ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–5802–8]

RIN–2060–AE83

National Emission Standards for Hazardous Air Pollutants Pharmaceuticals Production

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and notice of public hearing.

SUMMARY: The proposed standard would reduce air emissions of hazardous air pollutants (HAP) from existing and new facilities that manufacture pharmaceutical products. The agency intends that this proposed rule will have a common technology basis with a rule yet to be issued by EPA's Office of Water (OW); this will allow coordinated and cost effective compliance planning by the industry. In addition to soliciting comments on various aspects of the proposed rule, this document also solicits comments on possible approaches for the OW rule.

The major HAP emitted by facilities covered by this proposed rule include methylene chloride, methanol, toluene, and hydrogen chloride. Methylene chloride is considered to be a human carcinogen and the other pollutants can cause noncancer health effects in humans. The proposed rule is estimated to reduce HAP emissions from existing facilities by 22,000 megagrams per year (Mg/yr). It also reduces volatile organic compound (VOC) emissions.

DATES: *Comments.* Comments must be received on or before June 2, 1997.

Public Hearing. If anyone contacts EPA requesting to speak at a public hearing by April 23, 1997, a public hearing will be held on May 2, 1997 beginning at 10 a.m. Persons interested in attending the hearing should call Ms. Marguerite Thweatt at (919) 541–5673 to verify that a hearing will be held.

Request to Speak at Hearing. Persons wishing to present oral testimony must contact EPA by April 23, 1997, by contacting Ms. Marguerite Thweatt.

ADDRESSES: *Comments.* Comments should be submitted (in duplicate, if possible) to: Air Docket Section (LE–131), Attention: Docket No. A–96–03, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. The EPA requests that separate copies also be sent to the appropriate contact persons listed below. The public hearing, if required, will be held at the EPA's Office of Administration Auditorium, Research Triangle Park, North Carolina.

SUPPLEMENTARY INFORMATION: The information contained in this notice is also on the Technology Transfer Network (TTN). The TTN, EPA's electronic bulletin board, provides information and technology exchange in various areas of air pollution control. The service is free, except for the cost of a telephone call. Dial (919) 541–5472 for up to a 14,400 bps modem transfer. In addition, the basis and purpose document (BPD), containing much of the rationale for these proposed standards, is also available on the TTN. The supplementary information document (SID) for the proposed standard, which contains a compilation of technical memoranda, may be obtained from the docket (entry #II–B–1).

Docket. Docket No. A–96–03, containing supporting information used in developing the proposed standards, is available for public inspection and copying between 8:30 a.m. and 3:30 p.m., Monday through Friday, at EPA's Air Docket Section, Waterside Mall, Room 1500, 1st Floor, 401 M Street SW., Washington, DC 20460. A reasonable fee may be charged for copying.

For information concerning the MACT standard, contact Mr. Randy McDonald at (919) 541–5402, Organic Chemicals Group, Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. For further information concerning the effluent limitation guidelines pretreatment standards and new source performance standards, contact Dr. Frank H. Hund, at (202) 260–7786, Engineering and Analysis Division (4303), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC. 20460.

Regulated entities. Entities potentially regulated are those which produce pharmaceutical products and intermediates and are located at facilities that are major sources as defined in section 112 of the CAA. Regulated categories and entities include:

Category	Regulated entities
Industry	• Producers of material described by the SIC code 283. • Producers of fermentation, biological or natural extraction, chemical synthesis, and formulation products regulated by the Food and Drug Administration.
	• Producers of components (excluding excipients) of a pharmaceutical formulations or intermediates used in the production of a pharmaceutical product.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility, company, business, organization, etc., is regulated by this action, you should carefully examine the applicability criteria in § 63.1250 of the rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

The information presented in this preamble is organized as follows:

I. List of Source Categories

Section 112 of the amended Act requires that EPA evaluate and control emissions of HAP. The control of HAP is achieved through promulgation of emission standards under sections 112(d) and 112(f) and work practice and equipment standards under section 112(h) for categories of sources that emit HAP. On July 16, 1992, EPA published an initial list of major and area source categories to be regulated (57 FR 31576). Included on that list were major sources emitting HAP from pharmaceuticals production.

Production methods used in the manufacture of pharmaceutical products include both batch and continuous operations, although batch operations make up a majority of the processes. The sizes of the facilities range from those that make one product at the rate of several hundred kilograms per year (kg/yr) to those that produce numerous intermediates and final products on the scale of thousands of kilograms (megagrams [Mg]) per year. Air emissions of HAP compounds originate from breathing and withdrawal losses from storage tanks, venting of process vessels, leaks from piping and equipment used to transfer HAP compounds (equipment leaks), and volatilization of HAP from wastewater streams. Pollutants (HAP) emitted from the production processes include a range of compounds, including VOC. Among the most prevalent are methylene chloride and methanol, which account for nearly 70 percent of all HAP emissions from this industry. Detailed information describing manufacturing processes and emissions can be found in the Basis and Purpose Document.

As of 1992, over 80 U.S. companies at 270 facilities were producing pharmaceutical products. Manufacturing operations covered by this NESHAP include chemical synthesis, formulation, fermentation, and extraction processes and are generally classified under standard industrial classification 283. An estimated 101 facilities are considered to be major sources according to the CAA criterion of having the potential to emit 10 tons per year of any one HAP or 25 tons per year of combined HAP, based on 1992 emissions data. The proposed standard would apply to all major sources that produce pharmaceuticals. Area sources would not be subject to this standard.

II. Background

A. Summary of Considerations Made in Developing This Rule

This regulation reduces emissions of many of the HAP listed in section 112(b)(1) of the CAAA. The alternatives considered in the development of this regulation, including those alternatives selected as standards for new and existing sources, are based on process and emissions data received from the existing facilities known by the EPA to be in operation.

Regulatory alternatives more stringent than the MACT floor (minimum control level) were selected when they were judged to be reasonable, considering cost, nonair impacts, and energy requirements.

The proposed standards give existing affected sources 3 years from the date of promulgation to comply. This is the maximum amount of time allowed by the Act. New affected sources are required to comply with the standard upon startup.

Included in the proposed rule are methods for determining initial compliance as well as monitoring, recordkeeping and reporting requirements. All of these components are necessary to ensure that affected sources will comply with the standards both initially and over time. However, the EPA has made every effort to simplify the requirements in the rule. The EPA has also attempted to maintain consistency with existing regulations by either incorporating text from existing regulations or referencing the applicable sections.

In addition, this rule contains an important and innovative pollution prevention alternative for the pharmaceutical industry that provides an option to reduce solvent consumption in lieu of installing end-of-pipe controls. The EPA has developed a regulation that provides a pollution prevention compliance alternative to the traditional control requirements, and the EPA encourages the pharmaceutical industry to meet the CAA requirements through its use. This alternative demonstrates EPA's commitment to developing regulations that are cost effective and flexible, and that reduce monitoring, recordkeeping, and reporting burdens.

Representatives from other interested EPA offices and programs, including State and Regional environmental agency personnel, and representatives from industry participated in the regulatory development process as MACT partnership members. For example, Region II, acting as the lead, worked closely with the States of New York and New Jersey as well as the pharmaceutical industry in developing the pollution prevention alternative. The partnership members were given opportunities to review and comment on the regulation prior to proposal. Several issues presented in the solicitation of comments section reflect these comments. Industry, regulatory authorities, and environmental groups will have another opportunity to comment on the proposed standards and provide additional information during the public comment period.

B. Regulatory Background

The proposed rule implements section 112(d) of the Clean Air Act (CAA) amendments of 1990, which require the Administrator to regulate emissions of HAP listed in section 112(b) of the CAA. The intent of this rule is to protect the public health by requiring new and existing major sources to reduce generation of emissions by using pollution prevention strategies or to control emissions to the level achievable by the maximum achievable control technology (MACT), taking into consideration the cost of achieving such emission reductions, any nonair quality and other air quality related health and environmental impacts, and energy requirements.

In 1978, EPA published a control techniques document entitled ''Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products,'' EPA–450/2–78–029. The control technique guidelines document (CTG) contains a presumptive norm for reasonably available control technology (RACT) for the manufacturing operations covered under SIC Codes 2833 and 2834. This proposed rule does not affect the presumptive RACT guidelines, although a portion of emissions sources are covered by both the proposed regulation and the CTG document.

In 1994, EPA promulgated National Emission Standards for Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks. Pharmaceutical processes, defined as processes that synthesize pharmaceutical intermediates or final products using carbon tetrachloride or methylene chloride as a reactant or process solvent, are subject to this rule. The EPA is proposing today to require control of leaking components that are currently not subject to the Negotiated Regulation for Equipment Leaks, but that contain HAP and are associated with processes in this source category.

III. Authority for National Emission Standards for Hazardous Air Pollutants (NESHAP) Decision Process

A. Source of Authority for NESHAP Development

Section 112 of the Clean Air Act gives the Environmental Protection Agency the authority to establish national standards to reduce air emissions from sources that emit one or more HAP. Section 112(b) contains a list of HAP to be regulated by NESHAP. Section 112(c) directs the Agency to use this pollutant list to develop and publish a list of source categories for which NESHAP will be developed; this list was published in the **Federal Register** on July 16, 1992 (57 FR 31576). The Agency must list all known categories and subcategories of ''major sources'' that emit one or more of the listed HAP. A major source is defined in section 112(a) as any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit in the aggregate, considering controls, 10 tons per year or more of any one HAP or 25 tons per year or more of any combination of HAP.

B. Criteria for Development of NESHAP

The NESHAP are to be developed to control HAP emissions from both new and existing sources according to the statutory directives set out in section 112(d) of the Act. The statute requires the standards to reflect the maximum degree of reduction in emissions of HAP that is achievable for new or existing sources. This control level is referred to as the ''maximum achievable control technology'' (MACT). The selection of MACT must reflect consideration of the cost of achieving the emission reduction, any nonair quality health and environmental impacts, and energy requirements for control levels more stringent than the floor (described below).

The MACT floor is the least stringent level for MACT standards. For new sources, the standards for a source category or subcategory ''shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source, as determined by the Administrator'' (section 112(d)(3)). Existing source standards should be no less stringent than the average emission limitation achieved by the best performing 12 percent of the existing sources for categories and subcategories with 30 or more sources or the average emission limitation achieved by the best performing 5 sources for categories or subcategories with fewer than 30 sources (section 112(d)(3)). The determination of the MACT floor for existing sources under today's rule is that the average emission limitation achieved by the best performing sources is based on a measure of central tendency, such as the arithmetic mean, median, or mode. The determination of percentage reduction in the production-indexed consumption factors used in the pollution prevention alternative is based on the criteria that the alternative must achieve emissions reductions equivalent to what would have been achieved by complying with the MACT.

