation is called the Altman's Z-score. Scores below a certain value are considered indicative of poor financial health and a high likelihood of bankruptcy.

For Baseline 1, EPA used the current survey data in the Altman's Z model to determine a Baseline 1 Altman's Z-score. For Baseline 2, EPA took the MACT standards capital costs aggregated at the firm level (since firms often own more than one facility) and adjusted both assets and liabilities to reflect the acquisition of capital equipment through an increase in debt. EPA then adjusted earnings before interest and taxes by subtracting the annualized amount of operating costs plus depreciation computed by the cost annualization model, given the Baseline 2 MACT standards capital and operating costs (also aggregated at the firm level) and then computed a Baseline 2 Altman's Z-score.

EPA used the same approach using the Baseline 3 MACT standards operating and capital costs to create the Baseline 3 Altman's Z-score. If any of

these three baseline scores were below the cutoff point considered a sign of poor financial health, EPA considered the firm a baseline failure.

Compliance costs for the effluent guidelines were then used in the same manner to further adjust the financial data used in the Altman's Z model in each of the baselines. Where the Altman's Z-score changed from one reflecting a healthy firm or one in indeterminate status in any of the baselines to one of poor financial health, EPA considered the firm to be a postcompliance firm failure relative to the baseline under consideration.

EPA's methodology for computing output and employment effects is discussed in detail in Section V.C. These effects are presented as net effects in Section V.D.4. To compute net effects, EPA calculated both losses and gains in output and employment and subtracted losses from gains (or vice versa). Thus EPA calculated net national-level output effects, net national-level employment effects, and net direct employment effects (employment losses in the pharmaceutical industry driven by output losses in the industry). EPA also estimated the employment losses estimated to occur as a result of closures and failures. These types of losses were used to determine whether any community-level impacts are likely.

Trade impacts were assessed in the same way as in the EIA for the proposal, except that a profit margin analysis has been added, as described below in Section V.C. Impacts on inflation were assessed by comparing the cost of the regulation to gross domestic product (GDP). The potential for distributional impacts was assessed by identifying facilities where compliance costs were greater than 10 percent of operating costs and determining what types of products might be most affected if costs are passed through to consumers. The users of these products were then qualitatively identified to determine if these potential users might be disproportionately represented by economically disadvantaged groups. Impacts on environmental justice were also qualitatively addressed.

C. Changes to the Economic Analysis Since Proposal

The most significant change in the EA since proposal is associated with the change in costs. The costs of the effluent limitations guidelines and standards for the pharmaceutical industry point source category are now substantially lower than those estimated at proposal because the costs of controlling air emissions are now a part of EPA's MACT standards. Impacts from the final rule do not change measurably from proposal, however, mostly because impacts both now and at proposal were estimated to be very small.

Costs for control of air pollutants, previously assigned to the effluent guidelines at proposal, are now assigned to the MACT standards requirements. The economic analyses show the impacts of the effluent guidelines against three separate regulatory baselines: no MACT standards requirements in place, wastewater emissions control and treatment system requirements in place, and all MACT standards requirements in place (see Section II.E. of this preamble for a description of MACT standards requirements). In this way, EPA can present impacts from the effluent guidelines alone and in combination with impacts from the MACT standards requirements. The methods EPA used to assess the impact of MACT standards on the baselines against which the effluent guidelines are measured were discussed in Section V.B.

EPA is now using a seven percent discount rate in all of its analyses. Previously, the Agency used the seven percent rate only in determining the pretax cost of the regulation. EPA has chosen to use a seven percent social discount rate (in real terms) in this analysis, rather than the 11.4 percent discount rate used in the proposal, for two reasons. First, the seven percent discount rate is strongly recommended by the Office of Management and Budget for use in economic analyses (see the EA for more details). Second, the cost of capital has generally declined since 1990. This change in discount rate, however, has little effect on the analysis. A comparison of estimated impacts in the proposal to impacts as estimated here show that the analyses are not sensitive to assumptions about discount rates in the ranges used.

In terms of content, the economic analyses are now presented as a more comprehensive report, in which the EIA and Regulatory Impact Analysis (RIA) have been combined into one report (the EA). The cost-benefit portion of the RIA is now contained in Section 10 of the EA report.

EPA has also made a few methodological changes in its firm and facility analyses. In the EIA for the proposal, EPA included salvage value in the calculations for the facility closure analysis for projection of baseline closures (i.e., before compliance costs are considered) and postcompliance closures. EPA recognized some potential difficulties with the salvage value calculations and, in the proposal EIA, investigated the effects of assuming salvage value does not play a role in determining facility viability. EPA found that the facility closure projections were not sensitive to the alternate salvage value assumption. Furthermore, industry also commented that using salvage value overstated baseline closures. Thus EPA believes that its current analysis, which does not consider salvage value but rather uses negative posttax earnings as the indicator of closure, is the best methodology to use, given the uncertainty of salvage value data.

An additional difference in the closure analysis addresses the issue of non-self-supporting facilities (baseline facility closures). In the current analysis, EPA investigates all baseline closures at the firm level to determine if a multi-facility firm could install and operate pollution control equipment at all of its affected facilities, including those estimated as baseline closures. If the firms can continue to support a baseline closure facility without risk of failure, EPA determines that impacts to the firm and its affected facilities are minimal. EPA performed this analysis under the assumption that if the facility was not expected to support itself in the baseline, the firm level is the appropriate level at which to assess impacts.

EPA also modified the methodology for determining impacts on firms. In response to comments that baseline firm failures were overstated because the Agency used benchmarks that identified lowest quartile firms as baseline failures, EPA reassessed the methodology and turned to a more sophisticated method for determining firm financial health. EPA used a multi-discriminant analysis approach for evaluating the financial health of firms. This analysis, developed by Edward Altman, is known as Altman's Z-score analysis. This approach allows the simultaneous analysis of several common financial ratios and answers the question of how to determine financial health when some ratios appear strong and some appear weak. The equation developed by Altman assigns relative weights to the various ratios on the basis of how well they predict bankruptcy (determined using actual firm data and information on whether the firms did in fact go bankrupt). This approach reduced the proportion of firms considered baseline failures from 28 percent in the EIA for the proposal to about 10 percent (see Section V.D.3), thus allowing for substantially more firms to be evaluated at the firm level in the postcompliance

analysis. The Altman's Z analysis is also described in Section V.B above and is fully described in Section 6 of the EA Report.

The Agency has added an analysis of national-level output and employment effects to the EA for the final rule. Output is measured in terms of revenues, and under the assumption that industry cannot pass through compliance costs to consumers, the worst-case output loss to the pharmaceutical industry is equal to the pretax costs of compliance. The output losses occurring in the pharmaceutical industry (direct effects) affect input industries, which are industries that provide inputs (e.g., raw chemicals) to the pharmaceutical industry. These effects are known as indirect effects. The direct output losses also affect consumption, as workers lose jobs or work fewer hours and their households reduce purchases of goods and services. These effects are called induced effects. Thus a dollar of output lost in the pharmaceutical industry can also result in additional dollars lost in the U.S. economy as a whole through indirect and induced effects. EPA calculates these additional losses at the national level using input-output analysis. The relevant multipliers used in the analysis were developed by the U.S. Department of Commerce's Bureau of Economic Analysis (BEA).

In addition to output losses, EPA calculates national-level output gains based on output gains in pollution control industries. These industries receive revenues from the pharmaceutical industry for pollution control equipment and operations. Using BEA multipliers, the Agency calculates the subsequent effect of these gains on the pollution control industries' input industries and consumption (i.e., indirect and induced effects). By comparing national-level output losses and gains, EPA develops a net national-level output loss or gain.

In the EA, EPA no longer relies exclusively on employment losses from closures and failures to calculate employment losses in the pharmaceutical industry or national-level employment losses. Because output effects and employment are linked in input-output analysis, EPA calculates employment losses based on output effects using BEA's final demand and direct effect multipliers. EPA uses final demand employment multipliers to compute the total number of jobs lost (including direct, indirect, and induced job losses) given the total loss of output in millions of dollars in the pharmaceutical industry and uses direct effect multipliers to compute the total number of job losses occurring just in the pharmaceutical industry (direct losses), given the total jobs lost nationwide (which include direct, indirect, and induced losses).

Output-based employment losses can be thought of as longer-term losses associated with longer-term market equilibrium, whereas losses associated with closures and failures can be considered the more immediate impact of the rule before market equilibrium is achieved. Thus output-based employment losses may be greater than or less than the losses estimated on the basis of closures and failures, which means that nonclosing facilities might gain or lose production and employment depending on how many facilities close. If no facilities close, nonclosing facilities might lose some production and employment. If many facilities close, nonclosing facilities might actually gain production and employment if closure losses ''overshoot'' the expected losses at market equilibrium. Note, however, that both the output-based employment effects and the closure/failure employment effects derived here are worst-case impacts within the pharmaceutical industry since EPA assumes the industry cannot pass through the costs of compliance to consumers.

EPA also computes employment gains on the basis of output gains in pollution control industries in much the same way as was done for the EIA for the proposal. The approach has been changed slightly to accommodate labor costs estimated as a part of the engineering cost analysis rather than relying on assumed labor shares. EPA compares the employment losses and gains to estimate a net gain or loss in employment both at the national level and in the pharmaceutical industry alone (some gains will occur in the pharmaceutical industry since labor to operate pollution control equipment is required).

EPA now performs an assessment of impacts on profit margins to address commenter concerns that pharmaceutical firms will locate (or relocate) facilities outside of the U.S. because of environmental regulatory requirements. EPA assumes that those firms most likely to consider relocating facilities are those with measurable differences in profitability with sufficient means to effect a relocation. EPA also addresses comments that reductions in loadings to POTWs will result in substantial impacts on POTWs.

All other methodologies used and analyses undertaken in the EA remain substantively the same as those in the EIA for the proposal.

D. Estimated Economic Impacts

1. Costs of Compliance

Table V.D.1 presents a summary of compliance costs for the effluent limitations guidelines and standards and for the MACT standards. EPA estimated annualized compliance costs on both a pre-tax and post-tax basis; both sets of costs are shown in Table V.D.1. Post-tax costs reflect tax savings accruing to the industry from the installation and operation of pollution control equipment; the post-tax costs are used in the economic analysis to assess impacts to facilities and firms in the industry. Pre-tax costs are a component of the total social cost of the regulatory action (see Section V.F).

EPA describes the cost annualization procedure in Section V.B and in the EA. The annualized costs in Table V.D.1 for both the effluent limitations guidelines and standards and the MACT standards rule incorporate the same annualization period assumptions. The annualized costs reported in the preamble to the MACT standards rule are based on another annualization period and thus, do not correspond exactly to Table V.D.1. As noted in Section V.B, costs are annualized over 16 years (with an 1-year installation period and a 15-year project life), while in the preamble to the MACT standards rule, costs are annualized over 10 years (with no delay for installation). As an illustration, Table V.D.1 reports pre-tax annualized costs for the MACT standards rule for all facilities (referred to as ''existing sources'' in the MACT standards rule) at $58.4 million. In the preamble to the MACT standards rule, the corresponding annualized costs are reported at $64.8 million.

The annualized post-tax compliance costs for effluent guidelines for the selected options are $39.4 million. The annualized post-tax compliance costs of the MACT standards for the subset of facilities also subject to effluent guidelines are $32.4 million. The total annualized costs for facilities covered by both the effluent guidelines and MACT standards are $71.8 million, and the total annualized costs for all facilities (i.e., including those facilities covered by MACT standards only) are $77.5 million.

TABLE V.D.1—ANNUALIZED COSTS OF COMPLIANCE FOR EFFLUENT GUIDELINES AND MACT REQUIREMENTS

Subcategory	Option	Posttax annualized cost of compliance (million 1997$)	Pretax annualized cost of compliance (million 1997$)
A/C Direct	BPT=Revise COD and modify cyanide	$1.6	$2.5
	BAT=Add organics, ammonia and COD and modify cyanide.	2.3	3.6
B/D Direct	Revise BPT COD and withdraw cyanide	0.9	1.4
A/C Indirect	PSES=Add organics and ammonia and modify cyanide.	28.8	44.5
B/D Indirect	PSES=Add organics and withdraw cyanide	5.8	8.8
Total Annualized Cost of Effluent Guidelines for all Selected Options.		39.4	60.8
Cost of MACT Standards	Effluent Guidelines Facilities	32.4	49.6
	All Facilities	38.1	58.4
Total Annualized Cost of Effluent Guidelines and MACT Standards for Effluent Guidelines Facilities.		71.8	110.4
Total Annualized Costs of Effluent Guidelines and MACT Standards for All Facilities.		77.5	119.2

2. Economic Impacts on Facilities

EPA determined on the basis of zero or negative posttax earnings that 18 facilities, or 9 percent of all facilities in the analysis, would be likely to close even without the effect of the effluent guidelines or MACT standards requirements. The impacts to the firms of installing and operating pollution control equipment at these facilities are, however, assessed at the firm level to determine if the firms can continue to support these facilities postcompliance (see below under results of the firm analysis). When all MACT standards costs are incorporated into the initial baseline financial conditions (Baseline 3), no additional facilities close.

When the costs of compliance for this final effluent guidelines rule are incorporated into the financial conditions of facilities in the analysis (the postcompliance analysis), only one additional facility closes (an A/C indirect). Even though this facility does not close when faced with costs of meeting this effluent guidelines rule alone, EPA conservatively attributes this closure to the effluent guidelines. In general, however, neither MACT standards costs nor effluent guidelines costs singly or together have major impacts on pharmaceutical facilities operated by multifacility firms.

3. Economic Impacts on Firms

EPA projected that 18 firms would be likely to fail even without the effect of the effluent guidelines or MACT standards requirements (Baseline 1). Two additional firms are projected to fail before effluent guidelines costs are considered when all MACT standards costs are included in the initial baseline financial conditions (Baseline 3).

In the postcompliance analysis, EPA estimated that four firms would fail under the Baseline 1 scenario and two firms would fail under the Baseline 3 scenario. (There are two fewer postcompliance firm failures under the Baseline 3 scenario because these failures were estimated to be precompliance failures when all MACT standards costs were included.) Thus at most, regardless of baseline, four firms fail postcompliance. To be conservative in the EA, EPA attributes these failures to the Pharmaceutical Effluent Guidelines alone. Out of the four firm failures projected to occur, EPA estimates only one will result in both a firm failure and a facility closure (because earnings become negative at the only facility owned by the firm). The other three firms will incur substantial impacts, up to and including firm failure, but own financially viable facilities. Because the facilities are self-supporting, they are likely to be attractive for acquisition by financially stronger firms. Therefore, the three failing firms with viable facilities might not fail, but instead might be forced to sell their facilities.

As discussed in Section V.D.2, EPA evaluated all facilities projected to close in the baseline analysis at the firm level, under the assumption that perhaps these facilities are not expected to be self-supporting and thus might not close in the baseline. If this is so, the appropriate level of analysis is the firm. EPA determined that all facilities projected to close in the baseline facility closure analysis can continue to be supported by their firms postcompliance without significant impact on these firms.

TABLE V.D.3 FIRM FAILURE ANALYSIS RESULTS (BASELINE 1)

Type of discharger	Failures only			
	Number Failures with closures	Percentage of total firms in subcategory	Number	Percentage of total firms in subcategory
A/C Direct	0	0	0	0
B/D Direct	0	0	0	0
A/C Indirect	2	3.2	1	1.6
B/D Indirect	1	1.2	0	0

TABLE V.D.3 FIRM FAILURE ANALYSIS RESULTS (BASELINE 1)—Continued

Type of discharger	Failures only			
	Number Failures with closures	Percentage of total firms in subcategory	Number	Percentage of total firms in subcategory
Total All Firms	3	1.8	1	0.6

4. Impacts on Output and Employment

EPA estimates that at the national level, output gains will exceed output losses. EPA determines a net output gain of about $21.7 million (1996$) as a result of the effluent guidelines. Net output gains for the combined rulemakings (including MACT standards for facilities in the effluent guidelines analysis only) will total $40.1 million (1996$). EPA also determines that employment gains will exceed employment losses at the national level. The net gain in national-level employment as a result of the effluent guidelines alone will total 218 full-time equivalents (a full-time equivalent, or FTE, equals 2,080 hours per year of labor), and net employment gains for the combined rulemakings (including MACT standards for facilities in the effluent guidelines analysis only) will total 407 FTEs.

Despite net employment gains at the national level, EPA calculates that losses will exceed gains in the pharmaceutical industry. Direct losses in the pharmaceutical industry are composed of two types of losses—output-based losses and closure/failure type losses. As noted in Section V.C., closure/failure employment losses might be less than the output-based employment losses that are driven by the contraction in the pharmaceutical industry as it responds to the compliance costs and a new market equilibrium is achieved. Closure/failure employment losses can also be greater than these output-based losses if they ''overshoot'' the expected market equilibrium result. In this case, the direct losses computed on the basis of output losses (and net of gains in employment in the industry due to the need to operate the pollution control equipment) are slightly greater than the closure/failure losses (which are estimated to total 139 FTEs). Output-based losses total 138 FTEs, or 0.1 percent of pharmaceutical employment in the analysis. With MACT standards costs for facilities included in the effluent guidelines analysis, net direct employment losses will total 254 FTEs, or 0.1 percent of employment.

Because output-based employment losses are greater than closure/failure employment losses, nonclosing facilities might experience some small reductions in labor hours and production over time that are additional to the losses of labor hours and production associated with facilities that close or fail (assuming a worst-case scenario where no costs can be passed through to consumers).

The losses in employment due to closures/failures will have a negligible impact on individual communities. No community is expected to experience a change in its unemployment rate exceeding 0.4 percent.

5. Other Secondary Impacts

No trade losses or major changes in the balance of payments are associated with closures/failures of firms or facilities, as these firms and facilities indicate no foreign shipments. Thus EPA finds that neither rule, together or separately, will have a substantial impact on trade or the balance of payments.

An analysis of profit margin shows only a few firms will experience impacts on profit margin as a result of the effluent guidelines. A total of 8 firms (6 percent of the firms analyzed) have a greater than 10 percent change (e.g., go from a 5 percent profit margin to a 4.5 percent profit margin) in their profit margin. Most of these firms are considered the least likely to relocate their facilities to foreign countries. These firms tend to be small, and generally, they are unlikely to have experience in international locations. The transaction costs of learning how to operate in foreign countries, along with the expense of relocating, are likely to be prohibitively expensive for these firms. With the MACT standards costs included for the facilities analyzed as part of this effluent guidelines final rule, one additional firm shows a greater than 10 percent change in profit margin. Thus EPA has determined that even under the combined effect of the two rules, firms are unlikely to relocate to foreign countries to escape the impacts on profitability induced by the two rules.

The rules, together or separately, will have no major impact on inflation, as the costs of the two rules are at most only 0.001 percent of gross domestic product (GDP).

Although the Agency received comments on the proposal arguing otherwise, EPA expects that impacts on POTWS will be minimal. EPA is promulgating pretreatment standards for 24 VOCs for all four subcategories and ammonia for subcategories A and C. The Agency expects that the reduction in the BOD discharged to POTWs as the result of compliance with PSES for these pollutants will be minimal. As a result, EPA believes that any reduction in revenue to POTWs that charge industrial users subject to the PSES will be insignificant. Since many of these pollutants are highly volatile and are volatilized in the POTWs primary units before they can be biodegraded, EPA believes that the final PSES should not have any substantial effect on the variable operating costs of POTWs as well. In summary, EPA believes that compliance with the final PSES by pharmaceutical facilities should not have any significant effect on the POTW revenues. Furthermore, EPA believes that the benefits associated with reduced discharges of VOCs and ammonia to POTWs by pharmaceutical industrial users will outweigh any revenue losses.

Based on the analysis in the proposal EIA and further investigation in the EA for this final rule, the MACT standards and effluent guidelines, together or separately, will have no major distributional impacts. Compliance costs are generally a very small percentage of baseline operating costs, thus any cost increases are likely to be very small and are not likely to have any major effect on any one group of consumers.

Impacts on environmental justice also should be minimal. As noted above, any price increases on drugs will be very small and impacts on disadvantaged groups such as the poor and certain minority groups will be minimal. Furthermore, many of these groups will benefit from the effluent guidelines final rule. A large portion of the affected facilities are located in urban areas where poor or minority populations tend to be high. Although everyone benefits, it is these populations that will

likely benefit the most from the cleaner water resulting from both rules.

6. Impacts on New Sources

The selected options for new sources are equivalent to the selected options for existing sources. Because the costs for designing in pollution control technologies are generally no more expensive than and are usually less expensive than retrofitting pollution control technologies, costs for new facilities will be no more expensive than costs for existing facilities. Because EPA has shown that the requirements for existing sources are economically achievable, they should be economically achievable for new sources. Furthermore, since the requirements for new sources will not be more expensive than those for existing sources, the rule will not pose a barrier to entry for new sources. In response to proposal comments, EPA also investigated whether impacts from the effluent guidelines rule (with and without MACT standards) might contribute to firms locating new facilities in foreign countries. EPA found the median percentage of capital costs of compliance to total costs to build a new facility to be negligible (0.21 percent, on average including MACT standards costs among surveyed newer facilities). Thus compliance costs are unlikely to be a major impetus to locating new facilities outside the U.S.

E. Regulatory Flexibility Analysis

There are no major changes to EPA's Regulatory Flexibility Analysis (RFA), except that the Agency has undertaken a revenue test in addition to the closure analysis to better assess the potential impact on small firms. The revenue test measures impact on the basis of annual compliance costs as a percentage of annual revenues. The analysis indicates that out of 145 firms considered small (i.e., firms with fewer than 750 employees), only four firms will experience annual compliance costs that are greater than one percent of annual revenues (six with MACT costs included). No firms will experience annual compliance costs exceeding 3 percent. When MACT standards costs are included only one small firm will experience annual compliance costs that exceed three percent of annual revenues, but this firm is not estimated to incur any effluent guideline costs.

The RFA further also considered impacts to small firms in terms of firm failures or facility closures. Five small firms are significantly affected by the rule. The regulatory action is found to be economically achievable for all dischargers, including small entities as detailed in Section V.D. Further, the analysis indicates no disproportionate effect on small entities, compared to large entities. Based on these findings, EPA certifies that this final rule does not have a significant impact on a substantial number of small entities.

F. Cost-Benefit Analysis

Because the combined costs of the rules are at the level that defines a major rule both under Executive Order 12866 and UMRA (although neither rule considered separately would be near this level), EPA has undertaken a cost-benefit analysis. As in the proposal, pretax costs for all facilities are used as a proxy for social cost. The major portion of the social cost of the effluent guidelines is the total pretax annual cost, which is $60.8 million (1997$). Adding in the cost of administering the rule and providing administrative services to the unemployed (the only other significant cost categories), the total social cost of the rule is $61.0 million (1997$). Combined with the costs of the MACT standards rule for facilities in the effluent guidelines analysis, the two rules together have annual social cost of $110.7 million (1997$). (Costs of both rules including MACT standards costs to facilities that will not be affected by the effluent guidelines are $119.5 million (1997$)).

