



# Federal Register

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**Tuesday,  
August 29, 2000**

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**Part III**

## **Environmental Protection Agency**

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**40 CFR Part 63**

**National Emission Standards for  
Hazardous Air Pollutants for  
Pharmaceuticals Production; Final Rule**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 63**

[FRL-6855-1]

RIN 2060-AJ17

**National Emission Standards for Hazardous Air Pollutants for Pharmaceuticals Production**

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

**ACTION:** Final rule; amendments.

**SUMMARY:** On September 21, 1998 (63 FR 50280), EPA promulgated national emission standards for hazardous air pollutants (NESHAP) for Pharmaceuticals Production. On November 17 and 20, 1998, petitions for reconsideration and review of the September 1998 rule were filed in the U.S. Court of Appeals for the District of Columbia Circuit. The petitioners raised over 12 technical issues and concerns with the rule. Additional issues were raised by intervenors on the side of the petitioners. On April 10, 2000, EPA proposed amendments to the Pharmaceuticals Production NESHAP to address the issues raised by the petitioners. This document takes final action on those proposed amendments.

**EFFECTIVE DATE:** August 29, 2000.

**ADDRESSES:** Docket No. A-96-03 contains supporting information used in developing the NESHAP. The docket is located at the U. S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460 in Room M-1500, and may be inspected from 8:30 a.m. to 5:30 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** For information concerning these final amendments, contact Mr. Randy

McDonald, Organic Chemicals Group, Emission Standards Division (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5402, electronic mail address mcdonald.randy@epa.gov. For information concerning applicability and rule determinations, contact your State or local representative or the appropriate EPA Regional Office representative. Following is a listing of EPA Regional contacts.

**EPA Regional Office Contacts**

- Director, Office of Environmental Stewardship, Attn: Air Compliance Clerk: U.S. EPA Region I, 1 Congress Street, Suite 1100 (SEA), Boston, MA 02114-2023, (617) 918-1740
- Umesh Dholakia: U.S. EPA Region II, 290 Broadway Street, New York, NY 10007-1866, (212) 637-4023
- Doreen Au: U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103, (215) 814-5471
- Lee Page, U.S. EPA Region IV, 61 Forsyth Street, SW, Atlanta, GA 30303-3104, (404) 562-9131
- Shaun Burke, IL/IN, (312) 353-5713; Joseph Cardile, MI/WI, (312) 353-2151; Erik Hardin, MN/OH, (312) 353-2402; U.S. EPA Region V, 77 West Jackson Boulevard, Chicago, IL 60604-3507
- John Jones: U.S. EPA Region VI, 1445 Ross Avenue, Suite 1200 (6EN-AT), Dallas, TX 75202, (214) 665-7233
- Gary Schlicht: U.S. EPA Region VII, 726 Minnesota Avenue, Kansas City, KS 66101, (913) 551-7097
- Tami Thomas-Burton: U.S. EPA Region VIII, 999 18th Street, Suite 500, Denver, CO 80202, (303) 312-6581
- Ken Bigos: U.S. EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105, (415) 744-1240

Dan Meyer: U.S. EPA Region X, 1200 Sixth Street, Seattle, WA 98101, (206) 553-4150

**SUPPLEMENTARY INFORMATION: Docket.**

The docket is an organized and complete file of all the information considered by the EPA in the development of this rulemaking. The docket is a dynamic file because material is added throughout the rulemaking process. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the proposed and promulgated standards and their preambles, the contents of the docket will serve as the record in the case of judicial review. (See section 307(d)(7)(A) of the Clean Air Act (CAA).) The regulatory text and other materials related to this rulemaking are available for review in the docket or copies may be mailed on request from the Air Docket by calling (202) 260-7548. A reasonable fee may be charged for copying docket materials. *Worldwide Web (WWW).* In addition to being available in the docket, an electronic copy of this final rule will be available on the WWW through the Technology Transfer Network (TTN). Following signature, a copy of the rule will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules <http://www.epa.gov/ttn/oarpg>. The TTN provides information and technology exchange in various areas of air pollution control. 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 .. Typically 325199 .....	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 or precursor.</li> </ul>

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 promulgated rule, as well as in the amendments to the applicability sections contained in this action. 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.

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

- I. What is the history of the Pharmaceuticals Production NESHAP?
- II. What types of public comments were received on the April 10, 2000 proposal?

- III. What major issues were raised in the public comments and what changes were made for the final amendments?
  - A. Applicability
  - B. Compliance Dates
  - C. Process Vent Requirements
  - D. Wastewater Requirements
  - E. Recordkeeping
  - F. Delegation of Authority
  - G. Clarification of Statements in the Proposal Preamble
  - H. Technical Correction to Monitoring Requirements for Hydrogen Halides and Halogens

- I. Minor Corrections
- IV. What are the administrative requirements for these final amendments?
  - A. Executive Order 12866, Regulatory Planning and Review
  - B. Executive Order 13132, Federalism
  - C. Executive Order 13084, 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. Congressional Review Act

### **I. What Is the History of the Pharmaceuticals Production NESHAP?**

On September 21, 1998, we promulgated NESHAP for Pharmaceuticals Production as subpart GGG in 40 CFR part 63. On November 17 and 20, 1998, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed petitions for reconsideration and review of the promulgated Pharmaceuticals Production NESHAP in the U.S. Court of Appeals for the District of Columbia Circuit, *PhRMA v. EPA*, 98-1551 (D.C. Cir.). Issues raised by the petitioners included applicability of the rule, definition of a process, the 98 percent reduction requirement for certain process vents, the alternative standard, and recordkeeping requirements. The intervenors raised additional issues regarding the applicability of the rule to specialty chemical manufacturers and the clarity of the rule, especially with respect to the leak detection and repair (LDAR) provisions. On December 21, 1999, the parties filed a motion to lodge a settlement agreement with the court. The settlement agreement established a schedule by which EPA would propose revisions to the NESHAP and the preamble language agreed to by the parties. The settlement agreement provided that EPA would sign proposed rule amendments no later than 60 days after execution of the settlement. The settlement agreement also provided that EPA would sign final rule amendments no later than 180 days after the date on which the proposed amendments were signed. On February 22, 2000, the parties filed a motion to lodge a stipulation to modify the settlement agreement. The parties agreed to change the date by which EPA must sign the proposed rule amendments from 60 to 90 days after the execution of the settlement agreement (March 20, 2000). The date by which EPA must sign the

final amendments was not changed (August 21, 2000).

On April 10, 2000 (65 FR 19152), we proposed amendments to address the issues raised by PhRMA and the intervenors of the promulgated Pharmaceuticals Production NESHAP which include corrections and clarifications to ensure that the rule will be implemented as intended. In this action, we are promulgating the amendments proposed on April 10, 2000.

### **II. What Types of Public Comments Were Received on the April 10, 2000 Proposal?**

We received seven public comment letters on the April 10, 2000 proposed amendments. Six of the comment letters were from industry representatives, and one was from a university representative. The comments addressed the compliance dates, applicability, requirements for hydrogenation vents and wastewater, recordkeeping burden, and the delegation of authority. The commenters also identified errors and incomplete discussions in the preamble to the proposed amendments, minor inconsistencies between the proposed amendments and the settlement agreement, and miscellaneous typographical errors. Some commenters expressed support for the proposed changes. We considered these comments and, where appropriate, made changes to the proposed amendments. This preamble summarizes significant issues raised and the changes to the proposed amendments. Our response to all comments can be found in National Emission Standards for Hazardous Air Pollutants for Pharmaceuticals Production: Summary of Public Comments and Responses on Proposed Amendments. This document may be found in the docket.

### **III. What Major Issues Were Raised in the Public Comments and What Changes Were Made for the Final Amendments?**

#### **A. Applicability**

*Comment:* One commenter interprets the proposed changes to § 63.1250(b) to mean that a source that implements process changes that meet the new definition of the term "reconstruction" may be subject to new source requirements under the amended rule, whereas they would have been subject to less stringent existing source requirements under the original rule. However, after reading the discussion in the preamble to the proposed

amendments regarding compliance dates for new and reconstructed sources that would apply in the event the final amendments are more stringent than the original NESHAP, the commenter is unsure when such sources must comply with the new source requirements (or how long they may continue to comply with existing source requirements). The statement that such sources must "continue to comply with the NESHAP until October 21, 2002" was particularly confusing because it was not clear which requirements apply after the amendments are promulgated or whether the source must comply with existing source requirements after October 21, 2002 until it meets reconstruction.

*Response:* The proposed change to § 63.1250(b) would require compliance with the new source requirements for dedicated pharmaceutical manufacturing process units (PMPU) that have the potential to emit hazardous air pollutants (HAP) emissions above specified thresholds and for which reconstruction commenced after October 21, 1999. The commenter is correct that such a reconstructed PMPU would have been subject to existing source requirements under the September 21, 1998 promulgated rule. As a result, it is possible that the PMPU would be subject to more stringent requirements under the amended rule than under the September 21, 1998 promulgated rule. The date when the PMPU must be in compliance with the requirements for new sources depends on the date that reconstruction commenced, as specified in § 63.1250(f) (4) or (5). If you commenced reconstruction between October 21, 1999 and April 10, 2000, you must comply with the requirements for new sources beginning on October 21, 2002. If you commenced reconstruction after April 10, 2000 and before August 29, 2000, you must comply with the requirements for new sources beginning on the date 1 year after the effective date of the final amendments. In both cases, if you startup the reconstructed PMPU before the date when it must be in compliance with the new source requirements, you must, at a minimum, comply with the requirements for existing sources in the September 21, 1998 promulgated rule between startup and that date. If reconstruction commences after August 29, 2000, you must comply with the existing source requirements specified in today's amendments until you shutdown to commence reconstruction, and you must comply with the new source requirements upon startup of the

reconstructed source, as specified in § 63.1250(f)(2).

*Comment:* One commenter is uncertain whether their process to produce an imaging agent classified under SIC code 2835 would be subject to the NESHAP. This commenter was confused by the revised definitions of the terms “pharmaceutical product,” “precursor,” and “component,” as well as the corresponding discussion in the preamble to the proposed amendments. As an alternative, this commenter believes we should consider using the applicability language in 40 CFR 439.0 of the Pharmaceutical Manufacturing Point Source Category because the commenter considers that wording to be more definitive.

*Response:* The definition of pharmaceutical product includes any material whose manufacturing process is described by NAICS code 325411 or 325412. In-vivo diagnostic substances described by SIC code 2835 are also covered by NAICS 325412. If your imaging agent is one of these substances, it is a pharmaceutical product, and the process to produce it is subject to subpart GGG. If that imaging agent is produced at a facility whose primary manufacturing operations are described by SIC code 2833 or 2834, the processes used to produce precursors to the imaging agent would also be subject to subpart GGG. Conversely, if the imaging agent is an in-vitro diagnostic substance, it is excluded from the definition of active ingredient. Thus it is not a pharmaceutical product, and its production process is not subject to subpart GGG. We disagree with the commenter’s suggestion to use the same applicability language as in 40 CFR 439.0. The NESHAP and effluent limitation guidelines are developed under different statutes with different mandates; the applicability does not need to be identical.

#### B. Compliance Dates

*Comment:* Two commenters oppose the proposed delay in the compliance dates. One of the commenters believes the delay is unnecessary because cost-effective control technologies are available. The other commenter opposes the delay because we did not promulgate the NESHAP until 10 months after the scheduled promulgation date, the NESHAP specifies the maximum compliance time allowed by the CAA even though many control measures could be implemented in a much shorter time, and the commenter believes the proposed changes weaken the control requirements.

One of the commenters also disagrees with our assertion that the authority to revise emission standards under section 112(d) of the CAA also includes the authority to set new compliance dates. The commenter says the CAA does not provide the authority to delay the general applicability of the promulgated standard beyond 3 years from promulgation; it only allows compliance with the amendments, if more stringent than the original rule, to be extended to 3 years after promulgation of the amendments. The commenter further states that it is clear that we have not revised the NESHAP in accordance with section 112(d) of the CAA because there is no indication that we reevaluated the maximum achievable control technology (MACT) floor or beyond-the-floor options.

*Response:* As we explained in the preamble to the proposed amendments, we believe the scope of the changes are sufficiently far-reaching and complex that the amended rule would effectively be a new rule. We proposed a compliance date 3 years after the date the settlement agreement was signed and available. This time period was selected to be consistent with the time period that we considered to be reasonable for achieving compliance with the September 21, 1998 promulgated rule. We continue to believe this is reasonable.

#### C. Process Vent Requirements

*Comment:* Section 63.1254(a)(3)(ii)(C) of the proposed amendments would require 95 percent control for the sum of all process vents within some processes that contain hydrogenation steps. One commenter stated that the proposed requirement will be unattainable for some processes even if all nonhydrogenation vents are completely controlled. The commenter believes the required reduction should be 93 percent as for other existing processes. However, to fully address the safety issue of hydrogenation vents, the commenter also requested that we consider exempting all emissions from the hydrogenation step from the point hydrogen is added until after the excess hydrogen is purged from the reactor.

*Response:* The commenter’s reference is to the provision that would allow processes containing hydrogenation vents to achieve at least 95 percent reduction overall, rather than comply with the 98 percent requirement for the Total Resource Effectiveness (TRE) streams and either the 93 percent reduction or mass limit for other streams. The provision was added to address concerns that controlling some hydrogenation vents could be unsafe;

the 95 percent requirement is applied to the process and allows (in exchange for lessening of the requirement to control TRE vents to 98 percent) an overall emission reduction that is greater than the MACT floor. Contrary to the commenter’s assertion, other existing processes are required to achieve 93 percent control on vents other than TRE vents, and 98 percent on TRE vents, not just an overall 93 percent as stated. Therefore, the level of the standard is actually higher than 93 percent for processes containing TRE vents. This added provision is intended to allow greater flexibility in selecting streams for control, while preserving the emissions reductions associated with the standard. Additionally, the provision was suggested by the industry trade association, which suggests that this level of control (95 percent) is achievable in the industry.

#### D. Wastewater Requirements

*Comment:* One commenter disagrees with the proposed change in the annual load used to determine an affected wastewater stream from 1 Megagrams per year (Mg/yr) to 0.25 Mg/yr. The commenter notes that our rationale for changing the load threshold was that we changed the definition of process. However, according to the commenter, there is no definitive correlation between the terms “process” and “point of determination.” Furthermore, because we did not propose changes to the definition of “point of determination” or to the referenced terms “storage tank” and “last recovery device,” the commenter believes the load threshold should remain at 1 Mg/yr.

*Response:* We disagree with the commenter. For processes with wastewater discharges that either do not go through recovery devices or the recovery devices are dedicated to particular discharges, the change in the definition of the term “process” will result in less HAP discharged per process. In addition, storage tanks that are assigned to one process under the original definition of the term “process” may not all be assigned to a single process under the revised definition. Therefore, we continue to believe that it is reasonable to reduce the load threshold for a PMPU.

*Comment:* One commenter requested that we remove methanol from the list of soluble HAP. The commenter is concerned that without this change, publicly owned treatment works (POTW) will no longer accept methanol-containing wastewater that is determined to be affected wastewater under the Pharmaceuticals Production

NESHAP because the POTW do not want to become affected sources under the NESHAP for POTW. As evidence to support removing methanol from the list, the commenter refers to the preamble for the Pharmaceutical Manufacturing Point Source Category in which we recognize that methanol is adequately treated at POTW. The commenter also pointed out that the American Forest and Paper Association filed a petition requesting EPA to remove methanol from the list of HAP contained in section 112(b)(1) of the CAA, and that some of the data in that petition address the treatability of methanol in POTW.

*Response:* Under the NESHAP, every wastewater stream that meets the applicable concentration cutoff must be managed and treated in a manner consistent with MACT; this requirement applies to streams treated either onsite or offsite. Another point to remember is that the basis for the wastewater treatment requirements was steam stripping. Biological treatment that meets specific conditions is allowed as an alternative.

*Comment:* In § 63.1256(g)(13)(ii), which exempts owners and operators from the wastewater provisions in subpart GGG if they treat wastewater in boilers and process heaters that are permitted under the Resource Conservation and Recovery Act (RCRA), one commenter requested that we change the phrase “boilers and process heaters” to “boilers and industrial furnaces.” The commenter pointed out that 40 CFR 260.10 does not define process heaters, and that the existing language could be construed to mean that the exemptions in § 63.1256(g)(13)(ii) do not apply to energy recovery devices classified as industrial furnaces (*i.e.*, cement kilns, lime kilns, and blast furnaces).

*Response:* We did not intend to exclude industrial furnaces from the list of RCRA-permitted devices that are exempt from the wastewater provisions. We intended to apply exemptions in the same manner as in the Hazardous Organic NESHAP (HON), which addressed this issue by including industrial furnaces in the definition of the term “boiler.” The reasons for including industrial furnaces within the definition of the term “boiler” as opposed to defining a separate term are presented in the preamble to proposed amendments for the HON (61 FR 43705). Therefore, the final amendments include a definition for the term “boiler” that is identical to the definition in § 63.111 of the HON. Note that this change also affects industrial furnaces used as air pollution control

devices under § 63.1257(a)(4), as well as wastewater treatment units under § 63.1256(g)(13).

*Comment:* One commenter noted that the list of exempt wastewater in § 63.1256(a)(3)(i) omits two of the types of wastewater that are exempted in § 63.132(f) of the HON: equipment leaks and activities included in maintenance and startup, shutdown, and malfunction plans. The commenter requested that we add these two exemptions to the list in § 63.1256(a)(3)(i) so that pharmaceutical plants are not required to manage small, infrequent, and/or random leaks and discharges of wastewater in accordance with the provisions of § 63.1256. In subsequent discussions, the commenter cited an example of such small discharges as the small amount of water that drains from a hose when it is disconnected from one unit so that it can be moved and reconnected to another unit. Even though the hose is purged before being disconnected, some water remains.

*Response:* After considering the comments, we decided to provide exemptions for equipment leaks and for drips from disconnected hoses. The exemption for equipment leaks is consistent with the HON, which provides the basis for most of the wastewater provisions in subpart GGG. Specifically, § 63.132(f) exempts equipment leaks with HAP concentrations greater than 10,000 parts per million by weight (ppmw) from the management and treatment requirements for Group 1 wastewater. Equipment leaks with lower concentrations are also effectively exempted in the HON because they are unlikely to exceed the Group 1 wastewater flow rate threshold of 10 liters per minute (lpm). The drips from a disconnected hose are unintentional discharges that occur despite reasonable efforts to purge the hose before disconnecting it. We believe these drips can be considered spills, which are exempt from the wastewater provisions. However, to clarify this point, we have provided a specific exemption for drips from procedures such as disconnecting hoses after clearing lines.