IV. Summary of Proposed Standards

A. Source Categories to be Regulated

The proposed standards would regulate HAP emissions from pharmaceutical production facilities that are determined to be major sources. The standards would apply to existing sources as well as new sources.

B. Pollutants to be Regulated and Associated Environmental and Health Benefits

Pharmaceutical production facilities emit an estimated 34,000 Mg/yr of organic and inorganic HAP's. Organic HAP's include methylene chloride, methanol, toluene, dimethylformamide, and hexane as well as other HAP's. Hydrogen chloride is an inorganic HAP emitted by this industry. The proposed rule would reduce HAP emissions from pharmaceutical facilities by 65 percent. Some of these pollutants are considered to be carcinogenic, and all can cause toxic health effects following exposure, including nausea, headaches, and possible reproductive effects. The EPA does recognize that the degree of adverse effects to human health can range from mild to severe. The extent and degree to which the human health effects may be experienced is dependent upon (1) the ambient concentration observed in the area (e.g., as influenced by emission rates, meteorological conditions, and terrain), (2) the frequency of and duration of exposures, (3) characteristics of exposed individuals (e.g., genetics, age, pre-existing health conditions, and lifestyle) which vary significantly with the population, and (4) pollutant specific characteristics (toxicity, half-life in the environment, bioaccumulation, and persistence).

Most of the organic HAP's emitted from this industry are classified as VOC. The proposed emission controls for HAP's will reduce non-HAP VOC emissions as well. Emissions of VOC have been associated with a variety of health and welfare impacts. Volatile organic compound emissions, together with nitrogen oxides, are precursors to the formation of tropospheric ozone. Exposure to ambient ozone is responsible for a series of public health impacts, such as alterations in lung capacity; eye, nose, and throat irritation; nausea; and aggravation of existing respiratory disease. Among the welfare impacts from exposure to ambient ozone include damage to selected commercial timber species and economic losses for commercially valuable crops such as soybeans and cotton.

Hydrogen chloride is listed under section 112(r) of the CAA. The intent of section 112(r), Prevention of Accidental Releases, is to focus on chemicals that pose a significant hazard to the community should an accident occur, to prevent their accidental release, and to minimize consequences should a release occur. Hydrogen chloride, along with the other substances listed under section 112(r)(3), is listed because it is known to cause, or may be reasonably anticipated to cause death, injury, or serious adverse effects to human health or the environment (see 59 FR 4478, January 31, 1994). Sources that handle hydrogen chloride in greater quantities than the established threshold quantity under section 112(r)(5) will be subject to the risk management program requirements under section 112(r)(7) (see 58 FR 54190, October 20, 1993).

In essence, the MACT standards mandated by the CAA will ensure that all major sources of air toxic emissions achieve the level of control already being achieved by the better controlled and lower emitting sources in each category. This approach provides assurance to citizens that each major source of toxic air pollution will be required to effectively control its emissions. In addition, the emission reductions achieved by these proposed standards, when combined with the reductions achieved by other MACT standards, will contribute to achieving the primary goal of the CAA, which is to ''protect and enhance the quality of the Nations's air resources so as to promote the public health and welfare and the productive capacity of its population'' (the CAA, section 101(b)(1)).

C. Affected Sources

Emission points identified from pharmaceuticals production include process vents, equipment leaks, storage tanks, wastewater collection and treatment systems, and heat exchange systems.

The affected source for the purpose of this regulation is the facility-wide collection of process vents, storage

tanks, wastewater and associated treatment residuals, heat exchange systems, cooling towers, and equipment components that are associated with pharmaceutical manufacturing operations. Based on this definition of affected source, new sources are created by reconstructing existing sources or constructing new ''greenfield'' facilities. Also, if an additional pharmaceutical manufacturing process unit(s) is added to a plant site that is a major source, the addition will be subject to the requirements for a new source provided that the addition meets the definition of construction in § 63.2 of subpart A (General Provisions); the new unit has the potential to emit 10 tons per year or more of any one HAP or 25 tons per year or more of any combination of HAP; and the process unit(s) is dedicated.

D. Format of the Standards

The standards for process vents are presented in a combination of percent reduction and mass limit format. Facilities will have the option of using any control technology, as long as the HAP reductions or mass limitations are achieved. The format of the standards for storage tanks are a combination of equipment standard and performance standard—tanks which require control are required to be fitted with floating roofs or with add-on devices meeting a percent removal requirement. The standards for wastewater emission sources offer two alternative formats for achieving compliance, a percent removal, or the use of reference control technologies. Equipment leak standards are in the form of equipment/work practice standards. Facilities would be required to implement the program specified in the proposed regulation to achieve compliance with the standard.

An alternative pollution prevention standard is also being proposed. This standard can be met in lieu of meeting separate standards for the four emission source types associated with each pharmaceutical production process. The format for this alternative standard is in a kg HAP consumption reduction per kg product format.

E. Basis and Level of Proposed Standards

Detailed information describing the approach used to determine MACT floors and regulatory alternatives for the pharmaceuticals production source category can be found in the basis and purpose document.

The proposed standards for existing and new affected sources are summarized in Table 1. The MACT standard for most existing process vents was set at the floor level of control. The MACT floor was determined from the 12 facilities that represented the best performing 12 percent of the existing 101 major sources. The floor was calculated to be 93 percent control facility-wide. The proposed standards would require existing sources to reduce emissions from the sum of all vents within a process to 900 kg/yr (2,000 pounds per year [lb/yr]), considering control, or meet an overall process control level of 93 percent. Both calculations meet the requirements of the floor as determined on a facility wide basis. Additionally, a regulatory alternative beyond the floor was developed that requires 98 percent control of some large vents. An applicability cutoff was developed for this alternative based on a linear equation relating vent flowrate and HAP load. The cost of this alternative above the floor is $1,000/Mg and was judged to be reasonable. Process vents meeting the annual emissions and flowrate criteria are required to achieve 98 percent control, independent of the overall 93 percent requirement.

TABLE 1.—PROPOSED STANDARDS FOR NEW AND EXISTING SOURCES

Emission source	New or existing?	Applicability		Requirement	
		Applicability level	Cutoff	Control efficiency	Emission limit
Process	New	Processes	≥400 lb/yr uncontrolled	98%	
	Existing	Processes	≥2,000 lb/yr controlled	93%; 98% for individual vents meeting cutoff based on flow and emissions.	2,000 lb/yr.
Storage tanks	New and existing.	≥10,000 gal and <20,000 gal	≥1.9 psia vapor pressure of liquid stored.	90%	
		≥20,000	≥1.9 psia vapor pressure of liquid stored.	95%.	
Wastewater	New and existing.	>1 Mg/yr total HAP load from all POD within a process or any single POD.	≥1,300 ppm at POD of Table 2 HAP.	99% reduction of Table 2 HAP.	
			≥5,200 ppmw at POD of total HAP load.	99% reduction of Table 2 HAP. 90% reduction of Table 3 HAP. 95% reduction of total HAP using biotreatment.	
		>1 Mg/yr total HAP load from facility.	≥10,000 ppmw at POD of total HAP load.	99% reduction of Table 2 HAP. 90% reduction of Table 3 HAP. 95% reduction of total HAP using biotreatment.	
	New	>1 Mg/yr total HAP load from all POD within a process or any single POD.	≥110,000 ppmw at POD of Table 3 HAP.	99% reduction of Table 3 HAP.	
Equipment leaks.	New and existing.	All components in HAP service excluding components covered by subpart H.		LDAR program.	

The MACT standard for process vents at new sources was set at the floor level of control. The MACT floor was determined from the best controlled similar source and is based on the most stringent control level achieved for both chemical synthesis and formulation type processes. The proposed standards for new sources would require 98 percent control of process vents with uncontrolled emissions greater than 180 kg/yr (400 lb/yr).

The MACT floor for small, medium, and large storage tanks is 90 percent control for tanks storing liquids with total HAP vapor pressure greater than or equal to 1.9 psia at existing sources. The floor was determined from the twelve facilities that had the highest control level for storage tanks. The EPA evaluated the impacts of a regulatory alternative beyond the floor that would require 95 percent control of tanks greater than or equal to 20,000 gallons. Floating roof technology has been demonstrated to achieve 95 percent control and is considerably less expensive than add-on control; and it can be applied to 20,000 gallon tanks. Therefore, there is no additional cost for the regulatory alternative above the floor. The MACT for new sources is set at the same level as the MACT for existing sources because it has been determined that no facility is controlling tanks beyond the level required by the regulatory alternative for existing sources; therefore MACT would be no less stringent than the floor. The proposed standards would require existing and new sources to control storage tanks having volumes greater than or equal to 38 cubic meters (m^3) (10,000 gallons), and storing material with a vapor pressure of greater than or equal to 13.1 kPa (1.9 psi). The proposed standards require that tanks with capacities greater than or equal to 38 m^3 and less than 75 m^3 be controlled to a level of 90 percent and tanks greater than or equal to 75 m^3 be controlled to 95 percent. One of the following control systems can be applied to meet these requirements:

1. An internal floating roof with specified seals and fittings;
2. An external floating roof with specified seals and fittings;
3. An external floating roof converted to an internal floating roof with specified seals and fittings; or
4. A closed vent system with the appropriate 90 or 95 percent efficient control device.

The MACT floor for wastewater at existing sources was determined to be 54 percent control of HAP from the total wastewater streams at the top twelve facilities. The EPA calculated HAP concentration cutoffs for wastewater streams, cutoffs above which steam stripping of wastewater streams would result in a level of control as stringent as the floor. This approach is similar to the HON and allows for the control of those wastewater streams containing the most significant amount of HAP. The cutoffs represent the MACT floor level of control. The proposed standards would require existing sources to control wastewater with the following characteristics at the point of determination (POD):

1. Streams having partially soluble HAP compound concentrations of 1,300 ppmw or greater and a total yearly process HAP load of 1 Mg/yr or greater or any single POD load of 1 Mg/yr or greater;
2. Streams having a combined total HAP concentration of 5,200 ppmw or greater and a total yearly process HAP load of 1 Mg/yr or greater or any single POD load of 1 Mg/yr or greater; or
3. Streams having a total HAP concentration of 10,000 ppmw with a total facility HAP load of 1 Mg/yr or greater.