Benefits include the benefits of water removals and benefits of air removals. Types of benefits analyzed include human health risk, recreational use benefits, benefits to POTWs, and benefits of reductions in VOCs (other than human health). The benefits to POTWs, however, could not be monetized (see Section VI.E. of this preamble for more details). Total monetizable benefits of the effluent guidelines alone total $0.93 to $14.0 million (1997$), while the combined benefits of the two rules total $4.06 to $81.1 million (1997$).

TABLE V.F.1

Costs ($ millions)	
Total Social Cost of Effluent Guidelines.	$61.0
Total Social Cost of MACT (ELG facilities only).	49.7
Total Social Cost of MACT (all facilities).	58.4
Social Cost of Combined Rules (ELG facilities only).	110.7
Social Cost of Combined Rules (all facilities).	119.5
Benefits ($ millions)	
Effluent Guidelines	0.9 to 14.0
MACT Standards	3.9 to 67.2
Total	4.8 to 81.1

G. Cost-Effectiveness Analysis

Cost-effectiveness evaluates the relative efficiency of options in removing toxic pollutants. Costs evaluated include direct compliance costs, such as capital expenditures and operation and maintenance costs.

Cost-effectiveness results are expressed in terms of the incremental and average costs per pound-equivalent removed. A pound equivalent is a measure that addresses differences in the toxicity of pollutants removed. Total pound-equivalents are derived by taking the number of pounds of a pollutant removed and multiplying this number by a toxic weighting factor. EPA calculates the toxic weighting factor using ambient water quality criteria and toxicity values. The toxic weighting factors are then standardized by relating them to a particular pollutant, in this case copper. EPA's standard procedure is to rank the options considered for each subcategory in order of increasing pounds-equivalent (PE) removed. The Agency calculates incremental cost-effectiveness as the ratio of the incremental annual costs to the incremental pounds-equivalent removed under each option, compared to the previous (less effective) option. Average cost-effectiveness is calculated for each option as a ratio of total costs to total pounds-equivalent removed. EPA reports annual costs for all cost-effectiveness analyses in 1981 dollars to enable limited comparisons of the cost-effectiveness among regulated industries.

Table V.G.1 presents the results of the cost-effectiveness analysis for all subcategories. As the table shows, the average and incremental cost-effectiveness of the selected BAT option for subcategories A and C is $224/lb. eq., the average and incremental cost-effectiveness of the selected PSES option for subcategories A and C is $96/lb. eq. and the average and incremental cost-effectiveness of the selected PSES option for subcategories B and D is $66/lb. eq. The selected BAT option for the subcategories B and D directs is the no additional action alternative, so no cost-effectiveness results are calculated.

The cost-effectiveness determined for this rule does not represent an estimate of the removal of the toxic pounds resulting from the removal of COD. As discussed previously in section IV.C., discharges from pharmaceutical manufacturing facilities exhibit toxicity as measured by the whole effluent

toxicity test and reported as part of the routine NPDES discharge monitoring reports (DMRs). One study conducted by EPA at a pharmaceutical manufacturing facility showed a significant decrease in toxicity with a corresponding decrease in COD level for the tested effluent sample from the facility and a sample effluent of a pilot scale biological treatment plant study. Because of the limited amount of data, and the inability to identify the different mix of specific organic compounds represented by the COD measurement, the total amount of toxic pound-equivalent represented by the nonconventional pollutant parameter of COD could not be determined.

Based on the lack of pound-equivalents associated with COD removals the cost-effectiveness analysis results understates the true cost-effectiveness of this rule. EPA therefore considers these options to be cost-effective.

TABLE V.G.1—COST/EFFECTIVENESS ANALYSIS RESULTS

Option	Total Annual		Incremental		Average C-E ($/lb.eq.)	Incremental C-E ($/lb. eq.)
	Lb. eq. removed	Cost (1981$)	Lb. eq. removed	Cost (1981$)		
A/C Direct						
MACT Only	0	$0	0	$0	NA	NA
Advanced Bio	9,780	2,186,106	9,780	2,186,106	$224	$224
A/C Indirect						
MACT Only	0	0	0	0	NA	NA
Steam Stripping no alcohols	282,614	26,990,998	282,614	26,990,998	96	96
B/D Indirect						
MACT Only	0	0	0	0	NA	NA
Steam Stripping no alcohols	80,807	5,353,790	80,807	5,353,790	66	66

VI. Environmental Benefits

In addition to costs and impacts, EPA also estimated the environmental and human health benefits of implementing CWA requirements. Benefits identified as a result of this final rule are associated with improvements in both water quality and air quality, since many of the regulated and incidentally controlled pollutants are prone to volatilization from the effluent waste streams. Section IV of this preamble and Section IX of the TDD describe the estimated reductions in effluent discharges, and those reductions and the estimates of incremental environmental improvements noted in Section IV are derived compared to a baseline consisting of current discharges. Because current discharges are a function of current technology, this is the same baseline that is used to establish the costs of complying with this rule.

EPA is confident that its estimation of compliance costs is a full and accurate account of such costs; however, EPA is less confident that the estimation of benefits is similarly complete. EPA is not currently able to quantitatively evaluate all human health and ecosystem benefits associated with air and water quality improvements. EPA is even more limited in its ability to assign monetary values to these benefits. A comparison of costs to only the limited monetized subset compromises the validity of the cost-benefit analysis. The economic benefit values described below and in Section 10.4 of the EA should be considered a limited subset of the total benefits of this rule and should be evaluated along with descriptive assessments of benefits and the acknowledgment that even these may fall short of the real-world benefits that may result from this rule. For example, the analyses consider the impacts of toxic pollutants, but do not evaluate the impacts of other pollutants (such as BOD_5, COD, and TSS) which can produce significant adverse environmental impacts.

Within these limitations, EPA analyzes the effects of current air and water emissions and assesses the benefits of reductions in these emissions resulting from this final regulation. EPA expects a variety of human health, environmental, and economic benefits to result from these reductions in effluent loadings and air emissions (See *Environmental Assessment of the Final Effluent Guidelines for the Pharmaceutical Manufacturing Industry*, (July 1998, EPA–821–B–98–008). 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 hazard (systemic); ecological and recreational benefits due to improved water quality with respect to toxic pollutants, including intrinsic benefits; and benefits to publicly owned treatment works (POTWs) from reductions in interference, pass through, and sludge contamination problems, improvements in worker health and safety, and elimination of some of the efforts associated with establishing local pretreatment limits. EPA monetizes the estimated benefits for reductions in air emissions of ozone precursors, cancer risk reductions, improvements in recreational fishing opportunities, and improvements in intrinsic value, but is unable to quantify the dollar magnitude of benefits from the other benefit categories. Air benefits due to reductions in emissions of ozone precursors, are estimated using the methods and data summarized in the November 5, 1997 OAQPS memorandum titled ''Benefits-Transfer Analysis for Pulp and Paper''. This methodology is based on the recently published benefits analyses provided in the *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule.* The methodology and data used in the estimate of all benefits are described in detail in the Environmental Assessment.

a. Reduced Emissions of Ozone Precursors

These final effluent guidelines are expected to result in reductions in ambient ozone concentrations due to reductions in VOC emissions. Controlling VOC emissions is beneficial because some VOCs are precursors to ozone, which negatively affects human health and plant life.

EPA estimates that the annual monetized benefits resulting from reductions in VOC emissions due to this final rule range from $755,000 to $9.8 million ($1997). The benefits are monetized using a benefits-transfer-based approach. Specifically, the estimated reductions in VOC emissions in nonattainment areas alone, and in both nonattainment and attainment areas (1,254 Mg to 3,608 Mg, respectively) are multiplied by an existing estimate of the range of the value of a unit reduction in VOC emissions ($602/Mg to $2,723/Mg, $1997). This range is based on the ozone National Ambient Air Quality Standard (NAAQS) benefits analysis, which used new scientific studies to quantify the association between ozone exposure and premature mortality. The $602/Mg estimate does not include mortality effects associated with ozone exposure, while the $2,723/Mg estimate includes mortality effects.

The overall benefit estimate for ozone precursor reduction also includes an estimate of the potential adverse effects which may result from increased emissions of particulate matter (PM) and sulfur dioxide (SO_2) related to steam stripping of the VOCs. Emissions of PM and SO_2 arise from the use of fossil fuels as an energy source for the steam stripping technology basis. The quantity of these emissions is based on the type of fossil fuel (natural gas or fuel oil) used.

Particulate matter is associated with adverse human health and welfare effects. EPA estimates that the annual monetized adverse environmental impact resulting from increases in PM emissions due to this final rule is $266,000 ($1997). This value was obtained by using an estimated increase in PM emissions of 20 Mg multiplied by an estimate of the value of a unit reduction in PM emissions of $13,325 per Mg ($1997). This value is based on the PM NAAQS benefits analysis.

Sulfur dioxide is associated with the adverse human health effects and environmental impacts, including ''acid rain.'' EPA estimates that the annual monetized adverse environmental impact resulting from increases in SO_2 emissions range from $311,000 to $688,000 ($1997). This value was obtained using an estimated increase in SO_2 emissions of 52.1 Mg (51.8 Mg eastern U.S. and 0.3 Mg western U.S.) multiplied by an estimate of the value of a unit reduction in SO_2 emissions of $5,984 to $13,251 per Mg ($1997) for the eastern U.S. and $4,329 to $5,164 per Mg ($1997) for the western U.S. These ranges are based on the PM NAAQS benefits analysis and assumes emission reductions of SO_2 are proportional to emission reductions of PM. The lower values include a measure of premature mortality due to short-term exposure, and the higher values use a measure of premature mortality due to long-term exposure.

The benefits transfer method is utilized to value the pollutants discussed above (VOCs, PM, and SO_2). This method relies on previous benefit studies that have been conducted for the same pollutants that are identified in this rulemaking. These studies provide useful data that can be transferred across contexts in order to approximate the benefits of the pharmaceuticals industry's emission reductions.

The impacts and benefits associated with the different emission components are aggregated by adding the lower values separately from the higher values to give a maximum total range. Using this method of analysis, the total monetized air benefits from reduction of ozone precursors, including associated PM and SO_2 increases, range from an adverse environmental impact of $0.20 million ($1997) to a benefit of $9.2 million ($1997).

b. Reduced Human Health Cancer Risk

The benefits from the final rule include human health benefits from reductions in excess cancer risk. EPA expects the final 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 fugitive air emissions, EPA estimates that the final guidelines will result in 0.15 excess cancer cases avoided per year nationwide due to reduced exposure to four identified pollutants (benzene, chloroform, 1,2-dichloroethane, and methylene chloride). The estimated monetized value of the human health benefits from these cancer risk reductions ranges from $350,000 to $1.9 million ($1997) 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 $2.3 million to 12.6 million ($1997). This estimated range is based on EPA's Office of Policy, Planning and Evaluation (OPPE) review of willingness-to-pay studies for valuing an avoided event of premature mortality or a statistical life saved.

c. Reduced Noncarcinogenic Human Health Hazard

Exposure to toxic substances poses risk of systemic and other effects to humans, including effects on the circulatory, respiratory or digestive systems and neurological and developmental effects. This final rule is expected to generate human health benefits by reducing exposure to these substances, thus reducing the hazards of these associated effects.

As in the case of the cancer risk assessment, systemic hazards from exposure to fugitive air emissions and consumption of contaminated fish tissue and drinking water are evaluated. Based on this analysis, reductions in fugitive air emissions are expected to result in reduced systemic hazard to 32,300 individuals due to reduced exposure to four identified toxic pollutants (ammonia, chlorobenzene, methyl cellosolve, and triethylamine). No systemic hazards 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. Improved Ecological Conditions and Recreational Activity

EPA expects this final rule to generate environmental benefits by improving water quality. There are a wide range of benefits associated with the maintenance and improvement of water quality. These benefits include use values (e.g., recreational fishing), ecological values (e.g., preservation of habitat), and passive use (intrinsic) values (e.g., aesthetics). For example, water pollution might affect the quality of the fish and wildlife habitat provided by water resources, thus affecting the species using these resources. This in turn might affect the quality and value of recreational experiences of users, such as anglers fishing in the affected streams. EPA considers the value of the recreational fishing benefits and intrinsic benefits resulting from this final rule, but does not evaluate the

other types of ecological and environmental benefits (e.g., increased assimilative capacity of the receiving stream, protection of terrestrial wildlife and birds that consume aquatic organisms, and improvements to other recreational activities, such as swimming, boating, water skiing, and wildlife observation) due to data limitations.

To estimate some of the benefits from the improvements in water quality expected to result from this rule, instream concentration estimates are modeled and then compared to both aquatic life and human health ambient water quality criteria (AWQC) or toxic effect levels to evaluate whether these discharges pose risk to aquatic organisms or to human health. The projected reductions in toxic loadings to surface waters and POTWs are significant. Modeled end-of-pipe pollutant loadings are estimated to decline by 71 percent, from 11.2 million pounds per year under current conditions to 3.3 million pounds per year under this final rule.[1] The analysis comparing instream concentration levels to AWQC estimates that current discharge loadings result in excursions of AWQC at five locations. The analysis also indicates that no excursions are expected to occur at these five sites under this final rule.

EPA estimates that the annual monetized recreational benefits to anglers associated with the expected changes in water quality range from $520,000 to $1.8 million ($1997).[2] EPA evaluates these recreational benefits, applying a model that considers the increase in value of a ''contaminant-free fishery'' to recreational anglers resulting from the elimination of pollutant concentrations in excess of AWQC at these five sites. The monetized value of impaired recreational fishing opportunity is estimated by first calculating the baseline value of the receiving stream using a value per person day of recreational fishing, and the number of person-days fished on the receiving stream. The value of improving water quality in this fishery, based on the increase in value to anglers of achieving contaminant-free fishing, is then calculated.

In addition, EPA estimates that the annual monetized intrinsic benefits to the general public, as a result of the same improvements in water quality, range from at least $260,000 to $920,000 ($1997).[3] These intrinsic benefits are estimated as half of the recreational benefits and may be significantly underestimated.

e. Improved POTW Operations/ Conditions

EPA considers three potential sources of benefits to POTWs from this final regulation: (1) reductions in the likelihood of interference, pass through, and sewage sludge contamination problems; (2) reductions in health and safety risks to POTW workers; and (3) 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 EPA does not quantify all of these benefits due to data limitations.

First, regarding potential interference, pass through and sewage sludge contamination problems, this final 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 sampling 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 three POTWs for five pollutants (acetonitrile, diethylamine, N,N-dimethylacetamide, N,N-dimethylformamide, and triethylamine) under current conditions. Inhibition problems are projected to remain at the same three POTWs for three of these pollutants (acetonitrile, N,N-dimethylacetamide, and N,N-dimethylformamide) after this final rule.[4] While this rule is not expected to completely eliminate inhibition problems, the reduction in pollutant loadings is expected to reduce the severity of the impact. Sufficient data are not available to further quantify this benefit category.

Furthermore, toxic substances, particularly the VOCs, in effluent discharges to POTWs pose health risks to POTW workers. This final 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 the toxic pollutants (primarily acetonitrile, benzene, chloroform, diethylamine, n-heptane, n-hexane, methylene chloride, toluene, and triethylamine), this final rule is estimated to reduce occupational risk at nine POTWs.[5] Data are not available to monetize this benefit category.

Finally, reducing the pollutant load to local POTWs may eliminate some of the efforts associated with establishing local pollutant limits. Local limits are sometimes required to protect against pass-through and interference, and to protect worker health and safety. Establishing local limits involves labor and analytical costs to determine the relative contribution of each industrial discharger and to set limits which will be protective of the treatment works, the workers, and the receiving environment. Several POTWs contacted in EPA's survey indicated that establishment of more effective national pretreatment standards would help them avoid these significant costs. In addition, they indicated that where local limits are still required, stricter national pretreatment standards will bolster the validity of the limits they set.

Furthermore, reducing the discharge of toxic pollutants reduces the likelihood that the POTW effluents will exhibit excessive toxicity. When POTW effluent exhibits excessive toxicity, the POTW must enact a rigorous, costly analytical program to identify and reduce the source of toxicity.

f. Other Unquantified Benefits

The above benefit analyses focus mainly on identified compounds with quantifiable toxic or carcinogenic effects. This leads to a potentially large underestimation of benefits, since some significant pollutant characterizations are not considered. For example, the analyses do not include the benefits associated with reducing the particulate load (measured as TSS), or the oxygen demand (measured as BOD and COD) of the effluents. TSS loads can degrade ecological habitat by reducing light penetration and primary productivity, and from accumulation of solid particles that alter benthic spawning grounds and feeding habitats. BOD and COD loads can deplete oxygen levels, which can produce mortality or other adverse effects in fish, as well as reduce biological diversity.

The benefits of COD reduction extend beyond reducing oxygen depletion, since COD also represents the presence of organic chemicals in a waste stream. Due to a lack of analytical methods, not all of the compounds represented by COD are identified. In this benefits

[1] [2] [3] These benefits are a result of the CAA MACT Rule and/or the CWA Rule. Monetized benefits of $290,000 to $1.0 million ($1997) of the total recreational benefit to anglers can be solely attributed to the CWA Rule. Monetized benefits of $140,000 to $510,000 ($1997) of the total intrinsic benefit can be solely attributed to the CWA Rule.

[4] This benefit is a result of the CAA MACT Rule and/or the CWA Rule.

[5] This benefit is a result of the CAA MACT Rule and/or the CWA Rule. Reduction of occupational risk at five POTWs can be solely attributed to the CWA Rule.

assessment, specifically identified compounds represent only 2.2 million pounds of the 11.5 million pounds of COD projected to be removed. This limits the estimate of benefits, since the analysis relies on comparing instream concentrations to established criteria, and there are obviously no established criteria for unidentified compounds. However, there is inherent value in reducing pollutant loads, despite (or perhaps due to) the lack of quantifiable effects.

The benefits analyses are further limited because they concentrate on projected excursions from established minimum standards, and do not account for protection of higher quality conditions. Likewise, they do not account for prevention of future impacts which could occur due to increased effluent loadings.

g. Summary of Benefits from Effluent Limitations Guideline Final Rule

EPA estimates that the annual monetized benefits resulting from this final effluent guidelines rule will range from $0.93 million to $14 million ($1997). This range includes $0.34 to $1.2 million that cannot be differentiated between the effluent guidelines rule and the wastewater portion of the MACT standard. Table XI.B.9.g summarizes these benefits, by category. The range reflects the uncertainty in evaluating the effects of this final rule and in placing a dollar value on these effects. As indicated in the table, these monetized benefits ranges do not reflect many of the benefit categories expected to result under this final rule, including reduced noncarcinogenic human health hazards; improved ecological conditions from improvements in water quality; improved POTW operations; and improved worker health and safety at POTWs. Therefore the reported benefit estimate understates the total benefits of this final rule.

h. Benefits of the MACT Rule

The CAA MACT Rule will regulate an estimated 101 facilities. The Rule is expected to produce environmental and human health benefits due to reductions in fugitive air emissions from four planks: wastewater, process vents, storage tanks, and equipment leaks. EPA conducted analyses on the 23 facilities covered under the wastewater plank, based on site-specific raw loadings data from the 1990 Pharmaceuticals Section 308 Questionnaire. These analyses were conducted using the same methodologies, within the same limitations, as those conducted to evaluate the CWA Rule as discussed in the previous Sections. Data on emission reductions from the other planks were obtained by OAQPS, however, a detailed benefit analysis of these planks was not conducted due to data limitations (specifically, the lack of site-specific data).

Within these limitations, the estimated benefits are as follows:

Reduced Emissions of Ozone Precursors

EPA estimates that the final MACT Rule will produce benefits due to reductions in fugitive VOC emissions from wastewater, process vents, storage tanks, and equipment leaks at pharmaceutical manufacturing facilities. Considering the wastewater plank only, EPA estimates that the annual monetized benefits range from $1.2 million to $45 million ($1997). These benefits are based on estimated emission reductions in VOC emissions in nonattainment areas alone, and in both nonattainment and attainment areas (2,057 Mg to 16,619 Mg, respectively).

The annual monetized adverse environmental impacts for these 23 facilities due to increases in PM emissions is estimated by EPA at $56,000 ($1997). This value is based on an estimated increase in PM emissions of 4.2 Mg. EPA also estimates that the annual monetized adverse environmental impacts for these 23 facilities due to increases in SO_2 emissions due to the final MACT Rule range from $65,000 to $143,000 based on an estimated increase in SO_2 emissions of 11.0 Mg (10.6 Mg eastern U.S., and 0.4 Mg western U.S.).

The total monetized air benefits from reductions of ozone precursors from wastewater, after correction for PM and SO_2 increases, range from $1.0 million to $45 million ($1997).

In addition, based on the analysis of the 101 pharmaceutical manufacturing facilities covered by the MACT rule, EPA estimates that the reductions in fugitive VOC emissions from process vents, storage tanks, and equipment leaks would result in a range of annual monetized air benefits of $0.77 million to $11 million ($1997). These benefits are based on estimated reductions in VOC emissions in nonattainment areas alone, and in both nonattainment and attainment areas (1,278 Mg to 4,027 Mg, respectively). Adverse impacts due to increased energy consumption from control of these planks are not quantified due to data limitations. The total monetized benefits from reductions in VOC emissions from all four planks are estimated to be $1.8 million to $56 million ($1997).

Reduced Human Health Cancer Risk

The estimated monetized value of the human health benefits from cancer risk reductions due to reductions in fugitive air emissions from wastewater ranges from $2.1 million to $11 million ($1997) annually. This is based on EPA estimates that the MACT Rule will result in 0.88 cancer cases avoided per year nationwide, considering an inhalation exposure route. EPA also 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 tissues.

EPA estimates that cancer risk will be further reduced due to reductions in fugitive air emissions from process vents, storage tanks, and equipment leaks. However, these reductions were not quantified due to lack of site-specific data.

Reduced Noncarcinogenic Human Health Hazard

EPA estimates that reductions in fugitive air emissions from wastewater are expected to result in reduced systemic hazard to 370,000 individuals due to reduced exposure to four identified toxic pollutants. EPA also expects that reductions in fugitive air emissions from process vents, storage tanks, and equipment leaks will result in reduced systemic hazard. However, EPA does not quantify these benefits due to data limitations. No systemic hazard reductions are expected to result from reduced exposure to contaminated fish tissue or drinking water.

Improved Ecological Conditions and Recreational Activity

EPA estimates that the annual monetized recreational benefits to anglers associated with the expected changes in water quality at two locations range from $230,000 to $820,000 ($1997). The annual monetized intrinsic benefits to the general public range from at least $115,000 to $410,000 ($1997). These benefits are a result of the CAA MACT Rule and/or the CWA Rule. These monetized benefits cannot be solely attributed to the MACT Rule.