We decided not to add an exemption for wastewater that is discharged as a result of activities included in maintenance wastewater plans. Under the proposed amendments, § 63.1256(a)(3)(ii) exempts maintenance wastewater from the definition of wastewater, which means it is not subject to the wastewater provisions other than the requirements in § 63.1256(a)(3)(ii). Adding another exemption for wastewater generated as a result of activities covered by the

maintenance wastewater plan would be redundant.

We also decided not to add an exemption for wastewater that is discharged as a result of activities included in startup, shutdown, and malfunction plans. Section 63.1250(g) specifies that each provision in subpart GGG (except the emission limitations) applies during startups, shutdowns, and malfunctions. This provision effectively exempts wastewater generated during startups, shutdowns, and malfunctions from the management and treatment requirements in § 63.1256. According to § 63.1250(g), the only requirement for such wastewater is that the owner or operator must identify and implement procedures to prevent or minimize emissions during startups, shutdowns, and malfunctions; and the procedures must be documented in a written plan. Therefore, we believe adding an exemption in § 63.1256(a)(3) is unnecessary because existing provisions already accomplish the goal of such an exemption.

After considering the comments and the exemption provisions in general, we decided that the requirements would be clearer if we rearranged a few statements. Therefore, in the final amendments, we have moved the list of exemptions from § 63.1256(a)(3)(i) to the definition of the term “wastewater stream.” We also added equipment leaks and drips from procedures such as disconnecting hoses to the list. We then redesignated the multiphase discharge requirements in § 63.1256(a)(4) as § 63.1256(a)(3), and we redesignated the maintenance wastewater requirements in § 63.1256(a)(3)(ii) as § 63.1256(a)(4). We also added a statement to the redesignated § 63.1256(a)(4) to specify that maintenance wastewater is exempt from all other provisions in subpart GGG. Finally, we revised § 63.1256(a) introductory paragraph and § 63.1256(a)(1) to more clearly explain what provisions are specified in § 63.1256(a)(1) through (5). We believe these changes clarify the wastewater provisions without changing the intent.

#### *E. Recordkeeping*

*Comment:* One commenter believes the recordkeeping and reporting burden is excessive and suggests that we continue to work with the Food and Drug Administration to increase flexibility, perhaps by using the concepts of “Master Process” or “Batch Records.” The commenter acknowledges that the concept of a “standard batch” helps to alleviate this burden but cites our Agency Information Collection Request notice (65 FR 17258, March 31, 2000), which

estimates the average recordkeeping and reporting burden to be 694 hours per source per year, as evidence that more relief is needed.

*Response:* The recordkeeping and reporting requirements in the proposed amendments are needed to demonstrate compliance. These requirements received considerable scrutiny during the settlement negotiations. As the commenter noted, we introduced the concept of a "standard batch" as one way to minimize the burden. Another way to minimize the burden is to implement the alternative standard; the reduction in the burden associated with this compliance option is not reflected in the estimate in the Agency Information Collection Request.

#### F. Delegation of Authority

*Comment:* Several commenters oppose the proposed change to the delegation of authority language because it was not part of the settlement agreement, and we did not explain why the change is needed. One commenter also expressed concern that the proposed change could have a significant adverse impact on sources by requiring a second layer of regulatory agency approval of alternatives to monitoring or recordkeeping provisions in cases where a State rule and the Pharmaceuticals Production NESHAP apply to the same source. The commenter noted that getting approval from both the State and EPA would result in a substantial burden on the source without providing any additional environmental benefit.

*Response:* After considering the comments, we have decided not to amend the delegation of authority provisions in § 63.1261 of the September 21, 1998 promulgated rule. The proposed amendments to § 63.1261 reference terms that are defined in proposed amendments to § 63.90 of 40 CFR part 63, subpart E (64 FR 1880, January 12, 1999). The regulations in subpart E implement section 112(l) of the CAA and specify the procedures and criteria for approving State, local, territorial, and tribal rules, programs, or other requirements that would substitute for NESHAP. The proposed amendments to subpart E are intended to clarify these procedures and criteria, including the authorities which we will and will not delegate. Because the proposed amendments to subpart E may not be promulgated before the amendments to subpart GGG, we must remove the references to them from subpart GGG. We anticipate, however, that after amendments to subpart E are promulgated, we will also amend

subpart GGG (and all other NESHAP) to be consistent.

#### G. Clarification of Statements in the Proposal Preamble

Several commenters expressed concern that the discussions of some issues in the preamble to the proposed amendments could cause confusion because the discussions were either incomplete or inconsistent with the proposed regulatory language. The following paragraphs discuss each concern.

##### 1. Annual Mass Emission Limit for Process Vents

Section II.G of the preamble to the proposed amendments explains the proposed changes in the 900 kilograms per year (kg/yr) annual mass limit compliance option for process vents. For example, one of the proposed changes in this compliance option was to allow it to be used for all of the other vents in a process where at least one vent meets the requirements for control to 98 percent under § 63.1254(a)(3)(i).

*Comment:* One commenter believes the proposal preamble may cause confusion because it does not also say that you may comply with the 900 kg/yr annual mass limit for all of the other vents in a process where at least one vent complies with the alternative standard in § 63.1254(c), or at least one vent is routed to a control device subject to the grandfathering provisions in § 63.1254(a)(3)(ii).

*Response:* The commenter is correct that the proposed amendments extend the 900 kg/yr annual mass limit compliance option to more situations than the one described in the proposal preamble. Section 63.1254(a)(2)(iii) in the final amendments, which is identical to the language in the proposed amendments, specifies three types of vents that you may exclude when determining compliance with the 900 kg/yr annual mass limit: (1) All vents that must be controlled to 98 percent in accordance with § 63.1254(a)(3)(i), (2) all vents that otherwise would be subject to the 98 percent control requirement if they were not controlled by a grandfathered control device according to § 63.1254(a)(3)(ii), and (3) all vents that are controlled in accordance with the alternative standard in § 63.1254(c).

##### 2. Emission Reduction for Processes With Both TRE and Hydrogenation Vents

Section II.H of the proposal preamble includes a discussion of the emission limitations for vents in processes that include at least one TRE vent and at

least one hydrogenation vent that we proposed adding in § 63.1254(a)(3)(ii)(C).

*Comment:* One commenter believes the explanation of the proposed emission limitation is confusing because it does not clearly describe the two distinct parts to the proposed provision in § 63.1254(a)(3)(ii)(C). According to the commenter, the first part applies to processes that meet specified control criteria on or before April 2, 1997, and these processes must maintain the level of control achieved on the date of the proposed amendments (*i.e.*, April 10, 2000). The commenter also noted that the second part applies to any other process where the annual mass limit or process-based emission reduction (for the sum of the non-TRE vents) cannot be met because the hydrogenation vent(s) cannot be safely controlled, and the HAP emissions from the sum of all vents in these processes must be reduced by at least 95 percent.

*Response:* We agree with the commenter that the proposal preamble did not fully explain the two parts of the proposed provisions for processes with hydrogenation vents. The commenter's assessment of the second part of this provision is correct, but the first part needs additional discussion. Processes that had a TRE vent on or before April 2, 1997 and for which the HAP emissions from the sum of all process vents were controlled to between 93 and 98 percent by weight must continue to be controlled to the level achieved on or before April 2, 1997 (not on or before April 10, 2000).

##### 3. Recordkeeping Requirements for Process Vents

Section II.O of the proposal preamble describes several proposed changes to the recordkeeping requirements, including a discussion of the proposed concept of a "standard batch."

*Comment:* One commenter believes the discussion is confusing because it does not clearly state that the requirement to check whether standard batch conditions have been exceeded applies only to two types of processes: (1) Processes subject to the 900 kg/yr annual mass emission limit and (2) processes subject to a percent reduction requirement where at least one vent in the process is controlled to less than the percent reduction required for the process as a whole. The commenter is concerned that the proposal preamble could be interpreted to mean the check is required for all processes.

*Response:* The commenter is correct. You may define a standard batch for any process. However, the requirement to document whether each batch meets all

of the conditions of the standard batch applies only in the two cases identified by the commenter. Because changes in operating conditions may cause changes in emission levels, this documentation (along with the requirement to recalculate uncontrolled and controlled emissions for each nonstandard batch) is the procedure used to demonstrate ongoing compliance in these two situations. The documentation is not needed in other situations where other types of monitoring are sufficient to demonstrate ongoing compliance (e.g., a continuous emissions monitoring system (CEMS) for demonstrating compliance with the alternative standard) or the changes in emission levels do not affect ongoing compliance (e.g., when all vents in a process are routed to the same control device). The documentation requirements are specified in § 63.1259(b)(5) in both the proposed and final amendments.

4. Compliance With Subpart PPP

Section II.C of the proposal preamble discussed the proposed addition of a § 63.1250(h)(6) to address overlap situations between subparts GGG and PPP.

*Comment:* One commenter pointed out that the second reference to subpart GGG that says, “\* \* \* you will still be required to comply with all other requirements in subpart GGG \* \* \*” is incorrect and should say, “\* \* \* you would also be required to comply with all other requirements in subpart PPP for the corresponding PMPU \* \* \*”

*Response:* The commenter is correct. If you demonstrate compliance with subpart GGG by controlling process vents in accordance with the requirements in subpart PPP, you must also comply with all of the other requirements in subpart PPP for the corresponding PMPU.

H. Technical Correction to Monitoring Requirements for Hydrogen Halides and Halogens

*Comment:* One commenter raised an issue that involves the alternative

standard. Under the alternative standard in the promulgated NESHAP, the owner or operator must use CEMS to demonstrate ongoing compliance with the total organic compound (TOC) and total hydrogen halide and halogen outlet concentration limits. The commenter states that CEMS should not be required to demonstrate compliance with the hydrogen halide and halogen limits because we have not required CEMS to demonstrate compliance with hydrochloric acid (HCl) and chlorine limits in past rules (e.g., the hazardous waste combustion, municipal waste combustion, and hospital/medical/infectious waste incineration), and there are no EPA-approved, commercially available methods to monitor these pollutants in gas streams continuously. As an alternative, the commenter recommends that we require parametric monitoring like that already required to demonstrate compliance with the other outlet concentration limits in the rule.

*Response:* We agree with the commenter that clarification of the hydrogen halide and halogen monitoring requirements under the alternative standard is needed. As a result, we have made technical amendments to the standard for alternative procedures for monitoring hydrogen halides and halogens emitted under two scenarios: (1) When these pollutants are generated in combustion devices that are used to control halogenated vent streams, and (2) when these pollutants are emitted directly from the process.

One of the primary sources of hydrogen halide and halogen emissions is combustion devices that are used to control halogenated vent streams. In these situations, most of the chlorine is converted to HCl in the incinerator. Therefore, we believe that monitoring for HCl would serve as an acceptable surrogate for all of the hydrogen halides and halogens in the emission stream. We provided three options for monitoring to demonstrate compliance with the outlet concentration limit for

hydrogen halides and halogens under the alternative standard for these emission streams. The first option is to continuously monitor for HCl using an instrument based on Fourier Transform infrared (FTIR) spectroscopy that meets Performance Specification 15 in appendix B of 40 CFR part 60. Because HCl is readily controlled in a properly operated scrubber, the second option requires the owner or operator to conduct an initial demonstration that the scrubber reduces HCl by 95 percent, set scrubber operating parameters during the initial compliance determination, and demonstrate ongoing compliance by continuously monitoring the operating parameters. In the event an owner or operator wishes to monitor for HCl using a CEMS for which we have not promulgated a performance specification, we are also including a third option that requires the owner or operator to prepare a monitoring plan and submit it for approval in accordance with the procedures specified in § 63.8.

If you emit hydrogen halides and halogens directly from the process, the requirement to use CEMS to measure the total hydrogen halide and halogen concentration is unchanged from the September 21, 1998 promulgated rule. However, because we have not promulgated performance specifications for halogen monitors, we have amended the rule to require that the owner or operator prepare a monitoring plan and submit it for approval in accordance with § 63.8.

I. Minor Technical Corrections

We are making several changes throughout subpart GGG to correct referencing and typographical errors, to improve consistency in terminology, and to make the amendments consistent with the settlement agreement. Two of the commenters identified many of the needed corrections; we identified several others. All of the corrections are described in Table 1.

TABLE 1.—MINOR TECHNICAL CORRECTIONS TO SUBPART GGG

Section of subpart GGG	Description of correction
63.1250(f)(5)(i) .....	Changed the referenced date from April 2, 1997 to April 10, 2000. The intended date was the date of publication of the proposed amendments, not the date of publication of the proposed rule, because a source that commences construction or reconstruction after April 10, 2000 must, upon startup before August 29, 2000, comply with the proposed amendments.
63.1250(h)(1)(i) .....	Corrected a typographical error in this paragraph. The word “of” was replaced with “or” in the first sentence so that the sentence reads as follows: “* * * elect to comply with either the provisions of this subpart or the provisions of another subpart * * *”.
63.1250(h)(2) and (3) .....	Replaced the word “consistency” with “compliance” in the headings of both sections to be consistent with the language used in the headings in § 63.1250(h)(1), (4), (5), and (6).

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

Section of subpart GGG	Description of correction
63.1252(d)(6) through (d)(8) .....	Corrected these paragraphs by replacing the incorrect references to § 63.1254(a)(2) and (a)(3) with the correct references to § 63.1254(a)(1)(i). Replaced incorrect reference to § 63.1253(c)(1) with correct reference to § 63.1253(c)(1)(i). Replaced the word “requirements” with “criteria”.
63.1255(b)(4)(iv)(B) .....	Corrected this paragraph by replacing incomplete reference to § 63.178(c)(iii) with the complete reference to § 63.178(c)(3)(iii).
63.1255(c)(2)(i) and (e)(3) .....	Corrected these paragraphs by replacing references to § 63.178(b) with references to § 63.178. The more comprehensive reference allows an owner or operator to implement the monitoring interval adjustment option in § 63.178(c) for valves under § 63.1255(e)(3). However, the change has essentially no impact for pumps and agitators because § 63.1255(b)(4)(iv)(B) specifies that the monitoring interval adjustment for pumps and agitators is to be quarterly, which is the same monitoring frequency that is specified in § 63.1255(c)(2)(i). This is the intended result. In effect, because the HON requires monthly monitoring, the adjustment is already built in to § 63.1255(c)(2)(i). We do not believe that an additional adjustment is warranted.
63.1255(e)(5)(iii) .....	Corrected typographical errors in the definitions of two of the terms that follow Equation 4. The uppercase “I” for the variable that counts the number of subgroups has been replaced with the correct lowercase “i”.
63.1255(f)(1)(iii) .....	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(f)(4)(iv) .....	Corrected this paragraph by replacing the incorrect reference to paragraph (b)(3)(i) with the correct reference to paragraph (b)(4)(i).
63.1255(h)(3)(ii) .....	Corrected this paragraph by replacing the incorrect reference to paragraph (b)(3)(iv) with the correct reference to paragraph (b)(4)(iv).
63.1256(a)(1)(i)(B) .....	Revised this paragraph to specify that the wastewater stream is an affected wastewater stream if the concentration of partially soluble and/or soluble HAP is “greater than” 5,200 ppmw, whereas the original language specified a concentration “of” 5,200 ppmw. This change makes the terminology in this paragraph consistent with the terminology in § 63.1256(a)(1)(i)(A), (C), and (D).
63.1257(d)(2)(i)(C)(4)(i) .....	Corrected this paragraph by replacing the incorrect reference to paragraph (d)(2)(iii) with the correct reference to paragraph (d)(3)(iii).
63.1258(b)(5)(ii) .....	Added a sentence to the end of this paragraph that was part of the settlement agreement but was inadvertently left out of the proposed amendments. The sentence reads as follows: “If the owner or operator corrects for supplemental gases as specified in § 63.1257(a)(3)(ii) for noncombustion control devices, the flow must be evaluated as specified in paragraph (b)(5)(ii)(C) of this section.”

**IV. What Are the Administrative Requirements for These Final Amendments?**

*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 Office of Management and Budget (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 add any new control requirements. 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.” Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. The EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation. If EPA complies by consulting, Executive Order 13132 requires EPA to provide to OMB, in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA’s prior consultation with State and local officials, a summary of the nature of their concerns and EPA’s position



supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the Agency's Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner.

Today's amendments 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 today's action.

#### *C. Executive Order 13084, Consultation and Coordination With Indian Tribal Governments*

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

Today's amendments to subpart GGG do not significantly or uniquely affect the communities of Indian tribal governments. No tribal governments own or operate sources subject to these amendments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to today's action.

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

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, EPA must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by 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. Today's amendments are not subject to Executive Order 13045 because they are based on technology performance, not health or safety risks. Furthermore, this rule has been determined not to be "economically significant" as defined under Executive Order 12866.

#### *E. Unfunded Mandates Reform Act of 1995*

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with Federal mandates that may result in expenditures 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 to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The EPA has determined that today's 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, today's amendments are not subject to the requirements of sections 202 and 205 of the UMRA. In addition, EPA has determined that these 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, today's 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 RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's amendments on small entities, a small entity is defined as: (1) A small business in SIC code 2833 or 2834 that has as many as 750 employees; (2) a small business in SIC code 2869 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 amendments on small entities, we have concluded that this action will not have a significant economic impact on a substantial number of small entities. The EPA has determined that none of the small entities will experience a significant impact because the amendments impose no additional regulatory requirements on owners or operators of affected sources.

Although today's amendments will not have a significant economic impact, EPA nonetheless has tried to reduce the impact of the amendments on small entities. Many of the amendments define optional means of compliance. For example, vapor balancing was added as an optional means of compliance for storage tanks, a facilitywide limit on the mass of process vent emissions replaces the limit on the number of processes that may comply with the process-based emission limit, additional compliance alternatives are included for process vents that meet the criteria for 98 percent control, and optional parameter monitoring is included as an alternative to correcting to 3 percent oxygen when supplemental gas is introduced to a dense gas system or a system controlled with combustion devices and the owner or operator complies with the alternative standard. The proposed amendments also include simplified recordkeeping requirements when the owner or operator documents conditions that define a standard batch, and the process is operated within that range of conditions.

#### G. Paperwork Reduction Act

The OMB has approved the information collection requirements contained in the 1998 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.

