

who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

### Collection of Information

This rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

### Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that Order.

### Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

### Taking of Private Property

This rule would not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

### Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

### Protection of Children

The Coast Guard has analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

### Environment

We have considered the environmental impact of this rule and

concluded that, under figure 2-1, paragraph 34(g) of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation. A written categorical exclusion determination is available in the docket for inspection or copying where indicated under **ADDRESSES**.

### Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

### List of Subjects in 33 CFR Part 165

Harbors, Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05-1(g), 6.04-1, 6.04-6, 160.5; 49 CFR 1.46.

2. A new temporary § 165.T09-980 is added to read as follows:

#### § 165.T09-980 Safety Zone; Blue Water Offshore Classic, St. Clair River, MI.

(a) *Location.* This moving safety zone encompasses all waters within 1000 yards ahead, 1000 yards behind, and 50 yards on either side of any deep draft vessel that can only safely navigate within the channel of the St. Clair River. The moving safety zone will be enforced to the South, starting 500 yards East of the Newman and River Road Intersection at position 42°51'54" N, 082°28'00" W. To the North, the moving safety zone will be enforced starting 300 yards East of the St. Clair Michigan State Police Docks at position 42°28'54" N, 082°28'48" W. These coordinates are based upon North American Datum 1983 (NAD 83).

(b) *Enforcement times and dates.* This section will be enforced 8 a.m. until 6 p.m. on August 3, 4 and 5, 2001. The designated on-scene Patrol Commander may be contacted via VHF Channel 16.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of

this part, entry into the safety zone is prohibited unless authorized by the Coast Guard Captain of the Port Detroit, or his designated on-scene representative.

Dated: July 25, 2001.

**S.P. Garrity,**

*Captain, U.S. Coast Guard, Captain of the Port Detroit.*

[FR Doc. 01-19314 Filed 8-1-01; 8:45 am]

**BILLING CODE 4910-15-U**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 9 and 63

[FRL-7020-3]

RIN 2060-AE83

### National Emission Standards for Pharmaceuticals Production

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule and direct final rule; corrections and amendments.

**SUMMARY:** The EPA is taking direct final action to amend the national emission standards for hazardous air pollutants (NESHAP) for pharmaceuticals production. This direct final rule provides additional compliance options for process vent and storage tank emissions, specifies additional methods that may be used to analyze wastewater, shifts one compound from the list of partially soluble hazardous air pollutants (HAP) to the list of soluble HAP, eliminates an unintended restriction on the use of enhanced biological treatment, allows a sewer line between drains and the first downstream junction box to be vented, clarifies how to assign storage tanks that are shared among pharmaceutical manufacturing process units and other types of process units, clarifies the monitoring frequency requirements for connectors, clarifies and simplifies recordkeeping and reporting requirements, eliminates inconsistencies, and corrects several referencing and typesetting errors. We view these revisions to be minor and noncontroversial, and we anticipate no adverse comment.

In compliance with the Paperwork Reduction Act (PRA), this action also amends the table that lists the Office of Management and Budget (OMB) control numbers issued under the PRA for the pharmaceuticals production rule.

**DATES:** The amendments to 40 CFR part 9 are effective on August 2, 2001. The direct final rule amendments to 40 CFR

part 63 are effective on October 16, 2001 without further notice, unless EPA receives adverse comments by September 4, 2001, or by September 17, 2001 if a public hearing is requested. See the proposed rule in this issue of the **Federal Register** for information on the hearing. If we receive any adverse comments, and those comments apply to an amendment, paragraph, or section of this rule, and that provision may be addressed separately from the remainder of the rule, we will withdraw only those provisions on which we received adverse comments. We will publish a timely withdrawal in the **Federal Register** indicating which provisions will not take effect.

**ADDRESSES: Comments.** By U.S. Postal Service, send comments (in duplicate, if possible) to: Air and Radiation Docket and Information Center (6102), Attention Docket Number A-96-03, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. In person or by courier, deliver comments (in duplicate if possible) to: Air and Radiation Docket and Information Center (6102), Attention Docket Number A-96-03, U.S. EPA, 401 M Street, SW, Washington DC 20460. The EPA requests that a separate copy of each public comment be sent to the contact person listed below (see **FOR FURTHER INFORMATION CONTACT**). Comments may also be submitted electronically by following the instructions provided in **SUPPLEMENTARY INFORMATION. Docket.** Docket No. A-96-03 contains supporting information used in developing the NESHAP. The docket is located at the U.S. EPA, 401 M Street, SW, Washington, DC 20460 in Room M-1500, Waterside Mall (ground floor), and may be inspected from 8 a.m. to

5:30 p.m., Monday through Friday, excluding legal holidays.  
**FOR FURTHER INFORMATION CONTACT:** Mr. Randy McDonald, Organic Chemicals Group, Emission Standards Division (MD-13), U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5402, electronic mail address: mcdonald.randy@epa.gov.  
**SUPPLEMENTARY INFORMATION: Comments.** Comments and data may be submitted by electronic mail (e-mail) to: a-and-r-docket@epa.gov. Electronic comments must be submitted as an ASCII file to avoid the use of special characters and encryption problems and will also be accepted on disks in WordPerfect version 5.1, 6.1, or Corel 8 file format. All comments and data submitted in electronic form must note the docket number A-96-03. No confidential business information (CBI) should be submitted by e-mail. Electronic comments may be filed online at many Federal Depository Libraries.

Commenters wishing to submit proprietary information for consideration must clearly distinguish such information from other comments and clearly label it as CBI. Send submissions containing such proprietary information directly to the following address, and not to the public docket, to ensure that proprietary information is not inadvertently placed in the docket: Attention: Mr. Randy McDonald, c/o OAQPS Document Control Officer (Room 740B), U.S. EPA, 411 W. Chapel Hill Street, Durham, NC 27701. The EPA will disclose information identified as CBI only to the extent allowed by the procedures set forth in 40 CFR part 2. If no claim of confidentiality accompanies a submission when it is received by EPA,

the information may be made available to the public without further notice to the commenter.

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

**Worldwide Web (WWW).** In addition to being available in the docket, an electronic copy of this action will also be available through the WWW. Following signature, a copy of this action will be posted on the EPA's Technology Transfer Network (TTN) policy and guidance page for newly proposed or promulgated rules: <http://www.epa.gov/ttn/oarpg>. The TTN at EPA's web site provides information and technology exchange in various areas of air pollution control. If more information regarding the TTN is needed, call the TTN HELP line at (919) 541-5384.

**Regulated Entities.** The regulated category and entities affected by this action include:

Category	NAICS codes	SIC codes	Examples of regulated entities
Industry .....	325411 and 325412 .....	2833 and 2834 .....	<ul style="list-style-type: none"> <li>Producers of finished dosage forms of drugs (e.g., tablets, capsules, and solutions), active ingredients, or precursors.</li> <li>Producers of material whose primary use is as an active ingredient of precursor.</li> </ul>
	Typically 325199 .....	Typically 2869 .....	

This table is not intended to be exhaustive, but rather provides a guide for readers likely to be interested in the revisions to the regulation affected by this action. To determine whether your facility, company, business, organization, etc., is regulated by this action, you should carefully examine all of the applicability criteria in § 63.1250 of the rule. If you have questions regarding the applicability of these amendments to a particular entity,

consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

**Judicial Review.** Under section 307(b)(1) of the CAA, judicial review of this direct final rule is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia by October 1, 2001. Under section 307(d)(7)(B) of the CAA, only an objection to this direct final rule that was raised with reasonable specificity

during the period for public comment can be raised during judicial review. Moreover, under section 307(b)(2) of the CAA, the requirements established by this direct final rule may not be challenged separately in any civil or criminal proceeding brought to enforce these requirements. Also under section 307(b)(1) of the CAA, judicial review of the amendment to part 9 in this action is available by filing a petition for review in the U.S. Court of Appeals for

the District of Columbia Circuit within October 1, 2001. Under section 307(b)(2) of the CAA, the requirements that are the subject of this amendment may not be challenged later in civil or criminal proceedings brought by the EPA to enforce these requirements.

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

- I. Why are we publishing these amendments as a direct final rule?
- II. What amendments are we making to part 9 to reflect OMB approval of the information collection request for subpart GGG?
- III. What amendments are we making to the process vent provisions?
- IV. What amendments are we making to the wastewater provisions?
- V. What amendments are we making to the storage tank provisions?
- VI. What minor technical corrections are we making?
- VII. What are the administrative requirements for this direct final rule?
  - A. Executive Order 12866, Regulatory Planning and Review
  - B. Executive Order 13132, Federalism
  - C. Executive Order 13175, Consultation and Coordination with Indian Tribal Governments
  - D. Executive Order 13045, Protection of Children for Environmental Health Risks and Safety Risks
  - E. Unfunded Mandates Reform Act of 1995
  - F. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*
  - G. Paperwork Reduction Act
  - H. National Technology Transfer and Advancement Act
  - I. The Congressional Review Act
  - J. Executive Order 13211 (Energy Effects)

### **I. Why Are We Publishing These Amendments as a Direct Final Rule?**

In this direct final rule, we are correcting referencing and typesetting errors, identifying additional test methods that may be used to analyze wastewater, classifying triethylamine as a soluble HAP instead of a partially soluble HAP, adding an outlet concentration limit compliance option for storage tanks, clarifying the monitoring frequency for connectors, clarifying storage tank assignment procedures, and adding planned routine maintenance provisions for centralized combustion control devices (CCCD). These changes provide clarifications and additional compliance options. In all instances, we believe that these changes have the potential to reduce the burden on both owners and operators of affected sources and on the State or local agency implementing the rule, although we are unable to quantify reductions in hours for these amendments. For these reasons, we view these amendments as

noncontroversial and anticipate no adverse comments, and we are publishing these amendments in a direct final rule.