The proposed standards require that the control of wastewater emissions be accomplished in one of the following manners:

1. Using a design biotreatment system for soluble HAP;
2. Demonstrating removals achieving 99 percent by weight of partially soluble compounds, and 90 percent by weight of soluble compounds, from treatment systems; or
3. Demonstrating a removal of 95 percent by weight of total organic HAP from treatment systems.

For new sources, the MACT floor for wastewater is based on a facility that currently incinerates a significant percentage of wastewater containing HAP's in an incinerator combusting a mixture of wastes. The proposed standards would require the same applicability and control requirements described above for existing sources plus require an increased removal of solubles (from 90 to 99 percent) for streams having a soluble HAP concentration of 110,000 ppmw at any of the load criteria (1 Mg/yr total HAP from the process, POD, or facility).

The MACT floor for equipment leaks was found to be negligible for new and existing sources. The regulatory alternative above the floor is the implementation of a leak detection and repair program, patterned after 40 CFR part 63 subpart H. The cost of the regulatory alternative was estimated to be $1,000/Mg and was judged to be reasonable. The proposed standards would require that new and existing sources implement a leak detection and repair (LDAR) program that is modified from the program specified in the Negotiated Regulation for Equipment Leaks (40 CFR part 63, subpart H) to apply specifically to the pharmaceutical industry. The LDAR program specified under subpart H requires specific equipment modifications and work practices that reduce emissions from equipment leaks. Modifications to this program for this rule include the lessening of the monitoring frequency for pumps from monthly to quarterly monitoring (based on the specific data from pharmaceutical manufacturing operations) and the treatment of emissions from receivers and surge control vessels in the process vent provisions. In response to comments received from industry during the standard development process, EPA will consider consolidating the equipment leaks program specified in this subpart (appendix GGGA) with the part of the 40 CFR part 63 subpart H LDAR program that applies to pharmaceutical facilities after promulgation of subpart GGG. The EPA is currently in the process of separately proposing clarifying changes to certain provisions of 40 CFR part 63 subpart H, among them, provisions relating to the monitoring requirements for unsafe and difficult to monitor components. Lastly, based on current industry comments that suggest minimal use of a Quality Improvement Plan (QIP) at pharmaceutical plants, EPA is considering eliminating the requirement of implementing a QIP for the pharmaceutical rule in favor of allowing more frequent monitoring when nominal leakage rates are exceeded and is soliciting comments on whether the QIP should be included in the subpart GGG LDAR program.

1. Alternative Pollution Prevention Standard

The proposed rule also includes a pollution prevention (P2) alternative standard that meets the requirement of the MACT floor and can be implemented in lieu of the requirements described above for existing sources. Two options included in the alternative standard are described in Table 2. The P2 options were developed to provide a way for facilities to comply with the MACT standard by reducing overall consumption of HAP in their processes. This alternative does not apply to HAP that are used as reactants. In the first option, which is applicable to existing processes, owners and operators can satisfy the MACT requirements for all emission source types associated with each process by demonstrating that the

production-indexed consumption of HAP has decreased by 75 percent from a baseline set no earlier than the 1987 calendar year. The production-indexed consumption factor is expressed as kg HAP consumed/kg product produced. The numerator in the kg/kg factor is the total consumption of material, which describes all the different areas where material can be consumed, either through losses to the environment, consumption in the process as a reactant, or otherwise destroyed. Consumption, rather than emissions, is tracked because it can be used as a true measure of pollution prevention; any decrease in consumption for the same unit of product generated must involve some type of increase in process efficiency, including reduction of waste, increased product yield, and in-process recycling. Because HAP are used generally as solvents in this industry, reductions in consumption can be generally associated with reductions in losses to air, water, or solid waste.

TABLE 2.—ALTERNATIVE P2 STANDARD

Option	Description of P2 option
1	Demonstrate a 75% reduction in the kg consumption/kg production factor from a baseline year of 1987.
2	Demonstrate a 50% reduction in the kg/kg and additional reduction from add-on control equivalent to yield 75% overall reduction in kg/kg.

The second option also uses the production-indexed consumption factor and is also applied to existing processes. It encourages and allows owners and operators to supplement reductions achieved with P2 with add-on controls. The EPA believes that such an option will provide greater flexibility and cost efficiency to the operators who already may have some add-on controls. Owners and operators must demonstrate reductions in the kg/kg factor of 50 percent via P2 measures and the remaining 25 percent by add-on controls. A total reduction of 75 percent will be required under both P2 options.

F. Compliance and Performance Test Provisions

1. Proposed Standards

a. *Process Vents.* To determine compliance with the percent reduction requirement for pharmaceutical process vents, uncontrolled and controlled emissions from all process vents within the process shall be quantified to demonstrate the appropriate overall reduction requirements (93 percent or 98 percent). For process vents controlled by devices handling less than 10 tons per year, the owner or operator can either test or use calculational methodologies to determine the uncontrolled and controlled emission rates from individual process vents. For process vents controlled by devices handling more than 10 tons per year, tests are required to determine the reduction efficiency of each device. Performance test provisions have been structured to account for the worst case emissions for devices controlling streams with batch characteristics. Control devices that have previously been tested under conditions required by this standard and condensers are exempt from performance testing.

b. *Storage Tanks and Wastewater.* For demonstrating compliance with various requirements, the proposed rule allows the owners or operators to either conduct performance tests or to document compliance using engineering calculations. Appropriate compliance and monitoring provisions are specified in the regulation.

c. *Equipment Leaks.* To determine compliance with the standard for equipment leaks, facilities will have to demonstrate that a LDAR program meeting the requirements of the LDAR program specified in the rule is in use.

2. Pollution Prevention Alternative Standards

Initial demonstration of compliance with the P2 alternative standards would be accomplished by documenting yearly quantities of HAP raw materials and products using available records, including standard purchasing and accounting records, and calculating the kg/kg values. Procedures are also specified to demonstrate that the required reductions are achieved by the control devices used to meet option 2.

G. Monitoring Requirements

1. Actual Standards

Monitoring is required by the proposed standards to determine whether a source is in compliance on an ongoing basis. This monitoring is done either by continuously measuring emission reductions directly or by continuously measuring a site-specific operating parameter, the value of which is established by the owner or operator during the initial compliance determination. The operating parameter value is defined as the minimum or maximum value established for a control device or process parameter that, if achieved on a daily average by itself or in combination with one or more other operating parameter values, determines that an owner or operator is complying with the applicable emission standards. These parameters are required to be monitored at 15-minute intervals throughout the operation of the control device. For devices controlling streams totaling less than 1 ton/yr, only a site-specific periodic verification that the devices are operating as designed is required to demonstrate continuous compliance. Owners and operators must determine the most appropriate method of verification and propose this method to the Agency for approval in the precompliance report, which is due 1 year prior to the compliance date of the standard.

2. Alternative Standard

Owners and operators electing to use the P2 alternative can demonstrate ongoing compliance by calculating a monthly rolling average of the kg HAP/kg factor for each applicable process or portions of the process. In addition, owners and operator electing to use P2 Option 2 would have to monitor the emission reduction obtained through the use of traditional controls using the methods described above.

H. Reporting and Recordkeeping Requirements

The owner or operator of any pharmaceutical source subject to these standards would be required to fulfill all reporting requirements outlined in the General Provisions to 40 CFR part 63. A table included in the proposed rule designates which sections of subpart A apply to the proposed rule. Specific recordkeeping and reporting requirements for each type of emission point are also included in the proposed rule.

V. Summary of Environmental, Energy, Cost, and Economic Impacts

A. Facilities Affected by These NESHAP

These NESHAP would affect pharmaceutical production facilities that are major sources in themselves, or constitute a portion of a major source. There are 270 existing facilities manufacturing pharmaceuticals, 101 of which were assumed to be major sources for the purpose of developing these standards and calculating impacts. The expected rate of growth for the pharmaceutical industry is expected to be 2.4 percent per year through 1998.

B. Air Impacts

The proposed standards would reduce HAP emissions from existing sources by 22,000 (Mg/yr) (24,000 tons per year (tons/yr)) from the baseline level, a reduction of 65 percent from baseline,

and 75 percent from uncontrolled. These reductions would also occur if facilities elect to implement the alternative pollution prevention standard. The proposed standard would also reduce VOC emissions.

C. Water and Solid Waste Impacts

Much of the steam stripping operations will result in recoverable material. However, the new source requirement for very rich soluble HAP-containing wastewater is expected to generate solid waste. An average of 900 tons per year per facility was estimated to determine impacts.

D. Energy Impacts

The proposed standards for the pharmaceuticals source category would require an additional energy usage of 2,400 x 10^9 British thermal units per year (Btu/yr).

E. Cost Impacts

The emission reductions that would be required by this regulation could be met using one or more of several different techniques. To determine costs, certain control scenarios were assumed. The scenarios used in costing were judged to be the most feasible scenarios possible for meeting the requirements of the proposed standards from a technical and cost standpoint. The total control cost includes the capital cost to install the control device, the costs involved in operating the control device, and costs associated with monitoring the device to ensure compliance. Monitoring costs include the cost to purchase and operate monitoring devices, as well as reporting and recordkeeping costs required to demonstrate compliance. Nationwide, the total annual cost of this standard to the industry for existing and new sources is approximately $62 million and $11 million respectively. The EPA believes that monitoring, reporting, and recordkeeping costs will be substantially reduced for the facilities opting to comply via the P2 option. Additionally, EPA also believes that overall control costs will also be substantially reduced as a result of compliance with the P2 option.

F. Economic Impacts

The economic impact analysis of this standard shows that the estimated price increase from compliance with the recommended standard for process vents, storage tanks, and wastewater is 1.1 percent. Estimated reduction in market output is 1.9 percent.

No plant closures are expected from compliance with this set of alternatives. For more information, consult the economic impact report entitled ''Economic Analysis of Air Pollution Regulation Regulations: Pharmaceutical Industry, August 1996.''

VI. Emissions Averaging

Emissions averaging is being considered as part of this rule. The rule includes provisions that permit emissions averaging within existing process vent and storage tank planks. The industry is interested in emissions averaging for only these two emission point types. The provisions consist of a streamlined version of the Hazardous Organic NESHAP (HON) emissions averaging provisions (40 CFR part 63 subpart G) modified specifically for the pharmaceutical industry. However, the constraints are essentially the same as those contained in the HON.

VII. Regulation of the Pharmaceutical Manufacturing Industry Under the Clean Water Act

The Clean Water Act (CWA) and a recent settlement agreement (see 59 FR 25869) require EPA to develop effluent limitations guidelines and standards regulations for certain industrial categories. The Pharmaceutical Manufacturing Industry is one of the categories required to be regulated by this settlement agreement. The EPA's most recent regulatory proposal for the pharmaceutical industry was on May 2, 1995 (60 FR 21592.)