Today's amendments will have no net impact on the information collection burden estimates made previously. An

oversight has been corrected by adding recordkeeping and reporting requirements for storage tanks equipped with floating roofs. The promulgated rule only included recordkeeping and reporting requirements for add-on control devices for storage tanks even though add-on control devices and floating roofs were considered in the cost impacts and burden estimates. Also, the amendments clarify the intent of several provisions in the 1998 NESHAP and correct inadvertent omissions and minor drafting errors in the 1998 NESHAP. 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), Pub. L. 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 Congress, through OMB, with 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 today's amendments.

#### I. The Congressional Review Act

The Congressional Review Act, 5 U.S.C. § 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the U.S.

Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. § 804(2). This rule will be effective August 29, 2000.

#### List of Subjects in 40 CFR Part 63

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

Dated: August 15, 2000.

**Carol M. Browner,**  
*Administrator.*

For the reasons set out in the preamble, part 63 of title 40, chapter I of the Code of Federal Regulations is amended as follows:

#### PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

1. 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

2. Section 63.1250 is amended by:

- Revising paragraph (a),
- Revising paragraph (b),
- Revising paragraph (c),
- Revising paragraph (f);
- Revising paragraph (h)(1);
- Revising paragraph (h)(2) heading;
- Revising paragraph (h)(3) heading;
- Revising paragraphs (h) (4) and (5);

and

- Adding paragraph (h)(6).

The revisions and additions read as follows:

#### § 63.1250 Applicability.

(a) *Definition of affected source.* (1) The affected source subject to this subpart consists of the pharmaceutical manufacturing operations as defined in § 63.1251. Except as specified in paragraph (d) of this section, the provisions of this subpart apply to pharmaceutical manufacturing operations that meet the criteria specified in paragraphs (a)(1) (i) through (iii) of this section:

- Manufacture a pharmaceutical product as defined in § 63.1251;
- Are located at a plant site that is a major source as defined in section 112(a) of the Act; and

(iii) Process, use, or produce HAP.

(2) Determination of the applicability of this subpart shall be reported as part of an operating permit application or as otherwise specified by the permitting authority.

(b) *New source applicability.* A new affected source subject to this subpart and to which the requirements for new sources apply is: An affected source for which construction or reconstruction commenced after April 2, 1997, and the standard was applicable at the time of construction or reconstruction; or a pharmaceutical manufacturing process unit (PMPU) dedicated to manufacturing a single product that has the potential to emit 10 tons per year of any one HAP or 25 tons per year of combined HAP for which construction commenced after April 2, 1997 or reconstruction commenced after October 21, 1999.

(c) *General Provisions.* Table 1 of this subpart specifies and clarifies the provisions of subpart A of this part that apply to an owner or operator of an affected source subject to this subpart. The provisions of subpart A specified in Table 1 are the only provisions of subpart A that apply to an affected source subject to this subpart.

\* \* \* \* \*

(f) *Compliance dates.* The compliance dates for affected sources are as follows:

(1) An owner or operator of an existing affected source must comply with the provisions of this subpart no later than October 21, 2002.

(2) An owner or operator of a new or reconstructed affected source must comply with the provisions of this subpart on August 29, 2000 or upon startup, whichever is later.

(3) Notwithstanding the requirements of paragraph (f)(2) of this section, a new source which commences construction or reconstruction after April 2, 1997 and before September 21, 1998 shall not be required to comply with this subpart until September 21, 2001 if:

(i) The requirements of this subpart are more stringent than the requirements of this subpart in effect before August 29, 2000 and contained in the 40 CFR, part (63.1200–end), edition revised as of July 1, 2000; and

(ii) The owner or operator complies with the requirements published on April 2, 1997 (62 FR 15754) during the period until September 21, 2001.

(4) Notwithstanding the requirements of paragraph (f)(2) of this section, a new source which commences construction or reconstruction after September 21, 1998 and before April 10, 2000 shall not be required to comply with this subpart until October 21, 2002 if:

(i) The requirements of this subpart are more stringent than the requirements of this subpart in effect before August 29, 2000; and

(ii) The owner or operator complies with the requirements of this subpart in effect before August 29, 2000 during the period between startup and October 21, 2002.

(5) Notwithstanding the requirements of paragraph (f)(2) of this section, a new source which commences construction or reconstruction after April 10, 2000 and before August 29, 2000 shall not be required to comply with this subpart until August 29, 2001 if:

(i) The requirements of this subpart are more stringent than the requirements published on April 10, 2000 (65 FR 19152); and

(ii) The owner or operator complies with the requirements of this subpart in effect before August 29, 2000 during the period between startup and August 29, 2001.

(6) Pursuant to section 112(i)(3)(B) of the Act, an owner or operator may request an extension allowing the existing source up to 1 additional year to comply with section 112(d) standards.

(i) For purposes of this subpart, a request for an extension shall be submitted no later than 120 days prior to the compliance dates specified in paragraphs (f) (1) through (5) of this section, except as provided in paragraph (f)(6)(ii) of this section. The dates specified in § 63.6(i) for submittal of requests for extensions shall not apply to sources subject to this subpart.

(ii) An owner or operator may submit a compliance extension request after the date specified in paragraph (f)(6)(i) of this section provided the need for the compliance extension arose after that date and before the otherwise applicable compliance date, and the need arose due to circumstances beyond reasonable control of the owner or operator. This request shall include the data described in § 63.6(i)(6)(i) (A), (B), (C), and (D).

\* \* \* \* \*

(h) \* \* \*

(1) *Compliance with other MACT standards.* (i) After the compliance dates specified in this section, an affected source subject to the provisions of this subpart that is also subject to the provisions of any other subpart of this part 63 may elect to comply with either the provisions of this subpart or the provisions of another applicable subpart governing the maintenance of records and reporting to EPA. The affected source shall identify in the Notification of Compliance Status report required by § 63.1260(f) under which authority such records will be maintained.

(ii) After the compliance dates specified in paragraph (f) of this section, at an offsite reloading or cleaning facility subject to § 63.1253(f), compliance with the emission standards and associated initial compliance, monitoring, recordkeeping, and reporting provisions of any other subpart of this part 63 constitutes compliance with the provisions of § 63.1253(f)(7) (ii) or (iii). The owner or operator of the affected storage tank shall identify in the Notification of Compliance Status report required by § 63.1260(f) the subpart of this part 63 with which the owner or operator of the offsite reloading or cleaning facility complies.

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

\* \* \*

\* \* \* \* \*

(3) *Compliance with 40 CFR 60.112(b).* \* \* \*

\* \* \* \* \*

(4) *Compliance with subpart I of this part.* After the compliance dates specified in this section, an affected source with equipment subject to subpart I of this part may elect to comply with either the provisions of § 63.1255 or the provisions of subpart H of this part for all such equipment. The owner or operator shall identify in the Notification of Compliance Status report required by § 63.1260(f) the provisions with which the owner elects to comply.

(5) *Compliance with other regulations for wastewater.* After the compliance dates specified in this section, the owner or operator of an affected wastewater stream that is also subject to provisions in 40 CFR parts 260 through 272 may elect to determine whether this subpart or 40 CFR parts 260 through 272 contain the more stringent control requirements (e.g., design, operation, and inspection requirements for waste management units; numerical treatment standards; etc.) and the more stringent testing, monitoring, recordkeeping, and reporting. Compliance with provisions of 40 CFR parts 260 through 272 that are determined to be more stringent than the requirements of this subpart constitutes compliance with this subpart. For example, provisions of 40 CFR parts 260 through 272 for treatment units that meet the conditions specified in § 63.1256(g)(13) constitute compliance with this subpart. In the Notification of Compliance Status report required by § 63.1260(f), the owner or operator shall identify the more stringent provisions of 40 CFR parts 260 through 272 with which the owner or operator will comply. The owner or operator shall also identify in the

Notification of Compliance Status report required by § 63.1260(f) the information and procedures used to make any stringency determinations. If the owner or operator does not elect to determine the more stringent requirements, the owner or operator must comply with both the provisions of 40 CFR parts 260 through 272 and the provisions of this subpart.

(6) *Compliance with subpart PPP of this part.* After the compliance dates specified in this section, an affected source with equipment in a pharmaceutical manufacturing process unit that is also part of an affected source under subpart PPP of this part may elect to demonstrate compliance with § 63.1254 by controlling all process vents in accordance with § 63.1425 (b), (c)(1), (c)(3), (d), and/or (f). Alternatively, the owner or operator may elect to determine which process vents must be controlled to comply with the percent reduction requirements of § 63.1254 and control only those vents in accordance with § 63.1425 (b), (c)(1), (c)(3), (d), and/or (f). For any pharmaceutical manufacturing process unit controlled in accordance with the requirements of § 63.1425, the owner or operator must also comply with all other requirements in subpart PPP of this part. In the Notification of Compliance Status report required by § 63.1260(f), the owner or operator shall identify which pharmaceutical manufacturing process units are meeting the control requirements for process vents and all other requirements of subpart PPP of this part, and the owner or operator shall describe the calculations and other information used to identify which process vents must be controlled to comply with the percent reduction requirements of § 63.1254, if applicable.

\* \* \* \* \*

- 3. Section 63.1251 is amended by:
  - a. Revising the definitions for *Active ingredient*, *Annual average concentration*, *Construction*, *Consumption*, *Excipient*, *Large control device*, *Pharmaceutical manufacturing operations*, *Pharmaceutical product*, *Primary use*, *Process*, *Process tank*, *Repaired*, *Shutdown*, *Small control device*, *Startup*, *Storage tank*, *Vapor-mounted seal*, and *Wastewater stream*;
  - b. Removing the definition of *Component*;
  - c. Revising paragraphs (3) and (8) in the definition for *Operating scenario*; and
  - d. Adding definitions in alphabetical order for *Boiler*, *Combustion device burner*, *Dense gas system*, *Isolated intermediate*, *Maintenance wastewater*,

*Precursor*, *Reconstruction*, *Standard batch*, *Supplemental gases*, and *System flowrate*.

The revisions and additions read as follows:

**§ 63.1251 Definitions.**

\* \* \* \* \*

*Active ingredient* means any material that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. This term does not include food, food additives (except vitamins and other materials described by SIC code 2833 or 2834), color additives, cosmetics, in-vitro diagnostic substances, x-ray film, test indicator devices, and medical devices such as implants, artificial joints, surgical bandages, and stitching material.

\* \* \* \* \*

*Annual average concentration*, as used in the wastewater provisions in § 63.1256, means the total mass of partially soluble and/or soluble HAP compounds in a wastewater stream during the calendar year divided by the total mass of the wastewater stream discharged during the same calendar year, as determined according to the procedures specified in § 63.1257(e)(1) (i) and (ii).

\* \* \* \* \*

*Boiler* means any enclosed combustion device that extracts useful energy in the form of steam and is not an incinerator. Boiler also means any industrial furnace as defined in 40 CFR 260.10.

\* \* \* \* \*

*Combustion device burner* means a device designed to mix and ignite fuel and air to provide a flame to heat and oxidize waste organic vapors in a combustion device.

\* \* \* \* \*

*Construction* means the onsite fabrication, erection, or installation of an affected source or a PMPU. Addition of new equipment to a PMPU subject to existing source standards does not constitute construction, but it may constitute reconstruction of the affected source or PMPU if it satisfies the definition of reconstruction in this section.

*Consumption* means the quantity of all HAP raw materials entering a process in excess of the theoretical amount used as reactant, assuming 100 percent stoichiometric conversion. The raw materials include reactants, solvents, and any other additives. If a HAP is generated in the process as well as

added as a raw material, consumption includes the quantity generated in the process.

\* \* \* \* \*

*Dense gas system* means a conveyance system operated to limit oxygen levels below 12 percent.

\* \* \* \* \*

*Excipient* means any substance other than the active drug or product which has been appropriately evaluated for safety and is included in a drug delivery system to either aid the processing of the drug delivery system during its manufacture; protect, support, or enhance stability, bioavailability, or patient acceptability; assist in product identification; or enhance any other attribute of the overall safety and effectiveness of the drug delivery system during storage or use.

\* \* \* \* \*

*Isolated intermediate* means a product of a process. An isolated intermediate is usually a product of a chemical synthesis, fermentation, or biological extraction process; several different isolated intermediates may be produced in the manufacture of a finished dosage form of a drug. Precursors, active ingredients, or finished dosage forms are considered isolated intermediates. An isolated intermediate is stored before subsequent processing. Storage occurs at any time the intermediate is placed in equipment used solely for storage, such as drums, totes, day tanks, and storage tanks. The storage of an isolated intermediate marks the end of a process.

\* \* \* \* \*

*Large control device* means a control device that controls total HAP emissions of greater than or equal to 10 tons/yr, before control.

\* \* \* \* \*

*Maintenance wastewater* means wastewater generated by the draining of process fluid from components in the pharmaceutical manufacturing process unit into an individual drain system in preparation for or during maintenance activities. Maintenance wastewater can be generated during planned and unplanned shutdowns and during periods not associated with a shutdown. Examples of activities that can generate maintenance wastewater include descaling of heat exchanger tubing bundles, cleaning of distillation column traps, draining of pumps into an individual drain system, and draining of portions of the pharmaceutical manufacturing process unit for repair. Wastewater from cleaning operations is not considered maintenance wastewater.

\* \* \* \* \*

*Operating scenario, \* \* \**

(3) The applicable control requirements of this subpart, including the level of required control, and for vents, the level of control for each vent;

(8) For reporting purposes, a change to any of these elements not previously reported, except for paragraph (5) of this definition, shall constitute a new operating scenario.

*Pharmaceutical manufacturing operations* means the facilitywide collection of PMPU and any other equipment such as heat exchanger systems, wastewater and waste management units, or cooling towers that are not associated with an individual PMPU, but that are located at a facility for the purpose of manufacturing pharmaceutical products and are under common control.

*Pharmaceutical product* means any of the following materials, excluding any material that is a nonreactive solvent, excipient, binder, or filler, or any material that is produced in a chemical manufacturing process unit that is subject to the requirements of subparts F and G of this part 63:

(1) Any material described by the standard industrial classification (SIC) code 2833 or 2834; or

(2) Any material whose manufacturing process is described by North American Industrial Classification System (NAICS) code 325411 or 325412; or

(3) A finished dosage form of a drug, for example, a tablet, capsule, solution, etc.; or

(4) Any active ingredient or precursor that is produced at a facility whose primary manufacturing operations are described by SIC code 2833 or 2834; or

(5) At a facility whose primary operations are not described by SIC code 2833 or 2834, any material whose primary use is as an active ingredient or precursor.

*Precursor* means a material that is manufactured to undergo further chemical change or processing to ultimately manufacture an active ingredient or finished dosage form of a drug. This term does not include commodity chemicals produced by the synthetic organic chemical manufacturing industry.

*Primary use* means 50 percent or more of a material is used for a particular purpose.

*Process* means all equipment which collectively function to produce a

pharmaceutical product or isolated intermediate (which is also a pharmaceutical product). A process may consist of one or more unit operations. For the purposes of this subpart, process includes any, all, or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a pharmaceutical product or isolated intermediate. Cleaning operations conducted are considered part of the process. Nondedicated solvent recovery operations located within a contiguous area within the affected source are considered single processes. A storage tank that is used to accumulate used solvent from multiple batches of a single process for purposes of solvent recovery does not represent the end of the process. Nondedicated formulation operations occurring within a contiguous area are considered a single process that is used to formulate numerous materials and/or products. Quality assurance and quality control laboratories are not considered part of any process. Ancillary activities are not considered a process or part of any process. Ancillary activities include boilers and incinerators (not used to comply with the provisions of § 63.1253, § 63.1254, or § 63.1256(h)), chillers and refrigeration systems, and other equipment and activities that are not directly involved (*i.e.*, they operate within a closed system and materials are not combined with process fluids) in the processing of raw materials or the manufacturing of a pharmaceutical product.

*Process tank* means a tank that is used to collect material discharged from a feedstock storage tank or unit operation and to transfer this material to another unit operation within the process or to a product storage tank. Surge control vessels and bottoms receivers that fit these conditions are considered process tanks. Product storage tanks are considered process tanks and are part of the PMPU that produce the stored material. For the purposes of this subpart, vents from process tanks are considered process vents.

*Reconstruction*, as used in § 63.1250(b), shall have the meaning given in § 63.2, except that "affected or previously unaffected stationary source" shall mean either "affected facility" or "PMPU." As used in § 63.1254(a)(3)(ii)(A)(3), reconstruction shall have the meaning given in § 63.2,

except that "source" shall mean "control device."

*Repaired* means that equipment:

(1) Is adjusted, or otherwise altered, to eliminate a leak as defined in the applicable paragraphs of § 63.1255, and;

(2) Is, unless otherwise specified in applicable provisions of § 63.1255, monitored as specified in § 63.180(b) and (c) as appropriate, to verify that emissions from the equipment are below the applicable leak definition.

*Shutdown* means the cessation of operation of a continuous process for any purpose. Shutdown also means the cessation of a batch process or any related individual piece of equipment required or used to comply with this subpart as a result of a malfunction or for replacement of equipment, repair, or any other purpose not excluded from this definition. Shutdown also applies to emptying and degassing storage vessels. Shutdown does not apply to cessation of a batch process at the end of a campaign, for routine maintenance, for rinsing or washing of equipment between batches, or other routine operations.

*Small control device* means a control device that controls total HAP emissions of less than 10 tons/yr, before control.

*Standard batch* means a batch process operated within a range of operating conditions that are documented in an operating scenario. Emissions from a standard batch are based on the operating conditions that result in highest emissions. The standard batch defines the uncontrolled and controlled emissions for each emission episode defined under the operating scenario.

*Startup* means the setting in operation of a continuous process unit for any purpose; the first time a new or reconstructed batch process unit begins production; for new equipment added, including equipment used to comply with this subpart, the first time the equipment is put into operation; or, for the introduction of a new product/process, the first time the product or process is run in equipment. For batch process units, startup does not apply to the first time the equipment is put into operation at the start of a campaign to produce a product that has been produced in the past, after a shutdown for maintenance, or when the equipment is put into operation as part of a batch within a campaign. As used in § 63.1255, startup means the setting in operation of a piece of equipment or

a control device that is subject to this subpart.