If an adverse comment applies to an amendment, paragraph, or section of this direct final rule, and that provision may be addressed separately from the remainder of the rule, we will withdraw only those provisions on which we received adverse comments. In the "Proposed Rules" section of this **Federal Register**, we are publishing a separate document that will serve as the proposal for any provisions in this direct final rule on which we receive adverse comments. The EPA will publish a timely withdrawal before the effective date of this rule indicating which provisions are being withdrawn. If part or all of this direct final rule is withdrawn, all public comments received will be addressed in a subsequent final rule based on the proposal. We will not institute a second comment period on the subsequent final rule. Any parties interested in commenting must do so at this time. The nature of the changes contained in this direct final rule are such that it will benefit both industry and the States for these changes to become effective sooner, rather than later, as will be described in more detail below.

### **II. What Amendments Are We Making to Part 9 To Reflect OMB Approval of the Information Collection Request for Subpart GGG?**

This final rule amends the table of currently approved Information Collection Request (ICR) control numbers issued by OMB. As noted in section VII.G of this preamble, as well as in the preambles to earlier amendments and the promulgated rule, OMB has approved the information collection requirements contained in subpart GGG and assigned OMB control No. 2060-0358. However, when we amended § 9.1 on September 21, 1998, we entered the incorrect number 2060-0314. Because the correct number was listed in the earlier preambles and amendment of the table is technical in nature, we believe that another notice and comment period for this amendment is unnecessary and that there is good cause under the Administrative Procedure Act (5 U.S.C. 553(b)) to amend this table without prior notice and comment.

### **III. What Amendments Are We Making to the Process Vent Provisions?**

This direct final rule specifies requirements for meeting the process vent standards during periods of planned routine maintenance of CCCD.

Use of a CCCD, while not required by subpart GGG, is a common control technique at existing pharmaceutical production facilities because the facilities have found such a device to be more reliable and efficient than multiple point-of-use devices. However, under subpart GGG as currently written, when routine maintenance on a CCCD is needed, you must either shutdown all processes or have a backup control device that you have demonstrated achieves the same level of control. We understand that shutting down all processes is inefficient and costly for at least two reasons: (1) Because all processes have different cycles, the shutdown would almost certainly have to be staggered, which means some process equipment would have to be shutdown for a longer period than is needed simply to perform the maintenance on the control device; and (2) pharmaceutical production facilities often shutdown only a section of the facility for maintenance as opposed to the entire facility because it is impractical to have an in-house maintenance staff large enough to perform such maintenance in a short period of time, and outside resources may not be sufficiently skilled or available when needed. We also realize that demonstrating compliance for a backup device could be a significant burden. To address these concerns, this direct final rule provides an additional compliance option for periods of planned routine maintenance of a CCCD that is simple to implement and achieves reductions that are at least equivalent to the maximum achievable control technology (MACT) floor.

The new planned routine maintenance provisions specify separate requirements for organic HAP emissions and hydrogen chloride (HCl) emissions. You must route emissions from process vents with organic HAP emissions greater than 15 pounds per day (lb/day) through a closed vent system to a condenser that operates at: (1) Less than 50 degrees centigrade (C) when the emission stream contains HAP with a partial pressure greater than 20 kilopascals (kPa) and (2) less than -5 degrees C when the emission stream contains HAP with a partial pressure less than or equal to 20 kPa. The partial pressures must be determined at 25 C. These requirements are designed to be similar to State reasonably available control technology rules that are based on the generalized control program described on page 1-5 of the 1978 Control Techniques Guideline (CTG) Document for Control of Volatile Organic Emissions from Manufacture of

Synthesized Pharmaceutical Products (EPA 450/2-78-029). However, to achieve the MACT floor control level of 93 percent, the operating temperatures required by the planned routine maintenance provisions differ from those specified in the CTG, and all vents with organic HAP emissions greater than 15 lb/day must be controlled (not just vents from the unit operations listed in the CTG). The planned routine maintenance provisions are limited to the use of condensers as specified above to keep the compliance requirements simple and because many facilities typically already have backup condensers available onsite.

Because the CTG did not cover HCl emissions, the planned routine maintenance provisions specify that you must route emissions from process vents with HCl emissions greater than or equal to 15 lb/day through a closed vent system to a caustic scrubber. As with the condenser, we have kept compliance requirements simple. Compliance is demonstrated by daily monitoring of the scrubber effluent and maintaining the effluent at pH 9 or greater.

Although § 63.1258 of the pharmaceuticals production NESHAP specifies parameters for scrubbers, we are not requiring monitoring of the scrubber liquid flow rate or pressure drop for caustic scrubbers during periods of planned routine maintenance. The effectiveness of absorbing HCl into caustic solution is so great that monitoring effluent pH is adequate to demonstrate compliance. The relatively small amount of HCl generated during periods of planned routine maintenance does not justify the need to burden the industry with design evaluation demonstrations and continuous monitoring for each individual scrubber application during the limited period of planned routine maintenance.

Hydrogen chloride has a great affinity for water. Referencing the "Chemical Engineering Handbook" by Perry and Chilton, solubility of HCl is almost 70 grams per 100 grams of water at 30 degrees C. An aqueous solution at the same temperature can absorb up to 10 percent HCl before reaching an equilibrium of 20 parts per million volume (ppmv) of HCl in the gas phase. In addition, absorption increases as vapor pressure decreases, and vapor pressure of HCl can be decreased significantly by adding a chemical reactant such as sodium hydroxide (NaOH) to tie up the solute gas. The chemical reaction in a caustic scrubber frees up liquid volume for dissolving more gas. A caustic scrubber operating such that the effluent stays at or above

pH 9 is considered a very effective control device.

The 15 lb/day emission rate cutoffs apply to emissions from vents on individual unit operations, not to aggregated emissions from multiple unit operations that are manifolded together into a common header (i.e., the emission rates must be determined only at the equipment where the emissions enter the closed vent system prior to being combined with emissions from other unit operations). Therefore, a manifolded stream with emissions that exceed 15 lb/day is not subject to control requirements during periods of planned routine maintenance of the CCCD if the emissions from each of the unit operation vents that are combined in that manifold have emissions less than 15 lb/day. If any individual unit operation vents with emissions less than 15 lb/day are manifolded with a unit operation vent that has emissions greater than or equal to 15 lb/day, then the entire manifolded stream must be controlled (or the emissions from the unit operation with emissions greater than 15 lb/day must be diverted from the other vents in the manifold for control).

You may use the planned routine maintenance provisions if you use the CCCD to comply with any of the requirements in § 63.1254(a) of the pharmaceuticals production NESHAP for process vents from all non-dedicated pharmaceutical manufacturing process units (PMPU) that are controlled by the CCCD. However, there are several requirements to ensure that the level of control achieved is at least equivalent to the MACT floor. First, you may only route emissions from vents that are subject to the 98 percent reduction requirement in § 63.1254(a)(3) if you demonstrate that the planned routine maintenance is needed and that there is no way to perform it during periods when a process with such a vent is not operating. To make this demonstration, you must document your plans in either your Notification of Compliance Status Report or in a periodic report that is submitted prior to the planned routine maintenance event. Second, if you use the CCCD to control emissions so as to comply with the annual mass limit, you must calculate controlled emissions during periods of planned routine maintenance assuming the control efficiency is 93 percent. Third, whenever you implement the planned routine maintenance provisions, you must monitor the condenser outlet temperature as specified in § 63.1258(i). This requirement applies even if you comply with the alternative standard or if the CCCD is a boiler, process heater,

or hazardous waste incinerator that meets any of the criteria in § 63.1257(a)(4). Fourth, you may not use the process vents in emissions averaging during the period that you comply with the planned routine maintenance provisions. During this time period, the process vents are being controlled to the level of the MACT floor; thus, no debits or credits can be calculated.

There are also several other restrictions on how the planned routine maintenance provisions may be implemented. For example, the planned routine maintenance provisions may be implemented for no more than 240 hours per year (hr/yr). This time period is consistent with the time allowed in § 63.1253(e) of the pharmaceuticals production NESHAP for planned routine maintenance of a control device used to control storage tank emissions. As we have stated in previous rulemaking packages, we believe this time is sufficient to perform maintenance on combustion devices (59 FR 19441, April 22, 1994). In addition, the planned routine maintenance provisions are not available for process vents from dedicated PMPU because planning a shutdown for such a PMPU can be more easily scheduled than for non-dedicated PMPU whose operation is more unpredictable in nature. Finally, the planned routine maintenance provisions may not be used for emissions from wastewater systems or equipment leaks because the MACT floor level of control for these emissions is 95 percent. If the CCCD is used to control emissions from storage tanks, you may elect to control them with the condenser during periods of planned routine maintenance. However, this control is not required because § 63.1253(e) specifies that the emission limitations are not applicable during periods of planned routine maintenance up to 240 hr/yr.

#### **IV. What Amendments Are We Making to the Wastewater Provisions?**

This direct final rule makes four changes to the wastewater provisions. One change is that we are adding two EPA test methods to the list of acceptable test methods that may be used to analyze wastewater samples. The second change is that we are reclassifying triethylamine as a soluble HAP instead of as a partially soluble HAP. The third change is to allow wastewater streams with more than 50 parts per million weight (ppmw) of partially soluble HAP to be sent to an enhanced biological treatment unit if the partially soluble HAP has already been reduced by 99 percent or more. The fourth change is to modify the

venting requirements for individual drain systems. In addition, although we are not changing the sampling requirements, we are clarifying those requirements.