Improved POTW Operations

Inhibition problems are projected by EPA to occur at three POTWs for five pollutants under current conditions. Inhibition problems are projected to remain at the same three POTWs for three of these pollutants. The benefits cannot be solely attributed to the MACT Rule.

Additionally, the MACT Rule is expected to reduce health risks to POTW workers. This rule is estimated to reduce occupational risks at four POTWs. However, these benefits cannot be solely attributed to the MACT Rule.

Summary of Benefits From MACT Final Rule

EPA estimates that the annual monetized benefits resulting from the MACT final rule will range from at least $3.9 million to $67 million ($1997). Additional annual monetized benefits that cannot be solely attributed to the CAA portion of this final rule will range from $0.34 million to $1.2 million ($1997). Table VI.B.9.h summarizes these benefits, by category. As explained previously in Section g, the expected benefit estimate understates the total benefits of the MACT rule. The estimate is further constrained by data limitations.

TABLE VI.B.9.G.—POTENTIAL ECONOMIC BENEFITS FROM FINAL EFFLUENT LIMITATIONS GUIDELINES FOR THE PHARMACEUTICAL INDUSTRY

Benefit category	Millions of 1997 dollars per year
Reduced Emissions of Ozone Precursors	−$0.20 to $9.2.
Reduced Cancer Risk	$0.35 to $1.9.
Reduced Noncarcinogenic Hazard	Unquantified.
Improved Ecological Conditions	Unquantified.
Improved Recreational Activity	$0.52 to $1.8.
Improved Intrinsic Value	$0.26 to $0.92.
Improved POTW Operations (Inhibition and Sludge Contamination)	Unquantified.
Improved Occupational Conditions at POTWs	Unquantified.
Total Monetized Benefits	$0.93 to $14.0.

Note: These benefits include a portion of recreational and intrinsic monetized benefits attributed to the CAA Rule. Specifically, two facilities included in the modeling were required to have MACT strippers and were also costed for additional strippers to meet the CWA effluent guidelines. Overall removals due to these strippers cannot be differentiated between MACT and CWA requirements. These two facilities represent a total of $0.34 to $1.2 million based on improved recreational activity and improved intrinsic value.

TABLE VI.B.9.H.—POTENTIAL ECONOMIC BENEFITS FROM CAA MACT RULE FOR THE PHARMACEUTICAL INDUSTRY

Benefit category	Millions of 1997 dollars per year		
	Wastewater	Other fugitive emissions[1]	Total benefits
Reduced Emissions of Ozone Precursors	$1.0 to $45	$0.77 to 11	$1.8 to $56.
Reduced Cancer Risk	$2.1 to $11	Unquantified	$2.1 to $11.
Reduced Noncarcinogenic Hazard	Unquantified	Unquantified	Unquantified.
Improved Ecological Conditions	Unquantified	Unquantified	Unquantified.
Improved POTW Operations (Inhibition and Sludge Contamination)	Unquantified	Unquantified	Unquantified.
Improved Occupational Conditions at POTWs	Unquantified	Unquantified	Unquantified.
Total Monetized Benefits	$3.1 to $56	$0.77 to $11	$3.9 to $67.

[1] Includes process vents, storage tanks, and equipment leaks.

Notes: These benefits exclude a portion of the recreational and intrinsic monetized benefits attributed to the CAA Rule. Specifically, two facilities included in the modeling were required to have MACT strippers and were also costed for additional strippers to meet the CWA effluent guidelines. Overall removals due to these strippers cannot be differentiated between MACT and CWA requirements. These two facilities represent a total of $0.34 to $1.2 million dollars, based on improved recreational activity and improved intrinsic value.

The benefits analysis for the MACT Rule is particularly limited due to data constraints.

VII. Non-Water Quality Environmental Impacts

The elimination or reduction of one form of pollution may create or aggravate other environmental problems. Therefore, Sections 304(b) and 306 of the Act call for EPA to consider the non-water quality environmental impacts of effluent limitations guidelines and standards. Accordingly, EPA has considered the effect of these regulations on air pollution, solid waste generation, and energy consumption.

A. Air Pollution

EPA estimated the impacts of the selected technology options for the existing source BAT and PSES regulations and the technology basis for the MACT standard on air emissions. EPA considered emissions of HAPs and non-HAPs as well as criteria air pollutants (CO, No_X, SO_2 and particulate matter) in its analysis. EPA estimates that the MACT standards steam strippers will reduce air emissions of HAPs and non-HAPs at direct and indirect subcategory A and C facilities by 14.1 and 41.4 million lbs. per year, respectively. No emission reductions have been estimated for B and D subcategory direct and indirect dischargers as the result of the MACT standard because these facilities are not ''major sources'' of hazardous air pollutants (HAPs) (defined as facilities with total annual emissions of HAPs greater than 25,000 metric tons). EPA has estimated the reduction in air emissions of HAPs and non-HAPs as the result of steam strippers that may be installed to comply with PSES for VOC pollutants for A and C and B and D subcategory facilities to be 10.7 and 3.3 million lbs. per year, respectively. With

respect to criteria pollutants, EPA estimates that as a result of steam generation requirements for PSES steam strippers, emissions of criteria pollutants will increase by 616,000 pounds per year.

B. Solid Waste

EPA has estimated the increases in solid waste generation as from the use of advanced biological treatment (the basis for BPT/BCT limitations), and steam stripping technology (the basis for PSES). EPA also estimated an increase in waste hydrogen chloride due to scrubber liquor generated by facilities with wastewater containing ammonia.

EPA estimates that compliance with the BPT/BCT limitations will increase the mass of wastewater treatment sludge by subcategories A and C and B and D direct dischargers by 343 and 194 tons per year, respectively. Compliance with BAT ammonia and organic limitations by A and C subcategory plants is expected to increase wastewater sludge generation by 308 tons per year. No increase in sludge generation is expected as the result of the subcategories B and D BAT COD limitations because these limitations are equivalent to the BPT COD limitations and there are no BAT organic compound limitations for these subcategories. EPA does expect that indirect discharging A and C facilities will generate an increase in waste aqueous hydrogen chloride resulting from the use of wet hydrogen chloride scrubbers to control air emissions from steam strippers used to remove ammonia from wastewater. EPA estimates that waste aqueous hydrogen chloride generation will increase by 283 tons per year.

Compliance with PSES subcategory A and C and subcategory B and D facilities is expected to increase the amount of waste solvents generated. This increase in waste solvent generation is due to the waste solvents recovered from the in-plant steam stripping operations at these facilities. EPA anticipates that 10,600 and 3,310 tons/yr of waste solvents will be generated at subcategory A and C and B and D facilities, respectively.

Ten of the pollutants being regulated by BAT limitations and pretreatment standards are solvents listed as hazardous waste constituents (F0002, F0003, and F0005) under 40 CFR 261.31. These pollutants are acetone, 4-methyl-2-pentanone (MIBK), ethyl acetate, methanol, benzene, toluene, xylenes, methylene chloride, chlorobenzene, and o-dichlorobenzene. EPA is promulgating PSES for nine of these pollutants and has included costs for disposal of all overheads from steam stripping as hazardous wastes in its steam stripping cost estimates. As noted above, EPA has estimated increased sludge generation as a result of compliance with BAT limitations for 29 pollutants including the 10 pollutants listed above. EPA has assumed that this sludge will be incinerated in developing its final BAT cost estimates, but does not believe that the increased sludge generated will be considered as hazardous.

C. Energy Requirements

EPA has estimated the energy impacts on the pharmaceutical manufacturing industry associated with compliance with the final BPT, BAT and PSES regulations. The Agency estimates that electrical usage would increase for subcategory A and C and subcategory B and D facilities by 5.9×10^6 and 1.07×10^6 kilowatt hours (kWh) as the result of the final BPT and BAT regulations. This increase is equivalent to a 0.1 percent increase above current electrical usage by the industry. EPA also estimated the increase in electrical usage as the result of increased steam generation. The increased steam generation is required to operate the steam strippers that EPA anticipates will be installed to comply with the pretreatment standards for VOCs. (The impacts of the BPT and BAT regulations on electrical usage for steam generation are negligible). EPA estimates that electrical usage for steam generation will increase for subcategories A and C and subcategories B and D indirect dischargers by 454×10^6 and 58.8×10^6 kWh, respectively. The total of these two increases in electrical usage is equivalent to an eight percent overall increase in electrical usage above current levels.

VIII. Regulatory Implementation

The purpose of this section is to provide assistance and direction to permit writers and control authorities to aid in their implementation of this regulation and its unique compliance alternative. This section also discusses the relationship of upset and bypass provisions, variances and modifications, and analytical methods to the final limitations and standards.

A. Implementation of the Limitations and Standards

Upon the promulgation of these regulations, the effluent limitations for the appropriate subcategory must be applied in all Federal and State NPDES permits issued to direct dischargers in the pharmaceutical manufacturing industry. In addition, the pretreatment standards are directly applicable to indirect dischargers.

Permit writers and pretreatment authorities need to be aware of special circumstances involving compliance with the cyanide limitations and standards, ammonia pretreatment standards, pH monitoring and the portion of nonprocess wastewater in the final effluent. In the case of the cyanide limitations and standards, EPA determined that the monitoring point for purposes of compliance with the cyanide will generally be in-plant at a point before the cyanide-bearing wastewaters are commingled with noncyanide-bearing waste streams in accordance EPA permit and pretreatment program regulations at 40 CFR 122.44(i)(1)(iii) for direct dischargers and § 403.6(e) for indirect dischargers. These regulations allow permit writers and pretreatment control authorities to establish in-plant monitoring points for regulated pollutants in cases where it is impractical or infeasible to monitor at the normal end-of-pipe monitoring point e.g., because the regulated pollutant is not detectable at the end-of-pipe. This, in turn, is the result of the wastewater stream bearing the regulated pollutant being commingled with significantly higher volume streams not bearing the regulated pollutant. EPA's analysis of waste stream flow data, from subcategories A and C facilities containing cyanide in their wastewaters, indicate that the volume of cyanide-bearing wastewaters is, on average, less than 2.1 percent of the total process wastewater flow and that all but two of the facilities required to monitor for cyanide do so at an in-plant monitoring point. Facilities that can demonstrate that it is not impractical or infeasible to monitor for cyanide at the normal end-of-pipe point, i.e., cyanide can be detected at the end-of-pipe point, may do so.

In connection with the ammonia pretreatment standards being promulgated for subcategories A and C, EPA has determined that the pollutant ammonia does not passthrough POTWs that possess nitrification capability. As a result, ammonia pretreatment standards would not apply to subcategories A and C industrial users that discharge to these POTWs. In order to provide guidance to pretreatment authorities, EPA describes the treatment system requirements under which nitrification is considered to occur in section 17 of the final TDD and defines the basis for considering a POTW to have acceptable nitrification capability in § 439.1 of the final rule. POTWs that nitrify should impose local limits for

ammonia if they believe that the ammonia load from the pharmaceutical industrial user(s) will nevertheless pass through their facilities (see 40 CFR 403.5).

During the post-proposal period, EPA has received comments from industry commenters that complying with the pH requirements 100 percent of the time when using continuous monitoring is not practical for many facilities. Direct discharging pharmaceutical facilities are required by today's final regulation to maintain effluent pH in the 6.0–9.0 range. The general pretreatment regulations specifically in 40 CFR 403.5(b)(2), set a pH minimum of 5.0, except in certain design conditions, but do not set an upper boundary. EPA has addressed the problem of random excursions at 40 CFR 401.17 for direct discharging facilities. This regulation recognizes that random excursions from the pH range (6.0–9.0) may occur in the process of continuous monitoring and these random excursions should not be treated as violations. EPA is developing a proposal for a similar provision for indirect dischargers and expects to propose this provision by the end of this year.

In implementing the final limitations and standards, permit writers need to account for the facility's nonprocess wastewater contained in the effluent being discharged in developing either mass or concentration based permit limits. As discussed previously, in section IV of this preamble, the final limitations and standards are developed from data sets from plants which had less than 25 percent nonprocess wastewater in the total plant discharge. The flow basis of the final limitations and standards is discussed in section 13 of the TDD. In addition, examples of BPT and BAT permit limit calculations involving different plant flow configurations are provided in Appendix A to the TDD. In addition, permitting authorities have requested clarification on whether certain operations performed at pharmaceutical facilities would cause those facilities to be regulated under additional effluent guidelines. Specifically, guidance has been requested in cases where pharmaceutical facilities, during routine maintenance and cleaning periods, use acid containing solutions on or in stainless steel processing equipment. Some permitting authorities have inquired whether these operations are considered passivation operations which would place the wastewater generated during such cleaning operations under the limitations set forth by 40 CFR Part 433, the Metal Finishing Point Source Category. The Food and Drug Administration requires that pharmaceutical products must be of high purity and cannot be contaminated with dirt, biological organisms, or corrosion products. The pharmaceutical production equipment includes many interconnected pipes, storage vessels, and reactors. Most of the piping system and tanks are fabricated from austenitic stainless steel similar to AISI 304. The Agency is aware of several pharmaceutical facilities which clean production equipment with a mild alkaline ''soap'' followed by a flush with an acid containing solution. Some of these acid solutions contain nitric acid. The alkaline cleaner/acid-rinse operation is usually performed during plant shut-downs or routine preventative maintenance. Because much of the plant piping is fabricated from austenitic stainless steel, and such stainless steels are known to be ''passivated'' using nitric acid solutions, it has been asked if the nitric-acid-based process used by the pharmaceutical facilities would be considered ''passivation'' or ''cleaning'' for the purpose of regulation under the 40 CFR Part 433 Metal Finishing regulation.

The ''Development Document for Effluent Limitations Guidelines, New Source Performance Standards for the Metal Finishing Point Source Category'' describes the ''coating'' unit operation, which includes ''passivation'', as one of the six key ''trigger'' processes, while the ''cleaning'' operation description includes a discussion of acid cleaning as an operation that is not one of the six ''trigger'' processes. For a process wastestream to be regulated under 40 CFR Part 433, a facility must perform one of the six ''trigger'' operations. To determine the status of the alkaline ''soap''/acid-based operations performed at pharmaceutical facilities, key provisions of the ''passivation'' and ''cleaning'' definitions were reviewed. From the definitions provided in the Development Document ''passivation'' is a process in which iron particles are removed from a surface, while a protective coating is formed. ''Cleaning'' is a process in which acid can be used in combination with detergent to remove soil from metal surfaces. Based on these definitions from the Metal Finishing Development Document, the process conducted at pharmaceutical facilities should be considered cleaning for the following three reasons:

1. The processes in question use both acid and detergent.

2. The processes in question are not used to remove imbedded iron particles.

3. The processes in question are not used to form a coating on stainless steel piping. (This conclusion can be reached based on the inherent vulnerability of non-passivated stainless to corrosion. If the pipes in this system were not already passivated, they would corrode during the production operations and contaminate the pharmaceutical products.)

For the reasons listed above, the pharmaceutical production operations performed at these facilities should be considered ''acid cleaning'' and non ''passivation'' with respect to 40 CFR Part 433 Metal Finishing. Because the facilities only perform ''acid cleaning'' and not ''passivation'' there is no metal finishing ''trigger'' process performed at the facility and therefore the facility would not be regulated using 40 CFR Part 433.

B. Upset and Bypass Provisions

A recurring issue is whether industry limitations and standards should include provisions authorizing noncompliance with effluent limitations during periods of ''upset'' or ''bypass''. An upset, sometimes called an ''excursion,'' is an unintentional and temporary noncompliance with technology based effluent limitations occurring for reasons beyond the reasonable control of the permittee. EPA believes that upset provisions are necessary to recognize an affirmative defense for an exceptional incident. Because technology-based limitations can require only what properly designed, maintained and operated technology can achieve, it is claimed that liability for such situations is improper.

While an upset is an unintentional episode during which effluent limitations are exceeded, a bypass is an act of intentional noncompliance during which wastewater treatment facilities are circumvented in emergency situations.

EPA has both upset and bypass provisions in NPDES permits, and has promulgated NPDES and pretreatment regulations which include upset and bypass provisions. (40 CFR 122.41(m), 122.41(n) and 40 CFR 403.16 and 403.17.) The upset provision establishes an upset as an affirmative defense to prosecution for violation of technology-based effluent limitations. The bypass provision provides that EPA may enforce against facilities that bypass except where necessary to prevent loss of life, personal injury, or severe property damage; there were no feasible alternatives; or permittee submitted notices as required under 122.41(n)(3).

C. Variances and Modifications

Upon the promulgation of these regulations, the effluent limitations for

the appropriate subcategory must be applied in all Federal and State NPDES permits issued to direct dischargers in the pharmaceutical manufacturing industry. In addition, the pretreatment standards are directly applicable to indirect dischargers.

1. Fundamentally Different Factors Variances

For the BPT effluent limitations, the only exception to the binding limitations is EPA's ''fundamentally different factors'' (''FDF'') variance (40 CFR Part 125 Subpart D). This variance recognizes factors concerning a particular discharger which are fundamentally different from the factors considered in this rulemaking. Although this variance clause was set forth in EPA's 1973–1976 effluent guidelines, it is now included in the NPDES regulations and not the specific industry regulations. (See 44 FR 32854, 32893 [June 7, 1979] for an explanation of the ''fundamentally different factors'' variance). The procedures for application for a BPT FDF variance are set forth at 40 CFR 122.21(m)(1)(I)(A).

Dischargers subject to the BAT limitations and PSES in these final regulations may also apply for an FDF variance, under the provisions of sec. 301(n) of the Act, which regulates BAT, BCT, and PSES for existing sources pretreatment FDFs. (See 40 CFR 122.21 and 40 CFR 403.13, respectively) In addition, BAT limitations for nonconventional pollutants may be modified under sec. 301(c) (for economic reasons) and 301(g) (for water quality reasons) of the Act. Under sec. 301(l) of the Act, these latter two statutory modifications are not applicable to ''toxic'' or conventional pollutants.

2. Removal Credits

Congress, in enacting Section 307(b) of the CWA, recognized that, in certain instances, POTWs could provide some or all of the treatment of an industrial user's wastestream 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 amount of pollutants to 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 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 (3rd 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 which 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 which 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 February 19, 1993, EPA published the Round One sewage sludge regulations establishing standards, including numerical pollutant limits, for the use and disposal of sewage sludge. 58 FR 9248. EPA established pollutant limits for ten metals when sewage sludge is applied to land, for three metals when it is disposed of at surface disposal sites and for seven metals and total hydrocarbons, a surrogate for organic pollutant emissions, when sewage sludge is incinerated. These requirements are codified at 40 CFR Part 503.

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 at 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 sewage sludge. *See* 40 CFR 403.7(a)(3)(iv)(C).

Thus, given compliance with the requirements of EPA's removal credit regulations, following promulgation of the pretreatment standards in today's rule, 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. Currently there are two pretreatment programs authorized to issue removal credits. EPA is not promulgating pretreatment standards for metals, thus removal credits for metals are not applicable. Given compliance with § 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, chloroform, 1,2-dichloroethane, methylene chloride and toluene.

D. Analytical Methods

Section 304(h) of the Act directs EPA to promulgate guidelines establishing test methods for the analysis of pollutants. These methods are used to determine the presence and concentration of pollutants in wastewater, and are used for compliance monitoring and for filing applications for the NPDES program

under 40 CFR 122.21, 122.41, 122.44 and 123.25, and for the implementation of the pretreatment standards under 40 CFR 403.10 and 403.12. To date, EPA has promulgated methods for conventional pollutants, toxic pollutants, and for some nonconventional pollutants. The five conventional pollutants are defined at 40 CFR 401.16. Table I–B at 40 CFR Part 136 lists the analytical methods approved for these pollutants. The 65 toxic metals and organic pollutants and classes of pollutants are defined at 40 CFR 401.15. From the list of 65 classes of toxic pollutants EPA identified a list of 126 ''Priority Pollutants.'' This list of Priority Pollutants is shown, for example, at 40 CFR Part 423, Appendix A. The list includes non-pesticide organic pollutants, metal pollutants, cyanide, asbestos, and pesticide pollutants. Currently approved methods for metals and cyanide are included in the table of approved inorganic test procedures at 40 CFR 136.3, Table I–B. Table I–C at 40 CFR 136.3 lists approved methods for measurement of non-pesticide organic pollutants, and Table I–D lists approved methods for the toxic pesticide pollutants and for other pesticide pollutants. Dischargers must use the test methods promulgated at 40 CFR 136.3 or incorporated by reference in the tables, when available, to monitor pollutant discharges from the pharmaceutical manufacturing industry, unless specified otherwise by the permitting authority.

As a part of today's final rule, EPA is promulgating additional test methods for the additional pollutants to be regulated under Part 439 by adding a new Table IF at 40 CFR 136.3 listing test methods for the pharmaceutical pollutants. To support the Part 439 regulations at the time of proposal, EPA published test methods developed specifically for the pharmaceutical industry in a compendium entitled, ''Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater,'' EPA–821–B–94–001. These proposed test methods were discussed in the proposed rule. The proposed test methods have been revised in response to public comment and the revised test methods are available for monitoring some pollutants covered by today's final rule. The revised test methods have been published in a revised compendium (the ''Pharmaceutical Methods Compendium, Revision A''; EPA–821–B–98–016 [A, July 1998] with the same title as the proposed compendium. EPA does not anticipate that any dischargers from industrial categories other than the pharmaceutical manufacturing industry will ever need to monitor for the additional pollutants (with methods listed in Table 1F).

In addition, EPA is allowing use of applicable drinking water methods that have been promulgated at 40 CFR part 141 and use of ASTM Methods D3371, D3695, and D4763, for monitoring of the pollutants included in this rulemaking. The final rule allows for use of these additional test methods for several reasons: (1) it allows greater flexibility in monitoring as requested by some commenters; (2) it conforms use of methods in EPA's drinking water and wastewater programs, (3) it moves toward a performance-based measurement system, and (4) it allows use of technical standards as contemplated by the National Technology Transfer and Advancement Act of 1995 (NTTAA; see Section IX.G.).

For pollutants to be monitored under today's final rule, EPA has included a new table of methods in § 136.3(a). The methods in this table are in addition to other methods approved at 40 CFR 136.3. The listed methods are incorporated by reference into this rule.

With the allowed use the methods included in the new Table IF at 40 CFR 136.3, in addition to those already approved in other Tables at 40 CFR 136.3, EPA believes that dischargers in the pharmaceutical manufacturing point source category will have great flexibility in selection of a method for monitoring the pollutants being regulated in today's final rule.