Storage tank means a tank or other vessel that is used to store organic liquids that contain one or more HAP as raw material feedstocks. Storage tank also means a tank or other vessel in a tank farm that receives and accumulates used solvent from multiple batches of a process or processes for purposes of solvent recovery. The following are not considered storage tanks for the purposes of this subpart:

- (1) Vessels permanently attached to motor vehicles such as trucks, railcars, barges, or ships;
- (2) Pressure vessels designed to operate in excess of 204.9 kilopascals and without emissions to the atmosphere;
- (3) Vessels storing organic liquids that contain HAP only as impurities;
- (4) Wastewater storage tanks; and
- (5) Process tanks (including product tanks and isolated intermediate tanks).

Supplemental gases are any gaseous streams that are not defined as process vents, or closed-vent systems from wastewater management and treatment units, storage tanks, or equipment components and that contain less than 50 ppmv TOC, as determined through process knowledge, that are introduced into vent streams or manifolds. Air required to operate combustion device burner(s) is not considered supplemental gas.

\* \* \* \* \*

System flowrate means the flowrate of gas entering the control device.

\* \* \* \* \*

Vapor-mounted seal means a continuous seal that completely covers the annular space between the wall of the storage tank or waste management unit and the edge of the floating roof and is mounted such that there is a vapor space between the stored liquid and the bottom of the seal.

\* \* \* \* \*

Wastewater stream means water that is discarded from a PMPU through a single POD, that contains an annual average concentration of partially soluble and/or soluble HAP compounds of at least 5 parts per million by weight and a load of at least 0.05 kg/yr. The following are not considered wastewater streams for the purposes of this subpart:

- (1) Stormwater from segregated sewers;
- (2) Water from fire-fighting and deluge systems, including testing of such systems;
- (3) Spills;
- (4) Water from safety showers;
- (5) Samples of a size not greater than reasonably necessary for the method of analysis that is used;

- (6) Equipment leaks;
- (7) Wastewater drips from procedures such as disconnecting hoses after clearing lines; and
- (8) Noncontact cooling water.

\* \* \* \* \*

- 4. Section 63.1252 is amended by:
  - a. Revising the introductory paragraph;
  - b. Revising paragraph (d)(2);
  - c. Revising the first sentence in paragraph (d)(5);
  - d. Revising paragraph (d)(6) through (d)(8);
  - e. Revising paragraph (e) introductory text;
  - f. Revising the second sentence in paragraph (e)(1); and
  - g. Adding paragraph (e)(4).
 The revisions and additions read as follows:

**§ 63.1252 Standards: General.**

Each owner or operator of any affected source subject to the provisions of this subpart shall control HAP emissions to the level specified in this section on and after the compliance dates specified in § 63.1250(f). Initial compliance with the emission limits is demonstrated in accordance with the provisions of § 63.1257, and continuous compliance is demonstrated in accordance with the provisions of § 63.1258.

\* \* \* \* \*

(d) \* \* \*

(2) Only emission sources subject to the requirements of § 63.1253(b)(1) or (c)(1)(i) or § 63.1254(a)(1)(i) may be included in any averaging group.

\* \* \* \* \*

(5) Emission points controlled to comply with a State or Federal rule other than this subpart may not be credited in an emission averaging group, unless the level of control has been increased after November 15, 1990 above what is required by the other State or Federal rule. \* \* \*

(6) Not more than 20 processes subject to § 63.1254(a)(1)(i), and 20 storage tanks subject to § 63.1253(b)(1) or (c)(1)(i) at an affected source may be included in an emissions averaging group.

(7) Compliance with the emission standards in § 63.1253 shall be satisfied when the annual percent reduction efficiency is greater than or equal to 90 percent for those tanks meeting the criteria of § 63.1253(a)(1) and 95 percent for those tanks meeting the criteria of § 63.1253(a)(2), as demonstrated using the test methods and compliance procedures specified in § 63.1257(g).

(8) Compliance with the emission standards in § 63.1254(a)(1)(i) shall be

satisfied when the annual percent reduction efficiency is greater than or equal to 93 percent, as demonstrated using the test methods and compliance procedures specified in § 63.1257(h).

(e) Pollution prevention alternative. Except as provided in paragraph (e)(1) of this section, an owner or operator may choose to meet the pollution prevention alternative requirement specified in either paragraph (e)(2) or (3) of this section for any PMPU or for any situation described in paragraph (e)(4) of this section, in lieu of the requirements specified in §§ 63.1253, 63.1254, 63.1255, and 63.1256.

Compliance with paragraphs (e)(2) and (3) of this section shall be demonstrated through the procedures in § 63.1257(f). Any PMPU for which the owner or operator seeks to comply by using the pollution prevention alternative shall begin with the same starting material(s) and end with the same product(s). The owner or operator may not comply with the pollution prevention alternative by eliminating any steps of a process by transferring the step offsite (to another manufacturing location).

(1) \* \* \* The hydrogen halides that are generated as a result of combustion control of emissions must be controlled according to the requirements of paragraph (g)(1) of this section.

\* \* \* \* \*

(4) The owner or operator may comply with the requirements in either paragraph (e)(2) or (3) of this section for a series of processes, including situations where multiple processes are merged, subject to the following conditions:

(i) The baseline period shall be a single year beginning no earlier than the 1992 calendar year.

(ii) The term "PMPU" shall have the meaning provided in § 63.1251 except that the baseline and modified PMPU may include multiple processes (i.e., precursors, active ingredients, and final dosage form) if the owner or operator demonstrates to the satisfaction of the Administrator that the multiple processes were merged after the baseline period into an existing process or processes.

(iii) Nondedicated formulation and solvent recovery processes may not be merged with any other processes.

\* \* \* \* \*

5. Section 63.1253 is amended by:

- a. Revising paragraph (a);
- b. Revising paragraph (d); and
- c. Adding paragraph (f).

The revisions and additions read as follows:

**§ 63.1253 Standards: Storage tanks.**

(a) Except as provided in paragraphs (d), (e), and (f) of this section, the owner or operator of a storage tank meeting the criteria of paragraph (a)(1) of this section is subject to the requirements of paragraph (b) of this section. Except as provided in paragraphs (d), (e), and (f) of this section, the owner or operator of a storage tank meeting the criteria of paragraph (a)(2) of this section is subject to the requirements of paragraph (c) of this section. Compliance with the provisions of paragraphs (b) and (c) of this section is demonstrated using the initial compliance procedures in § 63.1257(c) and the monitoring requirements in § 63.1258.

(1) A storage tank with a design capacity greater than or equal to 38 m<sup>3</sup> but less than 75 m<sup>3</sup> storing a liquid for which the maximum true vapor pressure of total HAP is greater than or equal to 13.1 kPa.

(2) A storage tank with a design capacity greater than or equal to 75 m<sup>3</sup> storing a liquid for which the maximum true vapor pressure of total HAP is greater than or equal to 13.1 kPa.

\* \* \* \* \*

(d) As an alternative standard, the owner or operator of an existing or new affected source may comply with the storage tank standards by routing storage tank vents to a combustion control device achieving an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 20 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 20 ppmv or less. If the owner or operator is routing emissions to a noncombustion control device, it must achieve an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 50 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 50 ppmv or less. Compliance with the outlet concentrations shall be determined by the initial compliance procedures of § 63.1257(c)(4) and the continuous emission monitoring requirements of § 63.1258(b)(5).

\* \* \* \* \*

(f) *Vapor balancing alternative.* As an alternative to the requirements in paragraphs (b) and (c) of this section, the owner or operator of an existing or new affected source may implement vapor balancing in accordance with paragraphs (f)(1) through (7) of this section.

(1) The vapor balancing system must be designed and operated to route organic HAP vapors displaced from loading of the storage tank to the railcar

or tank truck from which the storage tank is filled.

(2) Tank trucks and railcars must have a current certification in accordance with the U.S. Department of Transportation (DOT) pressure test requirements of 49 CFR part 180 for tank trucks and 49 CFR 173.31 for railcars.

(3) Hazardous air pollutants must only be unloaded from tank trucks or railcars when vapor collection systems are connected to the storage tank's vapor collection system.

(4) No pressure relief device on the storage tank, or on the railcar, or tank truck shall open during loading or as a result of diurnal temperature changes (breathing losses).

(5) Pressure relief devices on affected storage tanks must be set to no less than 2.5 psig at all times to prevent breathing losses. The owner or operator shall record the setting as specified in § 63.1259(b)(12) and comply with the requirements for each pressure relief valve in paragraphs (f)(5)(i) through (iii) of this section:

(i) The pressure relief valve shall be monitored quarterly using the method described in § 63.180(b).

(ii) An instrument reading of 500 ppmv or greater defines a leak.

(iii) When a leak is detected, it shall be repaired as soon as practicable, but no later than 5 days after it is detected, and the owner or operator shall comply with the recordkeeping requirements of § 63.1255(g)(4)(i) through (iv).

(6) Railcars or tank trucks that deliver HAP to an affected storage tank must be reloaded or cleaned at a facility that utilizes one of the control techniques in paragraph (f)(6)(i) through (ii) of this section:

(i) The railcar or tank truck must be connected to a closed-vent system with a control device that reduces inlet emissions of HAP by 90 percent by weight or greater; or

(ii) A vapor balancing system designed and operated to collect organic HAP vapor displaced from the tank truck or railcar during reloading must be used to route the collected HAP vapor to the storage tank from which the liquid being transferred originated.

(7) The owner or operator of the facility where the railcar or tank truck is reloaded or cleaned must comply with the requirements in paragraph (f)(7)(i) through (iii) of this section:

(i) Submit to the owner or operator of the affected storage tank and to the Administrator a written certification that the reloading or cleaning facility will meet the requirements of this section. The certifying entity may revoke the written certification by

sending a written statement to the owner or operator of the affected storage tank giving at least 90 days notice that the certifying entity is rescinding acceptance of responsibility for compliance with the requirements of this paragraph (b)(7)(i).

(ii) If complying with paragraph (f)(6)(i) of this section, demonstrate initial compliance in accordance with § 63.1257(c), demonstrate continuous compliance in accordance with § 63.1258, keep records as specified in § 63.1259, and prepare reports as specified in § 63.1260.

(iii) If complying with paragraph (f)(6)(ii) of this section, keep records of:

(A) The equipment to be used and the procedures to be followed when reloading the railcar or tank truck and displacing vapors to the storage tank from which the liquid originates, and

(B) Each time the vapor balancing system is used to comply with paragraph (f)(6)(ii) of this section.

6. Section 63.1254 is revised to read as follows:

**§ 63.1254 Standards: Process vents.**

(a) *Existing sources.* For each process, the owner or operator of an existing affected source must comply with the requirements in paragraphs (a)(1) and (3) of this section or paragraphs (a)(2) and (3) of this section. Initial compliance with the required emission limits or reductions in paragraphs (a)(1) through (3) of this section is demonstrated in accordance with the initial compliance procedures described in § 63.1257(d), and continuous compliance is demonstrated in accordance with the monitoring requirements described in § 63.1258.

(1) *Process-based emission reduction requirement.*

(i) Uncontrolled HAP emissions from the sum of all process vents within a process that are not subject to the requirements of paragraph (a)(3) of this section shall be reduced by 93 percent or greater by weight, or as specified in paragraph (a)(1)(ii) of this section. Notification of changes in the compliance method shall be reported according to the procedures in § 63.1260(h).

(ii) Any one or more vents within a process may be controlled in accordance with any of the procedures in paragraphs (a)(1)(ii)(A) through (D) of this section. All other vents within the process must be controlled as specified in paragraph (a)(1)(i) of this section.

(A) 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;

(B) By a flare that meets the requirements of § 63.11(b);

(C) By a control device specified in § 63.1257(a)(4); or

(D) In accordance with the alternative standard specified in paragraph (c) of this section.

(2) *Process-based annual mass limit.*

(i) Actual HAP emissions from the sum of all process vents within a process must not exceed 900 kilograms (kg) in any 365-day period.

(ii) Actual HAP emissions from the sum of all process vents within processes complying with paragraph (a)(2)(i) of this section are limited to a maximum of 1,800 kg in any 365-day period.

(iii) Emissions from vents that are subject to the requirements of paragraph (a)(3) of this section and emissions from vents that are controlled in accordance with the procedures in paragraph (c) of this section may be excluded from the sums calculated in paragraphs (a)(2)(i) and (ii) of this section.

(iv) The owner or operator may switch from compliance with paragraph (a)(2) of this section to compliance with paragraph (a)(1) of this section only after at least 1 year of operation in compliance with paragraph (a)(2) of this section. Notification of such a change in the compliance method shall be reported according to the procedures in § 63.1260(h).

(3) *Individual vent emission reduction requirements.*

(i) Except as provided in paragraph (a)(3)(ii) of this section, uncontrolled HAP emissions from a process vent must be reduced by 98 percent or in accordance with any of the procedures in paragraphs (a)(1)(ii)(A) through (D) of this section if the uncontrolled HAP emissions from the vent exceed 25 tons per year, and the flow-weighted average flowrate (FRA) calculated using Equation 1 of this subpart is less than or equal to the flowrate index (FRI) calculated using Equation 2 of this subpart.

$$FR_a = \frac{\sum_{i=1}^n (D_i)(FR_i)}{\sum_{i=1}^n (D_i)} \quad (\text{Eq. 1})$$

$$FRI = 0.02 * (HL) - 1,000 \quad (\text{Eq. 2})$$

Where:

FR<sub>a</sub> = flow-weighted average flowrate for the vent, scfm.

D<sub>i</sub> = duration of each emission event, min.

FR<sub>i</sub> = flowrate of each emission event, scfm.

n = number of emission events.

FRI = flowrate index, scfm.

HL = annual uncontrolled HAP emissions, lb/yr, as defined in § 63.1251.

(ii) *Grandfathering provisions.* As an alternative to the requirements in paragraph (a)(3)(i) of this section, the owner or operator may comply with the provisions in paragraph (a)(3)(ii)(A), (B), or (C) of this section, if applicable.

(A) *Control device operation.* If the owner or operator can demonstrate that a process vent is controlled by a control device meeting the criteria specified in paragraph (a)(3)(ii)(A)(1) of this section, then the control device is required to be operated according to paragraphs (a)(3)(ii)(A)(2), (3), and (4) of this section:

(1) The control device was installed on any process vent that met the conditions of paragraph (a)(3)(i) of this section on or before April 2, 1997, and was operated to reduce uncontrolled emissions of total HAP by greater than or equal to 93 percent by weight, but less than 98 percent by weight;

(2) The device must be operated to reduce inlet emissions of total HAP by 93 percent or by the percent reduction specified for that control device in any preconstruction permit issued pursuant to regulations approved or promulgated through rulemaking under title I (including parts C or D) of the Clean Air Act, whichever is greater;

(3) The device must be replaced or upgraded to achieve at least 98 percent reduction of HAP or meet any of the conditions specified in paragraphs (a)(1)(ii)(A) through (D) of this section upon reconstruction or replacement.

(4) The device must be replaced or upgraded to achieve at least 98 percent reduction of HAP or meet any of the conditions specified in paragraphs (a)(1)(ii)(A) through (D) of this section by April 2, 2007, or 15 years after issuance of the preconstruction permit, whichever is later.

(B) *Process operations.* If a process meets all of the conditions specified in paragraphs (a)(3)(ii)(B)(1) through (3) of this section, the required level of control for the process is the level that was achieved on or before April 2, 1997. This level of control is demonstrated using the same procedures that are used to demonstrate compliance with paragraph (a)(1) of this section.

(1) At least one vent in the process met the conditions of paragraph (a)(3)(i) of this section on or before April 2, 1997; and

(2) The overall control for the process on or before April 2, 1997 was greater than or equal to 93 percent by weight, but less than 98 percent by weight; and

(3) The production-indexed HAP consumption factor for the 12-month period in which the process was

operated prior to the compliance date is less than one-half of the 3-year average baseline value established no earlier than the 1987 through 1989 calendar years.

(C) *Hydrogenation vents.* Processes meeting the conditions of paragraphs (a)(3)(ii)(C)(1) through (3) of this section are required to be operated to maintain the level of control achieved on or before April 2, 1997. For all other processes meeting the conditions of paragraph (a)(3)(ii)(C)(3) of this section, uncontrolled HAP emissions from the sum of all process vents within the process must be reduced by 95 percent or greater by weight.

(1) Processes containing a process vent that met the conditions of paragraph (a)(3)(i) of this section on or before April 2, 1997; and

(2) Processes that are controlled to greater than or equal to 93 percent by weight, but less than 98 percent by weight; and

(3) Processes with a hydrogenation vent that, in conjunction with all other process vents from the process that do not meet the conditions of paragraph (a)(3)(i) of this section, cannot meet the requirements of paragraph (a)(1) or (2) of this section.

(b) *New sources.* (1) Except as provided in paragraph (b)(2) of this section, uncontrolled HAP emissions from the sum of all process vents within a process at a new affected source shall be reduced by 98 percent or greater by weight or controlled in accordance with any of requirements of paragraphs (a)(1)(ii)(A) through (D) of this section. Initial compliance with the required emission limit or reduction is demonstrated in accordance with the initial compliance procedures in § 63.1257(d), and continuous compliance is demonstrated in accordance with the monitoring requirements described in § 63.1258.

(2) *Annual mass limit.* The actual HAP emissions from the sum of all process vents for which the owner or operator is not complying with paragraph (b)(1) of this section are limited to 900 kg in any 365-day period.

(c) *Alternative standard.* As an alternative standard, the owner or operator of an existing or new affected source may comply with the process vent standards by routing vents from a process to a combustion control device achieving an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 20 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 20 ppmv or less. If the owner or operator is routing emissions to a noncombustion control device, it must achieve an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 50 ppmv or



less, and an outlet concentration of hydrogen halides and halogens of 50 ppmv or less. Any process vents within a process that are not routed to this control device must be controlled in accordance with the provisions of paragraph (a) or (b) of this section, as applicable. Initial compliance with the outlet concentrations is demonstrated in accordance with the initial compliance procedures described in § 63.1257(d)(1)(iv), and continuous compliance is demonstrated in accordance with the emission monitoring requirements described in § 63.1258(b)(5).