Section 63.1257(b)(10)(ii) of the amended final rule states that you may use EPA Methods 624, 625, 1624, and 1625 of 40 CFR part 136 to determine the concentration of various HAP in wastewater samples (65 FR 52610, August 29, 2000). This direct final rule adds EPA Methods 1666 and 1671 to that list so that you may use them routinely without performing the method validation procedures required in § 63.1257(b)(10)(iv). The two new methods can be used to measure certain analytes (e.g., methanol, acetonitrile, and n-hexane) that cannot be measured using the other methods in 40 CFR part 136. These two methods were added to 40 CFR part 136 when the revisions to the pharmaceutical effluent limitation guidelines and standards were promulgated in September 1998. They have the same quality assurance/quality control requirements as the earlier methods; in particular, sampling must be conducted so as to minimize loss of volatile compounds. In addition, they can detect target HAP at the outlet concentrations that may be required by the rule (e.g., as low as 13 ppmw in the outlet from a treatment unit that must reduce partially soluble HAP by 99 percent).

For the final rule, compounds were classified as either partially soluble HAP or soluble HAP based on their Henry's Law constants. Triethylamine was classified as a partially soluble HAP listed in Table 2 of subpart GGG because its Henry's Law constant is relatively high. However, in this direct final rule, we are now removing triethylamine from Table 2 of subpart GGG and reclassifying it as a soluble HAP in Table 3 of subpart GGG because it has two unique characteristics that distinguish it from the listed partially soluble HAP. First, at pH ranges of 6 to 9 (typical for pharmaceutical production wastewater), triethylamine has unique ionic disassociative properties, unlike the listed partially soluble HAP. In the liquid phase, the nitrogen in triethylamine has an unshared pair of electrons that readily react with a proton in the liquid. As a result, virtually all of the free triethylamine in solution is converted to triethylammonium ions, which are soluble, non-volatile, and stable. Second, triethylamine is unique among the HAP used in the pharmaceutical production industry in that it typically is used as an organic base in reactions (in situations where an inorganic base is

not acceptable) and not as a primary solvent.

Section 63.1256(g)(10) of the pharmaceuticals production NESHAP specifies that the partially soluble HAP concentration in wastewater streams sent to an enhanced biological treatment unit must be less than 50 ppmw. An unintended effect of this restriction is that it applies even if the partially soluble HAP has been reduced by more than 99 percent by treatment upstream of the enhanced biological treatment unit. This restriction is unnecessary because a 99 percent reduction in the partially soluble HAP is otherwise sufficient; there is no reason to prevent the use of enhanced biological treatment to reduce the soluble HAP in the same stream. Therefore, we have amended § 63.1256(g)(10) to clarify that a wastewater stream may be sent to an enhanced biological treatment unit if the partially soluble HAP is reduced to a concentration less than 50 ppmw or by at least 99 percent (i.e., in accordance with § 63.1256(g)(8)) in a treatment unit upstream of the enhanced biological treatment unit.

Section 63.1256(e) of subpart GGG specifies work practice standards to suppress emissions from individual drain systems. These standards allow junction boxes to be vented, but not sewer lines. Without a vent, wastewater may backup in drains and not flow properly to the first downstream junction box if there are low points in the sewer line. To alleviate this problem, we have revised § 63.1256(e)(4)(iii) to allow venting of a sewer line between drains and the first downstream junction box, provided certain conditions are met. First, the drains must be equipped with either water seals or tightly fitting caps or plugs as specified in § 63.1256(e)(4)(i). Second, the sewer line entrance to the first downstream junction box must be water sealed. These provisions apply regardless of whether the junction box is vented to the atmosphere or to a process or control device. They also are standard operating practices, and they ensure that air will not flow through the sewer line and be emitted from the vent on the sewer line. Finally, the size of the atmospheric opening is minimized by having the sewer line vent pipe meet the same design criteria as for vents on junction boxes.

The final rule specifies that wastewater samples may be grab samples or composite samples, samples must be taken at approximately equally-spaced time intervals over a 1-hour period, each 1-hour period constitutes a run, and a performance test must consist of at least three runs

(§ 63.1257(e)(2)(iii)(B), (C)(1), (D)(1), and (E)(1)). Similar requirements are specified for gas stream samples at the exit of a combustion treatment unit or at the inlet or exit of control devices (§ 63.1257(e)(2)(iii)(D)(4) and (e)(3)(i)(C)). As in the Hazardous Organic NESHAP (HON) (40 CFR part 63, subpart G), we intentionally did not specify exactly how to take samples because the procedures will vary depending on the circumstances and the selected test method. In some cases, any of the options may be acceptable, whereas in other cases, some options may not be available. For example, if you conduct wastewater sampling in accordance with a sampling plan based on the sample handling requirements in EPA Method 25D of 40 CFR part 60, appendix A, you would have to take grab samples; you would not be able to take composite samples. On the other hand, for emission stream samples where concentration measurements are to be determined using EPA Method 18 of 40 CFR part 60, appendix A, you have the option of taking either grab samples or composite samples. The rule does not specify the number of samples that you must collect because we do not want to restrict the number of samples that you take to cover different, representative operating conditions (as opposed to supplementing with modeling or engineering assessments). However, you must take at least one sample per run. The requirement to take samples at equally-spaced time intervals over the 1-hour period means that the samples must be taken at the same point in the 1-hour period for each of the three runs; this requirement applies even if you take only one sample per run.

#### **V. What Amendments Are We Making to the Storage Tank Provisions?**

This direct final rule adds an outlet concentration limit compliance option for storage tank emissions. Under this option, you must conduct an initial performance test to demonstrate that emissions are reduced to outlet concentrations less than or equal to 20 ppmv as total organic compound (TOC) and less than or equal to 20 ppmv as hydrogen halides and halogens. You also must establish applicable operating parameter levels during the performance test to use as monitoring limits for ongoing compliance demonstrations. This option is identical to options already provided for process vent emissions and wastewater emissions.

The exclusion of this option for storage tanks was an oversight that was only recently discovered. We always intended to provide this option for storage tank emissions as well as other

types of emissions, as evidenced by the fact that we included a statement specifying how to demonstrate initial compliance with such an option in § 63.1257(c)(1) of the final rule (63 FR 50355, September 21, 1998). In previous amendments, we inadvertently modified this statement to refer to compliance

with the alternative standard (65 FR 52610, August 29, 2000). Therefore, in addition to providing the outlet concentration limit as an option in § 63.1253(b)(2) and (c)(2), this direct final rule also restores the original intent of the provision in § 63.1257(c)(1).

**VI. What Minor Technical Corrections Are We Making?**

This direct final rule corrects referencing errors, corrects drafting and typesetting errors, and clarifies the intent of several provisions. All of the minor technical corrections are described in Table 1.

TABLE 1.—MINOR TECHNICAL CORRECTIONS TO SUBPART GGG

Section of subpart GGG	Description of correction
§ 63.1250(e)	The original language in these paragraphs specified only how to determine ownership if a storage tank was shared among PMPU's. The revised language in paragraphs (e)(2) and (3) clarifies how to determine ownership of a tank that is shared among one or more PMPU's and other types of process units. The requirement to assign storage tanks to a process unit based on predominant use has not changed. We also revised the introductory text to paragraph (e) to specify that if you produce only pharmaceutical products, you do not need to assign storage tanks to a PMPU except when you comply with the pollution-prevention alternative and when you need to determine whether a dedicated PMPU is subject to new source standards. Otherwise, the assignment requirement is not needed at these facilities because all of the storage tanks are subject to storage tank requirements in the rule, and there are no other applicability requirements based on total emissions from a PMPU. We expect that this clarification will reduce the burden for some facilities.
§ 63.1250(h)(2)	Clarified the overlapping provisions by discussing the requirements in two paragraphs instead of one. One paragraph describes your options if you have a control device subject to both the pharmaceuticals production NESHAP and any of the subparts AA, BB, or CC in 40 CFR parts 264 and/or 265. The second paragraph describes your options if you have equipment subject to the equipment leak provisions in both § 63.1255 and in subpart BB of 40 CFR parts 264 and/or 265. Options for waste management units subject to both the pharmaceuticals production NESHAP and subpart CC of 40 CFR parts 264 and/or 265 are described in § 63.1250(h)(5).
§ 63.1253(f)(7)(i)	Corrected this paragraph by replacing the incorrect reference to paragraph (b)(7)(i) with the correct reference to paragraph (f)(7).
§ 63.1255(b)(4)(iii)(A)	Corrected this paragraph by replacing the incorrect reference to paragraph (b)(3)(iii)(B) with the correct reference to paragraph (b)(4)(iii)(B).
§ 63.1255(b)(4)(iii)(D)	Revised this paragraph to clarify that you must monitor leaking connectors once per year until the percent leaking connectors is less than 0.5 percent. After the percent leaking connectors falls below 0.5 percent, you may again implement the applicable less frequent monitoring schedule. Without this clarification, the paragraph could be interpreted to mean that you must always monitor leaking connectors once per year.
§ 63.1255(c)(2)(iii), (c)(3), and (5)(iv)	The original language in these paragraphs was inconsistent. Paragraph (c)(5)(iv) required EPA Method 21 monitoring to verify the presence of a leak if indications of liquids dripping were detected during a visual inspection. Paragraph (c)(2)(iii) simply stated that a leak was present if there were visual indications of liquids dripping. We revised both paragraphs to specify that if there are visual indications of liquids dripping during a weekly visual inspection, then you must either monitor using EPA Method 21 or eliminate the visual indication of liquids dripping before the next weekly inspection. These changes also make the paragraphs consistent with the Consolidated Federal Air Rule and 40 CFR part 63, subpart UU (the Generic MACT). We also revised paragraph (c)(3) to clarify that the repair provisions for all leaking pumps/agitators are the same.
§ 63.1255(c)(4)(ii)	The original language in this paragraph specified that you must monitor pumps monthly instead of quarterly if, on a 1-year rolling average, greater than 10 percent or 3 pumps have leaked in a group of processes. As written, this paragraph could be interpreted to mean that all subsequent monitoring for that group of processes must be monthly. This was not our intent. To correct this oversight, we have revised the paragraph to specify that you may revert to quarterly monitoring after the 1-year rolling average again indicates that less than 10 percent or fewer than 3 pumps have leaked.
§ 63.1255(e)(7)(iii)	Added a sentence to this paragraph to clarify that monitoring in the 3 months after repair is in addition to the monitoring required to demonstrate repair. This amendment is consistent with the language in the Consolidated Federal Air Rule and 40 CFR part 63, subpart UU. It is also consistent with the intent of the HON.
§ 63.1255(e)(9)	Corrected this paragraph by replacing the incomplete reference to paragraphs (e)(4)(iii) and (iv) with a reference to paragraphs (e)(4)(iii), (iv), and (v). The reference to paragraph (e)(4)(v) was inadvertently left out of the final rule. The change makes the paragraph consistent with the Consolidated Federal Air Rule.
§ 63.1255(h)(1)(ii)	Deleted the word "and" at the end of this paragraph because, as specified in paragraph (h)(1), the only reports that must be submitted are those specified in paragraphs (h)(1)(i) and (ii).
§ 63.1255(h)(3)(i)	Revised the schedule for submitting Periodic reports with information on equipment leak compliance to be consistent with the schedule specified in § 63.1260(g)(1).
§ 63.1256(c)(1)(i)(A)	Corrected this paragraph by replacing the incorrect reference to paragraph (c)(1)(iv) with the correct reference to paragraph (c)(1)(v).