In the May 2, 1995 proposal, EPA proposed best available technology (BAT) economically achievable and new source performance standards (NSPS) regulations for 53 volatile and semivolatile organic pollutants of which 17 are HAP. The Agency also proposed PSES and PSNS for 45 volatile organic pollutants of which 16 are HAP. (Air emissions of HAP by major sources will be controlled by this MACT rule provided that the wastewater streams containing the HAP meet concentration criteria for soluble and partially soluble HAP in today's proposal.)

The EPA identified the following industry subcategories in the proposed effluent guidelines: Fermentation (A), biological and natural extraction (B), chemical synthesis (C) and formulation (D).

The proposed BAT end-of-pipe limitations would control the discharge of 17 HAP and 36 non-HAP at both A and C and B and D manufacturing facilities. The technology basis for the BAT limitations for A and C subcategory facilities was in-plant steam stripping followed by advanced biological treatment while the technology basis of the BAT limitations for B and D subcategory facilities was advanced biological treatment. Since these proposed limitations are set at the end-of-pipe, they would not prevent air emissions of these pollutants prior to discharge.

Also proposed in the May 2, 1995 notice (see coproposal A) were PSES for 8 HAP and 4 non-HAP set in-plant at a point roughly equivalent to the MACT standards point of determination while PSES for 8 other HAP and 25 non-HAP were proposed at the end-of-pipe discharge point. The technology basis for the HAP and non-HAP pollutants alike was steam stripping. Under coproposal B, only in-plant PSES for the eight HAP would be established. The Agency decided to establish an in-plant monitoring point for 12 highly volatile pollutants (including the 8 HAP) because measuring compliance at the end-of-pipe monitoring point was not considered practical for these pollutants due to the high potential for air stripping associated with them and commingling with other process wastewater not containing any of the 12 pollutants. As is the case with the BAT end-of-pipe limitations, the end-of-pipe proposed PSES would not prevent air emissions of HAP at facilities prior to the discharge point to the municipal sewer systems.

The MACT standards being proposed today will control HAP emissions (if promulgated) at major source pharmaceutical plants with steam stripping as the reference control technology. The EPA is considering revising the BAT limitations for subcategories A and C based on only advanced biological treatment performance data. This would in effect shift control of HAP air emissions and wastewater pollutant discharges of the HAP to the MACT standards. With regard to control of non-HAP at major sources, the Agency believes that the significant reductions in HAP emissions required by the proposed MACT standards will also result in incidental reductions in non-HAP air emissions because many non-HAP are found in the same wastewater streams as the HAP, and thus will be steam stripped along with the HAP. While control of air emissions of HAP and non-HAP VOC's will be addressed to some extent under the CAA, additional control of water discharges of the VOC's from direct dischargers needs to be addressed under the Clean Water Act using as a basis the BAT limitations and NSPS proposed on May 2, 1995.

The MACT standards being proposed today would apply to select streams at 60, out of a possible 259, pharmaceutical indirect dischargers deemed to be major sources of air

emissions. Only those streams which meet the flow and concentration cutoffs established for HAP would require control. Assuming that EPA's pass-through analysis does not change and coproposal A is chosen, EPA estimates that today's proposed MACT rule would reduce the load of VOC's to POTW's from pharmaceutical manufacturing plants by approximately 48 percent. Part or all of the remainder of the pollutant loadings to POTW's may need to be controlled by additional pretreatment requirements. The Agency is considering three options for setting pretreatment standards (PSES and PSNS) to address HAP and non-HAP wastewater pollutant discharges not controlled by today's proposed MACT standard.

Under the first option (which has been suggested by commenters), compliance with today's MACT standards would constitute compliance with final PSES and PSNS for all manufacturing subcategories. However, since compliance with the MACT regulation requires only one demonstration by the facility, EPA is considering some form of regular monitoring to verify compliance with wastewater discharge standards. Facilities could either monitor for individual HAP or non-HAP on a regular basis or for some indicator pollutant parameter whose regulatory compliance level would be established at the same time that MACT rule compliance demonstration is performed. This option would result in control of about 48 percent of the VOC pollutant load that is currently being discharged to POTW's by pharmaceutical facilities.

Under the second option, and in addition to the MACT regulations on selected streams at 60 indirect dischargers, EPA would establish pretreatment standards for the streams and pollutants not controlled by the MACT regulations. The level of control dictated by these additional standards would be the same level as that of the MACT standards (90 percent reduction for soluble organics and 99 percent for partially soluble organics). The pretreatment standards could either be in the form of percent reduction requirements for individual pollutants or single number standards resulting from the application of the MACT percent reduction requirements. The EPA estimates that this option would reduce the discharge of pollutants to POTW's by an additional 45 percent over the first option.

The third option would involve promulgating the coproposal A pretreatment standards for all indirect dischargers at the end-of-pipe regulatory point. These pretreatment standards would apply to all streams at facilities designated as major sources regardless of whether the streams were within the concentration cutoffs for HAP and would be established for all pollutants which pass-through. The level of control dictated by these standards would be the coproposal A level with the exception that standards for 12 pollutants which were established in-plant will now be set at the end-of-pipe and adjusted downward to account for dilution due to mixing with other waste streams. Other changes in parameters or limitations may result from the evaluation of comments and receipt of additional performance data. Using the proposed limitations, EPA estimates that this option would reduce the discharge of pollutants to POTW's by an additional 29 percent over the first option.

The EPA is considering revising its pass-through analysis for water soluble, biodegradable pollutants such as methanol, acetone, isopropanol and ethanol based on approaches suggested by commenters on the May 2, 1995 pharmaceutical proposal as well as the approaches used in the Pesticide Chemicals Manufacturing and Organic Chemicals, Plastics, and Synthetic Fibers (OCPSF) rulemakings. In general, pollutants are considered to pass-through POTW's if the average percent removal achieved by well operated POTW's is less than that achieved by the BAT model treatment systems. The EPA is considering specifically the methodology modifications employed in the evaluation for phenol, a biodegradable water soluble pollutant as discussed in the Pesticides and OCPSF rulemakings (see 59 FR 50638, 50664–65, September 28, 1993 and 58 FR 36872, 36885–86, July 9, 1993). Among the modifications suggested by the commenters were: (1) Using only data from acclimated POTW systems to determine POTW removal; (2) finding no pass-through for pollutants if the differential between the model BAT percent removal and the POTW percent removal for a pollutant is less than 5 percent and; (3) utilizing a higher Henry's Law Constant cutoff when pass through is determined by the volatile override approach (pollutants which have a higher Henry's Law Constant value than the cutoff are presumed to pass-through using this methodology).

The Agency is reevaluating its proposed pass-through analysis because of the comments received concerning it and to be more consistent with today's proposed MACT standards for soluble organic HAP which allows the biodegradation achieved by POTW's to be included in the compliance demonstration for these pollutants. Today's MACT standards require a demonstration of at least a 90 percent reduction in air emissions from wastewater of water soluble biodegradable HAP. As a result, a finding of pass-through may result in duplicative and somewhat inconsistent control (by water and air regulations) for some pollutants. The EPA solicits comments on possible revisions to its pass-through methodology as applied to water soluble, biodegradable pollutants.

The EPA is soliciting comments on approaches for revising the limitations for direct and indirect dischargers in the proposed effluent guidelines for the pharmaceutical industry (60 FR 21592, May 2, 1995). The intent of all of these approaches is to integrate the regulation of emissions into the air and waters of the United States. If EPA develops any additional data related to the possible revisions, those data will be made available to the public.

The EPA may proceed with final action on the effluent guidelines, taking into account comments and data received in response to this notice.

VIII. Solicitation of Comments

The Administrator welcomes comments from interested persons on any aspect of the proposed rule, and on any statement in the preamble or the referenced supporting documents. The proposed rule was developed on the basis of information available. The Administrator is specifically requesting factual information that may support either the approach taken in the proposed standards or an alternate approach. In order to receive proper consideration, documentation or data should be provided. This section requests comments on specific issues identified during the development of the standard. Additionally, EPA is soliciting comments regarding the interaction of this standard with the Title V operating permits program.

The EPA is requesting comments and data on establishing the applicability of process vent control requirements on a process basis, as opposed to an equipment or facility basis. The basis and purpose document included in the administrative record outlines the rationale for establishing applicability on a process basis. Second, the EPA is soliciting general comments on the adequacy of emission estimation procedures to determine compliance for batch processes. Comments from State partnership members indicate that some batch operations, such as distillation, may contribute to considerably more emissions than would otherwise be

predicted. In some cases, unless 100 percent capture is achieved by the condenser acting as a recovery device on boiling operations, there may be uncontrolled emissions that are not being estimated. The State partnership members recommend that facilities compare their HAP mass balance to estimated HAP losses. When large discrepancies exist, the facility may need to monitor large process condensers. Third, the EPA is soliciting comments on the definition of a pharmaceutical product and isolated intermediate. In particular, whether Standard Industrial Classification code #283 and coverage by the Food and Drug Administration (FDA) rules are adequate to identify a pharmaceutical process covered by this regulation. The proposed rule considers isolated intermediates to be the same as pharmaceutical products in applicability determinations, e.g., the 2,000 lb/yr cutoff applies to isolated intermediates. The EPA is soliciting comments on the definition of isolated intermediates and the appropriateness of applying the cutoff to isolated intermediates. Fourth, EPA is soliciting comment on the adequacy and appropriateness of the new source MACT requirements for process vents. As set out in the basis and purpose document, EPA set the cutoff and level of control for the floor based on its analysis of the data showing that the characteristics of the emission streams are similar. The industry, however, believes that the basis of the cutoff is not representative of the industry as a whole. The EPA will consider other proposals for setting the cutoff at a less stringent level, taking into consideration statutory and regulatory requirements.

The EPA is soliciting comments on several aspects of performance testing and monitoring. The rule currently requires performance testing to document efficiencies for control devices that are used to reduce uncontrolled emissions of 10 tons per year or more. The rule currently requires that the performance test be conducted under ''worst-case'' conditions and provides for three options—absolute, representative, and hypothetical worst-case. The rule also allows for testing during normal operations. However, because of the noncontinuous, batch nature of processing in this industry, testing under normal conditions may not indicate control device performance under more challenging conditions. Therefore, the proposed rule requires that the test conditions be defined and operation be limited by those conditions that existed during testing. The rule requires that the test conditions be defined in the Precompliance report and characterized by the HAP composition and conditions of vent stream entering the control device. It is because of the batch nature of processing in this industry that the EPA has a higher level of confidence in a facility's compliance with the standard if the performance of the control device has been tested under worst-case conditions. Therefore, testing under less rigorous, normal conditions limits the range of vent stream conditions for which initial compliance has been demonstrated. The EPA is soliciting comments on appropriate test conditions to be defined for different types of control devices, especially scrubbers and carbon adsorbers.