7. Section 63.1255 is amended by:

- a. Revising paragraph (a)(1);
- b. Revising paragraph (a)(7);
- c. Revising paragraphs (a)(10)(ii) and (iii);
- d. Adding paragraphs (a)(11) and (12);
- e. Revising paragraph (b);
- f. Revising paragraph (c)(2)(i);
- g. Revising "paragraph (b)(1)(v)" to read "paragraph (b)(4)(i)" in paragraph (c)(3)(i);
- h. Revising the definitions of the terms "P<sub>L</sub>" and "P<sub>T</sub>" following Equation 3 in paragraph (c)(4)(iv);
- i. Removing the definition of the term "PS" following Equation 3 in paragraph (c)(4)(iv) and adding the definition of the term "P<sub>S</sub>" following Equation 3 in paragraph (c)(4)(iv);
- j. Revising "paragraph (b)(1)(vi)" to read "paragraph (b)(4)(ii)" in paragraph (c)(5)(i)(B);
- k. Revising paragraphs (c)(5)(vi)(B) and (C);
- l. Revising paragraphs (c)(6) and (7);
- m. Revising paragraph (c)(9);
- n. Revising paragraphs (d)(1)(ii);
- o. Revising paragraph (e)(3) introductory text;
- p. Revising the definitions of the terms "%V<sub>L</sub>" and V<sub>i</sub>" following Equation 4 in paragraph (e)(5)(iii);
- q. Revising the definition of the term "%V<sub>L</sub>" following Equation 5 in paragraph (e)(6)(ii);
- r. Revising "paragraph (b)(1)(v)" to read "paragraph (b)(4)(i)" in paragraph (e)(7)(i);
- s. Adding paragraphs (e)(7)(iii)(A) through (C);
- t. Revising the second sentence in paragraph (e)(9);
- u. Revising paragraph (f);
- v. Revising paragraph (g)(2) introductory text;
- w. Revising paragraph (g)(2)(i)(A);
- x. Removing paragraph (g)(2)(v), redesignating paragraphs (g)(2)(vi) through (ix) as paragraphs (g)(2)(v) through (viii), and revising redesignated paragraphs (g)(2)(vi) and (viii);
- y. Revising the first sentence in paragraph (g)(3);

z. Revising paragraph (g)(4) introductory text

- aa. Revising paragraph (g)(4)(iv)
  - bb. Revising paragraph (g)(4)(v)(A)
  - cc. Revising "§ 63.174(c)" to read "§ 63.174(c)(1)(i) and (c)(2)(ii)" in the first sentence in paragraph (g)(4)(vii)(B)
  - dd. Revising "§§ 63.178(c)(3)(ii) and (c)(3)(iii)" to read "§ 63.178(c)(3)(ii) and (iii)" in the first sentence in paragraph (g)(4)(viii)
  - ee. Revising the first sentence in paragraph (g)(5) introductory text
  - ff. Removing paragraph (g)(5)(ii), redesignating paragraphs (g)(5)(iii) through (vi) as paragraphs (g)(5)(ii) through (v), and revising "appendix" to read "section" in the second sentence of redesignated paragraph (g)(5)(ii)
  - gg. Revising paragraph (g)(6) heading
  - hh. Revising the first sentence in paragraph (g)(7) introductory text
  - ii. Revising "paragraph (b)(1)(vi)" to read "paragraph (b)(4)(ii)" in paragraph (g)(7)(i)(D)
  - jj. Revising paragraph (h)(2) heading
  - kk. Revising paragraph (h)(2)(i)(B)
  - ll. Revising "paragraph (b)(1)(ix)" to read "paragraph (b)(4)(iv)" in paragraph (h)(2)(ii)
  - mm. Revising "paragraph (b)(1)(vi)" to read "paragraph (b)(4)(ii)" in paragraph (h)(2)(iii)(B)
  - nn. Revising paragraph (h)(2)(iv)
  - oo. Revising "§ 63.1250(e)" to read "§ 63.1250(f)" in the second sentence in paragraph (h)(3)(i)
  - pp. Revising paragraph (h)(3)(ii) introductory text
  - qq. Revising paragraphs (h)(3)(ii)(C) and (D); and
  - rr. Revising paragraph (h)(3)(iv);
- The revisions and additions read as follows:

**§ 63.1255 Standards: Equipment leaks.**

- (a) \* \* \*
- (1) The provisions of this section apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems required by this section that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year within a source subject to the provisions of this subpart.

\* \* \* \* \*

(7) Equipment to which this section applies shall be identified such that it can be distinguished readily from equipment that is not subject to this section. Identification of the equipment does not require physical tagging of the equipment. For example, the equipment may be identified on a plant site plan,

in log entries, or by designation of process boundaries by some form of weatherproof identification. If changes are made to the affected source subject to the leak detection requirements, equipment identification for each type of component shall be updated, if needed, within 90 calendar days or by the next Periodic Report following the end of the monitoring period for that component, whichever is later.

\* \* \* \* \*

(10) \* \* \*

(ii) The identification on a valve in light liquid or gas/vapor service may be removed after it has been monitored as specified in paragraph (e)(7)(iii) of this section, and no leak has been detected during the follow-up monitoring.

(iii) The identification on equipment, except on a valve in light liquid or gas/vapor service, may be removed after it has been repaired.

(11) Except as provided in paragraph (a)(11)(i) of this section, all terms in this subpart that define a period of time for completion of required tasks (e.g., weekly, monthly, quarterly, annual) refer to the standard calendar periods unless specified otherwise in the section or paragraph that imposes the requirement.

(i) If the initial compliance date does not coincide with the beginning of the standard calendar period, an owner or operator may elect to utilize a period beginning on the compliance date, or may elect to comply in accordance with the provisions of paragraph (a)(11)(ii) or (iii) of this section.

(ii) Time periods specified in this subpart for completion of required tasks may be changed by mutual agreement between the owner or operator and the Administrator, as specified in subpart A of this part. For each time period that is changed by agreement, the revised period shall remain in effect until it is changed. A new request is not necessary for each recurring period.

(iii) Except as provided in paragraph (a)(11)(i) or (ii) of this section, where the period specified for compliance is a standard calendar period, if the initial compliance date does not coincide with the beginning of the calendar period, compliance shall be required according to the schedule specified in paragraph (a)(11)(iii)(A) or (B) of this section, as appropriate.

(A) Compliance shall be required before the end of the standard calendar period within which the initial compliance date occurs if there remain at least 3 days for tasks that must be performed weekly, at least 2 weeks for tasks that must be performed monthly, at least 1 month for tasks that must be

performed each quarter, or at least 3 months for tasks that must be performed annually; or

(B) In all other cases, compliance shall be required before the end of the first full standard calendar period after the period within which the initial compliance date occurs.

(iv) In all instances where a provision of this subpart requires completion of a task during each of multiple successive periods, an owner or operator may perform the required task at any time during each period, provided the task is conducted at a reasonable interval after completion of the task during the previous period.

(12) In all cases where the provisions of this subpart require an owner or operator to repair leaks by a specified time after the leak is detected, it is a violation of this section to fail to take action to repair the leaks within the specified time. If action is taken to repair the leaks within the specified time, failure of that action to successfully repair the leak is not a violation of this section. However, if the repairs are unsuccessful, a leak is detected and the owner or operator shall take further action as required by applicable provisions of this section.

(b) *References.* (1) The owner or operator of a source subject to this section shall comply with the provisions of subpart H of this part, as specified in paragraphs (b)(2) through (4) of this section. The term "process unit" as used in subpart H of this part shall be considered to be defined the same as "group of processes" for sources subject to this subpart GGG. The term "fuel gas system," as used in subpart H of this part, shall not apply for the purposes of this subpart GGG.

(2) Sections 63.160, 63.161, 63.162, 63.163, 63.167, 63.168, 63.170, 63.173, 63.175, 63.176, 63.181, and 63.182 shall not apply for the purposes of this subpart GGG. The owner or operator shall comply with the provisions specified in paragraphs (b)(2)(i) through (viii) of this section.

(i) Sections 63.160 and 63.162 shall not apply; instead, the owner or operator shall comply with paragraph (a) of this section;

(ii) Section 63.161 shall not apply; instead, the owner or operator shall comply with § 63.1251;

(iii) Sections 63.163 and 63.173 shall not apply; instead, the owner or operator shall comply with paragraph (c) of this section;

(iv) Section 63.167 shall not apply; instead, the owner or operator shall comply with paragraph (d) of this section;

(v) Section 63.168 shall not apply; instead, the owner or operator shall comply with paragraph (e) of this section;

(vi) Section 63.170 shall not apply; instead, the owner or operator shall comply with § 63.1254;

(vii) Section 63.181 shall not apply; instead, the owner or operator shall comply with paragraph (g) of this section; and

(viii) Section 63.182 shall not apply; instead, the owner or operator shall comply with paragraph (h) of this section.

(3) The owner or operator shall comply with §§ 63.164, 63.165, 63.166, 63.169, 63.177, and 63.179 in their entirety, except that when these sections reference other sections of subpart H of this part, the references shall mean the sections specified in paragraphs (b)(2) and (4) of this section. Section 63.164 applies to compressors. Section 63.165 applies to pressure relief devices in gas/vapor service. Section 63.166 applies to sampling connection systems. Section 63.169 applies to pumps, valves, connectors, and agitators in heavy liquid service; instrumentation systems; and pressure relief devices in liquid service. Section 63.177 applies to general alternative means of emission limitation. Section 63.179 applies to alternative means of emission limitation for enclosed-vented process units.

(4) The owner or operator shall comply with §§ 63.171, 63.172, 63.174, 63.178, and 63.180, except as specified in paragraphs (b)(4)(i) through (vi) of this section.

(i) Section 63.171 shall apply, except § 63.171(a) shall not apply. Instead, delay of repair of equipment for which leaks have been detected is allowed if one of the conditions in paragraphs (b)(4)(i)(A) through (B) exists:

(A) The repair is technically infeasible without a process shutdown. Repair of this equipment shall occur by the end of the next scheduled process shutdown.

(B) The owner or operator determines that repair personnel would be exposed to an immediate danger if attempting to repair without a process shutdown. Repair of this equipment shall occur by the end of the next scheduled process shutdown.

(ii) Section 63.172 shall apply for closed-vent systems used to comply with this section, and for control devices used to comply with this section only, except:

(A) Section 63.172(k) and (l) shall not apply. The owner or operator shall instead comply with paragraph (f) of this section.

(B) Owners or operators may, instead of complying with the provisions of § 63.172(f), design a closed-vent system to operate at a pressure below atmospheric pressure. The system shall be equipped with at least one pressure gage or other pressure measurement device that can be read from a readily accessible location to verify that negative pressure is being maintained in the closed-vent system when the associated control device is operating.

(iii) Section 63.174 shall apply except:

(A) Section 63.174(f), (g), and (h) shall not apply. Instead of § 63.174(f), (g), and (h), the owner or operator shall comply with paragraph (f) of this section.

Section 63.174(b)(3) shall not apply. Instead of § 63.174(b)(3), the owner or operator shall comply with paragraphs (b)(3)(iii)(B) through (F) of this section.

(B) If the percent leaking connectors in a group of processes was greater than or equal to 0.5 percent during the initial monitoring period, monitoring shall be performed once per year until the percent leaking connectors is less than 0.5 percent.

(C) If the percent leaking connectors in the group of processes was less than 0.5 percent, but equal to or greater than 0.25 percent, during the initial or last required monitoring period, the owner or operator may elect to monitor once every 4 years. An owner or operator may comply with the requirements of this paragraph by monitoring at least 40 percent of the connectors in the first 2 years and the remainder of the connectors within the next 2 years. The percent leaking connectors will be calculated for the total of all required monitoring performed during the 4-year period.

(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, the owner or operator shall monitor once per year if the percent leaking connectors is greater than or equal to 0.5 percent; if the percent leaking connectors is less than 0.5 percent, the owner or operator shall monitor in accordance with paragraph (b)(4)(iii)(C) or (F) of this section, as appropriate.

(E) If an owner or operator determines that 1 percent or greater of the connectors in a group of processes are leaking, the owner or operator shall monitor the connectors once per year. The owner or operator may elect to use the provisions of paragraph (b)(4)(iii)(C), (D), or (F) of this section, as appropriate,

after a monitoring period in which less than 1 percent of the connectors are determined to be leaking.

(F) The owner or operator may elect to perform monitoring once every 8 years if the percent leaking connectors in the group of processes was less than 0.25 percent during the initial or last required monitoring period. An owner or operator shall monitor at least 50 percent of the connectors in the first 4 years and the remainder of the connectors within the next 4 years. If the percent leaking connectors in the first 4 years is equal to or greater than 0.35 percent, the monitoring program shall revert at that time to the appropriate monitoring frequency specified in paragraph (b)(4)(iii)(C), (D), or (E) of this section.

(iv) Section 63.178 shall apply except:

(A) Section 63.178(b), requirements for pressure testing, may be applied to all processes (not just batch processes) and to supply lines between storage and processing areas.

(B) For pumps, the phrase "at the frequencies specified in Table 1 of this subpart" in § 63.178(c)(3)(iii) shall mean "quarterly" for the purposes of this subpart.

(v) Section 63.180 shall apply except § 63.180(b)(4)(ii)(A) through (C) shall not apply. Instead, calibration gases shall be a mixture of methane and air at a concentration of approximately, but less than, 10,000 parts per million methane for agitators; 2,000 parts per million for pumps; and 500 parts per million for all other equipment, except as provided in § 63.180(b)(4)(iii).

(vi) When §§ 63.171, 63.172, 63.174, 63.178, and 63.180 reference other sections in subpart H of this part, the references shall mean those sections specified in paragraphs (b)(2) and (b)(4)(i) through (v) of this section, as applicable.

(c) \* \* \*

(2)(i) *Monitoring.* Each pump and agitator subject to this section shall be monitored quarterly to detect leaks by the method specified in § 63.180(b) except as provided in §§ 63.177, 63.178, paragraph (f) of this section, and paragraphs (c)(5) through (9) of this section.

\* \* \* \* \*

(4) \* \* \*

(iv) \* \* \*

P<sub>L</sub> = number of pumps found leaking as determined through periodic monitoring as required in paragraphs (c)(2)(i) and (ii) of this section.

P<sub>T</sub> = total pumps in organic HAP service, including those meeting the criteria in paragraphs (c)(5) and (6) of this section.

P<sub>s</sub> = number of pumps in a continuous process leaking within 1 quarter of startup during the current monitoring period.

(5) \* \* \*

(vi) \* \* \*

(B) If indications of liquids dripping from the pump/agitator seal exceed the criteria established in paragraph (c)(5)(vi)(A) of this section, or if, based on the criteria established in paragraph (c)(5)(vi)(A) of this section, the sensor indicates failure of the seal system, the barrier fluid system, or both, a leak is detected.

(C) When a leak is detected, it shall be repaired as soon as practicable, but not later than 15 calendar days after it is detected, except as provided in paragraph (b)(4)(i) of this section.

\* \* \* \* \*

(6) Any pump/agitator that is designed with no externally actuated shaft penetrating the pump/agitator housing is exempt from the requirements of paragraphs (c)(1) through (3) of this section.

(7) Any pump/agitator equipped with a closed-vent system capable of capturing and transporting any leakage from the seal or seals back to the process or to a control device that complies with the requirements of paragraph (b)(4)(ii) of this section is exempt from the requirements of paragraphs (c)(2) through (5) of this section.

\* \* \* \* \*

(9) If more than 90 percent of the pumps in a group of processes meet the criteria in either paragraph (c)(5) or (6) of this section, the group of processes is exempt from the requirements of paragraph (c)(4) of this section.

(d) \* \* \*

(1) \* \* \*

(ii) The cap, blind flange, plug, or second valve shall seal the open end at all times except during operations requiring process fluid flow through the open-ended valve or line, or during maintenance or repair. The cap, blind flange, plug, or second valve shall be in place within 1 hour of cessation of operations requiring process fluid flow through the open-ended valve or line, or within 1 hour of cessation of maintenance or repair. The owner or operator is not required to keep a record documenting compliance with the 1-hour requirement.

\* \* \* \* \*

(e) \* \* \*

(3) *Monitoring.* The owner or operator of a source subject to this section shall monitor all valves, except as provided in paragraph (f) of this section and in § 63.177, at the intervals specified in paragraph (e)(4) of this section and shall

comply with all other provisions of this section, except as provided in paragraph (b)(4)(i) of this section, §§ 63.178 and 63.179.

\* \* \* \* \*

(5) \* \* \*

(iii) \* \* \*

%V<sub>Li</sub> = percent leaking valves in subgroup i, most recent value calculated according to the procedures in paragraphs (e)(6)(ii) and (iii) of this section.

V<sub>i</sub> = number of valves in subgroup i.

\* \* \* \* \*

\* \* \* \* \*

(6) \* \* \*

(ii) \* \* \*

%V<sub>L</sub> = percent leaking valves as determined through periodic monitoring required in paragraphs (e)(2) through (4) of this section.

\* \* \* \* \*

(7) \* \* \*

(iii) \* \* \*

(A) The monitoring shall be conducted as specified in § 63.180(b) and (c) as appropriate to determine whether the valve has resumed leaking.

(B) Periodic monitoring required by paragraphs (e)(2) through (4) of this section may be used to satisfy the requirements of paragraph (e)(7)(iii) of this section, if the timing of the monitoring period coincides with the time specified in paragraph (e)(7)(iii) of this section. Alternatively, other monitoring may be performed to satisfy the requirements of paragraph (e)(7)(iii) of this section, regardless of whether the timing of the monitoring period for periodic monitoring coincides with the time specified in paragraph (e)(7)(iii) of this section.

(C) If a leak is detected by monitoring that is conducted pursuant to paragraph (e)(7)(iii) of this section, the owner or operator shall follow the provisions of paragraphs (e)(7)(iii)(C)(1) and (2) of this section to determine whether that valve must be counted as a leaking valve for purposes of paragraph (e)(6) of this section.

(1) If the owner or operator elects to use periodic monitoring required by paragraphs (e)(2) through (4) of this section to satisfy the requirements of paragraph (e)(7)(iii) of this section, then the valve shall be counted as a leaking valve.

(2) If the owner or operator elects to use other monitoring prior to the periodic monitoring required by paragraphs (e)(2) through (4) of this section to satisfy the requirements of paragraph (e)(7)(iii) of this section, then the valve shall be counted as a leaking

valve unless it is repaired and shown by periodic monitoring not to be leaking.

\* \* \* \* \*

(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) or (iv) of this section, except as provided in paragraph (f) of this section.

(f) *Unsafe to monitor/inspect, difficult to monitor/inspect, and inaccessible equipment.* (1) Equipment that is designated as unsafe to monitor, unsafe to inspect, difficult to monitor, difficult to inspect, or inaccessible is exempt from the monitoring requirements as specified in paragraphs (f)(1)(i) through (iv) of this section provided the owner or operator meets the requirements specified in paragraph (f)(2), (3), or (4) of this section, as applicable. All equipment must be assigned to a group of processes. Ceramic or ceramic-lined connectors are subject to the same requirements as inaccessible connectors.