TABLE 1.—MINOR TECHNICAL CORRECTIONS TO SUBPART GGG—Continued

Section of subpart GGG	Description of correction
§ 63.1256(e)(4)(i)(B) .....	The original language in this paragraph used the terms “flexible cap” and “flexible shield,” interchangeably. To clarify our intent, we revised the paragraph to use only the term “flexible shield.”
§ 63.1256(g)(9)(ii) .....	Revised this paragraph to allow design evaluations, as well as performance tests, to demonstrate removal or destruction of soluble HAP by 90 percent in all treatment units except open biological treatment units. This change makes the requirements of this paragraph consistent with the requirements in paragraph (g)(4). It also makes this paragraph consistent with the amended requirements in paragraphs (g)(8)(ii), (11)(ii), and (12) of this section. We inadvertently neglected to amend this paragraph at the same time that the others were amended.
§ 63.1257(a)(6) .....	Corrected this paragraph by replacing the incorrect reference to § 63.1258(b)(1) through (5) with the correct reference to § 63.1258(b)(1) through (4). Section 63.1258(b)(5) is not applicable because it relates to the alternative standard, whereas § 63.1257(a)(6) is describing monitoring requirements to demonstrate compliance with the outlet concentration limits of 20 ppmv TOC and 20 ppmv hydrogen halides and halogens.
§ 63.1257(d)(2)(i)(D)(9) .....	Corrected Equation 31 by replacing “N <sub>HAP</sub> ” with “n <sub>HAP</sub> .”
§ 63.1257(d)(2)(i)(D)(10) .....	Corrected Equation 32 by replacing individual HAP partial pressures with partial pressures for individual condensable compounds.
§ 63.1257(d)(2)(i)(E) .....	Added a sentence specifying that individual HAP partial pressures in the equation to calculate emissions from vacuum systems may be calculated using Raoult’s Law. This change makes the procedures for this equation consistent with the procedures that are allowed for calculating emissions from other types of emission episodes.
§ 63.1257(d)(3)(iii)(B) .....	Corrected this paragraph by replacing the incorrect reference to paragraphs (d)(2)(iii)(B)(1) and (2) with the correct reference to paragraphs (d)(3)(iii)(B)(1) and (2).
§ 63.1257(e)(2)(iii)(B) .....	Corrected this paragraph by replacing the incorrect reference to paragraph (b)(10)(iii) with the correct reference to paragraph (b)(10)(vi) and replacing the incorrect reference to paragraphs (b)(10)(i), (ii), and (iii) with the correct reference to paragraphs (b)(10)(i) through (vi).
§ 63.1257(e)(2)(iii)(C)(1), (D)(1), and (E)(1) .....	Corrected these paragraphs by replacing the incorrect reference to paragraph (b)(10)(v) with the correct reference to paragraph (b)(10)(vi).
§ 63.1258(b)(3) .....	Deleted the reference to process vents from the heading to this paragraph. The intent of this paragraph is to specify procedures for setting parameter levels for all control devices, not just those used to control process vent emissions.
§ 63.1258(b)(5)(i)(A) .....	Deleted the last sentence in this paragraph because it conflicts with the requirement in § 63.1258(b)(1)(x) that calibration of CEMS include, at a minimum, quarterly cylinder gas audits.
§ 63.1258(b)(5)(ii)(A)(2) .....	Revised this paragraph to specify that it applies if you comply with the alternative standard instead of achieving a control efficiency of “98 percent,” not “98 percent or less.” Paragraph (b)(5)(ii)(A)(1) specifies requirements if you comply with the alternative standard instead of achieving a control efficiency of 95 percent or less. Subpart GGG has no control efficiency requirements between 95 and 98 percent. Therefore, the phrase “or less” in paragraph (b)(5)(ii)(A)(2) is both unnecessary and conflicts with paragraph (b)(5)(ii)(A)(1).
§ 63.1258(b)(8)(iii) .....	Revised this paragraph to clarify that violations of the alternative standard apply to the 50 ppmv option for noncombustion devices, as well as the 20 ppmv option for combustion devices. We inadvertently neglected to amend this paragraph when we added the 50 ppmv option to the alternative standard (65 FR 52588, August 29, 2000).
§ 63.1258(h)(6) and (7) .....	Corrected these paragraphs by replacing the incorrect references to paragraphs (h)(8)(i) and (ii) with the correct reference to paragraph (h)(8).
§ 63.1258(h)(10) .....	Added paragraph (h)(10) to specify that closed-vent systems operated and maintained under negative pressure are not subject to the inspection requirements for closed-vent systems. For this type of closed-vent system, you must install a pressure gauge or other pressure measurement device that can be used to verify that the negative pressure is being maintained when the control device is operating. This new provision is consistent with the provision in § 63.1255(b)(4)(ii)(B) for closed-vent systems used to route equipment leak emissions to a control device.
§ 63.1259(a)(3)(iii) and (b)(13) .....	Deleted the reference to § 63.10(b)(2)(iii) in paragraph (a)(3)(iii) because, as noted in Table 1 to subpart GGG, this section of the General Provisions does not apply to subpart GGG. The reference also is unnecessary because the requirement to record maintenance performed on the control device is clearly specified in this paragraph. However, because this maintenance recordkeeping requirement will not always be related to a startup, shutdown, or malfunction procedure, we also moved it to a new paragraph (b)(13).
§ 63.1259(b)(5)(i) .....	Corrected this paragraph by removing the references to individual process vents and § 63.1254(a)(3). This paragraph requires records of emissions for certain nonstandard batches. At an existing source, these records are needed to demonstrate compliance with a process-based percent reduction requirement for process vents from nonstandard batches if you control some vents to more than 93 percent and others to less than 93 percent (or 98 percent for new sources). Assuming the monitored operating parameters are at acceptable levels, the control efficiency for each control device is unchanged, but the overall control level for the process could change if the impact of the nonstandard batch on uncontrolled emissions is not identical for each vent. This situation cannot occur for individual vents that are subject to percent reduction requirements under § 63.1254(a)(3); thus, there is no need to maintain a record of nonstandard batch emissions for these vents.

TABLE 1.—MINOR TECHNICAL CORRECTIONS TO SUBPART GGG—Continued

Section of subpart GGG	Description of correction
§ 63.1259(b)(8) .....	Revised this paragraph to require a log or schedule of operating scenarios that is updated daily or, at a minimum, each time a different operating scenario takes effect. The original requirements to update the schedule or log daily and prior to making a change are unnecessarily burdensome.
§ 63.1259(i)(7) .....	Paragraph (i)(7) requires records of information associated with inspections of closed vent systems during which a leak is detected. As currently written, paragraph (i)(7)(i) requires records identifying the leaking equipment and records of the instrument identification number and operator name. This paragraph may be confusing because the instrument identification number and operator name can be recorded only for leaks that are detected using the instrument method. To clarify the requirements, we revised the language and split it into two paragraphs. The revised paragraph (i)(7)(i) requires records identifying the leaking equipment; this record is required regardless of the technique used to identify the leak. The revised paragraph (i)(7)(ii) requires a record of the instrument identification number and operator name for each leak that is detected using the instrument method. For each leak detected by sensory observations, this paragraph also requires a record indicating that the leak was detected by sensory observations. The original paragraphs (i)(7)(ii) through (viii) are redesignated as paragraphs (i)(7)(iii) through (ix).
§ 63.1260(g)(1) .....	Added statement specifying that each periodic report after the first report covers the 6-month period following the preceding report. Also deleted the requirement to submit the Periodic reports 60 operating days after the end of the applicable reporting period because it could conflict with the requirements to submit the first periodic report no later than 240 days after the Notification of Compliance Status Report is due and to submit subsequent reports every 6 months thereafter. These changes also make paragraph (g)(1) consistent with § 63.1255(h)(3)(i).
§ 63.1260(g)(2)(v) .....	Corrected this paragraph by replacing the incorrect reference to paragraph (g)(2)(iv)(A) with the correct reference to paragraph (g)(2)(v)(A).
§ 63.1260(g)(2)(vii) .....	Revised this paragraph to specify that the first periodic report must include each operating scenario operated since the due date of the Notification of Compliance Status Report, not since the compliance date. This change makes the time period for this information consistent with the time period covered by the first periodic report, as specified in § 63.1260(g)(1).
§ 63.1260(h) .....	Revised this paragraph to require process change notifications as part of the Periodic report instead of quarterly. We determined that requiring submittal of the process change notification more frequently than the Periodic report was an unnecessary burden.
§ 63.1260(i) .....	We made two changes to clarify this paragraph and make it more consistent with the startup, shutdown, and malfunction (SSM) reporting requirements in § 63.10(d)(5). First, we split the requirements into two paragraphs; the first paragraph specifies reporting requirements for actions that are consistent with the SSM plan, and the second paragraph specifies immediate reporting requirements for actions that are not consistent with the SSM plan. Second, we deleted the requirement to report records required by § 63.1259(a)(3)(iii) because reporting this information is inconsistent with § 63.10(d)(5)(i) of the General Provisions, which requires only a statement that the procedures in the SSM plan were followed.
Table 1 to subpart GGG .....	Corrected typesetting errors in entries §§ 63.1(c)(5), 63.5(e), and 63.8(e)(5)(i). Also corrected the entry for § 63.6(i) by replacing the incorrect reference to § 63.1250(f)(4) with the correct reference to § 63.1250(f)(6), and by indicating that the approval provisions in § 63.6(i)(7) through (14) apply to requests for approval of compliance extensions that are requested according to § 63.1250(f)(6).