On October 6, 1997, EPA published a Notice of the Agency's intent to implement a Performance Based Measurement System (PBMS) in all of its programs to the extent feasible (62 FR 52098). The Agency is currently determining the specifics steps necessary to implement PBMS in its programs and preparing an implementation plan. Final decisions have not yet been made concerning the implementation of PBMS in water programs. However, EPA is currently evaluating what relevant performance characteristics should be specified for monitoring methods used in the water programs under a PBMS approach to ensure adequate data quality. EPA would then specify performance requirements in its regulations to ensure that any method used for determination of a regulated analyte is at least equivalent to the performance achieved by other currently approved methods. EPA expects to publish its PBMS implementation strategy for water programs in the **Federal Register** by the end of calendar year 1998.

Once EPA has made its final determinations regarding implementation of PBMS in programs under the Clean Water Act, EPA would incorporate specific provisions of PBMS into its regulations, which may include specification of the performance characteristics for measurement of the regulated pollutants in today's final rule.

IX. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866, (58 FR 51735 (October 4, 1993)) the Agency must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of this Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may: (1) have an annual effect of the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, it has been determined that this rule is a ''significant regulatory action'' As such, this action was submitted to OMB for review. Changes made in response to suggestions or recommendations are documented in the public record.

B. Regulatory Flexibility Act and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, as amended by SBREFA, EPA generally is required to conduct a regulatory flexibility analysis describing the impact of the regulatory action on small entities as part of the rulemaking. However, under section 605 (b) of the RFA, EPA is not required to prepare the regulatory flexibility analysis if EPA certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Pursuant to section 605(b) of the RFA, the Administrator certifies that this rule will not have a significant impact on a substantial number of small entities. Nevertheless, the Agency prepared a small business analysis, which is presented in the Economic Analysis for Final Effluent Guidelines and Standards for the Pharmaceutical Industry and summarized in Section V.E. of this document. Briefly, EPA estimates that 145 small businesses will incur costs to comply with this rule (based on a small business definition of 750 or fewer employees as recommended by the U.S. Small Business Administration). EPA evaluated the compliance costs of the regulatory action relative to the company's annual revenue. When considering the effluent limitations guidelines and standards costs only, four small firms are estimated to incur annualized compliance costs exceeding one percent of revenue and no firms are estimated to incur annualized compliance costs exceeding three percent of revenue. When considering the aggregate costs of the effluent limitations guidelines and standards and the MACT standards, six small firms are estimated to incur annualized compliance costs exceeding one percent of revenue and one firm is estimated to incur annualized compliance costs exceeding three percent of revenue. No firms are expected to incur annualized compliance costs in excess of four percent of revenue.

Further, EPA's economic achievability analysis considers the potential for facility closure and corporate bankruptcy. The analysis indicates no disproportionate effects for small businesses compared to large businesses. The regulatory action is found to be economically achievable for all dischargers, including small businesses.

C. Submission to Congress and the General Accounting Office

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

D. Paperwork Reduction Act

This rule contains no new information collection activities requiring an information collection request, and therefore, no information collection request was submitted to OMB for review under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* OMB has approved information collection requirements for existing regulations (40 CFR Part 439) and assigned OMB Control No. 2040–0110 in connection with NPDES related information collection requirements and No. 2040–0009 in connection with pretreatment information collection requirements. The information collection requirements resulting from the regulations being promulgated today are covered by these OMB control numbers.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments, and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this CWA rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local or tribal governments, in the aggregate, or the private sector in any one year. EPA estimates that the annual compliance costs to the private sector are $61.0 million ($1996). Thus, this rule is not subject to the requirements of sections 202 and 205 of UMRA. EPA has also determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments and thus, this rule is not subject to the requirements of section 203 of UMRA. Nevertheless, EPA has consulted with state and local governments pertaining to implementation issues. EPA's evaluation of their comments is reflected in the final rules.

F. Executive Order 12875 Enhancing Intergovernmental Partnership

To reduce the burden of Federal regulations on States and small governments, the President issued Executive Order 12875, entitled Enhancing the Intergovernmental Partnership, on October 28, 1993 (58 FR 58093). Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or Tribal government unless the Federal government provides the necessary funds to pay the direct costs incurred by the State, local or Tribal government or EPA provides to the Office of Management and Budget a description of the extent of the Agency's prior consultation and written communications with elected officials and other representatives of affected State, local and Tribal governments, the nature of their concerns, and an Agency statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and Tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' As discussed above in paragraph IX.E, this regulation would not result in expenditures to state, local and tribal governments of $100 million or more in any one year. The discussion of the Unfunded Mandates Reform Act of 1995 that precedes this paragraph applies to Executive Order 12875 as well and is incorporated here by reference. Since this rule does not impose a significant unfunded mandate on governments subject to this Executive Order, the provisions of the Order do not apply. Nonetheless, EPA did consult with State and local

governments during development of this rule. In particular, EPA has had numerous discussions with representatives of the North Shore Sanitary District regarding PSES for pharmaceutical plants. In addition, EPA also consulted with the Puerto Rico Aqueducts and Sewer Authority (PRASA) regarding discharges of VOCs by pharmaceutical industrial users. In addition, prior to the proposal, EPA sent a questionnaire concerning pharmaceutical discharges to a number of POTWs receiving significant amounts of these discharges. The meeting summaries and questionnaire responses may be found in the record of this rule.

G. National Technology Transfer and Advancement Act

Under Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), the Agency is required to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. Where available and potentially applicable voluntary consensus standards are not used by EPA, the Act requires the Agency to provide Congress, through the Office of Management and Budget (OMB), an explanation of the reasons for not using such standards.

EPA performed a search of the technical literature to identify any applicable analytical test methods from industry, academia, voluntary consensus standard bodies, and other parties that could measure the analytes in this rule. EPA's search revealed that there are consensus standards for many of the analytes specified in the tables at 40 CFR 136.3. Even prior to enactment of the NTTAA, EPA has traditionally included any applicable consensus test methods in its regulations. Consistent with the requirements of the CWA, those applicable consensus test methods are incorporated by reference in the tables at 40 CFR 136.3. The consensus test methods in these tables include American Society for Testing Materials (ASTM) and Standard Methods.

Today's rule requires dischargers to monitor for 31 organic pollutants, ammonia nitrogen and COD. Examples of pollutants with consensus methods promulgated by reference in today's rule include various volatile organics such as benzene, chlorobenzene, chloroform, chloromethane, methylene chloride, and toluene. In addition, EPA developed several test methods for certain nonconventional pollutants not included in the tables at 40 CFR 136.3 in support of the pharmaceutical rule and these methods were discussed in the proposal. Examples of the pollutants for which methods were developed are acetone, cyclohexane, diethylamine, ethanol and methylamine. The test methods being promulgated for those pollutants without test methods listed at 40 CFR 136.3 are EPA Methods 1665, 1666, 1667, 1671 and 1673 which are found in a Methods Compendium, and EPA Method 8015. EPA notes that no applicable consensus methods were found for those pollutants.

H. Executive Order 13045 and Protecting Children's Health

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

EPA interprets the E.O. 13045 as encompassing only those regulatory actions that are risk based or health based, such that the analysis required under section 5–501 of the E.O. has the potential to influence the regulation. This rule is not subject to E.O. 13045 because it does not involve decisions regarding environmental health or safety risks.

X. Summary of Public Participation

The following section describes the major comments on the proposed rule and the NOA, and EPA's responses. The full comment summary and response document can be found in the public record for this rulemaking.

A. Summary of Proposal Comments and Response Summary

Sixty six different commenters provided detailed comments on all aspects of the May 2, 1995 proposal. In all, the comments dealt with 27 separate aspects of the proposal. In this comment and response summary, only major comments and responses will be summarized. Responses to all comments are contained in the Comment Response Document in the record for this final rule. In selecting comments and responses for summary in this section, the Agency has selected those major and controversial issues that received considerable numbers and types of comments. Alternatively, comments and responses on other less controversial issues and issues where EPA essentially agrees with the commenters are not included in the comment and response summaries below.

Comment: EPA's decision to set in-plant limits is primarily based on controlling air emissions. The appropriate statutory authority for regulating air emissions from wastewater is under the MACT rule, therefore, in-plant wastewater limits should not be used for the purpose of controlling air emissions. The intention of the Clean Water Act is to set limits at the end-of-pipe to protect surface water quality and POTW's from pass through and interference. Application of end-of-pipe standards and limitations will fulfill this intent.

Response: EPA agrees that the intention of the Clean Water Act is to set limits to protect surface water quality and POTWs from pass through and interference. EPA is promulgating effluent limitations guidelines and standards for which compliance will generally be monitored end-of-pipe, except for cyanide. EPA has the authority to control any pollutants found in wastewater. Although in-plant air emissions will be regulated under the MACT standards rule, organic pollutants in wastewater will be controlled by this effluent guidelines rule using limits monitored at end-of-pipe except in cases where end-of-pipe monitoring is impractical as authorized in § 122.45 or § 403.6(e).

Comment: Oxygenated organic solvents such as methanol, ethanol, acetone, and isopropanol should not be regulated by pretreatment standards because they do not volatilize in appreciable amounts and do not typically pass through the POTW or interfere with POTW operations.

Response: EPA agrees that oxygenated organic solvents such as methanol, ethanol, acetone and isopropanol with Henry's Law Constants less than 1.0×10^{-5} atm/gmole/m^3 will not volatilize in appreciable amounts in POTWs and sewers, and will biodegrade in POTW biological treatment units to a large extent. EPA has made this determination based on information submitted by PhRMA which estimated sewer losses of VOCs and EPA and PhRMA empirical sampling and modeling data from the Barceloneta POTW sampling episode. Based on an evaluation of this data, EPA agrees that

the oxygenated (alcohols and related) compounds under normal conditions will not pass through or interfere with POTW operations. Therefore, EPA is not promulgating categorical pretreatment standards for these pollutants for the pharmaceutical industry. However, local control authorities can set local limits for these compounds to take care of any site specific pass through or interference problems that may occur (§ 403.5.b.2).

Comment: Steam stripping with distillation is not a demonstrated treatment technology for the pharmaceutical industry since the Agency has not demonstrated the performance of this technology for any pollutant other than methanol and the data set used for proposing limits and standards was generated during treatment of a clean process wastewater which is not representative of typical industry process wastewaters.

Response: EPA agrees that the distillation data set used at proposal for setting limitations and standards based on steam stripping with distillation for alcohols were generated during treatment of a wastewater for a process which generated mostly methanol in the wastewater. EPA has not used these performance data in the calculation of final BAT limitations for the alcohols. Since the alcohols are not being regulated at PSES or PSNS because they do not pass through or interfere with the POTW operation, use of steam stripping with distillation technology is not an issue.

Comment: Solgar is a small business with process wastewater flow of approximately 100 gallons per day. They manufacture vitamins of natural origin and are not under the jurisdiction of the FDA. The definition of Subcategory D includes products and processes covered by SIC No. 2833 (Medical and Botanical Products). Being a regulated facility creates an adverse economic effect because of the operating costs related to permitting, sampling, analysis and reporting. EPA should consider exempting such facilities from the definition of pharmaceutical manufacturing.

Response: EPA has estimated compliance costs for all of the pharmaceutical manufacturing facilities which discharge pollutants for which effluent limitations and standards have been developed. If a facility does not discharge regulated pollutants, the compliance costs connected with sampling and analysis will be minimal. Permitting costs were not included in the cost estimates because these costs would be incurred by all dischargers regardless of category and are not specific to this regulation. EPA does not believe that small facilities such as the one described in the comment will incur significant costs in complying with the final rule. In a part of the economic analysis for this rule, special emphasis was placed on small businesses as required by the Regulatory Flexibility Act. Results of this analysis showed that there are no significant adverse impacts on small facilities or firms. (See the Economic Analysis Report)

Comment: Facilities should not be required to monitor for constituents that they do not use. In lieu of annual testing, facilities could submit annual (or on other frequencies) certifications regarding the constituent used or expected in the wastewater based on a review of all raw materials used and an assessment of all chemical processes used, considering resulting products and by-products. This would avoid incorrect data created by inflow of contaminated groundwater in facility sewers. Most commenters supported the certification approach.

Response: EPA agrees that facilities should not be required to monitor for constituents that they do not use. EPA disagrees that in lieu of annual testing, facilities could submit annual certifications regarding the constituents used or expected in the wastewater based on a review of all raw materials used and an assessment of all chemical processes used. Facilities will not have permit limits or be required to monitor regularly for constituents not used in their pharmaceutical processes, and EPA agrees that most commenters support the certification approach. In cases where groundwater may be contaminated by regulated pollutants which are not used in manufacturing operations at a facility, the facility should submit groundwater sampling data along with the other certification information to avoid regular monitoring for these regulated pollutants.

Comment: Provisions d and f of the applicability section of the Preamble, Section IV.B, would have the effect of extending the applicability of the proposed regulations to many diagnostic products listed in SIC Code 2835. The processes used in, and the wastewater produced from the manufacture of many of these products is substantially different from products listed in SIC code no. 2833, 2834, and 2836. EPA should define applicability by SIC code, without the exceptions contained in provisions d and f, and excluding SIC code no. 2835. Provisions d and f will be difficult to administer because they are based on subjective determinations.

Response: Defining applicability strictly by SIC code could result in considerable amounts of wastewater at some facilities not being covered by any categorical limitations and standards and therefore the Agency has not adopted this approach in the final regulation. The Agency agrees that regulatory decisions based on applicability section IV.B.f. may require a subjective judgement by the permit writer or pretreatment authority with regard to the nature of the wastewater generated by the manufacture of the products in question. In order to remove any ambiguity that may be associated with this applicability section, EPA has revised the applicability provision of the final rule in 439.1.

B. Summary of Notice of Availability Comments and Responses

EPA received comments on the August 8, 1997 Notice of Availability from 25 commenters regarding seven major topics and 35 subtopics. A summary of the major comments and EPA responses is provided below. Responses to all of the comments are contained in the Comment Response Document in the record for this final rule.

Comment: The commenters support Option 1 for PSES and PSNS that provided for compliance with the MACT standards plus some regular monitoring. Option 1 will reduce redundant regulation, needless cost, confusion, and potentially contradictory rulemakings.

Response: EPA disagrees with the commenters. EPA is promulgating PSES/PSNS limitations based on Option 2 because this option controls VOC wastewater discharges from pharmaceutical wastewaters that are not controlled by the final MACT standard for the pharmaceutical industry. Therefore, EPA does not believe that selecting Option 2 will result in a redundant, confusing, and potentially contradictory regulation. EPA is directed to control pollutants found in wastewater that pass through or interferes with POTWs. EPA has taken into account the effects of the MACT rule in estimating the compliance costs for the industry to meet the final effluent guidelines and standards.

Comment: The commenters believe EPA should also exclude benzene and o-dichlorobenzene from coverage under this regulation because they are each discharged by only one plant. The fact that a pollutant is a priority pollutant is not justification for regulating it when it is found at a small number of sources within an industrial point source category. EPA excluded 20 priority

pollutants from regulation by the Organic Chemicals, Plastics, and Synthetic Fibers (OCPSF) effluent guidelines under the authority of Paragraph 8(a)(iii) of the then applicable consent decree (Table VI–3, OCPSF Development Document, EPA 440/1–87/009). Another reason for excluding benzene is that the one plant that currently discharges this chemical has permanently shut down the process generating this pollutant.

Response: Benzene and o-dichlorobenzene were reported in the 1990 Questionnaire as discharged from one facility; however, EPA sampling data found they were present at more than one facility. Using industry supplied data, EPA has determined that benzene and o-dichlorobenzene were discharged in 1990 at quantities of approximately 120,200 and 21,500 lbs per year, respectively, well above the 3,000 lbs/year small discharge limit and there are estimated removals in excess of 1000 lbs/year. Both criteria that are used to determine which pollutants are excluded from this regulation. In addition, given the variable nature of the pharmaceutical industry, EPA has not excluded pollutants from regulation that may be present at more that one facility. Benzene is a good case in point, since even though only one facility identified it as discharged in 1990, it was found to be present in 10 of the samples taken by EPA in August 1996 at the Barceloneta Regional Wastewater Treatment Plant, which is a POTW that receives predominately pharmaceutical wastewaters.

Comment: Several commenters will be requesting fundamentally different factor (FDF) variances for ammonia production because EPA has not properly developed nitrification-based BAT ammonia limits. (1) EPA did not properly identify facilities that may have to treat ammonia, (2) it excluded data from the biological nitrification database for plants that had influent ammonia concentrations of greater than 100 mg/L, (3) it assumed ammonia in process wastewaters are all ammonium hydroxide and not ammonium nitrate or ammonium phosphate, (4) and it did not consider the effects of high organic nitrogen loading present with high ammonia nitrogen loading. Because of the incorrect chemistry and engineering assumptions, EPA has overestimated the feasibility to meet the proposed BAT limits on ammonia-nitrogen. Therefore, commenters would request that EPA handle wastewater discharges of ammonia-nitrogen from certain facilities in a fundamentally different manner.

Response: In response to point one, EPA has identified all facilities that may have to treat ammonia from information provided in the 1990 questionnaire responses and data submissions provided in response to the proposal. With regard to point two, the five plant data sets used to develop the final limits included numerous influent ammonia concentration points greater than 100 mg/L. With regard to point three, EPA has converted all ammonium salt and hydroxide loadings to NH3 nitrogen loadings. In response to point four, EPA did consider the effect of the presence of high organic ammonia along with high ammonia nitrogen with respect to achieving compliance with the final ammonia limitations. EPA has concluded that ability of nitrification systems to nitrify ammonia is not affected by large loadings of organic amines because these compounds are biodegraded to ammonia in the advanced biological treatment along with other carbonaceous waste. The ammonia thus generated is then nitrified in the nitrification system. In certain cases, where organic amine levels are sufficiently high, two-stage nitrification will be necessary. The limitations and standards for ammonia in the final rule were determined using all of the data (one and two stage), after comparing the single stage and two stage performance data, and then setting the limits at the levels that were reflected by the data bases being examined separately. In conclusion, EPA costed compliance with the limits by two-stage nitrification, and believes the final BAT limits based on two stage nitrification technology are appropriate.

Appendix A to the Preamble—Lists of Abbreviations, Acronyms, Defintions and Other Terms Used in This Document

I. Definitions, Acronyms, and Abbreviations

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. 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 Part 439, subpart B).

BMP or BMPs—Best management practices, as described in section 304(e) of the Clean Water Act.

BOD_5—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. BOD_5 is not related to the oxygen requirements in chemical combustion.

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 Part 439, subpart C).

Clarifier—A treatment unit designed to remove suspended materials from wastewater, typically by sedimentation.

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.

Condensate—Any material that has condensed from a gaseous phase into a liquid phase.

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 (BOD_5), 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.

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 Part 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 document, 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.

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 (10^6) grams, or one metric ton.

Metric ton—One thousand (10^3) 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 part 439, subpart D).

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.

Nitrification—Nitrification is the oxidation of ammonium salts to nitrites (via nitrosomonas bacteria) and the further oxidation of nitrite to nitrate via nitrobacter bacteria. Nitrification can be accomplished in either a single or two-stage activated sludge system. Indicators of nitrification capability are (1) biological monitoring for ammonia oxidizing bacteria (AOB) and nitrite oxidizing bacteria (NOB) to determine if nitrification is occurring, and (2) analysis of the nitrogen balance to determine if nitrifying bacteria reduce the amount of ammonia and increase the amount of nitrite and nitrate.

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 Determination—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 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© 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 part 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).

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—Any organic pollutant with a Henry's Law Constant greater than or equal to 3.97×10^{-7} atm/gmole/m^3.

Waters of the United States—the same meaning set forth in 40 CFR 122.2.

Zero discharge (ZD)—No discharge of pollutants to waters of the United States or to a POTW.

List of Subjects

40 CFR Part 136

Environmental protection, Incorporation by reference, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 439

Environmental protection, Pharmaceutical manufacturing pollution prevention, Waste treatment and disposal, Water pollution control.

Dated: July 30, 1998.

Carol M. Browner,

Administrator.

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

PART 136—[AMENDED]

1. The authority citation for part 136 continues to read as follows:

Authority: Secs. 301, 304(h), 307, and 501(a) Pub. L. 95-217, Stat. 1566, *et seq.* (33 U.S.C. 1251, *et seq.*) (The Federal Water Pollution Control Act Amendments of 1972 as amended by the Clean Water Act of 1977).

2. Section 136.3 is amended by revising paragraph (a) introductory text and by adding a new Table IF in numerical order to the end of paragraph (a) and revising paragraph (b) introductory text and adding paragraph (b)(40) to read as follows:

§ 136.3 Identification of test procedures.

(a) Parameters or pollutants, for which methods are approved, are listed together with test procedure descriptions and references in Tables IA, IB, IC, ID, IE, and IF. The full text of the referenced test procedures are incorporated by reference into Tables IA, IB, IC, ID, IE, and IF. The references and the sources which are available are given in paragraph (b) of this section. These test procedures are incorporated as they exist on the day of approval and a notice of any change in these test procedures will be published in the **Federal Register**. The discharge parameter values for which reports are required must be determined by one of the standard analytical test procedures incorporated by reference and described in Tables IA, IB, IC, ID, IE, and IF, or by any alternate test procedure which has been approved by the Administrator under the provisions of paragraph (d) of this section and §§ 136.4 and 136.5. Under certain circumstances (paragraph (b) or (c) of this section or 40 CFR 401.13) other test procedures may be used that may be more advantageous when such other test procedures have been previously approved by the Regional Administrator of the Region in which the discharge occur, and providing the Director of the State in which such discharge will occur does

not object to the use of such alternate test procedure.

* * * * *

TABLE IF.—LIST OF APPROVED METHODS FOR PHARMACEUTICAL POLLUTANTS

Pharmaceuticals pollutants	CAS registry No.	Analytical method number
acetonitrile	75–05–8	1666/1671/D3371/D3695.
n-amyl acetate	628–63–7	1666/D3695.
n-amyl alcohol	71–41–0	1666/D3695
benzene	71–43–2	D4763/D3695/502.2/524.2.
n-butyl-acetate	123–86–4	1666/D3695.
tert-butyl alcohol	75–65–0	1666.
chlorobenzene	108–90–7	502.2/524.2.
chloroform	67–66–3	502.2/524.2/551.
o-dichlorobenzene	95–50–1	1625C/502.2/524.2.
1,2-dichloroethane	107–06–2	D3695/502.2/524.2.
diethylamine	109–89–7	1666/1671.
dimethyl sulfoxide	67–68–5	1666/1671.
ethanol	64–17–5	1666/1671/D3695.
ethyl acetate	141–78–6	1666/D3695.
n-heptane	142–82–5	1666/D3695.
n-hexane	110–54–3	1666/D3695.
isobutyraldehyde	78–84–2	1666/1667.
isopropanol	67–63–0	1666/D3695.
isopropyl acetate	108–21–4	1666/D3695.
isopropyl ether	108–20–3	1666/D3695.
methanol	67–56–1	1666/1671/D3695.
Methyl Cellosolve®	109–86–4	1666/1671
methylene chloride	75–09–2	502.2/524.2
methyl formate	107–31–3	1666.
4-methyl-2-pentanone (MIBK)	108–10–1	1624C/1666/D3695/D4763/524.2.
phenol	108–95–2	D4763.
n-propanol	71–23–8	1666/1671/D3695.
2-propanone (acetone)	67–64–1	D3695/D4763/524.2.
tetrahydrofuran	109–99–9	1666/524.2.
toluene	108–88–3	D3695/D4763/502.2/524.2.
triethlyamine	121–44–8	1666/1671.
xylenes	(Note 1)	1624C/1666.