The proposed rule provides for parametric monitoring to comply with the standard and includes specific operating parameters to be monitored. The EPA is soliciting comments on the use of alternative parameters without the requirement of prior notification in the Precompliance report. Parameters other than those specified in the rule that could be used to demonstrate compliance include: (1) or condensers, coolant temperature and flow (only with emissions testing), (2) for scrubbers, measurement of pressure drop or scrubber fluid composition, and (3) for carbon adsorbers, periodic vent testing and/or predetermined scheduled replacement. The EPA is soliciting comment on the adequacy of these parameters for demonstrating continuous compliance with the rule.

An issue raised by industry associated with parametric monitoring is related to the setting of a parameter based on an initial compliance determination at conditions which represent the upper limit (with regard to achievable control) of conditions that will be encountered during the course of operations. The concern is that the rule effectively requires a control level that is greater than the standard because the control devices will presumably achieve higher control on conditions that are below this upper limit, which may occur frequently in this industry because of the predominance of batch processes. The EPA has tried to resolve this issue by allowing owners and operators to set more than one parameter level for a given control device for processes or portions of processes not requiring control levels as high as the worst-case or upper limit. These parametric levels are required to be defined in advance in the Notification of compliance report. If more than one level is set, owners and operators must make a determination of compliance with the standards based on what processes or emission characteristics are routed to the device at the time in which a monitoring reading is taken. Additionally, the determination of an exceedance is based on a maximum of 24 hours worth of data, or 96 15-minute readings, per process. Therefore, readings outside of acceptable ranges can be averaged in with readings that are within range and effectively normalized. The EPA believes that the approach taken offers the industry needed flexibility while preserving the assurance of continuous compliance.

Another issue raised by industry is related to predictability of operations. The industry believes that nondedicated, multiproduct facilities using control devices other than condensers (and, perhaps, combustion devices) for multiple vents may not be able to anticipate all possible operating scenarios for which a separate parametric level would need to be set. The industry has given the example of a scrubber that is used to control emissions from multiple processes. The parametric level that represents compliance with the applicable standard for each process may change depending on what is happening in each process and they argue it would be essentially impossible to predict the exact scrubber flow needed to achieve compliance at any given time. The industry has requested that the standard provide that an excursion from a parametric level does not automatically constitute a violation of the rule, but instead triggers reporting requirements that initiate a permitting authority's review to decide whether the excursion resulted in a violation for this type situation. The EPA has generally taken the position that ''after-the-fact'' justification of excursions is not an appropriate compliance strategy. Based on currently available information, the EPA has not seen a need to change this position. The proposed rule allows the facility flexibility in establishing the parameter monitoring level based on tests, engineering assessments, and/or manufacturers recommendations if included in the Precompliance report and approved. The EPA believes it is necessary to know the HAP load going to the control device to be able to properly operate the device to meet the emission limit (the agency has concerns about the industry's stated inability to predict or know the HAP load at certain times). In cases where the owner cannot predict exactly what is going to the control device over time, the standard provides for doing testing under conditions worse than average to cover

periods of uncertainty. In fact this is the reason for the focus on worst-case in the rule. The EPA is seeking comment on this part of the rule.

Related to testing and monitoring are management of change issues. The EPA is soliciting general comments on the clarity of the rule as it applies to process changes. Management of change issues are also related to title V of the Clean Air Act.

Currently, the Notification of Compliance report is the compliance ''blueprint'' for implementation of the standard. All information regarding documentation of the facility's compliance status with regard to the standard should be included in this report. Process descriptions, emission estimates, control device performance documentation, and continuous compliance demonstration strategies, including monitoring, are to be presented in the report. This report could be incorporated by reference into the facility's title V permit. If a change occurred at the facility which required the submittal of additional information, or if the plant chose to revise procedures that had been previously documented in the notification, this information would be submitted in quarterly reports, thus ensuring that the notification and associated reports would always contain the most current compliance strategy for the facility. Only changes requiring site-specific approval, such as the use of a monitoring parameter that was not specifically identified in the standard, would trigger some significant review action under title V. This would allow the facility enough flexibility to change processes, operating, and compliance procedures as necessary without prior approval, if the changes were straightforward, and would assure that the compliance plan for the facility would always be current. The EPA is also soliciting comments on the incorporation by reference of the Notification of Compliance report into the title V permit, and comments on the types of changes that should trigger review actions under title V.

IX. Administrative Requirements

A. Public Hearing

A public hearing will be held, if requested, to discuss the proposed standard in accordance with section 307(d)(5) of the Clean Air Act. Persons wishing to make oral presentation on the proposed standards for pharmaceutical production processes should contact EPA at the address given in the **ADDRESSES** section of this preamble. Oral presentations will be limited to 15 minutes each. Any member of the public may file a written statement before, during, or within 30 days after the hearing. Written statements should be addressed to the Air Docket Section address given in the **ADDRESSES** section of this preamble and should refer to Docket No. A–96–03.

A verbatim transcript of the hearing and written statements will be available for public inspection and copying during normal working hours at EPA's Air Docket Section in Washington, DC (see **ADDRESSES** section of this preamble).

B. Docket

The docket is an organized and complete file of all the information submitted to or otherwise considered by EPA in the development of this proposed rulemaking. The principal purposes of the docket are:

1. To allow interested parties to readily identify and locate documents so that they can intelligently and effectively participate in the rulemaking process; and

2. To serve as the record in case of judicial review (except for interagency review materials (section 307(d)(7)(A))).

C. Executive Order 12866

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

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

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

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

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

Pursuant to the terms of the Executive Order, the OMB has notified the EPA that it considers this a ''significant regulatory action'' within the meaning of the Executive Order. The EPA submitted this action to the OMB for review. Changes made in response to suggestions or recommendations from the OMB were documented and included in the public record.

D. Enhancing the Intergovernmental Partnership Under Executive Order 12875

In compliance with Executive Order 12875, EPA has involved State governments in the development of this rule. These governments will be required to implement the rule. They will collect permit fees which will be used to offset the resource burden of implementing the rule. Representatives of six State governments are members of the MACT partnership. This partnership group was consulted throughout the development of this proposed regulation. Comments from the partnership members were carefully considered. In addition, all States are encouraged to comment on this proposed rule during the public comment period, and the EPA intends to fully consider these comments in the final rulemaking.

E. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 1781.01), and a copy may be obtained from Sandy Farmer, Information Policy Branch, U. S. Environmental Protection Agency, 401 M Street SW. (2137), Washington, DC 20460, or by calling 202–260–2740. The public reporting burden for this collection of information is estimated to average 4,800 hours per respondent for the first year and 2,600 hours per respondent for each of the second and third years, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, 2137, U. S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) provides that, whenever an agency promulgates a final rule under 5 U.S.C.

553, after being required to publish a general notice of proposed rulemaking, an agency must prepare a final regulatory flexibility analysis unless the head of the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), I certify that this rule will not have a significant impact on a substantial number of small entities.

The EPA analyzed the potential impact of the rule on small entities and determined that only 16 of 56 pharmaceutical producing firms are small entities—not a substantial number of entities. Of these 16 firms, only four will experience an increase in costs as a result of the promulgation of today's rule that are greater than 1 percent of revenues. Therefore, the Agency did not prepare an initial regulatory flexibility analysis.

Although the statute does not require EPA to prepare an RFA because the Administrator has certified that the rule will not have a significant economic impact on a substantial number of small entities, EPA did undertake a limited assessment, to the extent it could, of possible outcomes and the economic effect of these on small pharmaceutical entities. The initial version of that evaluation is available in the administrative record for today's action.

G. Unfunded Mandates

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

The EPA has determined that the proposed standards do not include a Federal mandate that may result in estimated costs of, in the aggregate, $100 million or more to either State, local or Tribal governments, or to the private sector, nor do the standards significantly or uniquely impact small governments, because they contain no requirements that apply to such governments or impose obligations upon them. Therefore, the requirements of the Unfunded Mandates Act do not apply to this final rule.

H. Miscellaneous

In accordance with section 117 of the Act, publication of this proposal was preceded by consultation with appropriate advisory committees, independent experts, and Federal departments and agencies. The Administrator will welcome comments on all aspects of the proposed regulation, including health, economic and technical issues, and on the proposed test methods.

This regulation will be reviewed 8 years from the date of promulgation. This review will include an assessment of such factors as evaluation of the residual health and environmental risks, any overlap with other programs, the existence of alternative methods, enforceability, improvements in emission control technology and health data, and the recordkeeping and reporting requirements.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: March 20, 1997.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, part 63 of the Code of Federal Regulations is proposed to be 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.

2. It is proposed that part 63 be amended by adding subpart GGG to read as follows:

Subpart GGG—National Emission Standards for Pharmaceuticals Production

Sec.

Subpart GGG—National Emission Standards for Pharmaceuticals

§ 63.1250 Applicability.

(a) Except as specified in paragraph (d) of this section, the provisions of this subpart apply to pharmaceutical manufacturing operations located at a major source of hazardous air pollutant emissions.

(b) The affected source subject to this subpart is the facility-wide collection of pharmaceutical process vents, storage tanks, wastewater and associated treatment residuals, heat exchange systems, cooling towers, and equipment components (pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems) associated with pharmaceutical manufacturing operations.

(c) If an additional pharmaceutical manufacturing process unit(s) is added to a plant site that is a major source, as defined in section 112(a) of the Act, the addition shall be subject to the requirements for a new source in this subpart if: It is an addition that meets the definition of construction in § 63.2 of subpart A of this part; the addition has the potential to emit 10 tons per year or more of any HAP or 25 tons per year or more of any combination of

HAP, unless the Administrator establishes a lesser quantity; and the process unit(s) is dedicated to the manufacture of a single product or isolated intermediate.

(d) Table 1 specifies the provisions of subpart A that apply to an owner or operator of an affected source subject to this subpart, and clarifies specific provisions in subpart A as necessary for this subpart.

(e) The provisions of this subpart do not apply to research and development facilities.

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

(1) An owner or operator of an existing affected source must comply with the provisions of this subpart within 3 years after the effective date of the standard.