**VII. What Are the Administrative Requirements for This Direct Final Rule?**

*A. Executive Order 12866, Regulatory Planning and Review*

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

- (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the

environment, public health or safety, or State, local, or tribal governments or communities;

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

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

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

Pursuant to the terms of Executive Order 12866, it has been determined that these amendments do not constitute a “significant regulatory action” because they do not meet any of the above criteria. Consequently, this action was

not submitted to OMB for review under Executive Order 12866.

*B. Executive Order 13132, Federalism*

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



These rule amendments do not have federalism implications. They will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because State and local governments do not own or operate any sources that would be subject to these amendments. Thus, the requirements of section 6 of the Executive Order do not apply to these rules.

*C. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments*

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" are defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes."

These rule amendments do not have tribal implications. They will not have substantial direct effects on tribal governments, or on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. No tribal governments own or operate pharmaceutical production facilities. Thus, Executive Order 13175 does not apply to these rule amendments.

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

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Executive Order has the potential to influence the regulation. These rule amendments are not subject to Executive Order 13045 because they are based on technology performance, not health or safety risks. Furthermore, these rule amendments have been determined not to be "economically significant" as defined under Executive Order 12866.

*E. Unfunded Mandates Reform Act of 1995*

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, local, and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least-costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least-costly, most cost-effective, or least-burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The EPA has determined that these rule amendments do 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 1 year. The maximum total annual cost of the Pharmaceuticals Production NESHAP for any year has been estimated to be approximately \$64 million (63 FR 50287, September 21, 1998), and today's amendments do not add new requirements that would increase this cost. Thus, these rule amendments are not subject to the requirements of sections 202 and 205 of the UMRA. In addition, EPA has determined that these rule amendments contain no regulatory requirements that might significantly or uniquely affect small governments because they contain no requirements that apply to such governments or impose obligations upon them. Therefore, these rule amendments are not subject to the requirements of section 203 of the UMRA.

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

The EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this direct final rule. The EPA has also determined that this direct final rule will not have a significant impact on a substantial number of small entities. For purposes of assessing the impacts of this direct final rule on small entities, a small entity is defined as: (1) A small business in the North American Industrial Classification System (NAICS) code 325411 or 325412 that has as many as 750 employees; (2) a small business in NAICS code 325199 that has as many as 1,000 employees; (3) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (4) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's rule amendments on small entities, EPA has concluded that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives "which minimize any

significant economic impact on small entities” (5 U.S.C. sections 603 and 604). Thus, an agency may conclude that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. Today’s rule amendments impose no additional regulatory requirements on owners or operators of affected sources, many of the rule amendments provide additional compliance options, and other rule amendments clarify requirements and correct minor drafting errors. We have therefore, concluded that these rules will relieve regulatory burden for all small entities.

*G. Paperwork Reduction Act*

The OMB has approved the information collection requirements contained in the 1998 pharmaceuticals production NESHAP 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 by mail at U.S. Environmental Protection Agency, Office of Environmental Information, Collection Strategies Division (2822), 1200 Pennsylvania Avenue, NW, Washington DC 20460, by email at farmer.sandy@epa.gov, or by calling (202) 260–2740.

The amendments contained in these final rules will have no net impact on the information collection burden estimates made previously. Consequently, the ICR has not been revised.

*H. National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), Public Law 104–113 (March 7, 1996), directs all Federal agencies to use voluntary consensus standards instead of government-unique standards in their regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., material specifications, test methods, sampling and analytical procedures, and business practices) that are developed or adopted by one or more voluntary consensus bodies. Examples of organizations generally regarded as voluntary consensus standards bodies include the American Society for Testing and Materials (ASTM), the National Fire Protection Association (NFPA), and the Society of Automotive

Engineers (SAE). The NTTAA requires Federal agencies like EPA to provide explanations when an agency does not use available and applicable voluntary consensus standards.

During the rulemaking, EPA searched for voluntary consensus standards that might be applicable. The search identified no applicable voluntary consensus standards. Accordingly, the NTTAA requirement to use applicable voluntary consensus standards does not apply to this direct final rule.

*I. Congressional Review Act*

The Congressional Review Act (CRA), 5 U.S.C. 801, *et seq.*, as added by the SBREFA of 1996, generally provides that before a rule may take effect, the agency adopting 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 direct final rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This direct final rule is not a “major rule” as defined by 5 U.S.C. 804(2). This direct final rule will be effective on October 16, 2001.

Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement (5 U.S.C. 808(2)). As stated previously, for the amendments to the table that lists OMB control numbers, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of August 2, 2001. 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 action is not a “major rule” as defined by 5 U.S.C. 804(2).

*J. Executive Order 13211 (Energy Effects)*

This rule is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

**List of Subjects in 40 CFR Parts 9 and 63**

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

Dated: July 24, 2001.

**Christine Todd Whitman,**  
*Administrator.*

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

**PART 9—[AMENDED]**

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

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

2. Section 9.1 is amended by revising the entry “63.1259–63.1260” in 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. <sup>3</sup>	* * * * *
* * * * *	63.1259–63.1260 .....	2060–0358
* * * * *		* * * * *

<sup>3</sup> The ICR’s referenced in this section of the table encompass the applicable General Provisions contained in 40 CFR part 63, subpart A, which are not independent information collection requirements.

**PART 63—[AMENDED]**

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

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

**Subpart GGG—National Emission Standards for Pharmaceuticals Production**

4. Section 63.1250 is amended by:  
a. Revising paragraph (e); and

b. Revising paragraph (h)(2). The revisions read as follows:

**§ 63.1250 Applicability.**

\* \* \* \* \*

(e) *Storage tank ownership determination.* The owner or operator shall follow the procedures specified in paragraphs (e)(1) through (5) of this section to determine to which PMPU a storage tank shall belong. If an owner or operator produces only pharmaceutical products, the procedures specified in paragraphs (e)(1) through (5) of this section are required only to determine applicability and demonstrate compliance with the pollution-prevention alternative specified in § 63.1252(e), or to determine new source applicability for a PMPU dedicated to manufacturing a single product as specified in paragraph (b) of this section.

(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 process units (including at least one PMPU), then the storage tank shall belong to the process unit 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 or process unit has the predominant use of the storage tank).

(3) If predominant use cannot be determined for a storage tank that is shared among process units (including at least one PMPU), then the owner or operator shall assign the storage tank to any one of the PMPU's that shares it and is also subject to this subpart.

(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.

\* \* \* \* \*

(h) \* \* \*

(2) *Consistency with 40 CFR parts 264 and 265, subparts AA, BB, and/or CC.*

(i) After the compliance dates specified in this section, if any control device 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, recordkeeping, 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) and (i). 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.

(ii) After the compliance dates specified in this section, if any equipment at an affected source that is subject to § 63.1255, is also subject to 40 CFR part 264, subpart BB, or to 40 CFR part 265, subpart BB, then compliance with the recordkeeping and reporting requirements of 40 CFR parts 264 and/or 265 may be used to comply with the recordkeeping and reporting requirements of § 63.1255, to the extent that the requirements of 40 CFR parts 264 and/or 265 duplicate the requirements of § 63.1255. The owner or operator shall identify in the Notification of Compliance Status, required by § 63.1260(f), if the owner or operator will comply with the recordkeeping and reporting authority under 40 CFR parts 264 and/or 265.

\* \* \* \* \*

5. Section 63.1251 is amended by adding a definition in alphabetical order

for *centralized combustion control device* to read as follows:

**§ 63.1251 Definitions.**

\* \* \* \* \*

*Centralized combustion control device (CCCD)* means enclosed combustion devices that are used to control process vent emissions from non-dedicated PMPU's at a facility. Centralized combustion control devices may also be used to control emissions from source types including, but not limited to, storage tanks, waste management units, and equipment leaks.

\* \* \* \* \*

6. Section 63.1252 is amended by adding paragraph (h) to read as follows:

**§ 63.1252 Standards: General.**

\* \* \* \* \*

(h) *Planned routine maintenance for centralized combustion control devices.* The owner or operator may operate non-dedicated PMPU's during periods of planned routine maintenance for CCCD in accordance with the provisions specified in paragraphs (h)(1) through (6) of this section.

(1) For equipment leaks and wastewater emissions that normally are controlled by the CCCD, if any, the owner or operator must continue to comply with the requirements in §§ 63.1255(b)(4)(ii) and 63.1256(h), respectively, using other control devices during the planned routine maintenance period for the CCCD.

(2) During the planned routine maintenance period, the owner or operator must route emissions from process vents with organic HAP emissions greater than 15 pounds per day (lb/day) through a closed-vent system to a condenser that meets the conditions specified in paragraphs (h)(2)(i) through (iii) of this section.

(i) The outlet gas temperature must be less than  $-50^{\circ}\text{C}$  ( $-58^{\circ}\text{F}$ ) when the emission stream contains organic HAP with a partial pressure greater than 20 kPa (2.9 psia).