Table 1F note:

1. 1624C: m-xylene 108–38–3, o,p-xylene E–14095 (Not a CAS number; this is the number provided in the Environmental Monitoring Methods Index (EMMI) database.); 1666: m,p-xylene 136777–61–2, o-xylene 95–47–6.

* * * * *

(b) The full texts of the methods from the following references which are cited in Tables IA, IB, IC, ID, IE,and IF are incorporated by reference into this regulation and may be obtained from the sources identified. All costs cited are subject to change and must be verified from the indicated sources. The full texts of all the test procedures cited are available for inspection at the National Exposure Research Laboratory, Office of Research and Development, U.S. Environmental Protection Agency, 26 West Martin Luther King Dr., Cincinnati, OH 45268 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

* * * * *

(40) EPA Methods 1666, 1667, and 1671 listed in the table above are published in the compendium titled Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewaters (EPA 821–B–98–016). EPA Methods 502.2 and 524.2 have been incorporated by reference into 40 CFR 141.24 and are in Methods for the Determination of Organic Compounds in Drinking Water, EPA–600/4–88–039, December 1988, Revised, July 1991, and Methods for the Determination of Organic Compounds in Drinking Water-Supplement II, EPA–600/R–92–129, August 1992, respectively. These EPA test method compendia are available from the National Technical Information Service, NTIS PB91–231480 and PB92–207703, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll-free number is 800–553–6847. ASTM test methods D3371, D3695, and D4763 are available from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959.

* * * * *

PART 439—[AMENDED]

1. The authority citation for part 439 is revised to read as follows:

Authority: Secs. 301, 304, 306, 307, 308, 402 and 501 of the Clean Water Act, as amended; 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

2. Part 439 is amended by revising the undesignated heading ''GENERAL PROVISIONS'' to read ''General''.

3. Section 439.0 is revised to read as follows:

§ 439.0 Applicability.

(a) This part applies to process wastewater discharges resulting from the research and manufacture of pharmaceutical products, which are generally, but not exclusively, reported under SIC 2833, SIC 2834 and SIC 2836 (1987 Standard Industrial Classification Manual).

(b) Although not reported under SIC 2833, SIC 2834 and SIC 2836, discharges from the manufacture of other pharmaceutical products to which this part applies include (but are not limited to):

(1) Products manufactured by one or more of the four types of manufacturing

processes described in subcategories A, B, C or D of this part, and considered by the Food and Drug Administration to be pharmaceutical active ingredients;

(2) Multiple end-use products (e.g., components of formulations, chemical intermediates, or final products) derived from pharmaceutical manufacturing operations and intended for use primarily in pharmaceutical applications;

(3) Pharmaceutical products and intermediates not subject to other categorical limitations and standards, provided the manufacturing processes generate process wastewaters that are similar to those derived from the manufacture of pharmaceutical products elsewhere (an example of such a product is citric acid);

(4) Cosmetic preparations that are reported under SIC 2844 and contain pharmaceutical active ingredients, or active ingredients that are intended for the treatment of a skin condition. (These preparations do not include products such as lipsticks or perfumes that serve to enhance appearance, or provide a pleasing odor, but do not enhance skin care. Also excluded are deodorants, manicure preparations, shaving preparations and non-medicated shampoos that do not function primarily as a skin treatment.)

(c) The provisions of this part do not apply to wastewater discharges resulting from the manufacture of the following products, or as a result of providing one or more of the following services:

(1) Surgical and medical instruments and apparatus reported under SIC 3841;

(2) Orthopedic, prosthetic, and surgical appliances and supplies reported under SIC 3842;

(3) Dental equipment and supplies reported under SIC 3843;

(4) Medical laboratory services reported under SIC 8071;

(5) Dental laboratory services reported under SIC 8072;

(6) Outpatient care facility services reported under SIC 8081;

(7) Health and allied services reported under SIC 8091, and not classified elsewhere;

(8) Diagnostic devices other than those reported under SIC 3841;

(9) Animal feed products that include pharmaceutical active ingredients such as vitamins and antibiotics, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products;

(10) Food and beverage products fortified with vitamins or other pharmaceutical active ingredients, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products;

(11) Pharmaceutical products and intermediates subject to the provisions of 40 CFR part 414, provided their manufacture results in less than 50 percent of the total flow of process wastewater that is regulated by 40 CFR part 414 at the facility.

4. Section 439.1 is revised to read as follows:

§ 439.1 General definitions.

As used in this part:

(a) The general definitions, abbreviations and methods of analysis in 40 CFR part 401 shall apply.

(b) The term *bench-scale operation* means the laboratory testing of materials, methods, or processes on a small scale, such as on a laboratory worktable.

(c) The term *cyanide (T)* means the parameter total cyanide.

(d) The term *in-plant monitoring point* means a location within a plant, where an individual process effluent can be exclusively monitored before it is diluted or mixed with other process wastewaters enroute to the end-of-pipe.

(e) The term *minimum level* means the level at which an analytical system gives recognizable signals and an acceptable calibration point.

(f) The term *nitrification capability* means the capability of a POTW treatment system to oxidize ammonia or ammonium salts initially to nitrites (via *Nitrosomonas* bacteria) and subsequently to nitrates (via *Nitrobacter* bacteria). Criteria for determining the nitrification capability of a POTW treatment system are: bioassays confirming the presence of nitrifying bacteria; and analyses of the nitrogen balance demonstrating a reduction in the concentration of ammonia or ammonium salts and an increase in the concentrations of nitrites and nitrates.

(g) The term *non-detect (ND)* means a concentration value below the minimum level that can be reliably measured by the analytical method.

(h) The term *pilot-scale operation* means processing equipment being operated at an intermediate stage between laboratory-scale and full-scale operation for the purpose of developing a new product or manufacturing process.

(i) The term *POTW* means publicly owned treatment works (40 CFR 403.3).

(j) The term *process wastewater,* as defined at 40 CFR 122.2 and for the purposes of this part, does not include the following:

(1) Trimethyl silanol, any active anti-microbial materials, process wastewater from imperfect fermentation batches, and process area spills. Discharges containing such materials are not subject to the limitations and standards of this part.

(2) Non-contact cooling water, utility wastewaters, general site surface runoff, groundwater (e.g., contaminated groundwaters from on-site or off-site groundwater remediation projects), and other non-process water generated on site. Discharges of such waters and wastewaters are not subject to the limitations and standards of this part.

(k) The term *non-conventional pollutants* means parameters that are neither conventional pollutants (40 CFR 401.16), nor ''toxic'' pollutants (40 CFR 401.15).

(l) The term *surrogate pollutant* means a regulated parameter that, for the purpose of compliance monitoring, is allowed to serve as a surrogate for a group of specific regulated parameters. Plants would be allowed to monitor for a surrogate pollutant(s), when the other parameters for which it stands are receiving the same degree of treatment as the surrogate pollutant(s) and all of the parameters discharged are in the same treatability class(es) as their respective surrogate pollutant(s). Treatability classes have been identified in Appendix A to this part for both steam stripping and biological treatment technologies, which are the respective technology bases for PSES/PSNS and BAT/NSPS limitations controlling the discharge of regulated organic parameters.

(m) The term *xylenes* means a combination of the three isomers: o-xylene, p-xylene, and m-xylene.

5. Section 439.3 is added under the undesignated center heading ''General'' to read as follows:

§ 439.3 General pretreatment standards.

Any source subject to this part that introduces process wastewater pollutants into a publicly owned treatment works (POTW) must comply with 40 CFR part 403.

6. Section 439.4 is added under the undesignated center heading ''General'' to read as follows:

§ 439.4 Monitoring requirements.

Permit limits and compliance monitoring are required for each regulated pollutant generated or used at a pharmaceutical manufacturing facility, except where the regulated pollutant is monitored as a surrogate parameter. Permit limits and compliance monitoring are not required for regulated pollutants that are neither

used nor generated at the facility. Except for cyanide, for which an alternate monitoring requirement is established in subparts A and C of this part a determination that regulated pollutants are neither used nor generated should be based on a review of all raw materials in use, and an assessment of the process chemistry, products and by-products resulting from each of the manufacturing processes. This determination along with recommendation of any surrogate must be submitted with permit applications for approval by the permitting authority, and reconfirmed by an annual chemical analysis of wastewater from each monitoring location, and the measurement of a non-detect value for each regulated pollutant or its surrogate. Permits shall specify that such determinations will be maintained in the facility's permit records with their discharge monitoring reports and will be available to regulatory authorities upon request.

Subpart A—[Amended]

7. Section 439.10 is revised to read as follows:

§ 439.10 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by fermentation.

8. Section 439.11 is revised to read as follows:

§ 439.11 Specialized definitions.

For the purpose of this subpart:

(a) The term *fermentation* means 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.

(b) The term *product* means pharmaceutical products derived from fermentation processes.

9. Section 439.12 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.12 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The average monthly effluent limitation for BOD_5, expressed as mass loading (pounds, kilograms) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD_5 load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

(1) The long-term average daily BOD_5 load of the raw process wastewater (i.e., the base number to which the percent reduction is applied) is defined as the average daily BOD_5 load during any calendar month, over 12 consecutive months within the most recent 36 months, and must include one or more periods during which production was at a maximum.

(2) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or separate disposal or reuse. These residual amounts may be included in the calculation of the average influent BOD_5 loading.

(3) The practices of recovery, and/or separate disposal or reuse include: physical separation and removal of separable mycelia; recovery of solvents from waste streams; incineration of concentrated solvent wastestreams (including tar still bottoms); and concentration of broth for disposal other than to the treatment system. This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 may be achieved by any of several, or a combination, of these practices.

(b) The average monthly effluent limitation for TSS, expressed as mass loading (pounds, kilograms) per day, must be calculated as 1.7 times the BOD_5 limitation determined in paragraph (a) of this section.

(c) Except as provided in paragraph (d) of this section, the effluent limitations for COD and pH are as follows:

Regulated parameter	Effluent limitation [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
COD	1675	856
pH	([2])	([2])

[1] Mg/L (ppm).
[2] Within the range 6.0 to 9.0.

(d) If the average monthly COD concentrations in paragraph (c) of this section are higher than concentration values reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then the average monthly effluent limitations for COD corresponding to the lower concentration values must be applied.

(e) The effluent limitations for cyanide are as follows:

Regulated parameter	Effluent limitation [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(f) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide effluent limitations in paragraph (e) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 122.44(i) and 122.45(h). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(g) Compliance with the limitation in paragraph (e) or (f) of this section may be achieved by certifying to the permit issuing authority that the facility's manufacturing processes neither use nor generate cyanide.

10. Section 439.13 is revised to read as follows:

§ 439.13 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD_5, TSS and pH are the same as the corresponding limitations in § 439.12.

11. Section 439.14 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.14 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

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 application of BAT:

	Regulated parameter	Effluent limitations [1]	
		Maximum daily discharge	Average monthly discharge must not exceed
1	Ammonia (as N)	84.1	29.4
2	Acetone	0.5	0.2
3	4-Methyl-2-pentanone (MIBK)	0.5	0.2
4	Isobutyraldehyde	1.2	0.5
5	n-Amyl acetate	1.3	0.5
6	n-Butyl acetate	1.3	0.5
7	Ethyl acetate	1.3	0.5
8	Isopropyl acetate	1.3	0.5
9	Methyl formate	1.3	0.5
10	Amyl alcohol	10.0	4.1
11	Ethanol	10.0	4.1
12	Isopropanol	3.9	1.6
13	Methanol	10.0	4.1
14	Methyl Cellosolve	100.0	40.6
15	Dimethyl Sulfoxide	91.5	37.5
16	Triethyl Amine	250.0	102.0
17	Phenol	0.05	0.02
18	Benzene	0.05	0.02
19	Toluene	0.06	0.02
20	Xylenes	0.03	0.01
21	n-Hexane	0.03	0.02
22	n-Heptane	0.05	0.02
23	Methylene chloride	0.9	0.3
24	Chloroform	0.02	0.01
25	1,2-Dichloroethane	0.4	0.1
26	Chlorobenzene	0.15	0.06
27	o-Dichlorobenzene	0.15	0.06
28	Tetrahydrofuran	8.4	2.6
29	Isopropyl ether	8.4	2.6
30	Diethyl amine	250.0	102.0
31	Acetonitrile	25.0	10.2
32	pH	([2])	([2])

[1] Mg/L (ppm).
[2] Within the range of 6.0–9.0.

(a) The effluent limitations for COD are the same as the corresponding limitations in § 439.12(c) and (d).

(b) The effluent limitations for cyanide are as follows:

Regulated parameter	Effluent limitation [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide effluent limitations in paragraph (b) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 122.44(i) and 122.45(h). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Compliance with the limitation in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that a facility's manufacturing processes neither use nor generate cyanide.

12. Section 439.15 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.15 Standards of performance for new (point) sources (NSPS).

Any new source subject to this subpart must achieve the following performance standards:

	Regulated parameter	Effluent limitations [1]	
		Maximum daily discharge	Average monthly discharge must not exceed
1	BOD_5	267	111
2	TSS	472	166
3	COD	1675	856
4	Ammonia (as N)	84.1	29.4
5	Acetone	0.5	0.2
6	4-Methyl-2-pentanone (MIBK)	0.5	0.2
7	Isobutyraldehyde	1.2	0.5
8	n-Amyl acetate	1.3	0.5

Regulated parameter	Effluent limitations [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
9 n-Butyl acetate	1.3	0.5
10 Ethyl acetate	1.3	0.5
11 Isopropyl acetate	1.3	0.5
12 Methyl formate	1.3	0.5
13 Amyl alcohol	10.0	4.1
14 Ethanol	10.0	4.1
15 Isopropanol	3.9	1.6
16 Methanol	10.0	4.1
17 Methyl Cellosolve	25.0	10.2
18 Dimethyl Sulfoxide	91.5	37.5
19 Triethyl Amine	250.0	102.0
20 Phenol	0.05	0.02
21 Benzene	0.05	0.02
22 Toluene	0.06	0.02
23 Xylenes	0.03	0.01
24 n-Hexane	0.03	0.02
25 n-Heptane	0.05	0.02
26 Methylene chloride	0.9	0.3
27 Chloroform	0.02	0.01
28 1,2-Dichloroethane	0.4	0.1
29 Chlorobenzene	0.15	0.06
30 o-Dichlorobenzene	0.15	0.06
31 Tetrahydrofuran	8.4	2.6
32 Isopropyl ether	8.4	2.6
33 Diethyl amine	250.0	102.0
34 Acetonitrile	25.0	10.2
35 pH	([2])	([2])

[1] Mg/L (ppm).
[2] Within the range of 6.0—9.0.

(a) The performance standards for cyanide are as follows:

Regulated parameter	Performance standards [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(b) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide performance standards in paragraph (a) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 122.44(i) and 122.45(h). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(c) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the earlier version of this section 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 §§ 439.13 and 439.14.

(d) Compliance with the standard in paragraph (a) or (b) of this section may be achieved by certifying to the permit issuing authority that the facility's manufacturing processes neither use nor generate cyanide.

13. Section 439.16 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.16 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must continue to achieve compliance with cyanide pretreatment standards and achieve compliance with all the other pretreatment standards by September 21, 2001.

Regulated parameter	Pretreatment standards [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
1 Ammonia (as N) [2]	84.1	29.4
2 Acetone	20.7	8.2
3 4-Methyl-2-pentanone (MIBK)	20.7	8.2
4 Isobutyraldehyde	20.7	8.2
5 n-Amyl acetate	20.7	8.2
6 n-Butyl acetate	20.7	8.2
7 Ethyl acetate	20.7	8.2
8 Isopropyl acetate	20.7	8.2

	Regulated parameter	Pretreatment standards[1]	
		Maximum daily discharge	Average monthly discharge must not exceed
9	Methyl formate	20.7	8.2
10	Methyl Cellosolve	275.0	9.7
11	Isopropyl ether	20.7	8.2
12	Tetrahydrofuran	9.2	3.4
13	Benzene	3.0	0.6
14	Toluene	0.3	0.1
15	Xylenes	3.0	0.7
16	n-Hexane	3.0	0.7
17	n-Heptane	3.0	0.7
18	Methylene chloride	3.0	0.7
19	Chloroform	0.1	0.03
20	1,2-Dichloroethane	20.7	8.2
21	Chlorobenzene	3.0	0.7
22	o-Dichlorobenzene	20.7	8.2
23	Diethyl amine	255.0	100.0
24	Triethyl amine	255.0	100.0

[1] Mg/L (ppm).
[2] Not applicable to sources that discharge to a POTW with nitrification capability.

(a) Sources that discharge to a POTW with nitrification capability (defined at § 439.2(f)) are not required to achieve the pretreatment standard for ammonia.

(b) The pretreatment standards for cyanide are as follows:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide standards in paragraph (b) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(e)(2) and (4). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Compliance with the limitation in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that the facility's manufacturing processes neither use nor generate cyanide.

14. Section 439.17 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.17 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart must achieve the following pretreatment standards:

	Regulated parameter	Pretreatment standards[1]	
		Maximum daily discharge	Average monthly discharge must not exceed
1	Ammonia (as N)[2]	84.1	29.4
2	Acetone	20.7	8.2
3	4-Methyl-2-pentanone (MIBK)	20.7	8.2
4	Isobutyraldehyde	20.7	8.2
5	n-Amyl acetate	20.7	8.2
6	n-Butyl acetate	20.7	8.2
7	Ethyl acetate	20.7	8.2
8	Isopropyl acetate	20.7	8.2
9	Methyl formate	20.7	8.2
10	Methyl Cellosolve	275.0	59.7
11	Isopropyl ether	20.7	8.2
12	Tetrahydrofuran	9.2	3.4
13	Benzene	3.0	0.7
14	Toluene	0.3	0.1
15	Xylenes	3.0	0.7
16	n-Hexane	3.0	0.7
17	n-Heptane	3.0	0.7
18	Methylene chloride	3.0	0.7
19	Chloroform	0.1	0.03
20	1,2-Dichloroethane	20.7	8.2
21	Chlorobenzene	3.0	0.7
22	o-Dichlorobenzene	20.7	8.2
23	Diethyl amine	255.0	100.0

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
24 Triethyl amine	255.0	100.0

[1] Mg/L (ppm)
[2] Not applicable to sources that discharge to a POTW with nitrification capability.

(a) Sources that discharge to a POTW with nitrification capability (defined at § 439.2(f))are not required to achieve the pretreatment standard for ammonia.

(b) The pretreatment standards for cyanide are as follows:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide standards in § 439.17(b) must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(e)(2) and (4). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the earlier version of this section 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.

(e) Compliance with the standards in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that a facility's manufacturing processes neither use nor generate cyanide.

15. Section 439.20 is revised to read as follows:

§ 439.20 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by extraction.

16. Section 439.21 is revised to read as follows:

§ 439.21 Specialized definitions.

For the purpose of this subpart:

(a) The term *extraction* means process operations that derive pharmaceutically active ingredients from natural sources such as plant roots and leaves, animal glands, and parasitic fungi by chemical and physical extraction.

(b) The term *product* means any substance manufactured by an extraction process, including blood fractions, vaccines, serums, animal bile derivatives, endocrine products and medicinal products such as alkaloids that are isolated from botanical drugs and herbs.

17. Section 439.22 is revised to read as follows:

§ 439.22 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The average monthly effluent limitation for BOD_5, expressed as mass loading (pounds, kilograms) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD_5 load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

(1) The long-term average daily BOD_5 load of the raw process wastewater (i.e., the base number to which the percent reduction is applied) is defined as the average daily BOD_5 load during any calendar month, over 12 consecutive months within the most recent 36 months, and must include one or more periods during which production was at a maximum.

(2) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or separate disposal or reuse. Residual amounts of these substances may be included in the calculation of the average influent BOD_5 loading.

(3) The practices of recovery, and/or separate disposal or reuse include: physical separation and removal of separable mycelia; recovery of solvents from wastestreams; incineration of concentrated solvent wastestreams (including tar still bottoms); and broth concentration for disposal other than to the treatment system. This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 may be achieved by any of several, or a combination, of these practices.

(b) The average monthly effluent limitation for TSS, expressed as mass loading (pounds, kilograms) per day, must be calculated as 1.7 times the BOD_5 limitation determined in paragraph (a) of this section.

(c) Except as provided in paragraph (d) of this section, effluent limitations for COD and pH are as follows:

Regulated parameter	Effluent limitations[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
COD	228	86
pH	([2])	([2])

[1] Mg/L (ppm).
[2] Within the range 6.0 to 9.0.

(d) If the average monthly COD concentrations in paragraph (c) of this section are higher than concentration values reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then the average monthly effluent limitations for COD corresponding to the lower concentration values must be applied.

18. Section 439.23 is revised to read as follows:

§ 439.23 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point

source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD_5, TSS and pH are the same as the corresponding limitations in § 439.22.

19. Section 439.24 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.24 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

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 application of BAT: Limitations for COD are the same as the corresponding limitations in § 439.22(c) and (d).

20. Section 439.25 is revised to read as follows:

§ 439.25 Standards of performance for new (point) sources (NSPS).

Any new source subject to this subpart must achieve the following performance standards:

Regulated parameter	Performance standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
BOD_5	35	18
TSS	58	31
COD	228	86
pH	(2)	(2)

[1] Mg/L (ppm).
[2] Within the range 6.0 to 9.0.

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the earlier version of this section, 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 §§ 439.23 and 439.24.

21. Section 439.26 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.26 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must achieve the following pretreatment standards by October 22, 2001:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
1 Acetone	20.7	8.2
2 n-Amyl acetate	20.7	8.2
Ethyl acetate	20.7	8.2
4 Isopropyl acetate	20.7	8.2
5 Methylene chloride	3.0	0.7

[1] Mg/L (ppm).

22. Section 439.27 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.27 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7, this subpart must achieve the following pretreatment standards:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
1 Acetone	20.7	8.2
2 n-Amyl acetate	20.7	8.2
3 Ethyl acetate	20.7	8.2
4 Isopropyl acetate	20.7	8.2
5 Methylene chloride	3.0	0.7

[1] Mg/L (ppm).