(2) An owner or operator of a new or reconstructed affected source must comply with the provisions of this subpart immediately upon startup.

(3) Notwithstanding the requirements of paragraphs (f)(1) and (2) of this section, a new source which commences construction or reconstruction after April 2, 1997 and before effective date of final rule shall not be required to comply with such promulgated standard until 3 years after the date of promulgation if:

(i) The promulgated standard is more stringent than the proposed standard; and

(ii) The owner or operator complies with the standard as proposed during the 3-year period immediately after the effective date.

(g) For batch processes, the provisions of this subpart also apply during startup and shutdown. Periods of malfunction are regulated according to § 63.6 of subpart A.

(h) This subpart applies to all equipment leak emissions in the source category not covered by 40 CFR part 63 subpart I, which requires the implementation of subpart H requirements for components in methylene chloride and carbon tetrachloride service in pharmaceutical chemical synthesis operations. The requirements proposed in this rule do not affect the requirements of subpart I or H for these components. Only components not currently identified and affected by subpart I are considered in this standard.

§ 63.1251 Definitions.

Terms used in this subpart are defined in the Act, in subpart A of this part, or in this section. If the same term is defined in subpart A of this part and in this section, it shall have the meaning given in this section for the purposes of subpart GGG.

Air pollution control device means equipment installed on a process vent storage tank, wastewater treatment exhaust stack, or combination thereof that reduces the mass of HAP emitted to the air. Examples include incinerators, carbon adsorption units, condensers, and gas absorbers. Process condensers are not considered air pollution control devices.

Batch cycle refers to manufacturing an intermediate or product from start to finish in a batch unit operation.

Batch emission episode means a discrete venting episode that may be associated with a single unit operation. A unit operation may have more than one batch emission episode. For example, a displacement of vapor resulting from the charging of a vessel with HAP will result in a discrete emission episode that will last through the duration of the charge and will have an average flowrate equal to the rate of the charge. If the vessel is then heated, there will also be another discrete emission episode resulting from the expulsion of expanded vapor. Both emission episodes may occur in the same vessel or unit operation. There are possibly other emission episodes that may occur from the vessel or other process equipment, depending on process operations.

Batch operation or Batch process means a noncontinuous operation involving intermittent or discontinuous feed into equipment, and, in general, involves the emptying of the equipment after the batch operation ceases and prior to beginning a new operation. Addition of raw material and withdrawal of product do not occur simultaneously in a batch operation.

Closed-vent system means a system that is not open to the atmosphere and is composed of piping, ductwork, connections, and, if necessary, flow inducing devices that transport gas or vapor from an emission point to a control device or back into the process.

Combustion device means an individual unit of equipment, such as a flare, incinerator, process heater, or boiler, used for the combustion of HAP vapors.

Consumption means the makeup quantity of HAP entering a process that are not used as reactant. The quantity of material used as reactant is the theoretical amount needed assuming a 100 percent stoichiometric conversion. Makeup is the net amount of material that must be added to the process to replenish losses.

Container, as used in the wastewater provisions, means any portable waste management unit that has a capacity greater than or equal to 0.1 m^3 in which a material is stored, transported, treated, or otherwise handled. Examples of containers are drums, hoses, barrels, tank trucks, barges, dumpsters, tank cars, dump trucks, and ships.

Continuous process means a process where the inputs and outputs flow continuously throughout the duration of the process. Continuous processes are typically steady state.

Continuous seal means a seal that forms a continuous closure that completely covers the space between the wall of the storage vessel and the edge of the floating roof. A continuous seal may be a vapor-mounted, liquid-mounted, or metallic shoe seal.

Controlled HAP emissions means the quantity of HAP discharged to the atmosphere. If no air pollution control devices are present, controlled emissions are the same as uncontrolled emissions.

Cover, as used in the wastewater provisions, means a device or system which is placed on or over a waste management unit containing wastewater or residuals so that the entire surface area is enclosed and sealed to minimize air emissions. A cover may have openings necessary for operation, inspection, and maintenance of the waste management unit such as access hatches, sampling ports, and gauge wells provided that each opening is closed and sealed when not in use. Examples of covers include a fixed roof installed on a wastewater tank, a lid installed on a container, and an air-supported enclosure installed over a waste management unit.

External floating roof means a pontoon-type or double-deck type cover that rests on the liquid surface in a storage vessel or waste management unit with no fixed roof.

Fill or filling means the introduction of hazardous air pollutant into a storage vessel or the introduction of a wastewater stream or residual into a waste management unit, but not necessarily to complete capacity.

Fixed roof means a cover that is mounted on a waste management unit or storage vessel in a stationary manner and that does not move with fluctuations in liquid level.

Floating roof means a cover consisting of a double deck, pontoon single deck, internal floating cover or covered floating roof, which rests upon and is supported by the liquid being contained, and is equipped with a closure seal or seals to close the space between the roof edge and waste management unit or storage vessel wall.

Hard-piping means tubing that is manufactured and properly installed using good engineering judgment and standards, such as ANSI B31–3.

Individual drain system means the stationary system used to convey wastewater streams or residuals to a waste management unit. The term includes hard piping, all process drains and junction boxes, together with their associated sewer lines and other junction boxes, manholes, sumps, and lift stations, conveying wastewater streams or residuals. A segregated stormwater sewer system, which is a drain and collection system designed and operated for the sole purpose of collecting rainfall-runoff at a facility, and which is segregated from all other individual drain systems, is excluded from this definition.

Internal floating roof means a cover that rests or floats on the liquid surface (but not necessarily in complete contact with it) inside a storage vessel or waste management unit that has a permanently affixed roof.

Isolated intermediate means any intermediate that is removed from process equipment for temporary or permanent storage or transferred to shipping containers.

Junction box means a manhole or access point to a wastewater sewer system line or a lift station.

Liquid-mounted seal means a foam liquid-filled seal mounted in contact with the liquid between the wall of the storage vessel or waste management and the floating roof. The seal is mounted continuously around the vessel or unit.

Maximum true vapor pressure means the equilibrium partial pressure exerted by the total organic HAP in the stored or transferred liquid at the temperature equal to the highest calendar-month average of the liquid storage or transferred temperature for liquids stored or transferred above or below the ambient temperature or at the local maximum monthly average temperature as reported by the National Weather Service for liquids stored or transferred at the ambient temperature, as determined:

(1) In accordance with methods described in American Petroleum Institute Publication 2517, Evaporative Loss From External Floating-Roof Tanks (incorporated by reference as specified in § 63.14 of subpart A of this part); or

(2) As obtained from standard reference texts; or

(3) As determined by the American Society for Testing and Materials Method D2879–83 (incorporated by reference as specified in § 63.14 of subpart A of this part); or

(4) Any other method approved by the Administrator.

Metallic shoe seal or mechanical shoe seal means a metal sheet that is held vertically against the wall of the storage vessel by springs, weighted levers, or other mechanisms and is connected to the floating roof by braces or other means. A flexible coated fabric (envelope) spans the annular space between the metal sheet and the floating roof.

Partially soluble HAP means a HAP listed in Table 2 of this subpart.

Pharmaceutical manufacturing process unit (PMPU) means any processing equipment assembled to process materials and manufacture a pharmaceutical product and associated storage tanks, wastewater management units, or components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used in the manufacturing of a pharmaceutical product.

Pharmaceutical manufacturing operations include PMPU's and other processes and operations as well as associated equipment such as heat exchange systems that are located at a facility for the purpose of manufacturing pharmaceuticals.

Pharmaceutical product means any material described by the standard Industrial Classification (SIC) Code 283, or any other fermentation, biological or natural extraction, or chemical synthesis product regulated by the Food and Drug Administration, including components (excluding excipients) of pharmaceutical formulations, or intermediates used in the production of a pharmaceutical product.

Point of determination means the point where a wastewater stream exits the process or processes, storage tank, or equipment. The POD may be at the equipment or following the last recovery device.

Process means a logical grouping of processing equipment which collectively function to produce a pharmaceutical product or isolated intermediate. A process may consist of one or more unit operations. For the purpose of this subpart, process includes all or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a product or isolated intermediate. The physical boundaries of a process are flexible, providing a process ends with a product or isolated intermediate, or with cessation of onsite processing. Nondedicated solvent recovery and nondedicated formulation operations are considered single processes that are used to recover or formulate numerous materials and/or products.

Process condenser means a condenser whose primary purpose is to recover material as an integral part of a unit operation. The condenser must support a vapor-to-liquid phase change for periods of source equipment operation that are above the boiling or bubble point of substance(s). Examples of process condensers include distillation condensers, reflux condensers, process condensers in line prior to the vacuum source, and process condensers used in stripping or flashing operations.

Process tank means a tank that is physically located within the bounds of a process that is used to collect material discharged from a feedstock storage tank or unit operation within the process and transfer this material to another unit operation within the process or a product storage tank. Surge control vessels and bottoms receivers that fit these conditions are considered process tanks.

Process vent means a vent from a unit operation through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Process vents do not include vents on storage tanks regulated under § 63.1252(b), vents on wastewater emission sources regulated under § 63.1252(d), or pieces of equipment regulated under § 63.1252(e).

Production-indexed HAP consumption factor is the result of dividing the annual consumption of total HAP by the annual production rate, per process.

Production-indexed volatile organic compound (VOC) consumption factor is the result of dividing the annual consumption of total VOC by the annual production rate, per process.

Publicly owned treatment works (POTW) means any devices and systems used in the storage, treatment, recycling, and reclamation of municipal sewage or industrial wastes of a liquid nature as defined in section 212(2)(A) of the Clean Water Act, as amended (33 U.S.C. 1292(2)(A)). A POTW includes the treatment works, intercepting sewers, outfall sewers, sewage collection systems, pumping, power, and other equipment. The POTW is defined at 40 CFR 403.3(0).

Reactor means a device or vessel in which one or more chemicals or

reactants, other than air, are combined or decomposed in such a way that their molecular structures are altered and one or more new organic compounds are formed.

Recovery device means an individual unit of equipment used for the purpose of recovering chemicals for fuel value (i.e., net positive heating value), use, reuse, or for sale for fuel value, use, or reuse. Air pollution control devices are not recovery devices. Process condensers are recovery devices. Other examples of equipment that may be recovery devices include organic removal devices such as decanters, strippers, or thin-film evaporation units.

Research and development facility means research or laboratory operations whose primary purpose is to conduct research and development into new processes and products, where the operations are under the close supervision of technically trained personnel, and is not engaged in the manufacture of products for commercial sale, except in a de minimis manner.