(ii) The outlet gas temperature must be less than  $-5^{\circ}\text{C}$  ( $23^{\circ}\text{F}$ ) when the emission stream contains organic HAP with a partial pressure less than or equal to 20 kPa (2.9 psia).

(iii) The HAP partial pressures in paragraphs (h)(2)(i) and (ii) of this section must be determined at  $25^{\circ}\text{C}$ .

(3) The owner or operator must route HCl emissions from process vents with HCl emissions greater than 15 lb/day through a closed-vent system to a caustic scrubber, and the pH of the scrubber effluent must be maintained at or above 9.

(4) For the purposes of the emission calculations required in paragraphs (h)(2) and (3) of this section, the term "process vent" shall mean each vent from a unit operation. The emission calculation shall not be performed on the aggregated emission stream from multiple unit operations that are manifolded together into a common header. Once an affected process vent has been controlled in accordance with this section, it is no longer subject to the requirements of this section or § 63.1254 during the routine maintenance period.

(5) The total period of planned routine maintenance, during which non-dedicated PMPU's that are normally controlled by the CCCD continue to operate, and process vent emissions are controlled as specified in paragraphs (h)(2) and (3) of this section, must not exceed 240 hours in any 365-day period.

(6) While being controlled as specified in paragraphs (h)(2) and (3) of this section, the process vents may not be used in emissions averaging.

7. Section 63.1253 is amended by:

a. Redesignating paragraphs (b)(2) through (4) as paragraphs (b)(3) through (5) and adding paragraph (b)(2);

b. Redesignating paragraphs (c)(2) through (4) as paragraphs (c)(3) through (5) and adding paragraph (c)(2);

c. Revising the second sentence in paragraph (e); and

d. Revising "paragraph (b)(7)(i)" to read "paragraph (f)(7)" in paragraph (f)(7)(i).

The revisions and additions read as follows:

§ 63.1253 Standards: Storage tanks.

\* \* \* \* \*

(b) \* \* \*

(2) Reduces emissions 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;

\* \* \* \* \*

(c) \* \* \*

(2) Reduces emissions 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; STARS≤

(e) \* \* \* Periods of planned routine maintenance of the control devices (including CCCD subject to § 63.1252(h)), 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 in any 365-day period.

\* \* \* \* \*

8. Section 63.1254 is amended by adding paragraph (a)(4) to read as follows:

§ 63.1254 Standards: Process vents.

(a) \* \* \*

(4) *Planned routine maintenance.* For each PMPU that is controlled with a CCCD, the owner or operator must comply with the provisions specified in either paragraph (a)(4)(i), (ii), or (iii) of this section during periods of planned routine maintenance of the CCCD. The owner or operator is not required to comply with the same provision for all of the PMPU's controlled by the CCCD.

(i) Shutdown the affected process.

(ii) Comply with the requirements of paragraphs (a)(1) through (3) of this section by using other means.

(iii) For a non-dedicated PMPU, implement the procedures described in paragraphs (a)(4)(iii)(A) through (C) of this section for those process vents that are normally controlled by the CCCD. This option is not available for process vents from dedicated PMPU's.

(A) If the owner or operator uses a CCCD to comply with the 93 percent reduction requirement in paragraph (a)(1)(i) or (ii) of this section, the outlet concentration limit in paragraph (a)(1)(ii)(A) of this section, the alternative standard as specified in paragraphs (a)(1)(ii)(D) and (c) of this section, or the annual mass limit in paragraph (a)(2) of this section, implement the provisions in § 63.1252(h) during planned routine maintenance of the CCCD.

(B) If the owner or operator reduces HAP emissions from process vents by using a CCCD that is also a control device specified in § 63.1257(a)(4), implement the provisions in § 63.1252(h) during planned routine maintenance of the CCCD.

(C) If the owner or operator uses a CCCD to reduce emissions from a process vent subject to paragraph (a)(3) of this section, implement the planned routine maintenance provisions in § 63.1252(h) for that vent only if the reason the planned routine maintenance is needed, and the reason it cannot be performed at a time when the vent subject to paragraph (a)(3) of this section is not operating, has been described in the Notification of Compliance Status Report or a periodic report submitted before the planned routine maintenance event.

\* \* \* \* \*

9. Section 63.1255 is amended by:

a. Adding paragraph (b)(4)(ii)(C);

b. Revising "paragraphs (b)(3)(iii)(B) through (F)" to read "paragraphs (b)(4)(iii)(B) through (F)" in paragraph (b)(4)(iii)(A);

c. Revising paragraph (b)(4)(iii)(D);

d. Revising paragraph (c)(2)(iii);

e. Revising paragraph (c)(3)(i);

- f. Revising paragraph (c)(4)(ii);
- g. Revising paragraph (c)(5)(iv);
- h. Removing paragraphs (c)(5)(vi)(C) and (D) and adding paragraph (c)(5)(vii);
- i. Adding a sentence at the end of paragraph (e)(7)(iii) introductory left;
- j. Revising the second sentence in paragraph (e)(9);
- k. Revising paragraph (h)(1)(ii); and
- l. Revising paragraph (h)(3)(i).

The revisions and additions read as follows:

§ 63.1255 Standards: Equipment leaks.

\* \* \* \* \*

(a) \* \* \*

(4) \* \* \*

(ii) \* \* \*

(C) The requirements apply at all times, except as specified in § 63.1250(g). The owner or operator may not comply with the planned routine maintenance provisions in § 63.1252(h).

(iii) \* \* \*

(D) Except as provided in paragraph (b)(4)(iii)(B) of this section, if leaking connectors comprise at least 0.5 percent but less than 1.0 percent of the connectors during the last monitoring period, the owner or operator shall monitor at least once every 2 years for the next monitoring period. At the end of that 2-year monitoring period, if the percent leaking connectors is greater than or equal to 0.5 percent, the owner or operator shall monitor once per year until the percent leaking connectors is less than 0.5 percent. If, at the end of a monitoring period, the percent leaking connectors is less than 0.5 percent, the owner or operator shall monitor in accordance with paragraph (b)(4)(iii)(C) or (F) of this section, as appropriate.

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

(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 pump or agitator seal at the time of the weekly inspection, the owner or operator shall follow the procedure specified in either paragraph (c)(2)(iii)(A) or (B) of this section prior to the next weekly inspection.

(A) The owner or operator shall monitor the pump or agitator by the method specified in § 63.180(b). If the instrument reading indicates a leak as specified in paragraph (c)(2)(ii) of this section, a leak is detected.

(B) The owner or operator shall eliminate the visual indications of liquids dripping.

(3) \* \* \*

(i) When a leak is detected pursuant to paragraph (c)(2)(i), (c)(2)(iii)(A),

(c)(5)(iv)(A), or (c)(5)(vi)(B) of this section, 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)(4)(i) of this section.

\* \* \* \* \*

(4) \* \* \*

(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, until the calculated 1-year rolling average value drops below 10 percent or three pumps, as applicable.

\* \* \* \* \*

(5) \* \* \*

(iv) Each pump/agitator is checked by visual inspection each calendar week for indications of liquids dripping from the pump/agitator seal. If there are indications of liquids dripping from the pump or agitator seal at the time of the weekly inspection, the owner or operator shall follow the procedures specified in either paragraph (c)(5)(iv)(A) or (B) of this section prior to the next required inspection.

(A) The owner or operator shall monitor the pump or agitator using the method specified in § 63.180(b) to determine if there is a leak of organic HAP in the barrier fluid. If the instrument reading indicates a leak, as specified in paragraph (c)(2)(ii) of this section, a leak is detected.

(B) The owner or operator shall eliminate the visual indications of liquids dripping.

\* \* \* \* \*

(vii) When a leak is detected pursuant to paragraph (c)(5)(iv)(A) or (B) of this section, the leak must be repaired as specified in paragraph (c)(3) of this section.

\* \* \* \* \*

(e) \* \* \*

(7) \* \* \*

(iii) \* \* \* The monitoring required by this paragraph is in addition to the monitoring required to satisfy the definitions of "repaired" and "first attempt at repair."

\* \* \* \* \*

(9) \* \* \* Instead, the owner or operator shall monitor each valve in organic HAP service for leaks once each quarter, or comply with paragraph (e)(4)(iii), (iv), or (v) of this section, except as provided in paragraph (f) of this section.

\* \* \* \* \*

(h) \* \* \*

(1) \* \* \*

(ii) Periodic reports described in paragraph (h)(3) of this section.

\* \* \* \* \*

(3) \* \* \*

(i) A report containing the information in paragraphs (h)(3)(ii), (iii), and (iv) of this section shall be submitted semiannually. The first report shall be submitted no later than 240 days after the Notification of Compliance Status Report is due and shall cover the 6-month period beginning on the date the Notification of Compliance Status Report is due. Each subsequent report shall cover the 6-month period following the preceding period.

\* \* \* \* \*

10. Section 63.1256 is amended by:

a. Revising "paragraph (c)(1)(iv)" to read "paragraph (c)(1)(v)" in paragraph (c)(1)(i)(A);

b. Revising "flexible cap" to read "flexible shield" in the last sentence in paragraph (e)(4)(i)(B);

c. Revising paragraph (e)(4)(iii);

d. Revising paragraph (g)(9)(ii);

e. Revising the first sentence in paragraph (g)(10);

f. Revising paragraph (h) introductory text; and

g. Adding paragraph (h)(5).

The revisions and additions read as follows:

**§ 63.1256 Standards: Wastewater.**

\* \* \* \* \*

(e) \* \* \*

(4) \* \* \*

(iii) The owner or operator shall operate and maintain sewer lines as specified in paragraphs (e)(4)(iii)(A) and (B) of this section.

(A) Except as specified in paragraph (e)(4)(iii)(B) of this section, 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.