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in § 439.27, 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.

23. Section 439.30 is revised to read as follows:

§ 439.30 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by chemical synthesis.

24. Section 439.31 is revised to read as follows:

§ 439.31 Specialized definitions.

For the purpose of this subpart:

(a) The term *chemical synthesis* means using one or a series of chemical reactions in the manufacturing process of a specified product.

(b) The term *product* means any pharmaceutical product manufactured by chemical synthesis.

25. Section 439.32 is amended by removing the OMB control number cite and revising the section to read as follows:

§ 439.32 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The average monthly effluent limitation for BOD_5, expressed as mass loading (pounds, kilograms) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD_5 load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

(1) The long-term average daily BOD_5 load of the raw process wastewater (i.e., the base number to which the percent reduction is applied) is defined as the average daily BOD_5 load during any calendar month, over 12 consecutive months within the most recent 36 months, and must include one or more periods during which production was at a maximum.

(2) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or separate disposal or reuse. Residual amounts of these substances may be included in the calculation of the average influent BOD_5 loading.

(3) The practices of recovery, and/or separate disposal or reuse include: physical separation and removal of separable mycelia; recovery of solvents from wastestreams; incineration of concentrated solvent wastestreams (including tar still bottoms); and concentration of broth for disposal other than to the treatment system. This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 may be achieved by any of several, or a combination, of these practices.

(b) The average monthly effluent limitation for TSS, expressed as mass loading (pounds, kilograms) per day, must be calculated as 1.7 times the BOD_5 limitation determined in paragraph (a) of this section.

(c) Except as provided in paragraph (d) of this section, the effluent limitations for COD and pH are as follows:

Regulated parameter	Effluent limitation [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
COD	1675	856
pH	([2])	([2])

[1] Mg/L (ppm).
[2] Within the range 6.0 to 9.0.

(d) If the average monthly COD concentrations in paragraph (c) of this section are higher than concentration values reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then the average monthly effluent limitations for COD corresponding to the lower concentration values must be applied.

(e) The effluent limitations for cyanide are as follows:

Regulated parameter	Effluent limitation [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(f) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide effluent limitations in § 439.32(e) must be demonstrated at in-plant monitoring points pursuant to 40 CFR 122.44(i) and 122.45(h). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(g) Compliance with the limitation in paragraph (e) or (f) of this section may be achieved by certifying to the permit issuing authority that the facility's manufacturing processes neither use nor generate cyanide.

26. Section 439.33 is revised to read as follows:

§ 439.33 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD5, TSS and pH are the same as the corresponding limitations in § 439.32.

27. Section 439.34 is amended by removing the OMB control number cite and revising the section to read as follows:

§ 439.34 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

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 application of BAT:

	Regulated parameter	Effluent limitations [1]	
		Maximum daily discharge	Average monthly discharge must not exceed
1	Ammonia (as N)	84.1	29.4
2	Acetone	0.5	0.2
3	4-Methyl-2-pentanone (MIBK)	0.5	0.2
4	Isobutyraldehyde	1.2	0.5
5	n-Amyl acetate	1.3	0.5
6	n-Butyl acetate	1.3	0.5
7	Ethyl acetate	1.3	0.5
8	Isopropyl acetate	1.3	0.5
9	Methyl formate	1.3	0.5
10	Amyl alcohol	10.0	4.1
11	Ethanol	10.0	4.1
12	Isopropanol	3.9	1.6
13	Methanol	10.0	4.1
14	Methyl Cellosolve	25.0	10.2
15	Dimethyl Sulfoxide	91.5	37.5
16	Triethyl amine	250.3	101.5
17	Phenol	0.05	0.02
18	Benzene	0.05	0.02
19	Toluene	0.06	0.02
20	Xylenes	0.03	0.01
21	n-Hexane	0.03	0.02
22	n-Heptane	0.05	0.02
23	Methylene chloride	0.9	0.3
24	Chloroform	0.02	0.01
25	1,2-Dichloroethane	0.4	0.1
26	Chlorobenzene	0.15	0.06
27	o-Dichlorobenzene	0.15	0.06
28	Tetrahydrofuran	8.4	2.6
29	Isopropyl ether	8.4	2.6
30	Diethyl amine	250.0	102.0
31	Acetonitrile	25.0	10.2
32	pH	([2])	([2])

[1] Mg/L (ppm).
[2] Within the range of 6.0–9.0.E.

(a) Effluent limitations for COD are the same as the corresponding limitations in § 439.32(c) and (d).

(b) The effluent limitations for cyanide are as follows:

Regulated parameter	Effluent limitations [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide effluent limitations in paragraph (a) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 122.44(i) and 122.45(h). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Compliance with the limitation in § 439.34(b) or (c) may be achieved by certifying to the permit issuing authority that a facility's manufacturing processes neither use nor generate cyanide.

28. Section 439.35 is amended by removing the OMB control number cite and revising the section to read as follows:

§ 439.35 Standards of performance for new (point) sources (NSPS).

Any new source subject to this subpart must achieve the following performance standards:

	Regulated parameter	Effluent limitations [1]	
		Maximum daily discharge	Average monthly discharge must not exceed
1	BOD_5	267	111
2	TSS	472	166
3	COD	1675	856
4	Ammonia (as N)	84.1	29.4
5	Acetone	0.5	0.2
6	4-Methyl-2-pentanone (MIBK)	0.5	0.2
7	Isobutyraldehyde	1.2	0.5
8	n-Amyl acetate	1.3	0.5
9	n-Butyl acetate	1.3	0.5
10	Ethyl acetate	1.3	0.5
11	Isopropyl acetate	1.3	0.5
12	Methyl formate	1.3	0.5
13	Amyl alcohol	10.0	4.1
14	Ethanol	10.0	4.1
15	Isopropanol	3.9	1.6
16	Methanol	10.0	4.1
17	Methyl Cellosolve	100.0	40.6
18	Methyl Sulfoxide	91.5	37.5
19	Triethyl amine	250.0	102.0
20	Phenol	0.05	0.02
21	Benzene	0.05	0.02
22	Toluene	0.06	0.02
23	Xylenes	0.02	0.01
24	n-Hexane	0.03	0.02
25	n-Heptane	0.05	0.02
26	Methylene chloride	0.9	0.3
27	Chloroform	0.02	0.01
28	1,2-Dichloroethane	0.4	0.1
29	Chlorobenzene	0.15	0.05
30	o-Dichlorobenzene	0.15	0.06
31	Tetrahydrofuran	8.4	2.6
32	Isopropyl ether	8.4	2.6
33	Diethyl amine	250.0	102.0
34	Acetonitrile	25.0	10.2
35	pH	([2])	([2])

[1] Mg/L (ppm).
[2] Within the range of 6.0–9.0.

(a) The performance standards for cyanide are as follows:

Regulated parameter	Performance standards [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(b) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide standards in paragraph (a) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 122.44(i) and 122.45(h). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(c) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the earlier version of this section 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 §§ 439.33 and 439.34.

(d) Compliance with the standards in paragraph (a) or (b) of this section may be achieved by certifying to the permit issuing authority that a facility's manufacturing processes neither use nor generate cyanide.

29. Section 439.36 is amended by removing the OMB control number cite and revising the section to read as follows:

§ 439.36 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must continue to achieve compliance with cyanide pretreatment standards and achieve compliance with all other pretreatment standards by September 21, 2001.

	Regulated parameter	Pretreatment standards [1]	
		Maximum daily discharge	Average monthly discharge must not exceed
1	Ammonia (as N) [2]	84.1	29.4
2	Acetone	20.7	8.2
3	4–Methyl-2-pentanone (MIBK)	20.7	8.2
4	Isobutyraldehyde	20.7	8.2
5	n-Amyl acetate	20.7	8.2
6	n-Butyl acetate	20.7	8.2
7	Ethyl acetate	20.7	8.2
8	Isopropyl acetate	20.7	8.2
9	Methyl formate	20.7	8.2
10	Methyl Cellosolve	275.0	54.7
11	Isopropyl ether	20.7	8.2
12	Tetrahydrofuran	9.2	3.4
13	Benzene	3.0	0.7
14	Toluene	0.3	0.1
15	Xylenes	3.0	0.7
16	n-Hexane	3.0	0.7
17	n-Heptane	3.0	0.7
18	Methylene chloride	3.0	0.7
19	Chloroform	0.1	0.03
20	1,2–Dichloroethane	20.7	8.2
21	Chlorobenzene	3.0	0.7
22	o-Dichlorobenzene	20.7	8.2
23	Diethyl amine	255.0	100.0
24	Triethyl amine	255.0	100.0

[1] Mg/L (ppm).
[2] Not applicable to sources that discharge to a POTW with nitrification capability.

(a) Sources that discharge to a POTW with nitrification capability (defined at § 439.2(f)) are not required to achieve the pretreatment standard for ammonia.

(b) The pretreatment standards for cyanide are as follows:

Regulated parameter	Pretreatment standards [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide pretreatment standards in paragraph (b) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(e) (2) and (4). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Compliance with the pretreatment standards in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that the facility's manufacturing processes neither use nor generate cyanide.

30. Section 439.37 is amended by removing the OMB control number cite and revising the section to read as follows:

§ 439.37 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart must achieve the following pretreatment standards:

	Regulated parameter	Pretreatment standards [1]	
		Maximum daily discharge	Average monthly discharge must not exceed
1	Ammonia (as N)[2]	84.1	29.4
2	Acetone	20.7	8.2
3	4-Methyl-2-pentanone (MIBK)	20.7	8.2
4	Isobutyraldehyde	20.7	8.2
5	n-Amyl acetate	20.7	8.2

	Regulated parameter	Pretreatment standards [1]	
		Maximum daily discharge	Average monthly discharge must not exceed
6	n-Butyl acetate	20.7	8.2
7	Ethyl acetate	20.7	8.2
8	Isopropyl acetate	20.7	8.2
9	Methyl formate	20.7	8.2
10	Methyl Cellosolve	275.0	59.7
11	Isopropyl ether	20.7	8.2
12	Tetrahydrofuran	9.2	3.4
13	Benzene	3.0	0.7
14	Toluene	0.3	0.1
15	Xylenes	3.0	0.7
16	n-Hexane	3.0	0.7
17	n-Heptane	3.0	0.7
18	Methylene chloride	3.0	0.7
19	Chloroform	0.1	0.03
20	1,2-Dichloroethane	20.7	8.2
21	Chlorobenzene	3.0	0.7
22	o-Dichlorobenzene	20.7	8.2
23	Diethyl amine	255.0	100.0
24	Triethyl amine	255.0	100.0

[1] Mg/L (ppm).
[2] Not applicable to sources that discharge to a POTW with nitrification capability.

(a) Sources that discharge to a POTW with nitrification capability (defined at § 439.2(f)) are not required to achieve the pretreatment standard for ammonia.

(b) The pretreatment standards for cyanide are as follows:

Regulated parameter	Effluent limitation [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide pretreatment standards in paragraph (b) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(e) (2) and (4). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the earlier version of § 439.37, 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.

(e) Compliance with the standard in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that a facility's manufacturing processes neither use nor generate cyanide.

31. Section 439.40 is revised to read as follows:

§ 439.40 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by mixing, compounding and formulating operations.

32. Section 439.41 is revised to read as follows:

§ 439.41 Specialized definitions.

For the purpose of this subpart:

(a) The term *mixing, compounding, and formulating operations* means processes that put pharmaceutical products in dosage forms.

(b) The term *product* means any pharmaceutical product manufactured by blending, mixing, compounding, and formulating pharmaceutical ingredients. The term includes pharmaceutical preparations for both human and veterinary use, such as ampules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions.

33. Section 439.42 is amended by removing the OMB control number and revising the section to read as follows:

§ 439.42 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The average monthly effluent limitation for BOD_5, expressed as mass loading (pounds, kilograms) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD_5 load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

(1) The long-term average daily BOD_5 load of the raw process wastewater (i.e., the base number to which the percent reduction is applied) is defined as the average daily BOD_5 load during any calendar month, over 12 consecutive months within the most recent 36 months, and must include one or more periods during which production was at a maximum.

(2) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or separate disposal or reuse. Residual amounts of these substances may be included in the calculation of the average influent BOD_5 loading.

(3) The practices of recovery, and/or separate disposal or reuse include: physical separation and removal of separable mycelia; recovery of solvents from wastestreams; incineration of

concentrated solvent wastestreams (including tar still bottoms); and broth concentration for disposal other than to the treatment system. This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 may be achieved by any of several, or a combination, of these practices.

(b) The average monthly effluent limitation for TSS, expressed as mass loading (pounds, kilograms) per day, must be calculated as 1.7 times the BOD_5 limitation determined in paragraph (a) of this section.

(c) Except as provided in paragraph (d) of this section, effluent limitations for COD and pH are as follows:

Regulated parameter	Effluent limitations[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
COD	228	86
pH	(2)	(2)

[1] Mg/L (ppm).
[2] Within the range 6.0 to 9.0.

(d) If the average monthly COD concentrations in paragraph (c) of this section are higher than concentration values reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then the average monthly effluent limitations for COD corresponding to the lower concentration values must be applied.

34. Section 439.43 is revised to read as follows:

§ 439.43 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD_5, TSS and pH are the same as the corresponding limitations in § 439.42.

35. Section 439.44 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.44 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

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 application of BAT. Limitations for COD are the same as the corresponding limitations in § 439.42 (c) and (d).

36. Section 439.45 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.45 Standards of performance for new (point) sources (NSPS).

(a) Any new source subject to this subpart must achieve the following performance standards:

Regulated parameter	Performance standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
BOD_5	35	18
TSS	58	31
COD	228	86
pH	(2)	(2)

[1] Mg/L (ppm).
[2] Within the range 6.0 to 9.0.

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the earlier version of this section 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 § 439.43 and 439.44.

37. Section 439.46 is amended by removing the OMB control number cite, and revising the section to read as follows:

§ 439.46 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must achieve the following pretreatment standards by September 21, 2001:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
1 Acetone	20.7	8.2
2 n-Amyl acetate	20.7	8.2
3 Ethyl acetate ..	20.7	8.2
4 Isopropyl acetate	20.7	8.2
5 Methylene chloride	3.0	0.7

[1] Mg/L (ppm).

38. Section 439.47 is amended by removing the OMB control number cite, and revising the section to read as follows:

§ 439.47 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart must achieve the following pretreatment standards:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
1 Acetone	20.7	8.2
2 n-Amyl acetate	20.7	8.2
3 Ethyl acetate ..	20.7	8.2
4 Isopropyl acetate	20.7	8.2
5 Methylene chloride	3.0	0.7

[1] Mg/L (ppm).

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the earlier version of this section, 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.

39. Section 439.50 is revised to read as follows:

§ 439.50 Applicability.

This subpart applies to discharges of process wastewater resulting from pharmaceutical research.

40. Section 439.51 is revised to read as follows:

§ 439.51 Specialized definitions.

For the purpose of this subpart, the term product means products or services resulting from research and product development activities.

41. Section 439.52 is revised to read as follows:

§ 439.52 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The average monthly effluent limitation for BOD_5, expressed as mass loading (pounds, kilograms) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD_5 load of the raw (untreated) process wastewater, multiplied by a

variability factor of 3.0. No facility shall be required to attain a limitation for BOD_5 that is less than the equivalent of 45 mg/L.

(b) The average monthly effluent limitation for COD, expressed as mass loading (pounds, kilograms) per day, must reflect not less than 74 percent reduction in the long-term average daily COD load of the raw (untreated) process wastewater, multiplied by a variability factor of 2.2. No facility shall be required to attain a limitation for COD that is less than the equivalent of 220 mg/L.

(c) The long-term average daily BOD_5 or COD mass loading of the raw process wastewater (i.e., the base number to which the percent reduction is applied) is defined as the average daily BOD_5 or COD load during any calendar month, over 12 consecutive months within the most recent 36 months.

(1) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 or COD load in the influent to the wastewater treatment system must exclude any portion of the load associated with solvents, except for residual amounts of solvents remaining after the practices of recovery and/or separate disposal or reuse. Residual amounts of these substances may be included in the calculation of the average influent BOD_5 or COD loading.

(2) The practices of recovery, and/or separate disposal or reuse include: recovery of solvents from wastestreams; and incineration of concentrated solvent wastestreams (including tar still bottoms). This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 or COD may be achieved by any of several, or a combination, of these practices.

(d) The average monthly effluent limitation for TSS, expressed as mass loading (pounds, kilograms) per day, must be calculated as 1.7 times the BOD_5 limitation determined in paragraph (a) of this section.

(e) The pH must be within the range 6.0 to 9.0.

§§ 439.33 through 439.57 [Removed]

41. Sections 439.53 through 439.57 are removed.

Appendix A to part 439 [Added]

42. Appendix A is added to part 439 to read as follows:

Appendix A to Part 439—Tables

TABLE 1.—SURROGATE PARAMETERS FOR DIRECT DISCHARGERS

[Utilizing biological treatment technology]

Regulated parameter	Treatability class
Amyl alcohol	Alcohols.
Ethanol	
Isopropanol	
Methanol	
Phenol	
Isobutyraldehyde	Aldehydes.
n-Heptane	Alkanes.
n-Hexane	
Diethylamine	Amines.
Triethylamine	
Benzene	Aromatics.
Toluene	
Xylenes	
Chlorobenzene	
o-Dichlorobenzene	
Chloroform	Chlorinated Alkanes.
Methylene chloride	
1,2-Dichloroethane	
Ethyl acetate	Esters.
Isopropyl acetate	
n-Amyl acetate	
n-Butyl acetate	
Methyl formate	
Tetrahydrofuran	Ethers.
Isopropyl ether	
Acetone	Ketones.
4-Methyl-2-pentanone (MIBK).	

TABLE 1.—SURROGATE PARAMETERS FOR DIRECT DISCHARGERS—Continued

[Utilizing biological treatment technology]

Regulated parameter	Treatability class
Ammonia (aqueous).	Miscellaneous.
Acetonitrile	
Methyl Cellosolve	
Dimethyl Sulfoxide	

Notes:

1. Parameters in bold may be used as a surrogate to represent other parameters in the same treatability class.
2. Surrogates have not been identified for the ''Miscellaneous'' treatability class.

TABLE 2.—SURROGATE PARAMETERS FOR INDIRECT DISCHARGERS

[Utilizing steam stripping treatment technology]

Regulated parameters	Treatability class
Benzene	High strippability.
Toluene	
Xylenes	
n-Heptane	
n-Hexane	
Chloroform	
Methylene chloride	
Chlorobenzene	
Methyl cellosolve	
Ammonia (aqueous).	Medium strippability.
Diethyl amine	
Triethyl amine	
Acetone 4-Methyl-2-pentanone (MIBK).	
n-Amyl acetate	
n-Butyl acetate	
Ethyl acetate	
Isopropyl acetate	
Methyl formate	
Isopropyl ether	
Tetrahydrofuran	
1,2-Dichloroethane	
o-Dichlorobenzene	

Notes:

1. Parameters in bold may be used as a surrogate to represent other parameters in the same treatability class.

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Federal Register

Monday
September 21, 1998

Part IV

Department of Transportation

Coast Guard

Mariner Licensing and Documentation; Notice

DEPARTMENT OF TRANSPORTATION

Coast Guard

[USCG–1998–4448]

Mariner Licensing and Documentation

AGENCY: Coast Guard, DOT.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Coast Guard's National Maritime Center is holding a public meeting to discuss the feasibility of and alternatives available for privatizing certain aspects of its Mariner Licensing and Documentation (MLD) program, specifically, examinations for mariner licenses and merchant mariner documents. In addition, the Coast Guard seeks written comments from any party who is unable to attend the meeting or who wishes to submit comments on this topic.

DATES: The meeting will be held on October 22 through 23, 1998, from 8:30 a.m. to 4:30 p.m. Comments must reach the Docket Management Facility on or before October 23, 1998.

ADDRESSES: The meeting will be held at the Best Western Hotel New Orleans East, 12340 Interstate 10 Service Road, New Orleans, LA 70128; hotel telephone (504) 241–5100. You may mail your comments to the Docket Management Facility [USCG–1998–4448], U.S. Department of Transportation (DOT), room PL–401, 400 Seventh Street, SW, Washington, DC 20590–0001, or deliver them to room PL–401 on the Plaza Level of the Nassif Building at the same address, between the hours of 10 a.m. and 5 p.m., Monday through Friday, except for Federal holidays. The telephone number is 202–366–9329.

The Docket Management Facility maintains the public docket for this notice. Comments, and documents as indicated in this notice, will become part of this docket and will be available for inspection or copying at room PL–401, on the Plaza Level of the Nassif Building at the same address, between 10 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also access this docket on the Internet at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: For questions on this notice, contact Mr. Albert G. Kirchner, Jr., National Maritime Center, U.S. Coast Guard, 4200 Wilson Boulevard, Suite 510, Arlington, VA 22203–1804, telephone 8703–235–1950, facsimile 703–235–0017, or electronic mail address akirchner@ballston.uscg.mil. For questions on viewing or submitting material to the docket contact Ms. Dorothy Walker, Chief, Dockets, Department of Transportation, telephone 202–366–9329.

SUPPLEMENTARY INFORMATION:

Requests for Comments

The Coast Guard encourages interested persons to respond to this request by submitting written data, views or arguments. Persons submitting comments should include their names and addresses, identify this notice [USCG–1998–4448] and the specific section of this document to which each comment or question applies, and give the reason for each comment. Please submit all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing to the Docket Management Facility at the address under **ADDRESSES**. Persons wanting acknowledgment of receipt of comments should enclose stamped, self-addressed postcards or envelopes. The Coast Guard will consider all comments received during the comment period.

Information on Service for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Mr. Albert G. Kirchner Jr at the address or phone number under **FOR FURTHER INFORMATION CONTACT** as soon as possible.

Background Information

The Coast Guard focus group report, ''Licensing 2000 and Beyond'' (November, 1993), recommended that the Coast Guard's Mariner Licensing and Documentation (MLD) program adopt new methods of verifying competency of mariners and that the Coast Guard consider Third Party and Fourth Party testing systems that maximize the significant benefits new technology offers. The focus group defined a ''Third Party'' as one who trains or teaches the mariner, and a ''Fourth Party'' as someone, other than the Coast Guard or a Third Party, who administers a test or makes an objective judgment about the competency of the mariner. A copy of this report is available for inspection in the Docket at the address listed under **ADDRESSES.**

In response to work of the focus group, a final rule (61 FR 47060) was published on September 6, 1996, that enabled the Coast Guard to implement recommendations for alternative testing and evaluation systems, and modernize examination methods. This meeting will address initiating Fourth Party services in the Coast Guard's MLD program.

Presently, 17 Regional Examination Centers (RECs), listed in Table 1, administer the Coast Guard's MLD program. The Coast Guard currently issues 72 different licenses and documents. Tables 2.0 and 2.1 depict the names of these licenses and documents, and also provide the numbers of original applications, renewals, endorsements, and duplicates processed for each.