(i) For pumps and agitators, paragraphs (c)(2), (3), and (4) of this section do not apply.

(ii) For valves, paragraphs (e)(2) through (7) of this section do not apply.

(iii) For connectors, § 63.174(b) through (e) and paragraphs (b)(4)(iii)(B) through (F) of this section do not apply.

(iv) For closed-vent systems, § 63.172(f)(1) and (2) and § 63.172(g) do not apply.

(2) *Equipment that is unsafe to monitor or unsafe to inspect.* (i) Valves, connectors, agitators, and pumps may be designated as unsafe to monitor if the owner or operator determines that monitoring personnel would be exposed to an immediate danger as a consequence of complying with the monitoring requirements referred to in paragraphs (f)(1)(i) through (iii) of this section.

(ii) Any part of a closed-vent system may be designated as unsafe to inspect if the owner or operator determines that monitoring personnel would be exposed to an immediate danger as a consequence of complying with the monitoring requirements referred to in paragraph (f)(1)(iv) of this section.

(iii) The owner or operator of equipment that is designated as unsafe to monitor must have a written plan that requires monitoring of the equipment as frequently as practicable during safe to monitor times, but not more frequently than the periodic monitoring schedule otherwise applicable to the group of processes in which the equipment is located.

(iv) For any parts of a closed-vent system designated as unsafe to inspect,

the owner or operator must have a written plan that requires inspection of the closed-vent systems as frequently as practicable during safe to inspect times, but not more frequently than annually.

(3) *Equipment that is difficult to monitor or difficult to inspect.* (i) A valve, agitator, or pump may be designated as difficult to monitor if the owner or operator determines that the valve, agitator, or pump cannot be monitored without elevating the monitoring personnel more than 2 meters above a support surface, or it is not accessible in a safe manner when it is in organic HAP service.

(ii) Any part of a closed-vent system may be designated as difficult to inspect if the owner or operator determines that the equipment cannot be inspected without elevating the monitoring personnel more than 2 meters above a support surface, or it is not accessible in a safe manner when it is in organic HAP service.

(iii) At an existing source, any valve, agitator or pump within a group of processes that meets the criteria of paragraph (f)(3)(i) of this section may be designated as difficult to monitor, and any parts of a closed-vent system that meet the requirements of paragraph (f)(3)(ii) of this section may be designated as difficult to inspect. At a new affected source, an owner or operator may designate no more than 3 percent of valves as difficult to monitor.

(iv) The owner or operator of valves, agitators, or pumps designated as difficult to monitor must have a written plan that requires monitoring of the equipment at least once per calendar year or on the periodic monitoring schedule otherwise applicable to the group of processes in which the equipment is located, whichever is less frequent. For any part of a closed-vent system designated as difficult to inspect, the owner or operator must have a written plan that requires inspection of the closed-vent system at least once every 5 years.

(4) *Inaccessible, ceramic, or ceramic-lined connectors.* (i) A connector may be designated as inaccessible if it is:

(A) Buried;

(B) Insulated in a manner that prevents access to the connector by a monitor probe;

(C) Obstructed by equipment or piping that prevents access to the connector by a monitor probe;

(D) Unable to be reached from a wheeled scissor-lift or hydraulic-type scaffold which would allow access to equipment up to 7.6 meters (25 feet) above the ground; or

(E) Not able to be accessed at any time in a safe manner to perform monitoring.

Unsafe access includes, but is not limited to, the use of a wheeled scissor-lift on unstable or uneven terrain, the use of a motorized man-lift basket in areas where an ignition potential exists, or access would require near proximity to hazards such as electrical lines, or would risk damage to equipment.

(ii) A connector may be designated as inaccessible if it would require elevating the monitoring personnel more than 2 meters above a permanent support surface or would require the erection of scaffold.

(iii) At an existing source, any connector that meets the criteria of paragraph (f)(4)(i) or (ii) of this section may be designated as inaccessible. At a new affected source, an owner or operator may designate no more than 3 percent of connectors as inaccessible.

(iv) If any inaccessible, ceramic, or ceramic-lined connector is observed by visual, audible, olfactory, or other means to be leaking, the leak shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in paragraph (b)(4)(i) of this section.

(v) Any connector that is inaccessible or that is ceramic or ceramic-lined is exempt from the recordkeeping and reporting requirements of paragraphs (g) and (h) of this section.

(g) \* \* \*

(2) *General recordkeeping.* Except as provided in paragraph (g)(5)(i) of this section and in paragraph (a)(9) of this section, the following information pertaining to all equipment subject to the requirements in this section shall be recorded:

(i)(A) A list of identification numbers for equipment (except connectors that are subject to paragraph (f)(4) of this section) subject to the requirements of this section. Except for equipment subject to the recordkeeping requirements in paragraphs (g)(2)(ii) through (viii) of this section, equipment need not be individually identified if, for a particular type of equipment, all items of that equipment in a designated area or length of pipe subject to the provisions of this section are identified as a group, and the number of subject items of equipment is indicated. The list for each type of equipment shall be completed no later than the completion of the initial survey required for that component. The list of identification numbers shall be updated, if needed, to incorporate equipment changes identified during the course of each monitoring period within 90 calendar days, or by the next Periodic Report, following the end of the monitoring period for the type of equipment

component monitored, whichever is later.

\* \* \* \* \*

(vi) A list of equipment designated as unsafe to monitor/inspect or difficult to monitor/inspect under paragraph (f) of this section and a copy of the plan for monitoring or inspecting this equipment.

\* \* \* \* \*

(viii) For equipment that the owner or operator elects to monitor as provided under § 63.178(c), a list of equipment added to batch product processes since the last monitoring period required in § 63.178(c)(3)(ii) and (iii). This list must be completed for each type of equipment within 90 calendar days, or by the next Periodic Report, following the end of the monitoring period for the type of equipment monitored, whichever is later. Also, if the owner or operator elects to adjust monitoring frequency by the time in use, as provided in § 63.178(c)(3)(iii), records demonstrating the proportion of the time during the calendar year the equipment is in use in a manner subject to the provisions of this section are required. Examples of suitable documentation are records of time in use for individual pieces of equipment or average time in use for the process unit.

(3) *Records of visual inspections.* For visual inspections of equipment subject to the provisions of paragraphs (c)(2)(iii) and (c)(5)(iv) of this section, the owner or operator shall document that the inspection was conducted and the date of the inspection. \* \* \*

(4) *Monitoring records.* When each leak is detected as specified in paragraph (c) of this section and § 63.164, paragraph (e) of this section and § 63.169, and §§ 63.172 and 63.174, the following information shall be recorded and kept for 5 years (at least 2 years onsite, with the remaining 3 years either onsite or offsite):

\* \* \* \* \*

(iv) The maximum instrument reading measured by Method 21 of 40 CFR part 60, appendix A, after the leak is successfully repaired or determined to be nonreparable.

(v) \* \* \*

(A) The owner or operator may develop a written procedure that identifies the conditions that justify a delay of repair. The written procedures shall be included either as part of the startup/shutdown/malfunction plan, required by § 63.1259(a)(3), or in a separate document that is maintained at the plant site. Reasons for delay of repair may be documented by citing the

relevant sections of the written procedure.

\* \* \* \* \*

(5) *Records of pressure tests.* The owner or operator who elects to pressure test a process equipment train or supply lines between storage and processing areas to demonstrate compliance with this section is exempt from the requirements of paragraphs (g)(2), (3), (4), and (6) of this section.

\* \* \* \* \*

(6) *Records of compressor and relief device compliance tests.* \* \* \*

\* \* \* \* \*

(7) *Records for closed-vent systems.* The owner or operator shall maintain records of the information specified in paragraphs (g)(7)(i) through (iii) of this section for closed-vent systems and control devices subject to the provisions of paragraph (b)(4)(ii) of this section.

\* \* \* \* \*

(h) \* \* \*

(2) *Notification of compliance status report.* \* \* \*

(i) \* \* \*

(B) Number of each equipment type (e.g., valves, pumps) in organic HAP service, excluding equipment in vacuum service.

\* \* \* \* \*

(iv) Section 63.9(j) shall not apply to the Notification of Compliance Status report described in this paragraph (h)(2).

(3) \* \* \*

(ii) For equipment complying with the provisions of paragraphs (b) through (g) of this section, except paragraph (b)(4)(iv) of this section and § 63.179, the summary information listed in paragraphs (h)(3)(ii)(A) through (L) of this section for each monitoring period during the 6-month period.

\* \* \* \* \*

(C) Separately, the number of pumps and agitators for which leaks were detected as described in paragraph (c)(2) of this section, the total number of pumps and agitators monitored, and, for pumps, the percent leakers;

(D) Separately, the number of pumps and agitators for which leaks were not repaired as required in paragraph (c)(3) of this section;

\* \* \* \* \*

(iv) Any revisions to items reported in earlier Notification of Compliance Status report, if the method of compliance has changed since the last report.

8. Section 63.1256 is amended by:  
a. Revising paragraph (a) introductory text;

b. Revising paragraph (a)(1) introductory text;

c. Revising paragraphs (a)(1)(i)(A) and (B);

d. Removing paragraph (a)(3) and redesignating paragraph (a)(4) as paragraph (a)(3);

e. Adding paragraph (a)(4);

f. Revising paragraph (a)(5) introductory text;

g. Revising paragraph (a)(5)(ii)(C);

h. Adding paragraph (a)(5)(ii)(D);

i. Adding paragraph (b)(6)(i);

j. Revising paragraphs (d)(2) introductory text and paragraph (d)(2)(i);

k. Revising paragraph (g)(8)(ii);

l. Revising paragraph (g)(11)(ii); and

m. Revising paragraph (g)(12).

The revisions and additions read as follows:

#### § 63.1256 Standards: Wastewater.

(a) *General.* Each owner or operator of any affected source (existing or new) shall comply with the general wastewater requirements in paragraphs (a)(1) through (3) of this section and the maintenance wastewater provisions in paragraph (a)(4) of this section. An owner or operator may transfer wastewater to a treatment operation not owned by the owner or operator in accordance with paragraph (a)(5) of this section.

(1) *Identify wastewater that requires control.* For each POD, the owner or operator shall comply with the requirements in either paragraph (a)(1)(i) or (ii) of this section to determine whether a wastewater stream is an affected wastewater stream that requires control for soluble and/or partially soluble HAP compounds or to designate the wastewater stream as an affected wastewater stream, respectively. The owner or operator may use a combination of the approaches in paragraphs (a)(1)(i) and (ii) of this section for different affected wastewater generated at the source.

(i) \* \* \*

(A) The wastewater stream contains partially soluble HAP compounds at an annual average concentration greater than 1,300 ppmw, and the total soluble and partially soluble HAP load in all wastewater from the PMPU exceeds 0.25 Mg/yr.

(B) The wastewater stream contains partially soluble and/or soluble HAP compounds at an annual average concentration greater than 5,200 ppmw, and the total soluble and partially soluble HAP load in all wastewater from the PMPU exceeds 0.25 Mg/yr.

\* \* \* \* \*

(4) *Maintenance wastewater requirements.* Each owner or operator of a source subject to this subpart shall comply with the requirements of

paragraphs (a)(4)(i) through (iv) of this section for maintenance wastewater containing partially soluble or soluble HAP listed in Tables 2 and 3 of this subpart. Maintenance wastewater is exempt from all other provisions of this subpart.

(i) The owner or operator shall prepare a description of maintenance procedures for management of wastewater generated from the emptying and purging of equipment in the process during temporary shutdowns for inspections, maintenance, and repair (i.e., a maintenance turnaround) and during periods which are not shutdowns (i.e., routine maintenance). The descriptions shall:

(A) Specify the process equipment or maintenance tasks that are anticipated to create wastewater during maintenance activities; and

(B) Specify the procedures that will be followed to properly manage the wastewater and minimize organic HAP emissions to the atmosphere; and

(C) Specify the procedures to be followed when clearing materials from process equipment.

(ii) The owner or operator shall modify and update the information required by paragraph (a)(4)(i) of this section as needed following each maintenance procedure based on the actions taken and the wastewater generated in the preceding maintenance procedure.

(iii) The owner or operator shall implement the procedures described in paragraphs (a)(4)(i) and (ii) of this section as part of the startup, shutdown, and malfunction plan required under § 63.6(e)(3).

(iv) The owner or operator shall maintain a record of the information required by paragraphs (a)(4)(i) and (ii) of this section as part of the startup, shutdown, and malfunction plan required under § 63.6(e)(3).

(5) *Offsite treatment or onsite treatment not owned or operated by the source.* The owner or operator may elect to transfer affected wastewater streams or a residual removed from such affected wastewater to an onsite treatment operation not owned or operated by the owner or operator of the source generating the wastewater or residual, or to an offsite treatment operation.

\* \* \* \* \*

(ii) \* \* \*

(C) Section 63.6(g); or

(D) If the affected wastewater streams or residuals removed from affected wastewater streams received by the transferee contain less than 50 ppmw of partially soluble HAP, then the

transferee must, at a minimum, manage and treat the affected wastewater streams and residuals in accordance with one of the following:

(1) Comply with paragraph (g)(10) of this section and cover the waste management units up to the activated sludge unit; or

(2) Comply with paragraphs (g)(11)(i), (ii), and (h) of this section and cover the waste management units up to the activated sludge unit; or

(3) Comply with paragraph (g)(10) of this section provided that the owner or operator of the affected source demonstrates that less than 5 percent of the total soluble HAP is emitted from waste management units up to the activated sludge unit; or

(4) Comply with paragraphs (g)(11)(i), (ii), and (h) of this section provided that the owner or operator of the affected source demonstrates that less than 5 percent of the total soluble HAP is emitted from waste management units up to the activated sludge unit.

\* \* \* \* \*

(b) \* \* \*

(6) \* \* \*

(i) The owner or operator shall measure the seal gaps or inspect the wastewater tank within 30 calendar days of the determination that the floating roof is unsafe.

\* \* \* \* \*

(d) \* \* \*

(2) *Filling of large containers.* Pumping affected wastewater or a residual removed from affected wastewater into a container with a capacity greater than or equal to 0.42 m<sup>3</sup> shall be conducted in accordance with the conditions in paragraphs (d)(2)(i) and (ii) of this section.

(i) Comply with any one of the procedures specified in paragraph (d)(2)(i)(A), (B), or (C) of this section.

(A) Use a submerged fill pipe. The submerged fill pipe outlet shall extend to no more than 6 inches or within two fill pipe diameters of the bottom of the container while the container is being filled.

(B) Locate the container within an enclosure with a closed-vent system that routes the organic HAP vapors vented from the container to a control device.

(C) Use a closed-vent system to vent the displaced organic vapors vented from the container to a control device or back to the equipment from which the wastewater is transferred.

\* \* \* \* \*

(g) \* \* \*

(8) \* \* \*

(ii) *Percent mass removal/destruction option.* The owner or operator shall reduce, by removal or destruction, the

mass of total partially soluble HAP compounds by 99 percent or more. The removal destruction efficiency shall be determined by the procedures specified in § 63.1257(e)(2)(ii) or (iii)(C) for noncombustion, nonbiological treatment processes; § 63.1257(e)(2)(ii) or (iii)(D) for combustion processes; § 63.1257(e)(2)(iii)(F) for open biological treatment processes; and § 63.1257(e)(2)(ii) or (iii)(G) for closed biological treatment processes.

\* \* \* \* \*

(11) \* \* \*

(ii) For open biological treatment processes, compliance shall be determined using the procedures specified in § 63.1257(e)(2)(iii)(E). For closed aerobic biological treatment processes, compliance shall be determined using the procedures specified in § 63.1257(e)(2)(ii), (iii)(E), or (iii)(G). For closed anaerobic biological treatment processes, compliance shall be determined using the procedures specified in § 63.1257(e)(2)(ii) or (iii)(G).

\* \* \* \* \*

(12) *Percent mass removal/destruction option for soluble HAP compounds at new sources.* The owner or operator of a new source shall reduce, by removal or destruction, the mass flow rate of total soluble HAP from affected wastewater by 99 percent or more. The removal/destruction efficiency shall be determined by the procedures in § 63.1257(e)(2)(ii) or (iii)(C) for noncombustion, nonbiological treatment processes; § 63.1257(e)(2)(ii) and (iii)(D) for combustion processes; § 63.1257(e)(2)(iii)(F) for open biological treatment processes; and § 63.1257(e)(2)(ii) or (iii)(G) for closed biological treatment processes.