Residual means any HAP-containing liquid or solid material that is removed from a wastewater stream by a waste management unit or treatment process that does not destroy organics (nondestructive unit). Examples of residuals from nondestructive wastewater management units are: The organic layer and bottom residue removed by a decanter or organic-water separator and the overheads from a steam stripper or air stripper. Examples of materials which are not residuals are: Silt; mud; leaves; bottoms from a steam stripper or air stripper; and sludges, ash, or other materials removed from wastewater being treated by destructive devices such as biological treatment units and incinerators.

Sewer line means a lateral, trunk line, branch line, or other conduit including, but not limited to, grates, trenches, etc., used to convey wastewater streams or residuals to a downstream waste management unit.

Single-seal system means a floating roof having one continuous seal that completely covers the space between the wall of the storage vessel and the edge of the floating roof. This seal may be a vapor-mounted, liquid-mounted, or metallic shoe seal.

Soluble HAP means a HAP listed in Table 3 of this subpart.

Storage tank means a tank or other vessel that is used to store organic liquids that contain one or more HAP. The following are not considered storage tanks for the purposes of this subpart:

(1) Vessels permanently attached to motor vehicles such as trucks, railcars, barges, or ships;

(2) Pressure vessels designed to operate in excess of 204.9 kilopascals and without emissions to the atmosphere;

(3) Vessels storing organic liquids that contain HAP only as impurities;

(4) Wastewater storage tanks; and

(5) Process tanks.

Surface impoundment means a waste management unit which is a natural topographic depression, manmade excavation, or diked area formed primarily of earthen materials (although it may be lined with manmade materials), which is designed to hold an accumulation of liquid wastes or waste containing free liquids. A surface impoundment is used for the purpose of treating, storing, or disposing of wastewater or residuals, and is not an injection well. Examples of surface impoundments are equalization, settling, and aeration pits, ponds, and lagoons.

Treatment process means a specific technique that removes or destroys the organics in a wastewater or residual stream such as a stream stripping unit, thin-film evaporation unit, waste incinerator, biological treatment unit, or any other process applied to wastewater streams or residuals to comply with § 63.138 of this subpart. Most treatment processes are conducted in tanks. Treatment processes are a subset of waste management units.

Uncontrolled HAP emissions means a gas stream containing HAP which has exited the last recovery device, but which has not yet been introduced into an air pollution control device to reduce the mass of HAP in the stream. If the process vent is not routed to an air pollution control device, uncontrolled emissions are those HAP emissions released to the atmosphere.

Unit operation means those processing steps that occur within distinct equipment that are used, among other things, to prepare reactants, facilitate reactions, separate and purify products, and recycle materials. Equipment used for these purposes includes but is not limited to reactors, distillation columns, extraction columns, absorbers, decanters, dryers, condensers, and filtration equipment.

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

Volatile organic compounds are defined in 40 CFR part 51, § 51.100.

Wastewater means water containing partially soluble or soluble HAP that is discarded from equipment that is part of the affected source and that is not exempted by the provisions of § 63.1252(d)(2). For the purposes of this subpart, noncontact cooling water is not considered a wastewater stream.

Waste management unit means a component, piece of equipment, structure, or transport mechanism in conveying, storing, treating, or disposing of wastewater streams or residuals. Examples of waste management units include wastewater tanks, air flotation units, surface impoundments, containers, oil-water or organic-water separators, individual drain systems, biological treatment units, waste incinerators, and organic removal devices such as steam and air stripper units, and thin film evaporation units. If such equipment is used for recovery then it is part of a pharmaceutical process and is not a waste management unit.

Wastewater tank means a stationary waste management unit that is designed to contain an accumulation of wastewater or residuals and is constructed primarily of nonearthen materials (e.g., wood, concrete, steel, plastic) which provide structural support. Wastewater tanks used for flow equalization are included in this definition.

Water seal controls means a seal pot, p-leg trap, or other type of trap filled with water (e.g., flooded sewers that maintain water levels adequate to prevent air flow through the system) that creates a water barrier between the sewer line and the atmosphere. The water level of the seal must be maintained in the vertical leg of a drain in order to be considered a water seal.

§ 63.1252 Standards.

(a) 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 of this subpart.

(b) Storage tanks:

(1) The owner or operator of a storage tank meeting the criteria of paragraph (b)(1)(i) of this section is subject to the requirements of paragraph (b)(2) of this section. The owner or operator of a storage tank meeting the criteria of paragraph (b)(1)(ii) of this section is subject to the requirements of paragraph (b)(3) of this section.

(i) A storage tank with a design capacity greater than or equal to 38 m^3

(10,000 gallons) but less than 75 m^3 (20,000 gallons), and storing a liquid for which the maximum true vapor pressure of total HAP is greater than or equal to 13.1 kPa (1.9 psia).

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

(2) The owner or operator of a storage tank shall equip the affected storage tank with either a fixed roof with internal floating roof, an external floating roof, an external floating roof converted to an internal floating roof, or a closed vent system with control device that reduces inlet emissions of total HAP by 90 percent or greater, as demonstrated through the test methods and procedures in § 63.1253(c).

(3) The owner or operator of a storage tank shall equip the affected storage tank with either a fixed roof with internal floating roof, an external floating roof, an external floating roof converted to an internal floating roof, or a closed vent system with control device that meets the requirements of paragraphs (b)(3)(i) and (b)(3)(ii) of this section.

(i) Except as provided in paragraph (b)(3)(ii) of this section, the control device shall be designed and operated to reduce inlet emissions of total HAP by 95 percent or greater, as demonstrated through the test methods and procedures in § 63.1253(c).

(ii) If the owner or operator can demonstrate that a control device installed on a storage tank on or before April 2, 1997, is designed to reduce inlet emissions of total HAP by greater than or equal to 90 percent but less than 95 percent, then the control device is required to be operated to reduce inlet emissions of total HAP by 90 percent or greater, as demonstrated through the test methods and procedures in § 63.1253(c).

(c) Process vents:

(1) The owner or operator of an existing affected source must comply with the process vent requirements of paragraphs (c)(2) and (c)(4) of this section or the requirements of paragraphs (c)(3) and (c)(4) of this section. The owner or operator of a new affected source must comply with the process vent requirements of paragraph (c)(5) of this section. Compliance with the required emission reductions shall be demonstrated through the applicable test methods and compliance procedures described in § 63.1253 of this subpart.

(2) Annual controlled HAP emissions shall not exceed 900 kilograms per year (2,000 pounds per year) from the sum of all process vents within a process that do not meet the criteria specified in paragraph (c)(4)(i) of this section.

(3) Annual uncontrolled HAP emissions from the sum of all process vents within a process that do not meet the criteria specified in paragraph (c)(4)(i) of this section shall be reduced by 93 percent or greater.

(4) Annual uncontrolled HAP emissions from each process vent meeting the requirements of paragraph (c)(4)(i) of this section and not meeting the requirements of paragraph (c)(4)(ii) of this section shall be reduced by 98 percent or greater.

(i) Process vents having a flowrate equal to or less than the flowrate calculated when multiplying the annual uncontrolled HAP emissions, in lb/yr, by 0.02 and subtracting 1,000 according to the following equation:

$FR = 0.02*(HL)-1,000$

Where:

FR = flowrate, scfm,

HL = yearly uncontrolled HAP emissions, lb/yr;

(ii) If the owner or operator can demonstrate that a control device, installed on a process vent subject to the requirements of paragraph (c)(4)(i) of this section on or before April 2, 1997, was designed to reduce uncontrolled HAP emissions of total HAP by greater than or equal to 93 percent but less than 98 percent, then the control device is required to be operated to reduce inlet emissions of total HAP by 93 percent or greater.

(5) If the annual uncontrolled HAP emissions from the sum of all the process vents within a process is greater than 180 kg/yr (400 lb/yr) then the owner or operator shall reduce annual uncontrolled HAP emissions from the sum of all process vents within a process by 98 percent.

(d) Wastewater:

(1) The owner or operator of a new or existing affected source discharging wastewater with the concentrations described in paragraphs (d)(1)(i) through (d)(1)(v) of this section at the point of determination (POD) must comply with the provisions of paragraphs (d)(3) through (d)(4)(ii) of this section. The owner or operator of a new source discharging wastewater with concentrations described in paragraph (d)(1)(vi) of this section at the POD must comply with the provisions of paragraph (d)(4)(i) or (d)(4)(ii)(A) and (d)(4)(iii) of this section.

(i) Wastewater containing partially soluble HAP at a total concentration of greater than 1,300 parts per million by weight (ppmw) from any POD within a process with a total yearly load of soluble and/or partially soluble HAP of greater than 1 megagram per year (Mg/yr).

(ii) Wastewater containing partially soluble and/or soluble HAP at a total concentration of greater than 5,200 ppmw from any POD within a process with a total yearly load of soluble and/or partially soluble HAP of greater than 1 Mg/yr of total HAP.

(iii) Wastewater with a concentration of partially soluble and/or soluble HAP of greater than 10,000 ppmw total HAP at facilities that discharge greater than 1 Mg/yr of soluble and/or partially soluble HAP in the total yearly volume of all wastewaters generated.

(iv) Wastewater containing partially soluble HAP at a total concentration of greater than 1,300 parts per million by weight (ppmw) from any single POD with a total yearly load of soluble and/or partially soluble HAP of greater than 1 Mg/yr.

(v) Wastewater containing partially soluble and/or soluble HAP at a total concentration of greater than 5,200 ppmw from any single POD with a total yearly load of soluble and/or partially soluble HAP from any single POD of greater than 1 Mg/yr.

(vi) Wastewater containing soluble HAP at a total concentration of greater than 110,000 ppmw from any POD within a process or from any single POD with a total yearly load of soluble and/or partially soluble HAP of greater than 1 Mg/yr of total HAP.

(2) The following wastewaters are not subject to the wastewater provisions of this part:

(i) Stormwater from segregated sewers;

(ii) Water from fire-fighting and deluge systems, including testing of such systems;

(iii) Spills; and

(iv) Water from safety showers.

(3) An owner or operator of a facility shall comply with the requirements of §§ 63.133 through 63.137, and the control device requirements and inspection requirements of §§ 63.139 and 63.148, respectively, of subpart G for each waste management unit or treatment process that receives an affected wastewater. The affected wastewater for purposes of this subpart is synonymous with the ''Group 1'' identification for wastewater used in the provisions of subpart F and G. Also for the purposes of this subpart, tanks for which it can be demonstrated that less than 5 percent of the total soluble and/or partially soluble HAP is emitted from a wastewater tank described in § 63.133(a)(1), in addition to a tank with surface agitation, shall be equipped with a fixed roof. The owner or operator shall also comply with the treatment

requirements specified in paragraphs (d)(4) or (d)(5) of this section for each affected wastewater stream.