(B) A sewer line connected to drains that are in compliance with paragraph (e)(4)(i) of this section may be vented to the atmosphere, provided that the sewer line entrance to the first downstream junction box is water sealed and the sewer line vent pipe is designed as specified in paragraph (e)(4)(ii)(B)(1) of this section.

\* \* \* \* \*

(g) \* \* \*

(9) \* \* \*

(ii) *Percent mass removal/destruction option.* The owner or operator shall reduce the mass of total soluble HAP by 90 percent or more, either by removal or destruction. The removal/destruction efficiency shall be determined by the procedures in § 63.1257(e)(2)(ii) or

(e)(2)(iii)(C) for noncombustion, nonbiological treatment processes; § 63.1257(e)(2)(ii) or (e)(2)(iii)(D) for combustion processes; § 63.1257(e)(2)(iii)(F) for open biological treatment processes; and § 63.1257(e)(2)(ii) or (e)(2)(iii)(G) for closed, 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 in an enhanced biological treatment system, as defined in § 63.1251, provided the wastewater stream contains less than 50 ppmw partially soluble HAP, or the owner or operator complies with the requirements of paragraph (g)(8) of this section before treating the affected wastewater stream in the enhanced biological treatment system. \* \* \*

\* \* \* \* \*

(h) 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 (5) of this section.

\* \* \* \* \*

(5) The provisions in paragraphs (h)(1) through (4) of this section apply at all times, except as specified in § 63.1250(g). The owner or operator may not comply with the planned routine maintenance provisions in § 63.1252(h) for vent streams from waste management units.

\* \* \* \* \*

11. Section 63.1257 is amended by:

a. Revising the last sentence in paragraph (a)(6);

b. Revising paragraph (b)(10)(ii);

c. Revising paragraph (c)(1) introductory text;

d. Adding a sentence at the end of paragraph (d)(1)(i);

e. Revising " $N_{HAP}$ " to read " $n_{HAP}$ " in equation 31 in paragraph (d)(2)(i)(D)(9);

f. Revising paragraph (d)(2)(i)(D)(10);

g. Adding a sentence after the first sentence in paragraph (d)(2)(i)(E);

h. Revising "paragraphs (d)(2)(iii)(B)(1) and (2)" to read "paragraphs (d)(3)(iii)(B)(1) and (2)" in paragraph (d)(3)(iii)(B) introductory text;

i. Revising "paragraph (b)(10)(iii)" to read "paragraph (b)(10)(vi)" and revising "paragraphs (b)(10)(i), (ii), and (iii)" to read "paragraphs (b)(10)(i) through (vi)" in paragraph (e)(2)(iii)(B); and

j. Revising "paragraph (b)(10)(v)" to read "paragraph (b)(10)(vi)" in

paragraphs (e)(2)(iii)(C)(1), (D)(1), and (E)(1).

The revisions and additions read as follows:

**§ 63.1257 Test methods and compliance procedures.**

(a) \* \* \*  
 (6) \* \* \* The owner or operator shall comply with the monitoring provisions in § 63.1258(b)(1) through (4) on the initial compliance date.

\* \* \* \* \*

(b) \* \* \*  
 (10) \* \* \*

(ii) *EPA Method 624, 625, 1624, 1625, 1666, or 1671.* Use procedures specified in EPA Method 624, 625, 1624, 1625, 1666, or 1671 of 40 CFR part 136,

appendix A, and comply with requirements in paragraph (b)(10)(vi) of this section.

\* \* \* \* \*

(c) \* \* \*

(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. To demonstrate initial compliance with the outlet concentration requirements in § 63.1253(b)(2) and (c)(2), the owner or operator must conduct a performance

test and fulfill the requirements of paragraph (a)(6) of this section.

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(i) \* \* \* Controlled emissions during periods of planned routine maintenance of a CCCD as specified in § 63.1252(h), must be calculated assuming the HAP emissions are reduced by 93 percent.

\* \* \* \* \*

(2) \* \* \*

(i) \* \* \*

(D) \* \* \*

(10) Emissions from depressurization may be calculated using equation 32 of this subpart:

$$E = \frac{V}{(R)(T)} \times \ln \left( \frac{P_1 - \sum_{j=1}^m (P_j)}{P_2 - \sum_{j=1}^m (P_j)} \right) \times \sum_{i=1}^n (P_i)(MW_i) \quad (\text{Eq. 32})$$

Where:

V = free volume in vessel being depressurized

R = ideal gas law constant

T = temperature of the vessel, absolute

P<sub>1</sub> = initial pressure in the vessel

P<sub>2</sub> = final pressure in the vessel

P<sub>j</sub> = partial pressure of the individual condensable compounds (including HAP)

MW<sub>i</sub> = molecular weight of the individual HAP compounds

n = number of HAP compounds in the emission stream

m = number of condensable compounds (including HAP) in the emission stream

i = identifier for a HAP compound

j = identifier for a condensable compound.

(E) \* \* \* The individual HAP partial pressures may be calculated using Raoult's Law. \* \* \*

\* \* \* \* \*

- 12. Section 63.1258 is amended by:
  - a. Revising paragraph (b)(3) heading;
  - b. Revising paragraph (b)(5)(i)(A);
  - c. Revising paragraph (b)(5)(ii)(A)(2);
  - d. Revising paragraph (b)(8)(iii);
  - e. Adding a sentence between the first and second sentences in paragraph (c);
  - f. Revising "paragraph (h)(9)" to read "paragraphs (h)(9) and (10)" in paragraph (h)(1);
  - g. Revising "paragraph (h)(8)(i)" to read "paragraph (h)(8)" in paragraph (h)(6) introductory text;
  - h. Revising "paragraph (h)(8)(ii)" to read "paragraph (h)(8)" in paragraph (h)(7) introductory text;

i. Adding paragraph (h)(10); and

j. Adding paragraph (i).

The revisions and additions read as follows:

**§ 63.1258 Monitoring requirements.**

\* \* \* \* \*

(b) \* \* \*

(3) *Procedures for setting parameter levels for control devices used to control emissions.* \* \* \*

\* \* \* \* \*

(5) \* \* \*

(i) \* \* \*

(A) A TOC monitor meeting the requirements of EPA Performance Specification 8, 9, or 15 of appendix B of 40 CFR part 60 shall be installed, calibrated, and maintained according to § 63.8.

\* \* \* \* \*

(ii) \* \* \*

(A) \* \* \*

(2) If complying with the alternative standard instead of achieving a control efficiency of 98 percent, the owner or operator must maintain a minimum residence time of 0.75 seconds and a minimum combustion chamber temperature of 816°C.

\* \* \* \* \*

(8) \* \* \*

(iii) Except as provided in paragraph (b)(8)(iv) of this section, exceedances of the 20 or 50 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 or 50

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.

\* \* \* \* \*

(c) \* \* \* During periods of planned routine maintenance when emissions are controlled as specified in § 63.1252(h), the owner or operator must calculate controlled emissions assuming the HAP emissions are reduced by 93 percent. \* \* \*

\* \* \* \* \*

(h) \* \* \*

(10) Instead of complying with the provisions of paragraphs (h)(2) through (8) of this section, an owner or operator may design a closed-vent system to operate at a pressure below atmospheric pressure. The system shall be equipped with at least one pressure gauge 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.

(i) *Planned routine maintenance.* During periods of planned routine maintenance when organic HAP emissions are controlled as specified in § 63.1252(h)(2), the owner or operator must monitor the condenser outlet gas temperature according to the procedures specified in paragraph (b)(1)(iii) of this section. During periods of planned routine maintenance when HCl emissions are controlled as specified in § 63.1252(h)(3), the owner or operator

must monitor the pH of the scrubber effluent once per day.

13. Section 63.1259 is amended by:

- a. Revising paragraph (a)(3)(iii);
- b. Revising paragraph (b)(5)(i)

introductory text;

- c. Redesignating paragraphs (b)(5)(ii)(D) and (E) as paragraphs (b)(5)(ii)(E) and (F);

- d. Adding paragraph (b)(5)(ii)(D);
- e. Revising paragraph (b)(8);
- f. Revising paragraph (b)(10);
- g. Adding paragraph (b)(13);
- h. Revising "paragraphs (i)(7)(i)

through (viii)" to read "paragraphs (i)(7)(i) through (ix)" in paragraph (i)(7) introductory text; and

- i. Redesignating paragraphs (i)(7)(i) through (viii) as paragraphs (i)(7)(ii) through (ix), adding paragraph (i)(7)(i), and revising redesignated paragraph (i)(7)(ii).

The revisions and additions read as follows:

**§ 63.1259 Recordkeeping requirements.**

- (a) \* \* \*
- (3) \* \* \*

(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).

- (b) \* \* \*
- (5) \* \* \*

(i) For processes that are in compliance with the percent reduction requirements of § 63.1254(a)(1) or (b)(1) and that contain vents controlled to less than the percent reduction requirement, the records specified in paragraphs (b)(5)(i)(A) through (C) of this section are required.

- (ii) \* \* \*

(D) Actual controlled emissions for each batch operated during periods of planned routine maintenance of a CCCD, calculated according to § 63.1258(c).

(8) A schedule or log of each operating scenario updated daily or, at a minimum, each time a different operating scenario is put into operation.

(10) Periods of planned routine maintenance as described in §§ 63.1252(h) and 63.1257(c)(5).

(13) All maintenance performed on the air pollution control equipment.

- (i) \* \* \*
- (7) \* \* \*

(i) Identification of the leaking equipment.

(ii) The instrument identification numbers and operator name or initials, if the leak was detected using the procedures described in § 63.1258(h)(3); or a record that the leak was detected by sensory observations.