\* \* \* \* \*

- 9. Section 63.1257 is amended by:
  - a. Revising paragraph (a)(3);
  - b. Revising paragraph (a)(5);
  - c. Revising paragraph (b)(6) introductory text;
  - d. Revising paragraph (b)(6)(iii);
  - e. Adding a new sentence at the end of paragraph (b)(8)(i)(A) introductory text;
  - f. Revising paragraph (b)(8)(i)(A)(3)(i);
  - g. Revising paragraph (b)(10) introductory text;
  - h. Revising paragraphs (b)(10)(i) and (ii);
  - i. Redesignating paragraphs (b)(10)(iii) through (v) as paragraphs (b)(10)(iv) through (vi) and revising redesignated paragraphs (b)(10)(iv) introductory text and (b)(10)(v);
  - j. Adding paragraph (b)(10)(iii);
  - k. Revising the second sentence in paragraph (c)(1) introductory text;

- l. Revising paragraph (c)(3)(v);
  - m. Revising paragraphs (d)(1)(i) through (iii);
  - n. Revising equation 13 and the definitions of the terms “(P<sub>i</sub>)<sub>Tn</sub>” and “MW<sub>i</sub>” for Equations 13 through 17 in paragraph (d)(2)(i)(C)(1);
  - o. Removing the definitions of the terms “(P<sub>i</sub>\*)” and “(P<sub>j</sub>\*)” for Equations 13 through 17 in paragraph (d)(2)(i)(C)(1) and adding definitions for the terms “P<sub>i</sub>” and “P<sub>j</sub>” for Equations 13 through 17 in paragraph (d)(2)(i)(C)(1);
  - p. Removing the last sentence in paragraph (d)(2)(i)(C)(2)(i);
  - q. Revising paragraph (d)(2)(i)(C)(4) introductory text;
  - r. Revising paragraph (d)(2)(i)(C)(4)(ii);
  - s. Revising the definition of the term “x<sub>j</sub>” after Equation 24 in paragraph (d)(2)(i)(D)(2);
  - t. Revising paragraphs (d)(2)(i)(D)(3) and (4);
  - u. Revising paragraph (d)(2)(i)(E);
  - v. Revising the first sentence in paragraph (d)(2)(i)(H);
  - w. Adding a new sentence between the third and fourth sentences in paragraph (d)(2)(ii);
  - x. Revising paragraph (d)(3) introductory text;
  - y. Revising paragraph (d)(3)(ii)(A);
  - z. Adding paragraph (d)(3)(iii);
  - aa. Removing the definition of the term “P” for Equation 45 in paragraph (e)(2)(iii)(C)(3) and adding the definition of the term “ρ” for Equation 45 in paragraph (e)(2)(iii)(C)(3);
  - bb. Revising “Equation 44” to read “Equation 46” in the first sentence in paragraph (e)(2)(iii)(C)(5);
  - cc. Removing the definition of the term “π” for Equation 47 in paragraph (e)(2)(iii)(D)(3) and revising the definition of the term “ρ” for Equation 47 in paragraph (e)(2)(iii)(D)(3);
  - dd. Adding the definition of the term “p” as the last definition for Equation 47 in paragraph (e)(2)(iii)(D)(3);
  - ee. Revising paragraph (e)(2)(iii)(E)(3) introductory text;
  - ff. Revising “Equation 49” to read “Equation 50” in the first sentence in paragraph (e)(2)(iii)(E)(3)(ii);
  - gg. Revising the definitions of the terms “QMW<sub>a</sub>,” “QMW<sub>b</sub>” and “QMG<sub>b</sub>” for Equation 51 in paragraph (e)(2)(iii)(G)(3);
  - hh. Revising the first sentence in paragraph (f)(1)(iii)(B);
  - ii. Revising paragraph (f)(2)(ii)(A); and
  - jj. Redesignating paragraphs (h)(2)(i) and (h)(3) as paragraphs (h)(3) and (4), revising redesignated paragraph (h)(3), and removing Equation 61 from redesignated paragraph (h)(4).
- The revisions and additions read as follows:

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

(a) \* \* \*

(3) *Outlet concentration correction for supplemental gases.* (i) *Combustion devices.* Except as provided in § 63.1258(b)(5)(ii)(A), for a combustion device used to comply with an outlet concentration standard, the actual TOC, organic HAP, and hydrogen halide and halogen must be corrected to 3 percent oxygen if supplemental gases, as defined in § 63.1251, are added to the vent stream or manifold. The integrated sampling and analysis procedures of Method 3B of 40 CFR part 60, appendix A, shall be used to determine the actual oxygen concentration (%O<sub>2d</sub>). The samples shall be taken during the same time that the TOC or total organic HAP or hydrogen halides and halogen samples are taken. The concentration corrected to 3 percent oxygen (C<sub>d</sub>) shall be computed using Equation 7A of this subpart:

$$C_c = C_m \left( \frac{17.9}{20.9 - \%O_{2d}} \right) \quad (\text{Eq. 7A})$$

Where:

C<sub>c</sub> = concentration of TOC or total organic HAP or hydrogen halide and halogen corrected to 3 percent oxygen, dry basis, ppmv.

C<sub>m</sub> = total concentration of TOC or total organic HAP or hydrogen halide and halogen in vented gas stream, average of samples, dry basis, ppmv.

%O<sub>2d</sub> = concentration of oxygen measured in vented gas stream, dry basis, percent by volume.

(ii) *Noncombustion devices.* Except as provided in § 63.1258(b)(5)(ii)(B), if a control device other than a combustion device is used to comply with a TOC, organic HAP, or hydrogen halide outlet concentration standard, the owner or operator must correct the actual concentration for supplemental gases using Equation 7B of this subpart; process knowledge and representative operating data may be used to determine the fraction of the total flow due to supplemental gas.

$$C_a = C_m \left( \frac{V_s + V_a}{V_a} \right) \quad (\text{Eq. 7B})$$

Where:

C<sub>a</sub> = corrected outlet TOC, organic HAP, and hydrogen halides and halogens concentration, dry basis, ppmv

C<sub>m</sub> = actual TOC, organic HAP, and hydrogen halides and halogens concentration measured at control device outlet, dry basis, ppmv

V<sub>a</sub> = total volumetric flow rate of all gas streams vented to the control device, except supplemental gases

V<sub>s</sub> = total volumetric flow rate of supplemental gases

\* \* \* \* \*

(5) *Initial compliance with alternative standard.* Initial compliance with the alternative standards in §§ 63.1253(d) and 63.1254(c) for combustion devices is demonstrated when the outlet TOC concentration is 20 ppmv or less, and the outlet hydrogen halide and halogen concentration is 20 ppmv or less. Initial compliance with the alternative standards in §§ 63.1253(d) and 63.1254(c) for noncombustion devices is demonstrated when the outlet TOC concentration is 50 ppmv or less, and the outlet hydrogen halide and hydrogen concentration is 50 ppmv or less. To demonstrate initial compliance, the owner or operator shall be in compliance with the monitoring provisions in § 63.1258(b)(5) on the initial compliance date. The owner or operator shall use Method 18 to determine the predominant organic HAP in the emission stream if the TOC monitor is calibrated on the predominant HAP.

\* \* \* \* \*

(b) \* \* \*

(6) The following methods are specified for concentration measurements:

\* \* \* \* \*

(iii) Method 26 or 26A of appendix A of part 60 shall be used to determine hydrogen chloride, hydrogen halide and halogen concentrations in control device efficiency determinations or in the 20 ppmv outlet hydrogen halide concentration standard.

\* \* \* \* \*

(8) \* \* \*

(i) \* \* \*

(A) \* \* \* The owner or operator must consider all relevant factors, including load and compound-specific characteristics in defining absolute worst-case conditions.

\* \* \* \* \*

(3) \* \* \*

(i) Periods when the stream contains the highest combined VOC and HAP load, in lb/hr, described by the emission profiles in paragraph (b)(8)(ii) of this section;

\* \* \* \* \*

(10) *Wastewater testing.* Wastewater analysis shall be conducted in accordance with paragraph (b)(10)(i), (ii), (iii), (iv), or (v) of this section.

(i) *Method 305.* Use procedures specified in Method 305 of 40 CFR part 63, appendix A, and comply with

requirements specified in paragraph (b)(10)(vi) of this section.

(ii) *Method 624, 625, 1624, or 1625.* Use procedures specified in Method 624, 625, 1624, or 1625 of 40 CFR part 136, appendix A, and comply with requirements in paragraph (b)(10)(vi) of this section.

(iii) *Method 8260 or 8270.* Use procedures specified in Method 8260 or 8270 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW-846, Third Edition, September 1986, as amended by Update I, November 15, 1992. As an alternative, an owner or operator may use any more recent, updated version of Method 8260 or 8270 approved by the EPA. For the purpose of using Method 8260 or 8270 to comply with this subpart, the owner or operator must maintain a formal quality assurance program consistent with either Section 8 of Method 8260 or Method 8270, and this program must include the following elements related to measuring the concentrations of volatile compounds:

- (A) Documentation of site-specific procedures to minimize the loss of compounds due to volatilization, biodegradation, reaction, or sorption during the sample collection, storage, and preparation steps.
- (B) Documentation of specific quality assurance procedures followed during sampling, sample preparation, sample introduction, and analysis.
- (C) Measurement of the average accuracy and precision of the specific procedures, including field duplicates and field spiking of the material source before or during sampling with compounds having similar chemical characteristics to the target analytes.

(iv) *Other EPA methods.* Use procedures specified in the method, validate the method using the procedures in paragraph (b)(10)(iv)(A) or (B) of this section, and comply with the procedures in paragraph (b)(10)(vi) of this section.

(v) *Methods other than an EPA method.* Use procedures specified in the method, validate the method using the procedures in paragraph (b)(10)(iv)(A) of this section, and comply with the requirements in paragraph (b)(10)(vi) of this section.

(c) \* \* \*  
 (1) \* \* \* Initial compliance with the outlet concentration requirement of § 63.1253(d) is demonstrated by fulfilling the requirements of paragraph (a)(5) of this section.

(3) \* \* \*  
 (v) When the phrase "the maximum true vapor pressure of the total organic HAP's in the stored liquid falls below the values defining Group 1 storage vessels specified in table 5 or table 6 of this subpart" is referred to in § 63.120(b)(1)(iv), the phrase "the maximum true vapor pressure of the total organic HAP in the stored liquid falls below 13.1 kPa" shall apply for the purposes of this subpart.

(d) \* \* \*  
 (1) \* \* \*  
 (i) Initial compliance with § 63.1254(a)(2)(i) is demonstrated when the actual emissions of HAP from the sum of all process vents within a process is less than or equal to 900 kg/yr. Initial compliance with

§ 63.1254(a)(2)(ii) is demonstrated when the actual emissions of HAP from the sum of all process vents in compliance with § 63.1254(a)(2)(i) is less than or equal to 1,800 kg/yr. Uncontrolled HAP emissions and controlled HAP emissions shall be determined using the procedures described in paragraphs (d)(2) and (3) of this section.

(ii) Initial compliance with the percent reduction requirements in § 63.1254(a)(1)(i), (a)(3), and (b) is demonstrated by:

- (A) Determining controlled HAP emissions using the procedures described in paragraph (d)(3) of this section, and uncontrolled HAP emissions determined using the procedures described in paragraph (d)(2) of this section, and demonstrating that the reductions required by § 63.1254(a)(1)(i), (a)(3), and (b) are met; or
- (B) Controlling the process vents using a device meeting the criteria specified in paragraph (a)(4) of this section.

(iii) Initial compliance with the outlet concentration requirements in § 63.1254(a)(1)(ii)(A), (a)(3), and (b)(1) is demonstrated when the outlet TOC concentration is 20 ppmv or less and the outlet hydrogen halide and halogen concentration is 20 ppmv or less. The owner or operator shall demonstrate compliance by fulfilling the requirements in paragraph (a)(6) of this section.

\* \* \* \* \*  
 (2) \* \* \*  
 (i) \* \* \*  
 (C) \* \* \*  
 (1) \* \* \*

$$E = \frac{\sum_{i=1}^n ((P_i^*)(x_i)(MW_i))}{760 - \sum_{j=1}^m ((P_j^*)(x_j))} \times \Delta\eta \quad (\text{Eq. 13})$$

\* \* \* \* \*  
 $P_i^*$  = vapor pressure of each HAP in the vessel headspace at any temperature between the initial and final heatup temperatures, mmHg.  
 $P_j^*$  = vapor pressure of each condensable VOC (including HAP) in the vessel headspace at any temperature between the initial and final heatup temperatures, mmHg.  
 $(P_i)_{T_n}$  = partial pressure of each HAP in the vessel headspace at initial ( $T_1$ ) and final ( $T_2$ ) temperature.

$MW_i$  = molecular weight of the individual HAP. \* \* \*  
 (4) If the vessel contents are heated to the boiling point, emissions must be calculated using the procedure in paragraphs (d)(2)(i)(C)(4)(i) and (ii) of this section.  
 (ii) While boiling, the vessel must be operated with a properly operated process condenser. An initial demonstration that a process condenser is properly operated is required for

some process condensers, as described in paragraph (d)(3)(iii) of this section.  
 (D) \* \* \*  
 (2) \* \* \*  
 $x_j$  = mole fraction of each condensable (including HAP) in the liquid phase.  
 \* \* \* \* \*  
 (3) The average ratio of moles of noncondensable to moles of an individual HAP in the emission stream is calculated using Equation 25 of this subpart; this calculation must be



repeated for each HAP in the emission stream:

$$n_{Ri} = \frac{\left( \frac{P_{nc1}}{(P_i^*)(x_i)} + \frac{P_{nc2}}{(P_i^*)(x_i)} \right)}{2} \quad (\text{Eq. 25})$$

Where:

$n_{Ri}$  = average ratio of moles of noncondensable to moles of individual HAP.  
 $P_{nc1}$  = initial partial pressure of the noncondensable gas, as calculated using Equation 23 of this subpart.

$P_{nc2}$  = final partial pressure of the noncondensable gas, as calculated using Equation 24 of this subpart.  
 $P_i^*$  = vapor pressure of each individual HAP.  
 $x_i$  = mole fraction of each individual HAP in the liquid phase.

$n$  = number of HAP compounds.

$i$  = identifier for a HAP compound.

(4) The mass of HAP emitted shall be calculated using Equation 26 of this subpart:

$$E = (V_{nc1} - V_{nc2}) \times \frac{P_{atm}}{RT} \times \sum_{i=1}^n \frac{MW_i}{n_{Ri}} \quad (\text{Eq. 26})$$

Where:

$E$  = mass of HAP emitted.  
 $V_{nc1}$  = initial volume of noncondensable gas in the vessel, as calculated using Equation 21 of this subpart.  
 $V_{nc2}$  = final volume of noncondensable gas in the vessel, as calculated using Equation 22 of this subpart.

$n_{Ri}$  = average ratio of moles of noncondensable to moles of individual HAP, as calculated using Equation 25 of this subpart.  
 $P_{atm}$  = atmospheric pressure, standard.  
 $R$  = ideal gas law constant.  
 $T$  = temperature of the vessel, absolute.

$MW_i$  = molecular weight of each HAP.

\* \* \* \* \*

(E) *Vacuum systems.* Emissions from vacuum systems may be calculated using Equation 33 of this subpart if the air leakage rate is known or can be approximated.

$$E = \frac{(La)(t)}{MW_{nc}} \left( \frac{\sum_{i=1}^n P_i MW_i}{P_{system} - \sum_{j=1}^m P_j} \right) \quad (\text{Eq. 33})$$

Where:

$E$  = mass of HAP emitted.  
 $P_{system}$  = absolute pressure of receiving vessel or ejector outlet conditions, if there is no receiver.  
 $P_i$  = partial pressure of the HAP at the receiver temperature or the ejector outlet conditions.  
 $P_j$  = partial pressure of condensable (including HAP) at the receiver temperature or the ejector outlet conditions.  
 $La$  = total air leak rate in the system, mass/time  
 $MW_{nc}$  = molecular weight of noncondensable gas.  
 $t$  = time of vacuum operation.  
 $MW_i$  = molecular weight of the individual HAP in the emission stream, with HAP partial pressures calculated at the temperature of the receiver or ejector outlet, as appropriate.

subpart (Note: The term  $e^{-Fv/v}$  can be assumed to be 0): \* \* \*

(ii) \* \* \* Modified versions of the engineering evaluation methods in paragraphs (d)(2)(i)(A) through (H) may be used if the owner or operator demonstrates that they have been used to meet other regulatory obligations, and they do not affect applicability assessments or compliance determinations under this subpart GGG.  
 \* \* \*

(3) *Controlled emissions.* An owner or operator shall determine controlled emissions using the procedures in either paragraph (d)(3)(i) or (ii) of this section.  
 \* \* \*

(ii) \* \* \*

(A) The performance test shall be conducted by performing emission testing on the inlet and outlet of the control device following the test methods and procedures of § 63.1257(b). Concentrations shall be calculated from the data obtained through emission

testing according to the procedures in paragraph (a)(2) of this section.

\* \* \* \* \*

(iii) *Initial compliance demonstration for condensers.*

(A) *Air pollution control devices.* During periods in which a condenser functions as an air pollution control device, controlled emissions shall be calculated using the emission estimation equations described in paragraph (d)(3)(i)(B) of this section.

(B) *Process condensers.* During periods when the condenser is operating as a process condenser, the owner or operator is required to demonstrate that the process condenser is properly operated if the process condenser meets either of the criteria described in paragraphs (d)(2)(iii)(B)(1) and (2) of this section. The owner or operator must either measure the condenser exhaust gas temperature and show it is less than the boiling or bubble point of the substance(s) in the vessel, or perform a material balance around the vessel and condenser to show that at least 99

(H) *Empty vessel purging.* Emissions from empty vessel purging shall be calculated using Equation 36 of this

percent of the material vaporized while boiling is condensed. The initial demonstration shall be conducted for all appropriate operating scenarios and documented in the Notification of Compliance Status report described in § 63.1260(f).

(1) The process condenser is not followed by an air pollution control device; or

(2) The air pollution control device following the process condenser is not a condenser or is not meeting the alternative standard of § 63.1254(c).

\* \* \* \* \*

(e) \* \* \*

(2) \* \* \*

(iii) \* \* \*

(C) \* \* \*

(3) \* \* \*

$\rho$  = density of the wastewater, kg/m<sup>3</sup>.

\* \* \* \* \*

(D) \* \* \*

(3) \* \* \*

$\rho$  = density of the wastewater stream, kg/m<sup>3</sup>.

\* \* \* \* \*

$p$  = number of runs.

\* \* \* \* \*

(E) \* \* \*

(3) *Destruction efficiency.* The owner or operator shall comply with the provisions in either paragraph (e)(2)(iii)(E)(3)(i) or (ii) of this section. Compliance is demonstrated if the destruction efficiency,  $E$ , is equal to or greater than 95 percent.

\* \* \* \* \*

(G) \* \* \*

(3) \* \* \*

$QMW_a$ ,  $QMW_b$  = mass flow rate of partially soluble and/or soluble HAP compounds in wastewater entering ( $QMW_a$ ) and exiting ( $QMW_b$ ) the treatment process,

kilograms per hour (as calculated using Equations 44 and 45).

$QMG_b$  = mass flow rate of partially soluble and/or soluble HAP compounds in vented gas stream exiting the control device, kg/hr.

\* \* \* \* \*

(f) \* \* \*

(1) \* \* \*

(iii) \* \* \*

(B) For batch processes, the annual factor shall be calculated either every 10 batches for the 12-month period preceding the 10th batch (10-batch rolling average) or a maximum of once per month, if the number of batches is greater than 10 batches per month.

\* \* \*

(2) \* \* \*

(ii) \* \* \*

(A) The mass of HAP calculated using Equation 55 of this subpart:

$$M = [kg/kg]_b (0.75 - P_R) (M_{prod}) \quad (\text{Eq. 55})$$

Where:

$[kg/kg]_b$  = the baseline production-indexed HAP consumption factor, in kg/kg.

$M_{prod}$  = the annual production rate, in kg/yr.

$M$  = the annual reduction required by add-on controls, in kg/yr.

$P_R$  = the fractional reduction in the annual kg/kg factor achieved using pollution prevention where  $P_R$  is  $\geq 0.5$ .