BILLING CODE 4910–15–M

Table 1.0 Regional Examination Centers (RECs)

COMMANDING OFFICER (REC) USCG MARINE SAFETY OFFICE 510 L. STREET SUITE 100 ANCHORAGE, AK 99501-1946 (907) 271-6736	U.S. COAST GUARD REGIONAL EXAMINATION CENTER U.S. CUSTOM HOUSE 40 SOUTH GAY STREET BALTIMORE, MD 21202-4022 (410) 962-5132/33/34/35	COMMANDING OFFICER (REC) USCG MARINE SAFETY OFFICE 455 COMMERCIAL STREET BOSTON, MA 02109-1899 (617) 223-3040/41/42
COMMANDING OFFICER U.S. COAST GUARD MARINE SAFETY OFFICE (REC) 196 TRADD STREET CHARLESTON, SC 29401-1899 (803) 720-7693	COMMANDING OFFICER USCG MARINE SAFETY OFFICE 433 ALA MONA BOULEVARD HONOLULU, HI 96813 (808) 522-8264	U.S. COAST GUARD REGIONAL EXAMINATION CENTER 8876 GULF FREEWAY SUITE 200 HOUSTON, TX 77017-6595 (713) 947-0044/45
U.S. COAST GUARD REGIONAL EXAMINATION CENTER 2760 SHERWOOD LANE SUITE 2A JUNEAU, AK 99801-8545 (907) 463-2458	U.S. COAST GUARD MARINE SAFETY OFFICE REGIONAL EXAMINATION CENTER 165 NORTH PICO AVENUE LONG BEACH, CA 90802 (310) 980-4485	U.S. COAST GUARD MARINE SAFETY OFFICE REGIONAL EXAMINATION CENTER 200 JEFFERSON AVENUE SUITE 1302 MEMPHIS, TN 38103 (901) 544-3297
COMMANDING OFFICER USCG MARINE SAFETY OFFICE REGIONAL EXAMINATION CENTER CLAUDE PEPPER FEDERAL BUILDING 51 SW 1ST AVENUE 6TH FLOOR MIAMI, FL 33103-1608 (305) 536-6548/49/6874/4484	COMMANDING OFFICER USCG MARINE SAFETY OFFICE (REC) 1615 POYDRAS STREET NEW ORLEANS, LA 70112 (504) 589-6183/84/85	U.S. COAST GUARD ACTIVITIES NEW YORK (REC) BATTERY PARK BUILDING NEW YORK, NY 10004-8545 (212) 668-7492
U.S. COAST GUARD MARINE SAFETY OFFICE (REC) 6767 NORTH BASIN AVENUE PORTLAND, OR 97217-3992 (503) 240-9346	U.S. COAST GUARD MARINE SAFETY OFFICE REGIONAL EXAMINATION CENTER 1519 ALASKAN WAY SOUTH SEATTLE, WA 98134-1192 (206) 217-6115	U.S. COAST GUARD MARINE SAFETY OFFICE REGIONAL EXAMINATION CENTER 1222 SPRUCE STREET SUITE 8104E ST. LOUIS, MO 63103-2835 (314) 539-2657
U.S. COAST GUARD REGIONAL EXAMINATION CENTER FEDERAL BUILDING ROOM 501 234 SUMMIT STREET TOLEDO, OH 43604-1590 (419) 259-6395	MARINE SAFETY OFFICE SAN FRANCISCO BAY BUILDING 14 COAST GUARD ISLAND ALAMEDA, CA 94501-5100 (510) 437-3093	

Table 2.0 License Statistics for Deck Department

LICENSE STATISTICS

FROM 01/01/95 TO 12/31/95

DECK DEPARTMENT

		DESCRIPTION	ORIGINAL	ENDORSEMENTS	FAILURES	RENEWALS	DUPLICATE	Suspension & Revocation
UPPER LEVEL LICENSES		Master Ocean Any	114	79	2	764	16	0
		Master Near Coastal Any	100	28	0	375	13	0
		Chief Mate Ocean Any	111	33	7	207	8	0
		Chief Mate Near Coastal Any	1	0	0	3	0	0
		Second Mate Ocean Any	109	20	2	188	8	0
		Second Mate Near Coastal Any	0	3	0	4	1	0
		Third Mate Ocean Any	351	29	20	441	14	0
		Third Mate Near Coastal Any	9	1	1	6	0	0
LOWER LEVEL LICENSES		Master Ocean Not More Than 1.6 K GT	252	144	5	666	31	2
		Master Near Coastal Not More Than 1.6 K GT	118	97	17	423	20	3
		Mate Ocean Not More Than 1.6 K GT	18	17	2	59	4	2
		Mate Near Coastal Not More Than 1.6 K GT	126	31	15	136	14	5
		Master Ocean Not More Than 500 GT	19	24	2	122	7	2
		Master Near Coastal Not More Than 500 GT	53	59	4	342	14	10
		Mate Ocean Not More Than 500 GT	1	4	0	15	2	0
		Mate Near Coastal Not More Than 500 GT	11	8	0	60	1	2
	*	Mate Inland Not More Than 100 GT	17	0	1	3	0	0
	*	Mate Inland Not More Than 200 GT	21	3	0	13	2	0
		Master Ocean Not More Than 200 GT	3	9	0	46	5	0
	*	Master Near Coastal Not More Than 200 GT	62	75	9	321	8	6
	*	Mate Near Coastal Not More Than 200 GT	162	25	7	85	9	1
	*	Master Near Coastal Not More Than 100 GT	1863	334	105	4830	152	30
	*	Master Uninspected Fishing Industry Vessel	36	22	2	154	4	1
	*	Mate Uninspected Fishing Industry Vessel	30	11	0	37	7	0
		Master MODU	1	0	0	3	0	0
		Mate MODU	0	0	0	0	0	0
		Master Great Lakes and In Any	7	9	0	43	0	0
		Master Inland Any	37	14	2	192	4	0
		Mate Great Lakes and In. Any	17	7	1	63	1	0
		Master Great Lakes and In. Not More Than 1.6 K GT	2	4	2	6	0	0
		Mate Great Lakes and In. Not More Than 1.6 K GT	2	2	0	2	0	0
	*	Master Great Lakes and In. Not More Than 200 GT	0	10	0	8	0	0
		Mate Great Lakes and In. Not More Than 200 GT	9	1	0	4	0	0
		Offshore Installation Manager	75	3	0	35	1	0
		Barge Supervisor	15	4	0	140	6	0
		Ballast Control Operator	23	3	2	6	0	0
	*	Master Inland Not More Than 100 GT	1211	97	74	1562	60	4
	*	Master Inland Not More Than 200 GT	14	23	7	36	1	1
		Master Great Lakes and Inland	411	67	8	555	6	0
		First Class Pilot	99	307	4	964	24	1
		Operator Uninspected Towing Vessel	317	105	34	1837	61	34
		2ND-Class Operator Uninspected Towing Vessel	34	6	4	61	4	0
	*	Operator Uninspected Passenger Vessel	1893	74	247	2515	59	0
	*	Assistant Towing Endorsement	1835	145	64	764	50	0
		Total	9589	1937	650	18096	617	104

* Indicates existence of Coast Guard approved courses in lieu of Coast Guard examination

Table 2.1 License Statistics for Engine Department, Radio Officer and Certificates of Registry, and Summary of License Transactions

LICENSE STATISTICS

FROM 01/01/95 TO 12/31/95

ENGINE DEPARTMENT

	DESCRIPTION	ORIGINAL	ENDORSEMENTS	FAILURES	RENEWALS	DUPLICATE	Suspension & Revocation
UPPER LEVEL LICENSES	Chief Engineer Motor	202	48	9	742	17	3
	1ST Asst. Eng. Motor	85	13	6	88	2	0
	2ND Asst. Eng. Motor	65	13	5	120	5	0
	3RD Asst. Eng. Motor	100	10	5	283	5	0
	Chief Engineer Steam	45	6	3	175	1	0
	1ST Asst. Eng. Steam	45	2	2	130	2	0
	2ND Asst. Eng. Steam	66	6	3	149	1	0
	3RD Asst. Eng. Steam	79	2	3	172	4	0
	Chief Engineer Steam or Motor	83	17	6	415	11	1
	1ST Asst. Eng. Steam or Motor	61	3	3	91	7	1
	2ND Asst. Eng. Steam or Motor	54	5	0	95	2	0
	3RD Asst. Eng. Steam or Motor	382	15	7	446	10	3
LOWER LEVEL LICENSES	Chief Engineer Ocean	129	39	6	534	15	2
	Chief Engineer Near Coastal	59	5	3	74	2	1
	Assistant Engineer	100	14	13	111	5	0
	Designated Duty Eng.	216	66	34	150	8	2
	Chief Engineer Uninspected Fishing Industry Vessel	30	8	1	134	8	0
	Assistant Engineer UnisnpectedFishing Ind. Vessel	14	2	1	17	0	0
	Chief Engineer MODU	4	0	0	13	0	0
	Assistant Engineer MODU	1	0	0	8	0	0
	Total	1820	274	110	3947	105	13

RADIO OFFICER AND CERTIFICATES OF REGISTRY

DESCRIPTION	ORIGINAL	ENDORSEMENTS	FAILURES	RENEWALS	DUPLICATE	Suspension & Revocation
Radio Officer	27	1	0	154	4	0
Chief Purser	22	0	0	16	0	0
Purser	7	0	0	2	0	0
Sr. Asst. Purser	2	0	0	2	0	0
Jr. Asst. Purser	10	0	0	4	0	0
Medical Doctor	22	0	0	1	1	0
Professional Nurse	9	0	0	2	0	0
Surgeon	3	0	0	4	1	0
Total	102	1	0	185	6	0

SUMMARY LICENSE TRANSACTIONS

DESCRIPTION	ORIGINAL	ENDORSEMENTS	FAILURES	RENEWALS	DUPLICATE	Suspension & Revocation
Deck Department	9589	1937	650	18096	617	104
Engine Department	1820	274	110	3947	105	13
Radio and Staff Officers	102	1	0	185	6	0
Total	11511	2212	760	22228	728	117

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For MLD transactions, the RECs may provide up to three distinct services to the mariner: (1) evaluation of qualifications of the applicant; (2) conduct of examination(s) related to the license or document; and (3) issuance of the license or document to the mariner who meets all requirements. The Coast Guard is currently interested in privatizing only the examination portion of these services.

The current fees for these services are published in 46 CFR Parts 10 and 12. The Coast Guard bases its fees for a particular service on the latest calculations of the costs involved in providing that service, without overcharging. Not all license and document processes involve examinations; most licenses and documents require an evaluation of qualifications transaction, and all require an issuance transaction. When examining 46 CFR Parts 10 and 12, the indication of an examination fee for a particular license or document means that an examination is given.

Recently, the Coast Guard implemented a program in which mariners may take a Coast Guard-approved course at a privately operated training school and the Coast Guard will accept satisfactory completion of that course in lieu of a Coast Guard examination. Thus, in some cases, the mariner may present the REC with a certificate of completion for a Coast Guard-approved course taken in lieu of a Coast Guard examination, and not be required to pay for and take the Coast Guard examination at the REC. Licenses for which Coast Guard-approved courses in lieu of Coast Guard examinations exist are marked with an asterisk in Table 2.0. Additional courses in those license categories and courses for additional license categories may be approved in the future. No data is available to indicate how many mariners are using this Coast Guard-approved training in lieu of Coast Guard examination alternative.

When the Coast Guard conducts an examination for a particular license or document, that examination is made up of various modules, some of which may also be used in more than one of the licensing or documentation examinations. A Coast Guard test question data bank randomly generates questions for each module. The number of modules in any particular license or document examination and the time the full examination takes, varies. Generally, the larger the vessel the mariner is being licensed to operate and the fewer the operating restrictions on the license, the longer and more exhaustive the examination is. Some examinations involve only a few modules and take as little as 4 hours to complete while others can involve up to 19 modules and take five days to complete.

Discussion

The Coast Guard seeks information that may be useful when it considers the feasibility of and alternatives in privatizing examinations in its Mariner Licensing and Documentation (MLD) program.

The Coast Guard needs feedback on the following issues

1. Feasibility of a Privatized Examination System

Before the Coast Guard can determine the desirability of a privatized examination system, we need to learn about its feasibility and know that it is advantageous for both the Coast Guard and the mariner. As part of this process, the Coast Guard will provide an overview to the commercial learning and examination industry of its present mariner licensing and documentation program, including the Coast Guard's reduced reliance on REC administered examinations and the potential impact this would have on the business decision to enter the market. After the overview is presented, small group visits to nearby REC New Orleans will be conducted to permit first hand observation of Coast Guard examinations being administered to actual customers from the marine profession. We expect the overview presentation and the on-site visit to provide the core information necessary for commercial suppliers to determine whether the administration of MLD examinations is a potentially attractive business opportunity. Included in this assessment would be the views from industry on the levels of automation that would be desirable for such a system, and the ability of commercial providers to provide quality services to the mariner that are affordable, yet profitable.

2. The Effect of Such a System on the Quality of Services, and the Costs of These Licenses and Documents to the Mariner

If the administration of MLD licensing and documentation examinations is an attractive business opportunity to certain segments of the commercial training and examination industry, we would like their views on how better, more responsive examination services could be delivered and what the cost estimates for the various services would be. As part of these cost estimates, the Coast Guard is interested in how costs are determined, the three factors having the greatest effect on cost, and the ''break even'' points associated with these cost estimates.

3. Maintaining the Integrity of the Licensing and Documentation System to Ensure That Those Who are Licensed and Documented are Fully Competent and do not Jeopardize Marine Safety or Environmental Protection

Among the concerns in privatization of our MLD examinations are the potential for compromise of the present integrity of the system, and the need for the highest level of protection of the private information about individual mariners. We would like to learn more about the capabilities of commercial providers in these areas and how they address similar concerns with their current clientele.

4. Determining the Timing and Sequence To Implement Privatized MLD Examinations

The core activities of a MLD examination privatization would be largely confined to the conduct of the actual licensing and documentation examinations. We would like to engage in dialogue with commercial training and examination service providers to learn how they could implement a privatized examination process, how long the process would take, what staff training would be required, what site preparations would be necessary, and how they would interface with the Coast Guard's random test generation capability.

5. The Range of Options and Arrangements Open for Providing Privatized Mariner Licensing and Documentation Examination Administration Services

We think there are a number of ways MLD privatized examination services could be structured. These could range from awarding a no-cost contract to a single, nation-wide provider to opening this opportunity to an unlimited number of ''qualified'' service providers. Another possibility is that the current Regional Examination Centers could be run as Government-owned, Contractor operated (GO–CO) facilities or, converted entirely, to Contractor-owned, Contractor operated (CO–CO) facilities. Another possibility for privatization is to encourage the expansion of the current Coast Guard program for training courses in lieu of examinations until requirements for every Coast Guard license and document can be verified through this means. We believe there are certain advantages, disadvantages, and vulnerabilities

associated with each of the many possible options across this range. For example, there is concern that a service provider could go out of business after the Coast Guard and mariners have come to depend on its service. We would like to gauge commercial interest prior to developing a design for privatized MLD examination services. Once we understand the advantages and disadvantages various options pose to commercial providers, the Coast Guard, and the mariner, we will work towards an optimal system design for a potential pilot test and evaluation. This evaluation may occur as early as 1999.

6. Identification of the Coast Guard Resources Needed To Effectively Operate and Conduct Oversight of a Privatized System

To decide if a privatized examination system has value, the costs must be weighed against the benefits. Privatized examination administration will shift many of the current Coast Guard costs of MLD to the service provider(s) and reconfigure those costs that remain with the Coast Guard. Because of the sensitivities of system integrity, security, and safeguarding of private information, one of the Coast Guard costs will be to maintain an active and effective oversight mechanism, no matter what form a privatized MLD examination administration system takes. We need to know more about how the commercial examination industry handles these matters in order to determine the resources that might be required of the Coast Guard to properly conduct oversight of a privatized examination administration system.

7. Experience of Other Agencies, Professional Organizations, and Service Providers in Privatizing Licensing and Similar Functions in Other Professions or Industries

We would like to learn more from others who have undergone privatization of a critical professional examination system or from those who have helped others successfully put these types of systems in place.

8. Other Valuable Lessons Learned To Assist the Coast Guard in Determining If Privatizing Merchant Mariner Licensing and Documentation Examination Administration Can Be Accomplished in a Smooth, Effective and Cost Efficient Manner

Finally, we would like to have help from anyone who is willing to share ''lessons learned'' in making the decision to privatize, or not to privatize, a professional qualifications or competency system similar to MLD licensing and document examinations. This can be in such areas as making cost calculations and comparisons, writing performance specifications, developing audit and oversight systems, deciding on quality control techniques and performance metrics, or any other insights that would help the Coast Guard in its decision on whether or not to privatize MLD examinations.

Public Meeting

The meeting will be held in the form of an informal workshop open to the public. It is intended to bring together people knowledgeable about the issues addressed in this notice to assist the Coast Guard in assessing the feasibility and best course of action in the privatization of merchant mariner licensing and documentation examination administration.

The proposed agenda is as follows:

October 22, 1998

8:30 a.m	Call to Order, Review of Agenda & Introductions	Captain M.M. Rosecrans, Commanding Officer, National Maritime Center.
8:45 a.m	''Licensing 2000 and Beyond''	Captain M.M. Rosecrans, Commanding Officer, National Maritime Center.
9:00 a.m	Overview of MLD Processes & Business Dimensions	Mr. S. A. Walker, Chief, Mariner licensing & Evaluations Branch.
9:30 a.m	Move to Regional Examination Center, New Orleans	Private Transportation.
10:00 a.m	Visits begin to Regional Examination Center, New Orleans	Coast Guard Staff.
1:00 p.m	Lunch Break	
2:00 p.m	Visits resume at Regional Examination Center, New Orleans ...	Coast Guard Staff.
3:30 p.m.	Move to Conference Site	Private Transportation.
4:00 p.m	General Questions and Summary of Day's Observations	Facilitator.
4:30 p.m	Adjournment	Captain M.M. Rosecrans.

October 23, 1998

8:30 a.m	Call to Order & Review of Agenda	Facilitator.
9:00 a.m	Issue 1: Feasibility of MLD Privatization	Facilitator.
9:45 a.m.	Issue 2: Service Possibilities and Cost Implications to the Mariner.	Facilitator.
10:30 a.m	Issue 3: System Integrity and Privacy of Records	Facilitator.
11:15 a.m.	Issue 4: Elements and Sequencing Considerations of MLD Privatization.	Facilitator.
12 noon	Lunch	
1:00 p.m.	Issue 5: Options and Arrangements Facilitator for Privatized Service Delivery.	Facilitator.
1:45 p.m	Issue 6: Resource Requirements and Professional Organizations.	Facilitator.
2:30 p.m	Break	
2:45 p.m	Issue 7: Experience of Other Agencies	Facilitator.
3:30 p.m	Issue 8: Valuable Lessons of Others	Facilitator.
4:15 p.m	Summary and Wrap Up	Facilitator.
4:30 p.m	Adjournment	Captain M.M. Rosecrans.

Dated: September 11, 1998.

Joseph J. Angelo,

Director of Standards, Marine Safety and Environmental Protection.

[FR Doc. 98–25163 Filed 9–18–98; 8:45 am]

BILLING CODE 4910–15–M

Monday
September 21, 1998

Part V

The President

Proclamation 7123—Citizenship Day and Constitution Week, 1998

Federal Register
Vol. 63, No. 182
Monday, September 21, 1998

Presidential Documents

Title 3—

The President

Proclamation 7123 of September 16, 1998

Citizenship Day and Constitution Week, 1998

By the President of the United States of America

A Proclamation

Two hundred eleven years ago, on September 17, 1787, our Nation's Founders signed the Constitution that established our system of government. This extraordinary document, the product of passionate debate and grudging compromise, was crafted by a handful of individuals in the late 18th century; yet it has safely charted America's course through more than two centuries of enormous change and growth and has served as the model for democratic governments around the globe.

The United States Constitution has endured in large part because of its remarkable fairness and flexibility. It created an inspired balance of powers and responsibilities among the executive, legislative, and judicial branches of government and among the Federal Government, the States, and individual citizens. It also provided for a system of amendment that allows our democracy to correct past errors and omissions and to respond to new challenges. As we mark this anniversary of the signing of the Constitution, we celebrate the effort, the dedication, and the wisdom of our Founders and the blessings of liberty that resulted from their labors.

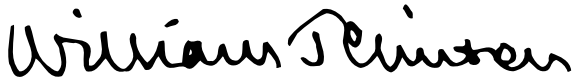
We also celebrate those who have struggled to move America closer to fulfilling the first and fundamental purpose expressed in the Constitution: ''. . . to form a more perfect Union.'' Among these heroes were the thousands who fought and died during the Civil War to keep our Nation united and to banish slavery from our land. The 13th Amendment to the Constitution is the fruit of their sacrifice: ''Neither slavery nor involuntary servitude . . . shall exist within the United States.'' The courageous women and men who met at Seneca Falls, New York, 150 years ago also set the highest standards of citizenship. Recognizing that women, too, are entitled to share in America's promise of equality, they began a crusade that resulted in the ratification of the 19th Amendment, guaranteeing women the right to vote. Likewise, we honor American citizens of our century, black and white, who worked together, faced danger together, and sometimes died together in the struggle to end racial injustice in our society and move our Nation closer to the constitutional ideal of equality under the law. The 24th Amendment, guaranteeing all citizens the right to vote, reflects their spirit and commitment to true democracy.

As we seek to form a more perfect union at home, we also bear the responsibilities of citizenship in our world community. Throughout our history, we have sought to secure the blessings of liberty not only for ourselves, but for all people everywhere. We remember the Americans who fought two world wars against tyranny and oppression and who triumphed in the Cold War through faith in the promise of democracy. These men and women cared so intensely about our Nation and their fellow human beings that they were willing to forego their own comfort and sometimes even to sacrifice their own lives for the ideal of freedom envisioned by our Founders.

In commemoration of the signing of the Constitution and in recognition of the importance of active, responsible citizenship in preserving the Constitution's blessings for our Nation, the Congress, by joint resolution of February 29, 1952 (36 U.S.C. 153), designated September 17 as ''Citizenship Day,'' and by joint resolution of August 2, 1956 (36 U.S.C. 159), requested that the President proclaim the week beginning September 17 and ending September 23 of each year as ''Constitution Week.''

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim September 17, 1998, as Citizenship Day and September 17 through September 23, 1998, as Constitution Week. I call upon Federal, State, and local officials, as well as leaders of civic, educational, and religious organizations, to conduct meaningful ceremonies and programs in our schools, houses of worship, and other community centers to foster a greater understanding and appreciation of the Constitution and the rights and duties of citizenship.