- \* \* \* \* \*

14. Section 63.1260 is amended by:

- a. Adding paragraph (f)(7);
- b. Revising paragraph (g)(1) introductory text;
- c. Revising "paragraphs (g)(2)(iv)(A) through (D)" to read "paragraphs (g)(2)(v)(A) through (D)" in paragraph (g)(2)(v) introductory text;
- d. Revising paragraph (g)(2)(vi);
- e. Revising the last sentence in paragraph (g)(2)(vii);
- f. Revising paragraph (h)(1) introductory text; and
- g. Revising paragraph (i).

The revisions and additions read as follows:

**§ 63.1260 Reporting requirements.**

- \* \* \* \* \*
- (f) \* \* \*

(7) Anticipated periods of planned routine maintenance of a CCCD subject to § 63.1252(h) during the period between the compliance date and the end of the period covered by the first Periodic report, and if applicable, the rationale for why the planned routine maintenance must be performed while a process with a vent subject to § 63.1254(a)(3) will be operating.

(g) \* \* \*

(1) *Submittal schedule.* Except as provided in paragraphs (g)(1)(i), (ii), and (iii) of this section, an owner or operator shall submit Periodic reports semiannually. The first report shall be submitted no later than 240 days after 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. Each subsequent Periodic report shall cover the 6-month period following the preceding period.

- \* \* \* \* \*
- (2) \* \* \*

(vi) The information specified in paragraphs (g)(2)(vi)(A) through (C) for periods of planned routine maintenance.

(A) For each storage 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).

(B) For a CCCD subject to § 63.1252(h), periods of planned routine maintenance during the current reporting period and anticipated periods of planned routine maintenance during the next reporting period.

(C) Rationale for why planned routine maintenance of a CCCD subject to § 63.1252(h) must be performed while a process with a vent subject to § 63.1254(a)(3) will be operating, if applicable. This requirement applies only if the rationale is not in, or differs from that in, the Notification of Compliance Status report.

(vii) \* \* \* For the initial Periodic report, each operating scenario for each process operated since the due date of the Notification of Compliance Status Report shall be submitted.

- \* \* \* \* \*

- (h) \* \* \*

(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 the information specified in paragraphs (h)(1)(i) through (iv) of this section with the next Periodic report required under paragraph (g) of this section.

- \* \* \* \* \*

(i) *Reports of startup, shutdown, and malfunction.* An owner or operator shall prepare startup, shutdown, and malfunction reports as specified in paragraphs (i)(1) and (2) of this section.

(1) If actions taken by an owner or operator during a startup, shutdown, or malfunction of an affected source (including actions to correct a malfunction) are consistent with the procedures specified in the source's startup, shutdown, and malfunction plan, the owner or operator shall state this fact in a startup, shutdown, or malfunction report. The report shall also include the information specified in § 63.1259(a)(3)(i) and (ii) and shall contain the name, title, and signature of the owner or operator or other responsible official who is certifying its accuracy. 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). Reports are only required if a startup, shutdown, or malfunction occurred during the reporting period.

(2) 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 immediate startup,

shutdown, and malfunction reports as specified in § 63.10(d)(5)(ii).

\* \* \* \* \*

15. Table 1 to subpart GGG is amended by:

a. Revising entries "63.1(c)(5)," "63.5(e)," and "63.8(e)(5)(i)"; and  
 b. Removing entry "63.6(i)" and adding entries "63.6(i) (1) through (7)" and "63.6(i) (8) through (14)."  
 The revisions and additions read as follows:

TABLE 1 TO SUBPART GGG.—GENERAL PROVISIONS APPLICABILITY TO SUBPART GGG

General provisions reference	Summary of requirements	Applies to subpart GGG	Comments
* § 63.1(c)(5) .....	* Notification requirements for an area source that increases HAP emissions to major source levels.	* Yes	* *
* § 63.5(e) .....	* Construction/reconstruction approval .....	* Yes	* *
* § 63.6(i)(1) through (7) .....	* Requests for compliance extensions .....	* No .....	* § 63.1250(f)(6) specifies provisions for compliance extensions.
* § 63.6(i)(8) through (14) .....	* Approval of compliance extensions .....	* Yes .....	* Except references to § 63.6(i)(4) through (6) mean § 63.1250(f)(6).
* § 63.8(e)(5)(i) .....	* Reporting performance evaluation results	* Yes .....	* See § 63.1260(a).
* .....	* .....	* .....	* .....

16. Table 2 to subpart GGG is revised to read as follows:

TABLE 2 TO SUBPART GGG.—PARTIALLY SOLUBLE HAP

1,1,1-Trichloroethane (methyl chloroform) .....	Chloroform
1,1,2,2-Tetrachloroethane .....	Chloromethane
1,1,2-Trichloroethane .....	Chloroprene
1,1-Dichloroethylene (vinylidene chloride) .....	Cumene
1,2-Dibromoethane .....	Dichloroethyl ether
1,2-Dichloroethane (ethylene dichloride) .....	Dinitrophenol
1,2-Dichloropropane .....	Epichlorohydrin
1,3-Dichloropropene .....	Ethyl acrylate
2,4,5-Trichlorophenol .....	Ethylbenzene
2-Butanone (mek) .....	Ethylene oxide
1,4-Dichlorobenzene .....	Hexachlorobenzene
2-Nitropropane .....	Hexachlorobutadiene
4-Methyl-2-pentanone (MIBK) .....	Hexachloroethane
Acetaldehyde .....	Methyl methacrylate
Acrolein .....	Methyl-t-butyl ether
Acrylonitrile .....	Methylene chloride
Allyl chloride .....	N,N-dimethylaniline
Benzene .....	Propionaldehyde
Benzyl chloride .....	Propylene oxide
Biphenyl .....	Styrene
Bromoform (tribromomethane) .....	Tetrachloroethene (perchloroethylene)
Bromomethane .....	Tetrachloromethane (carbon tetrachloride)
Butadiene .....	Toluene
Carbon disulfide .....	Trichlorobenzene (1,2,4-)
Chlorobenzene .....	Trichloroethylene
Chloroethane (ethyl chloride) .....	Trimethylpentane
Vinyl acetate .....	Xylene (p)
Vinyl chloride .....	N-hexane
Xylene (m).	
Xylene (o).	



17. Table 3 to subpart GGG is revised to read as follows:

TABLE 3 TO SUBPART GGG.— SOLUBLE HAP—Continued

TABLE 3 TO SUBPART GGG.— SOLUBLE HAP—Continued

TABLE 3 TO SUBPART GGG.— SOLUBLE HAP
Compound
1,1-Dimethylhydrazine.
1,4-Dioxane.
Acetonitrile.
Acetophenone.

Compound
Diethyl sulfate.
Dimethyl sulfate.
Dinitrotoluene.
Ethylene glycol dimethyl ether.
Ethylene glycol monobutyl ether acetate.
Ethylene glycol monomethyl ether acetate.
Isophorone.

Compound
Methanol (methyl alcohol).
Nitrobenzene.
Toluidene.
Triethylamine.

18. Table 9 to subpart GGG. is revised to read as follows:

TABLE 9 TO SUBPART GGG—DEFAULT BIORATES FOR SOLUBLE HAP

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 monobutyl ether acetate .....	0.496
Ethylene glycol monomethyl ether acetate .....	0.159
Isophorone .....	0.598
Methanol .....	<sup>a</sup>
Nitrobenzene .....	2.300
Toluidine (-0) .....	0.859
Triethylamine .....	1.064

<sup>a</sup>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.

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[FL-83-1-200101; FRL-7022-3]

**Approval and Promulgation of Implementation Plans: Florida; Approval of Revisions to the Florida State Implementation Plan**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is approving revisions to the Florida State Implementation Plan (SIP) submitted on December 10, 1999, by the State of Florida through the Florida Department of Environmental Protection (FDEP). This submittal consists of revisions to the ozone air quality maintenance plans for the Jacksonville (Duval County) and Southeast Florida (Broward, Dade, and Palm Beach Counties) areas to remove the emission reduction credits attributable to the Motor Vehicle Inspection Program (MVIP) from the future year emission projections

contained in those plans. Florida submitted technical amendments to this revision on January 18, 2000. This revision updates the control strategy by removing emissions credit for the MVIP, and as such, transportation conformity must be redetermined by the Metropolitan Planning Organizations (MPOs) within 18 months of the final approval of this notice. EPA proposed approval of this revision to the Florida SIP on March 17, 2000.

**EFFECTIVE DATE:** This rule will be effective September 4, 2001.

**ADDRESSES:** Materials relevant to this rulemaking are contained in Docket No. FL83-200101. The docket is available at the following address for inspection during normal business hours: Environmental Protection Agency, Atlanta Federal Center, Region 4 Air Planning Branch, 61 Forsyth Street S.W., Atlanta, Georgia 30303-3104.

**FOR FURTHER INFORMATION CONTACT:** Joey LeVasseur at 404/562-9035 (E-mail: [levasseur.joey@epa.gov](mailto:levasseur.joey@epa.gov)).

**SUPPLEMENTARY INFORMATION:** The following sections: Background, Response to Comments, and Final Action, provide additional information concerning the revisions to the ozone air quality maintenance plans for the Jacksonville and Southeast Florida areas

to remove the emission reduction credits attributable to the MVIP from the future year emission projections contained in those plans.

**I. Background**

Today's action finalizes EPA's approval of the maintenance plan revisions submitted on December 10, 1999. A detailed description of Florida's submittal may be found in the Notice of Proposed Rulemaking for today's action, which was published in the **Federal Register** on March 17, 2000. On April 13, 2000, EPA extended the proposal's comment period and on June 20, 2000, EPA reopened the comment period and announced a public hearing. The hearing was held on July 20, 2000. EPA received numerous comments during the comment period. In addition to comments on the proposed action, EPA also received comments on the Florida Legislature's decision to shutdown the MVIP in all areas in the State. That decision and action by the Florida Legislature has no bearing on today's action and such comments will not be addressed here.

**II. Response to Comments**

1. *Comment:* "Elimination of the MVIP will result in adverse consequences. The likelihood that