\* \* \* \* \*

(h) \* \* \*

(3) Equations 60 and 61 of this subpart shall be used to calculate total HAP emissions:

$$E_{TU} = \sum_{i=1}^n E_{Ui} \quad (\text{Eq. 60})$$

$$E_{TC} = \sum_{i=1}^n E_{Ci} \quad (\text{Eq. 61})$$

Where:

$E_{Ui}$  = yearly uncontrolled emissions from process  $i$ .

$E_{Ci}$  = yearly actual emissions for process  $i$ .

$E_{TU}$  = total yearly uncontrolled emissions.

$E_{TC}$  = total yearly actual emissions.

$n$  = number of processes included in the emissions average.

\* \* \* \* \*

10. Section 63.1258 is amended by:  
a. Revising paragraph (b)(5);

b. Revising paragraph (b)(6)(iii);  
c. Revising the first sentence in paragraph (b)(8) introductory text; and  
d. Revising paragraph (c).

The revisions read as follows:

**§ 63.1258 Monitoring requirements.**

\* \* \* \* \*

(b) \* \* \*

(5) *Monitoring for the alternative standards.* (i) For control devices that are used to comply with the provisions of § 63.1253(d) or § 63.1254(c), the owner or operator shall monitor and record the outlet TOC concentration and the outlet hydrogen halide and halogen concentration every 15 minutes during the period in which the device is functioning in achieving the HAP removal required by this subpart using CEMS as specified in paragraphs (b)(5)(i)(A) through (D) of this section.

(A) A TOC monitor meeting the requirements of Performance Specification 8, 9, or 15 of appendix B of part 60 shall be installed, calibrated, and maintained according to § 63.8. For any TOC monitor meeting Performance Specification 8, the owner or operator must also comply with Appendix F, procedure 1 of 40 CFR part 60.

(B) Except as specified in paragraphs (b)(5)(i)(C) and (D) of this section, the owner or operator must monitor HCl using either a FTIR CEMS that meets Performance Specification 15 of appendix B of part 60 or any other CEMS capable of measuring HCl for which a performance specification has been promulgated in appendix B of part

60. To monitor HCl with a CEMS for which a performance specification has not been promulgated, the owner or operator must prepare a monitoring plan and submit it for approval in accordance with the procedures specified in § 63.8.

(C) As an alternative to using a CEMS as specified in paragraph (b)(5)(i)(B) of this section to monitor halogenated vent streams that are controlled by a combustion device followed by a scrubber, the owner or operator may elect to monitor scrubber operating parameters as specified in paragraph (b)(1)(ii) of this section that demonstrate the HCl emissions are reduced by at least 95 percent by weight.

(D) The owner or operator need not monitor the hydrogen halide and halogen concentration if, based on process knowledge, the owner or operator determines that the emission stream does not contain hydrogen halides or halogens.

(ii) An owner or operator complying with the alternative standard using control devices in which supplemental gases are added to the vents or manifolds must either correct for supplemental gases as specified in § 63.1257(a)(3) or comply with the requirements of paragraph (b)(5)(ii)(A) or (B) of this section. If the owner or operator corrects for supplemental gases as specified in § 63.1257(a)(3)(ii) for noncombustion control devices, the flow rates must be evaluated as specified in paragraph (b)(5)(ii)(C) of this section.

(A) *Provisions for combustion devices.* As an alternative to correcting for supplemental gases as specified in § 63.1257(a)(3), the owner or operator may monitor residence time and firebox temperature according to the requirements of paragraphs (b)(5)(ii)(A)(1) and (2) of this section. Monitoring of residence time may be accomplished by monitoring flowrate into the combustion chamber.

(1) If complying with the alternative standard instead of achieving a control efficiency of 95 percent or less, the owner or operator must maintain a minimum residence time of 0.5 seconds and a minimum combustion chamber temperature of 760°C.

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

(B) *Provisions for dense gas systems.* As an alternative to correcting for supplemental gases as specified in § 63.1257(a)(3), for noncombustion devices used to control emissions from dense gas systems, as defined in § 63.1251, the owner or operator shall monitor flowrate as specified in paragraphs (b)(5)(ii)(B)(1) through (4) of this section.

(1) Use Equation 63 of this subpart to calculate the system flowrate setpoint at which the average concentration is 5,000 ppmv TOC:

$$F_s = \frac{721 \times E_{an}}{5,000} \quad (\text{Eq. 63})$$

Where:

$F_s$  = system flowrate setpoint, scfm.  
 $E_{an}$  = annual emissions entering the control device, lbmols/yr.

(2) Annual emissions used in Equation 63 of this subpart must be based on the actual mass of organic compounds entering the control device, as calculated from the most representative emissions inventory data submitted within the 5 years before the Notification of Compliance Status report is due. The owner or operator must recalculate the system flowrate setpoint once every 5 years using the annual emissions from the most representative emissions inventory data submitted during the 5-year period after the previous calculation. Results of the initial calculation must be included in the Notification of Compliance Status report, and recalculated values must be included in the next Periodic report after each recalculation. For all calculations after the initial calculation, to use emissions inventory data

calculated using procedures other than those specified in § 63.1257(d), the owner or operator must submit the emissions inventory data calculations and rationale for their use in the Notification of Process Change report or an application for a part 70 permit renewal or revision.

(3) In the Notification of Compliance Status report, the owner or operator may elect to establish both a maximum daily average operating flowrate limit above the flowrate setpoint and a reduced outlet concentration limit corresponding to this flowrate limit. The owner or operator may also establish reduced outlet concentration limits for any daily average flowrates between the flowrate setpoint and the flowrate limit. The correlation between these elevated flowrates and the corresponding outlet concentration limits must be established using Equation 64 of this subpart:

$$C_a = \frac{F_s}{F_a} \times 50 \quad (\text{Eq. 64})$$

Where:

$C_a$  = adjusted outlet concentration limit, dry basis, ppmv.

50 = outlet concentration limit associated with the flowrate setpoint, dry basis, ppmv.

$F_s$  = system flowrate setpoint, scfm.

$F_a$  = actual system flowrate limit, scfm.

(4) The owner or operator must install and operate a monitoring system for measuring system flowrate. The flowrate into the control device must be monitored and recorded at least once every hour. The system flowrate must be calculated as the average of all values measured during each 24-hour operating day. The flowrate monitoring device must be accurate to within 5 percent of the system flowrate setpoint, and the flowrate monitoring device must be calibrated annually.

(C) *Flow rate evaluation for noncombustion devices.* To demonstrate continuous compliance with the requirement to correct for supplemental gases as specified in § 63.1257(a)(3)(ii) for noncombustion devices, the owner or operator must evaluate the volumetric flow rate of supplemental gases,  $V_s$ , and the volumetric flow rate of all gases,  $V_a$ , each time a new operating scenario is implemented based on process knowledge and representative operating data. The procedures used to evaluate the flow rates, and the resulting correction factor used in Equation 7B of this subpart, must be included in the Notification of Compliance Status report and in the next Periodic report submitted after an operating scenario change.

(6) \* \* \*

(iii) Each loss of all pilot flames for flares.

\* \* \* \* \*

(8) *Violations.* Exceedances of parameters monitored according to the provisions of paragraphs (b)(1)(ii), (iv) through (ix), and (b)(5)(ii)(A) and (B) of this section, or excursions as defined by paragraphs (b)(7)(i) through (iii) of this section, constitute violations of the operating limit according to paragraphs (b)(8)(i), (ii), and (iv) of this section.

\* \* \* \* \*

(c) *Monitoring for emission limits.* The owner or operator of any affected source complying with the provisions of § 63.1254(a)(2) shall demonstrate continuous compliance with the 900 and 1,800 kg/yr emission limits by calculating daily 365-day rolling summations of emissions. For any owner or operator opting to switch compliance strategy from the 93 percent control requirement to the annual mass emission limit method, as described in § 63.1254(a)(1)(i), the rolling summations, beginning with the first day after the switch, must include emissions from the past 365 days.

\* \* \* \* \*

11. Section 63.1259 is amended by:

- a. Revising paragraph (a)(3)(i);
- b. Revising paragraph (a)(3)(iii);
- c. Revising paragraph (b)(4);
- d. Revising paragraphs (b)(5)(i) and (b)(5)(ii);
- e. Removing paragraph (b)(6), redesignating paragraphs (b)(7) through (b)(11) as paragraphs (b)(6) through (b)(10), and revising the redesignated paragraphs (b)(6) and (b)(9); and
- f. Adding paragraphs (b)(11) and (12).

The revisions and additions read as follows:

**§ 63.1259 Recordkeeping requirements.**

(a) \* \* \*

(3) \* \* \*

(i) The owner or operator shall record the occurrence and duration of each malfunction of the process operations or of air pollution control equipment used to comply with this subpart, as specified in § 63.6(e)(3)(iii).

\* \* \* \* \*

(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), and shall record all maintenance performed on the air pollution control equipment, as specified in § 63.10(b)(2)(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) \* \* \*

(4) For purposes of compliance with the annual mass limits of § 63.1254(a)(2) and (b)(2), daily records of the rolling annual total emissions.

(5) \* \* \*

(i) For processes or process vents that are in compliance with the percent reduction requirements of § 63.1254(a)(1), (a)(3), or (b)(1) and containing vents controlled to less than the percent reduction requirement, the following records are required:

(A) Standard batch uncontrolled and controlled emissions for each process;

(B) Actual uncontrolled and controlled emissions for each nonstandard batch; and

(C) A record whether each batch operated was considered a standard batch.

(ii) For processes in compliance with the annual mass limits of § 63.1254(a)(2) or (b)(2), the following records are required:

(A) The number of batches per year for each batch process;

(B) The operating hours per year for continuous processes;

(C) Standard batch uncontrolled and controlled emissions for each process;

(D) Actual uncontrolled and controlled emissions for each nonstandard batch;

(E) A record whether each batch operated was considered a standard batch.

(6) Wastewater concentration per POD or process, except as provided in § 63.1256(a)(1)(ii).

\* \* \* \* \*

(9) Description of worst-case operating conditions as required in § 63.1257(b)(8).

\* \* \* \* \*

(11) If the owner or operator elects to comply with § 63.1253(b) or (c) by installing a floating roof, the owner or operator must keep records of each inspection and seal gap measurement in accordance with § 63.123(c) through (e) as applicable.

(12) If the owner or operator elects to comply with the vapor balancing alternative in § 63.1253(f), the owner or operator must keep records of the DOT certification required by § 63.1253(f)(2) and the pressure relief vent setting and the leak detection records specified in § 63.1253(f)(5).

\* \* \* \* \*

12. Section 63.1260 is amended by:

a. Adding paragraphs (e)(6) and (7);

b. Revising paragraph (g)(1)(ii);

c. Revising paragraph (g)(2)(vii);

d. Adding paragraph (g)(2)(viii);

e. Adding a new sentence after the first sentence in paragraph (h)(1) introductory text; and

f. Revising the reference

“§ 63.10(d)(4)(ii)” to read

“§ 63.10(d)(5)(ii)” in the last sentence in paragraph (i).

The revisions and additions read as follows:

§ 63.1260 Reporting requirements.

\* \* \* \* \*

(e) \* \* \*

(6) Data and other information supporting the determination of annual average concentrations by process simulation as required in § 63.1257(e)(1)(ii).

(7) Bench scale or pilot-scale test data and rationale used to determine annual average concentrations as required in § 63.1257(e)(1)(ii)(C).

\* \* \* \* \*

(g) \* \* \*

(1) \* \* \*

(ii) Quarterly reports shall be submitted when the source experiences an exceedance of a temperature limit monitored according to the provisions of § 63.1258(b)(1)(iii) or an exceedance of the outlet concentration monitored according to the provisions of § 63.1258(b)(1)(x) or (b)(5). Once an affected source reports quarterly, the affected source shall follow a quarterly reporting format until a request to reduce reporting frequency is approved. If an owner or operator submits a request to reduce the frequency of reporting, the provisions in § 63.10(e)(3)(ii) and (iii) shall apply, except that the phrase “excess

emissions and continuous monitoring system performance report and/or summary report” shall mean “Periodic report” for the purposes of this section.

\* \* \* \* \*

(2) \* \* \*

(vii) Each new operating scenario which has been operated since the time period covered by the last Periodic report. For each new operating scenario, the owner or operator shall provide verification that the operating conditions for any associated control or treatment device have not been exceeded, and that any required calculations and engineering analyses have been performed. For the initial Periodic report, each operating scenario for each process operated since the compliance date shall be submitted.

(viii) If the owner or operator elects to comply with the provisions of § 63.1253(b) or (c) by installing a floating roof, the owner or operator shall submit the information specified in § 63.122(d) through (f) as applicable. References to § 63.152 from § 63.122 shall not apply for the purposes of this subpart.

(h) \* \* \*

(1) \* \* \* For the purposes of this section, a process change means the startup of a new process, as defined in § 63.1251.

\* \* \* \* \*

13. Table 1 to subpart GGG is amended by:

a. Revising the entries “63.5(b)(3),” “63.7(a)(1),” “63.9(a)–(d),” “63.9(e),” “63.9(g)(1),” “63.9(g)(3),” “63.9(h),” “63.9(j),” “63.10(a),” “63.10(b)(1),” “63.10(b)(3),” and “63.10(c)–(d)(2);”

b. Removing the entry “63.7(a)(2)(I–ix)” and adding the entry “63.7(a)(2)(i)–(ix);”

c. Removing the entry “63.8(b)(3)–(c)(3)” and adding the entry “63.8(b)(3)–(c)(4);”

d. Removing the entry “63.8(c)(4–5)” and adding the entry “63.8(c)(5);”

e. Removing the entry “63.8(c)(6–8)” and adding the entry “63.8(c)(6)–(8).”

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
*	*	*	*
63.5(b)(3) .....	New construction/reconstruction .....	Yes .....	Except for changes and additions authorized under §52.2454 of this title. However, the requirement to submit the Precompliance report at least 90 days before the compliance date still applies.
*	*	*	*
63.7(a)(1) .....	Performance testing requirements .....	Yes .....	Subpart GGG also specifies required testing and compliance procedures.
63.7(a)(2)(i)–(ix) .....	.....	Yes .....	Except substitute “150 days” instead of “180 days.”
*	*	*	*
63.8(b)(3)–(c)(4) .....	CMS requirements .....	Yes .....	§ 63.1259 also specifies recordkeeping for CMS.
63.8(c)(5) .....	COMS operation requirements .....	No.	
63.8 (c)(6)–(8) .....	CMS calibration and malfunction provisions ..	No .....	Calibration procedures are provided in § 63.1258.
*	*	*	*
63.9(a)–(d) .....	Notification requirements—Applicability and general information.	Yes .....	§ 63.1260 (b) also specifies initial notification requirement.
63.9(e) .....	Notification of performance test .....	Yes .....	§ 63.1260 (l) also specifies notification requirement for performance test.
*	*	*	*
63.9(g)(1) .....	Additional notification requirements for sources with CMS.	Yes .....	§ 63.1260 (d) also specifies notification requirement for performance evaluation.
*	*	*	*
63.9(g)(3) .....	Notification that criterion to continue use of alternative to relative accuracy testing has been exceeded.	Yes .....	§ 63.1260 (d) also specifies notification requirement for performance evaluation.
63.9(h) .....	Notification of compliance status .....	Yes .....	Specified in § 63.1260(f). Due 150 days after compliance date.
*	*	*	*
63.9(j) .....	Change in information provided .....	No .....	Subpart GGG specifies procedures for notification of changes.
*	*	*	*
63.10(a) .....	Recordkeeping requirements .....	Yes.	
63.10(b)(1) .....	Records retention .....	Yes .....	Also stated in § 63.1259.
*	*	*	*
63.10(b)(3) .....	Records retention for sources not subject to relevant standard.	Yes .....	Also stated in § 63.1259 (a)(2).
63.10(c)–(d)(2) .....	Other recordkeeping and reporting provisions	Yes .....	Also stated in § 63.1259 (a)(4).
*	*	*	*

14. Table 5 to subpart GGG is revised to read as follows:

TABLE 5 TO SUBPART GGG.—CONTROL REQUIREMENTS FOR ITEMS OF EQUIPMENT THAT MEET THE CRITERIA OF § 63.1252(F)

Item of equipment	Control requirement <sup>a</sup>
Drain or drain hub .....	(a) Tightly fitting solid cover (TFSC); or (b) TFSC with a vent to either a process or to a control device meeting the requirements of § 63.1256(h)(2); or (c) Water seal with submerged discharge or barrier to protect discharge from wind.
Manhole <sup>b</sup> .....	(a) TFSC; or (b) TSFC with a vent to either a process or to a control device meeting the requirements of § 63.1256(h)(2); or (c) If the item is vented to the atmosphere, use a TFSC with a properly operating water seal at the entrance or exit to the item to restrict ventilation in the collection system. The vent pipe shall be at least 90 cm in length and not exceeding 10.2 cm in nominal inside diameter.
Lift station .....	(a) TFSC; or (b) TFSC with a vent to either a process or to a control device meeting the requirements of § 63.1256(h)(2); or (c) If the lift station is vented to the atmosphere, use a TFSC with a properly operating water seal at the entrance or exit to the item to restrict ventilation in the collection system. The vent pipe shall be at least 90 cm in length and not exceeding 10.2 cm in nominal inside diameter. The lift station shall be level controlled to minimize changes in the liquid level.
Trench .....	(a) TFSC; or (b) TFSC with a vent to either a process or to a control device meeting the requirements of § 63.1256(h)(2); or (c) If the item is vented to the atmosphere, use a TFSC with a properly operating water seal at the entrance or exit to the item to restrict ventilation in the collection system. The vent pipe shall be at least 90 cm in length and not exceeding 10.2 cm in nominal inside diameter.
Pipe .....	Each pipe shall have no visible gaps in joints, seals, or other emission interfaces.
Oil/Water separator .....	(a) Equip with a fixed roof and route vapors to a process or equip with a closed-vent system that routes vapors to a control device meeting the requirements of § 63.1256(h)(2); or (b) Equip with a floating roof that meets the equipment specifications of § 60.693(a)(1)(i), (a)(1)(ii), (a)(2), (a)(3), and (a)(4).
Tank .....	Maintain a fixed roof and consider vents as process vents. <sup>c</sup>

<sup>a</sup> Where a tightly fitting solid cover is required, it shall be maintained with no visible gaps or openings, except during periods of sampling, inspection, or maintenance.

<sup>b</sup> Manhole includes sumps and other points of access to a conveyance system.

<sup>c</sup> A fixed roof may have openings necessary for proper venting of the tank, such as pressure/vacuum vent, j-pipe vent.