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



[FR Doc. 98–25287
Filed 9–18–98; 8:45 am]
Billing code 3195–01–P

Monday
September 21, 1998

Part VI

The President

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Presidential Documents

Title 3—

The President

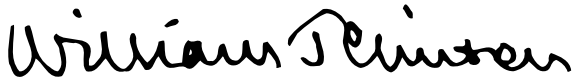
Presidential Determination No. 98–34 of September 9, 1998

Determination Pursuant to Section 2(c)(1) of the Migration and Refugee Assistance Act of 1962, as Amended

Memorandum for the Secretary of State

Pursuant to section 2(c)(1) of the Migration and Refugee Assistance Act of 1962, as amended, 22 U.S.C. 2601(c)(1), I hereby determine that it is important to the national interest that up to $20,000,000 be made available from the U.S. Emergency Refugee and Migration Assistance Fund to meet the urgent and unexpected needs of refugees, displaced persons, conflict victims, and other persons at risk due to the Kosovo crisis. These funds may be used, as appropriate, to provide contributions to international and nongovernmental organizations.

You are authorized and directed to inform the appropriate committees of the Congress of this determination and the obligation of funds under this authority and to publish it in the **Federal Register**.



THE WHITE HOUSE,
Washington, September 9, 1998.

[FR Doc. 98–25345
Filed 9–18–98; 8:45 am]
Billing code 4710–10–M

Presidential Documents

Presidential Determination No. 98–35 of September 11, 1998

Extension of the Exercise of Certain Authorities Under the Trading With the Enemy Act

Memorandum for the Secretary of State [and] the Secretary of the Treasury

Under section 101(b) of Public Law 95–223 (91 Stat. 1625; 50 U.S.C. App. 5(b) note), and a previous determination made by me on September 12, 1997 (62 *Fed. Reg.* 49729), the exercise of certain authorities under the Trading With the Enemy Act is scheduled to terminate on September 14, 1998.

I hereby determine that the extension for 1 year of the exercise of those authorities with respect to the applicable countries is in the national interest of the United States.

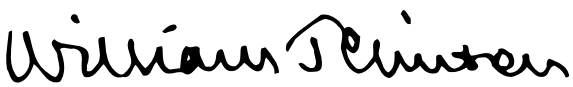
Therefore, pursuant to the authority vested in me by section 101(b) of Public Law 95–223, I extend for 1 year, until September 14, 1999, the exercise of those authorities with respect to countries affected by:

(1) the Foreign Assets Control Regulations, 31 CFR Part 500;

(2) the Transaction Control Regulations, 31 CFR Part 505; and

(3) the Cuban Assets Control Regulations, 31 CFR Part 515.

The Secretary of the Treasury is authorized and directed to publish this determination in the **Federal Register**.



THE WHITE HOUSE,
Washington, September 11, 1998.

[FR Doc. 98–25343
Filed 9–18–98; 8:45 am]
Billing code 4810–31–M

Monday
September 21, 1998

Part VII

The President

Proclamation 7124—National POW/MIA Recognition Day, 1998

Federal Register
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Monday, September 21, 1998

Presidential Documents

Title 3—

The President

Proclamation 7124 of September 17, 1998

National POW/MIA Recognition Day, 1998

By the President of the United States of America

A Proclamation

For more than two centuries, America has been blessed by the service and sacrifice of the men and women of our Armed Forces. Often leaving home and family, they have fought to preserve our freedom, protect our national interests, and advance American values and ideals around the globe. These valiant heroes have risked—and many have lost—their lives in service to our Nation and for the well-being of their fellow Americans.

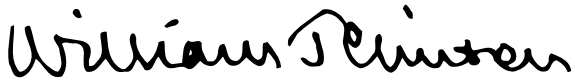
Each year, on National POW/MIA Recognition Day, we acknowledge with special gratitude and profound respect those who paid for our freedom with their own, and we remember with deep sorrow those whose fate has never been resolved. Americans who were held as prisoners of war throughout our history endured the indignities and brutality of captivity without surrendering their devotion to duty, honor, and country. With steadfast hearts and indomitable spirit, these patriots never gave up on America because they knew that America, and the American people, would never give up on them.

In the same way, we will never give up on our efforts to obtain the fullest possible accounting of every American missing in service to our country. We reaffirm our pledge to their families to search unceasingly for information about those missing and to seek the repatriation of those who have died and whose remains have not been recovered. By doing so we keep faith with our men and women in the Armed Forces and with the families who have suffered the anguish of not knowing the fate of their loved ones.

On September 18, 1998, the flag of the National League of Families of American Prisoners of War and Missing in Southeast Asia, a black and white banner symbolizing America's missing and our fierce determination to account for them, will be flown over the White House, the U.S. Capitol, the Departments of State, Defense, and Veterans Affairs, the Selective Service System Headquarters, the Vietnam Veterans Memorial, the Korean War Veterans Memorial, national cemeteries, and other locations across our country.

NOW, THEREFORE, I, WILLIAM J. CLINTON, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim September 18, 1998, as National POW/MIA Recognition Day. I ask all Americans to join me in honoring former American prisoners of war and those whose fate is still undetermined. I also encourage the American people to remember with compassion and concern the courageous families who persevere in their quest to know the fate of their missing loved ones.

IN WITNESS WHEREOF, I have hereunto set my hand this seventeenth day of September, in the year of our Lord nineteen hundred and ninety-eight, and of the Independence of the United States of America the two hundred and twenty-third.



[FR Doc. 98–25399
Filed 9–18–98; 10:58 am]
Billing code 3195–01–P

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CFR CHECKLIST

This checklist, prepared by the Office of the Federal Register, is published weekly. It is arranged in the order of CFR titles, stock numbers, prices, and revision dates.

An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

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Title	Stock Number	Price	Revision Date
1, 2 (2 Reserved)	(869–034–00001–1)	5.00	[5] Jan. 1, 1998
3 (1997 Compilation and Parts 100 and 101)	(869–034–00002–9)	19.00	[1] Jan. 1, 1998
4	(869–034–00003–7)	7.00	[5] Jan. 1, 1998
5 Parts:			
1–699	(869–034–00004–5)	35.00	Jan. 1, 1998
700–1199	(869–034–00005–3)	26.00	Jan. 1, 1998
1200–End, 6 (6 Reserved)	(869–034–00006–1)	39.00	Jan. 1, 1998
7 Parts:			
1–26	(869–034–00007–0)	24.00	Jan. 1, 1998
27–52	(869–034–00008–8)	30.00	Jan. 1, 1998
53–209	(869–034–00009–6)	20.00	Jan. 1, 1998
210–299	(869–034–00010–0)	44.00	Jan. 1, 1998
300–399	(869–034–00011–8)	24.00	Jan. 1, 1998
400–699	(869–034–00012–6)	33.00	Jan. 1, 1998
700–899	(869–034–00013–4)	30.00	Jan. 1, 1998
900–999	(869–034–00014–2)	39.00	Jan. 1, 1998
1000–1199	(869–034–00015–1)	44.00	Jan. 1, 1998
1200–1599	(869–034–00016–9)	34.00	Jan. 1, 1998
1600–1899	(869–034–00017–7)	58.00	Jan. 1, 1998
1900–1939	(869–034–00018–5)	18.00	Jan. 1, 1998
1940–1949	(869–034–00019–3)	33.00	Jan. 1, 1998
1950–1999	(869–034–00020–7)	40.00	Jan. 1, 1998
2000–End	(869–034–00021–5)	24.00	Jan. 1, 1998
8	(869–034–00022–3)	33.00	Jan. 1, 1998
9 Parts:			
1–199	(869–034–00023–1)	40.00	Jan. 1, 1998
200–End	(869–034–00024–0)	33.00	Jan. 1, 1998
10 Parts:			
0–50	(869–034–00025–8)	39.00	Jan. 1, 1998
51–199	(869–034–00026–6)	32.00	Jan. 1, 1998
200–499	(869–034–00027–4)	31.00	Jan. 1, 1998
500–End	(869–034–00028–2)	43.00	Jan. 1, 1998
11	(869–034–00029–1)	19.00	Jan. 1, 1998
12 Parts:			
1–199	(869–034–00030–4)	17.00	Jan. 1, 1998
200–219	(869–034–00031–2)	21.00	Jan. 1, 1998
220–299	(869–034–00032–1)	39.00	Jan. 1, 1998
300–499	(869–034–00033–9)	23.00	Jan. 1, 1998
500–599	(869–034–00034–7)	24.00	Jan. 1, 1998
600–End	(869–034–00035–5)	44.00	Jan. 1, 1998
13	(869–034–00036–3)	23.00	Jan. 1, 1998
14 Parts:			
1–59	(869–034–00037–1)	47.00	Jan. 1, 1998
60–139	(869–034–00038–0)	40.00	Jan. 1, 1998
140–199	(869–034–00039–8)	16.00	Jan. 1, 1998
200–1199	(869–034–00040–1)	29.00	Jan. 1, 1998
1200–End	(869–034–00041–0)	23.00	Jan. 1, 1998
15 Parts:			
0–299	(869–034–00042–8)	22.00	Jan. 1, 1998
300–799	(869–034–00043–6)	33.00	Jan. 1, 1998
800–End	(869–034–00044–4)	23.00	Jan. 1, 1998
16 Parts:			
0–999	(869–034–00045–2)	30.00	Jan. 1, 1998
1000–End	(869–034–00046–1)	33.00	Jan. 1, 1998
17 Parts:			
1–199	(869–034–00048–7)	27.00	Apr. 1, 1998
200–239	(869–034–00049–5)	32.00	Apr. 1, 1998
240–End	(869–034–00050–9)	40.00	Apr. 1, 1998
18 Parts:			
1–399	(869–034–00051–7)	45.00	Apr. 1, 1998
400–End	(869–034–00052–5)	13.00	Apr. 1, 1998
19 Parts:			
1–140	(869–034–00053–3)	34.00	Apr. 1, 1998
141–199	(869–034–00054–1)	33.00	Apr. 1, 1998
200–End	(869–034–00055–0)	15.00	Apr. 1, 1998
20 Parts:			
*1–399	(869–034–00056–8)	29.00	Apr. 1, 1998
400–499	(869–034–00057–6)	28.00	Apr. 1, 1998
500–End	(869–034–00058–4)	44.00	Apr. 1, 1998
21 Parts:			
1–99	(869–034–00059–2)	21.00	Apr. 1, 1998
100–169	(869–034–00060–6)	27.00	Apr. 1, 1998
170–199	(869–034–00061–4)	28.00	Apr. 1, 1998
200–299	(869–034–00062–2)	9.00	Apr. 1, 1998
300–499	(869–034–00063–1)	50.00	Apr. 1, 1998
500–599	(869–034–00064–9)	28.00	Apr. 1, 1998
600–799	(869–034–00065–7)	9.00	Apr. 1, 1998
800–1299	(869–034–00066–5)	32.00	Apr. 1, 1998
1300–End	(869–034–00067–3)	12.00	Apr. 1, 1998
22 Parts:			
1–299	(869–034–00068–1)	41.00	Apr. 1, 1998
300–End	(869–034–00069–0)	31.00	Apr. 1, 1998
23	(869–034–00070–3)	25.00	Apr. 1, 1998
24 Parts:			
0–199	(869–034–00071–1)	32.00	Apr. 1, 1998
200–499	(869–034–00072–0)	28.00	Apr. 1, 1998
500–699	(869–034–00073–8)	17.00	Apr. 1, 1998
700–1699	(869–034–00074–6)	45.00	Apr. 1, 1998
1700–End	(869–034–00075–4)	17.00	Apr. 1, 1998
25	(869–034–00076–2)	42.00	Apr. 1, 1998
26 Parts:			
§§ 1.0-1–1.60	(869–034–00077–1)	26.00	Apr. 1, 1998
§§ 1.61–1.169	(869–034–00078–9)	48.00	Apr. 1, 1998
§§ 1.170–1.300	(869–034–00079–7)	31.00	Apr. 1, 1998
§§ 1.301–1.400	(869–034–00080–1)	23.00	Apr. 1, 1998
§§ 1.401–1.440	(869–034–00081–9)	39.00	Apr. 1, 1998
§§ 1.441-1.500	(869-034-00082-7)	29.00	Apr. 1, 1998
§§ 1.501–1.640	(869–034–00083–5)	27.00	Apr. 1, 1998
§§ 1.641–1.850	(869–034–00084–3)	32.00	Apr. 1, 1998
§§ 1.851–1.907	(869–034–00085–1)	36.00	Apr. 1, 1998
§§ 1.908–1.1000	(869–034–00086–0)	35.00	Apr. 1, 1998
§§ 1.1001–1.1400	(869–034–00087–8)	38.00	Apr. 1, 1998
*§§ 1.1401–End	(869–034–00088–6)	51.00	Apr. 1, 1998
2–29	(869–034–00089–4)	36.00	Apr. 1, 1998
30–39	(869–034–00090–8)	25.00	Apr. 1, 1998
40–49	(869–034–00091–6)	16.00	Apr. 1, 1998
50–299	(869–034–00092–4)	19.00	Apr. 1, 1998
300–499	(869–034–00093–2)	34.00	Apr. 1, 1998
500–599	(869–034–00094–1)	10.00	Apr. 1, 1998
600–End	(869–034–00095–9)	9.00	Apr. 1, 1998
27 Parts:			
*1–199	(869–034–00096–7)	49.00	Apr. 1, 1998

Title	Stock Number	Price	Revision Date
200–End	(869–034–00097–5)	17.00	[6] Apr. 1, 1997
28 Parts:			
0-42	(869–034–00098–3)	36.00	July 1, 1998
43-end	(869-032-00099-9)	30.00	July 1, 1997
29 Parts:			
0–99	(869–034–00100–9)	26.00	July 1, 1998
100–499	(869–034–00101–7)	12.00	July 1, 1998
500–899	(869–034–00102–5)	40.00	July 1, 1998
900–1899	(869–034–00103–3)	20.00	July 1, 1998
1900–1910 (§§ 1900 to 1910.999)	(869–032–00104–9)	43.00	July 1, 1997
1910 (§§ 1910.1000 to end)	(869–032–00105–7)	29.00	July 1, 1997
1911–1925	(869–032–00106–5)	19.00	July 1, 1997
1926	(869–032–00107–3)	31.00	July 1, 1997
1927–End	(869–034–00108–4)	41.00	July 1, 1998
30 Parts:			
1–199	(869–034–00109–2)	33.00	July 1, 1998
200–699	(869–032–00110–3)	28.00	July 1, 1997
700–End	(869–032–00111–1)	32.00	July 1, 1997
31 Parts:			
0–199	(869–034–00112–2)	20.00	July 1, 1998
200–End	(869–032–00113–8)	42.00	July 1, 1997
32 Parts:			
1–39, Vol. I		15.00	[2] July 1, 1984
1–39, Vol. II		19.00	[2] July 1, 1984
1–39, Vol. III		18.00	[2] July 1, 1984
1–190	(869–034–00114–9)	47.00	July 1, 1998
191–399	(869–032–00115–4)	51.00	July 1, 1997
400–629	(869–032–00116–2)	33.00	July 1, 1997
630–699	(869–032–00117–1)	22.00	July 1, 1997
700–799	(869–032–00118–9)	28.00	July 1, 1997
800–End	(869–032–00119–7)	27.00	July 1, 1997
33 Parts:			
1–124	(869–032–00120–1)	27.00	July 1, 1997
125–199	(869–032–00121–9)	36.00	July 1, 1997
200–End	(869–034–00122–0)	30.00	July 1, 1998
34 Parts:			
1–299	(869–032–00123–5)	28.00	July 1, 1997
300–399	(869–032–00124–3)	27.00	July 1, 1997
400–End	(869–032–00125–1)	44.00	July 1, 1997
35	(869–032–00126–0)	15.00	July 1, 1997
36 Parts			
1–199	(869–034–00127–1)	20.00	July 1, 1998
200–299	(869–034–00128–9)	21.00	July 1, 1998
300–End	(869–032–00129–4)	34.00	July 1, 1997
37	(869–032–00130–8)	27.00	July 1, 1997
38 Parts:			
0–17	(869–034–00131–9)	34.00	July 1, 1998
18–End	(869–032–00132–4)	38.00	July 1, 1997
39	(869–034–00133–5)	23.00	July 1, 1998
40 Parts:			
1–49	(869–032–00134–1)	31.00	July 1, 1997
50–51	(869–032–00135–9)	23.00	July 1, 1997
52 (52.01–52.1018)	(869–032–00136–7)	27.00	July 1, 1997
52 (52.1019–End)	(869–034–00137–8)	33.00	July 1, 1998
53–59	(869–032–00138–3)	14.00	July 1, 1997
60	(869–032–00139–1)	52.00	July 1, 1997
61–62	(869–032–00140–5)	19.00	July 1, 1997
63–71	(869–032–00141–3)	57.00	July 1, 1997
64–71	(869–034–00142–4)	11.00	July 1, 1998
72–80	(869–032–00142–1)	35.00	July 1, 1997
81–85	(869–032–00143–0)	32.00	July 1, 1997
86	(869–032–00144–8)	50.00	July 1, 1997
87-135	(869–032–00145–6)	40.00	July 1, 1997
136–149	(869–032–00146–4)	35.00	July 1, 1997
150–189	(869–032–00147–2)	32.00	July 1, 1997
190–259	(869–032–00148–1)	22.00	July 1, 1997
260–265	(869–032–00149–9)	29.00	July 1, 1997
266–299	(869–032–00150–2)	24.00	July 1, 1997
300–399	(869–032–00151–1)	27.00	July 1, 1997
400–424	(869–032–00152–9)	33.00	[5] July 1, 1996
425–699	(869–032–00153–7)	40.00	July 1, 1997
700–789	(869–032–00154–5)	38.00	July 1, 1997
790–End	(869–032–00155–3)	19.00	July 1, 1997
41 Chapters:			
1, 1–1 to 1–10		13.00	[3] July 1, 1984
1, 1–11 to Appendix, 2 (2 Reserved)		13.00	[3] July 1, 1984
3–6		14.00	[3] July 1, 1984
7		6.00	[3] July 1, 1984
8		4.50	[3] July 1, 1984
9		13.00	[3] July 1, 1984
10–17		9.50	[3] July 1, 1984
18, Vol. I, Parts 1–5		13.00	[3] July 1, 1984
18, Vol. II, Parts 6–19		13.00	[3] July 1, 1984
18, Vol. III, Parts 20–52		13.00	[3] July 1, 1984
19–100		13.00	[3] July 1, 1984
1–100	(869–034–00157–2)	13.00	July 1, 1998
101	(869–032–00157–0)	36.00	July 1, 1997
102–200	(869–034–00158–9)	15.00	July 1, 1998
201–End	(869–032–00159–6)	15.00	July 1, 1997
42 Parts:			
1–399	(869–032–00160–0)	32.00	Oct. 1, 1997
400–429	(869–032–00161–8)	35.00	Oct. 1, 1997
430–End	(869–032–00162–6)	50.00	Oct. 1, 1997
43 Parts:			
1–999	(869–032–00163–4)	31.00	Oct. 1, 1997
1000–end	(869–032–00164–2)	50.00	Oct. 1, 1997
44	(869–032–00165–1)	31.00	Oct. 1, 1997
45 Parts:			
1–199	(869–032–00166–9)	30.00	Oct. 1, 1997
200–499	(869–032–00167–7)	18.00	Oct. 1, 1997
500–1199	(869–032–00168–5)	29.00	Oct. 1, 1997
1200–End	(869–032–00169–3)	39.00	Oct. 1, 1997
46 Parts:			
1–40	(869–032–00170–7)	26.00	Oct. 1, 1997
41–69	(869–032–00171–5)	22.00	Oct. 1, 1997
70–89	(869–032–00172–3)	11.00	Oct. 1, 1997
90–139	(869–032–00173–1)	27.00	Oct. 1, 1997
140–155	(869–032–00174–0)	15.00	Oct. 1, 1997
156–165	(869–032–00175–8)	20.00	Oct. 1, 1997
166–199	(869–032–00176–6)	26.00	Oct. 1, 1997
200–499	(869–032–00177–4)	21.00	Oct. 1, 1997
500–End	(869–032–00178–2)	17.00	Oct. 1, 1997
47 Parts:			
0–19	(869–032–00179–1)	34.00	Oct. 1, 1997
20–39	(869–032–00180–4)	27.00	Oct. 1, 1997
40–69	(869–032–00181–2)	23.00	Oct. 1, 1997
70–79	(869–032–00182–1)	33.00	Oct. 1, 1997
80–End	(869–032–00183–9)	43.00	Oct. 1, 1997
48 Chapters:			
1 (Parts 1–51)	(869–032–00184–7)	53.00	Oct. 1, 1997
1 (Parts 52–99)	(869–032–00185–5)	29.00	Oct. 1, 1997
2 (Parts 201–299)	(869–032–00186–3)	35.00	Oct. 1, 1997
3–6	(869–032–00187–1)	29.00	Oct. 1, 1997
7–14	(869–032–00188–0)	32.00	Oct. 1, 1997
15–28	(869–032–00189–8)	33.00	Oct. 1, 1997
29–End	(869–032–00190–1)	25.00	Oct. 1, 1997
49 Parts:			
1–99	(869–032–00191–0)	31.00	Oct. 1, 1997
100–185	(869–032–00192–8)	50.00	Oct. 1, 1997
186–199	(869–032–00193–6)	11.00	Oct. 1, 1997
200–399	(869–032–00194–4)	43.00	Oct. 1, 1997
400–999	(869–032–00195–2)	49.00	Oct. 1, 1997
1000–1199	(869–032–00196–1)	19.00	Oct. 1, 1997
1200–End	(869–032–00197–9)	14.00	Oct. 1, 1997
50 Parts:			
1–199	(869–032–00198–7)	41.00	Oct. 1, 1997
200–599	(869–032–00199–5)	22.00	Oct. 1, 1997
600–End	(869–032–00200–2)	29.00	Oct. 1, 1997

Title	Stock Number	Price	Revision Date
CFR Index and Findings Aids	(869–034–00049–6)	46.00	Jan. 1, 1998
Complete 1998 CFR set		951.00	1998
Microfiche CFR Edition:			
Subscription (mailed as issued)		247.00	1998
Individual copies		1.00	1998
Complete set (one-time mailing)		247.00	1997
Complete set (one-time mailing)		264.00	1996

[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period July 1, 1996 to June 30, 1997. The volume issued July 1, 1996, should be retained.

[5] No amendments to this volume were promulgated during the period January 1, 1997 through December 31, 1997. The CFR volume issued as of January 1, 1997 should be retained.

[6] No amendments to this volume were promulgated during the period April 1, 1997, through April 1, 1998. The CFR volume issued as of April 1, 1997, should be retained.