(4) Each affected wastewater stream shall be treated by one of the following methods:

(i) Recycle to the process in accordance with the requirements specified in § 63.138(f). Once a wastewater stream is returned to the process, the wastewater stream is no longer subject to this section.

(ii) Treat using a waste management unit or treatment process which meets conditions in paragraph (d)(4)(ii)(A) and (B) or (C) of this section:

(A) Reduces, by removal or destruction, the total mass of each individual partially soluble HAP by 99 percent, as determined by the procedures specified in § 63.145(c), 63.145(d), or 63.138(j); or to a level less than 50 parts per million by weight of total partially soluble HAP as determined by the procedures specified in § 63.145(b). This option shall not be used when the treatment process is a biological treatment process, or when the wastewater stream is designated as a Group 1 wastewater stream as specified in § 63.132(e). Dilution shall not be used to achieve compliance with this option. Treatment process residuals shall be treated according to § 63.138(h) or § 63.138(m).

(B) Reduces, by removal or destruction, the total mass of each individual soluble HAP by 90 percent, as determined by the procedures specified in §§ 63.145(c), 63.145(d), or § 63.138(j). Treatment process residuals shall be treated according to § 63.138(h) or § 63.138(m).

(C) Reduces, by biological treatment, the mass of total soluble and partially soluble HAP in wastewater for all pharmaceutical processes at the facility by 95 percent, as determined by the procedures specified in 40 CFR part 63 appendix C.

(iii) Treat using a waste management unit or treatment process which reduces, by removal or destruction, the total mass of each soluble HAP by 99 percent, as determined by the procedures specified in §§ 63.145(c), 63.145(d), or § 63.138(j). Treatment process residuals shall be treated according to § 63.138(h) or § 63.138(m).

(5) As an alternative to the treatment requirements in paragraph (d)(4)(ii)(B) of this section, an owner or operator may elect to treat affected wastewaters containing soluble HAP and less than 50 ppmw partially soluble HAP in the following manner if it can be demonstrated that less than 5 percent of the total soluble HAP is emitted from the municipal sewer system:

(i) Treat in an enhanced biological treatment system that meets all of the following criteria:

(A) The biological treatment system is an aerated treatment unit(s) that contains biomass suspended in water followed by a clarifier that removes biomass from the treated water and recycles the recovered biomass to the aeration unit;

(B) The mixed liquor volatile suspended solids (biomass) is greater than 1 kg/m^3 homogeneously distributed throughout each aeration unit;

(C) The biomass in the enhanced biotreatment system is suspended and aerated in the water of the aeration unit(s) by either submerged air flow or mechanical agitation; and

(D) The enhanced biotreatment system is in compliance with requirements of the permitting authority.

(ii) Treat in a publicly-owned treatment works (POTW) that meets all of the following criteria:

(A) The POTW uses biological treatment that meets the criteria of paragraph (d)(5)(i) of this section.

(B) The POTW is in compliance with the General Pretreatment Regulations in 40 CFR part 403, including any applicable categorical pretreatment standards, and has pretreatment permit or equivalent approval under the authority of 40 CFR part 403.

(C) The POTW is in compliance with all applicable pretreatment standards adopted at 40 CFR part 439.

(6) For each treatment process used to comply with the requirements of paragraph (d)(4) of this section, the owner or operator shall comply with § 63.138(i), (k), and (l).

(7) Except as provided in paragraph (d)(7)(i) and (ii) of this section, the owner or operator shall not discharge a separate phase that can be isolated through gravity separation from the aqueous phase to a wastewater management or treatment unit.

(i) Owners and operators discharging a separate organic phase shall separate and treat the organic according to § 63.138(h).

(ii) Owners and operators shall treat any aqueous phases having the characteristics of paragraphs (d)(1)(i) through (d)(1)(iv) of this section according to the requirements of paragraphs (d)(3) through (d)(6) of this section.

(e) Equipment leaks: The owner or operator shall comply with the requirements of Appendix A to this subpart GGG.

(f) Planned routine maintenance: The specifications and requirements in paragraphs (b) and (c) of this section for control devices do not apply during periods of planned routine maintenance. Maintenance wastewaters meeting the criteria for control as specified in paragraph (d)(1) of this section shall be treated in accordance with the requirements of paragraphs (d)(3) through (d)(7) of this section.

(g) Periods of planned routine maintenance of the control device, during which the control device does not meet the specifications of paragraphs (b) and (c) of this section, as applicable, shall not exceed 240 hours per year.

(h) Pollution prevention alternative: Except as provided in paragraph (h)(1) of this section, owners and operators may choose to meet the pollution prevention alternative requirement specified in either paragraph (h)(2) or (h)(3) of this section for any process, in lieu of the requirements specified in paragraphs (b), (c), (d), and (e) of this section. Compliance with paragraphs (h)(2) and (h)(3) of this section shall be demonstrated through the procedures in § 63.1253(f).

(1) Processes emitting HAP that are generated in the process must be controlled according to the requirements of paragraphs (b), (c), (d), and (e) of this section.

(2) The production-indexed HAP consumption factor (kg HAP consumed/kg produced) shall be reduced by 75 percent from an average baseline established no earlier than the 1987 calendar year, or the first year thereafter in which the process was operational and data are available. No increase in the production-indexed VOC consumption factor for the applicable period of demonstration shall occur.

(3) Both requirements specified in paragraphs (h)(3)(i) and (ii) of this section are met.

(i) The production-indexed HAP consumption factor (kg HAP consumed/kg produced) shall be reduced by 50 percent from an average baseline established no earlier than the 1987 calendar year, or the first year thereafter in which the process was operational and data is available. No increase in the production-indexed VOC consumption factor for the applicable period of demonstration shall occur.

(ii) The total process HAP emissions shall be reduced from an uncontrolled baseline by an amount, in kg/yr, that, when divided by the annual production rate, in kg, will yield a value of at least 25 percent of the average baseline HAP production-indexed consumption factor established in paragraph (h)(3)(i) of this section. The annual reduction in HAP

air emissions must be due to the use of the following control devices:

(A) Combustion control devices such as incinerators, flares or process heaters.

(B) Recovery control devices such as condensers and carbon adsorbers whose recovered product is destroyed or shipped offsite for destruction.

(C) Any control device that does not ultimately allow for recycling of material back to the process.

(D) Any control device for which the owner or operator can demonstrate that the use of the device in controlling HAP emissions will have no effect on the production-indexed consumption factor for the process.

(i) Heat exchange systems: Except as provided in paragraph (i)(2) of this section, owners and operators of affected sources shall comply with the requirements in paragraphs (i)(1) of this section for heat exchange systems that cool process equipment or materials used in pharmaceutical manufacturing operations.

(1) The heat exchange system shall be treated according to the provisions of § 63.104.

(2)(i) The monitoring frequency shall be no less than quarterly.

(ii) The owner or operator of heat exchange systems which meet current good manufacturing practice (CGMP) requirements at 21 CFR part 211 may elect to use the physical integrity of the reactor as the surrogate indicator of heat exchange system leaks.

(j) Emissions averaging provisions: With the exception of paragraphs (j)(1) through (j)(5) of this section, owners or operators of storage tanks or processes subject to paragraph (b) or (c) of this section may choose to comply with the emission standards in paragraph (b) or (c) of this section by using emissions averaging requirements specified in § 63.1253(h) or (i) of this subpart for any storage tank or process.

(1) A State may restrict the owner or operator of an existing source to use only the procedures in § 63.1252(b) and (c) to comply with the emission standards where State Authorities prohibit averaging of HAP emissions.

(2) Emission sources subject to the requirements of paragraphs (b)(3)(ii) and (c)(2), (c)(4), and (c)(5) of this section may not be included in any averaging group.

(3) Processes which have been permanently shutdown or storage tanks permanently taken out of HAP service may not be included in any averaging group.

(4) Processes and storage tanks already controlled on or before November 15, 1990 may not be included in an emissions averaging group, except where the level of control is increased after November 15, 1990. In these cases, the uncontrolled emissions shall be the controlled emissions as calculated on November 15, 1990 for the purpose of determining the uncontrolled emissions as specified in § 63.1253(h) and (i) of this subpart.

(5) Emission points controlled to comply with a State or Federal rule other than this subpart, unless the level of control has been increased after November 15, 1990 above what is required by the other State or Federal rule. Only the control above what is required by the other State or Federal rule will be credited. However, if an emission point has been used to generate emissions averaging credit in an approved emissions average, and the point is subsequently made subject to a State or Federal rule other than this subpart, the point can continue to generate emissions averaging credit for the purpose of complying with the previously approved average.

(6) Not more than 20 processes and 20 tanks at an affected source may be included in an emissions averaging group.

(7) Compliance with the emissions standards in paragraph (b) of this section shall be satisfied when the overall percent reduction efficiency is greater than or equal to 90 percent for those tanks meeting the requirements of paragraph (b)(1)(i) of this section and 95 percent for those tanks meeting the requirements of paragraph (b)(1)(ii) of this section, as demonstrated using the test methods and compliance procedures specified in § 63.1253(h) of this subpart.

(8) Compliance with the emissions standards in paragraph (c) of this section shall be satisfied when the overall percent reduction efficiency is greater than or equal to 93 percent, as demonstrated using the test methods and compliance procedures specified in § 63.1253(i) of this subpart.

§ 63.1253 Test methods and compliance procedures.

(a) Emissions testing or engineering evaluations, as specified in paragraphs (c), (d), (e), and (f) of this section, are required to demonstrate initial compliance with § 63.1252 (b), (c), (d), and (h) respectively, of this subpart.

(b) Test methods: When testing is conducted to measure emissions from an affected source, the test methods specified in paragraphs (b)(1) through (b)(9) of this section shall be used.

(1) EPA Method 1 or 1A of appendix A of part 60 is used for sample and velocity traverses.

(2) EPA Method 2, 2A, 2C, or 2D of appendix A of part 60 is used for velocity and volumetric flow rates.

(3) EPA Method 3 of appendix A of part 60 is used for gas analysis.

(4) EPA Method 4 of appendix A of part 60 is used for stack gas moisture.

(5) EPA Methods 2, 2A, 2C, 2D, 3, and 4 shall be performed, as applicable, at least twice during each test period.

(6) Methods 25A, 26 and/or Methods 18 and 25A, as appropriate, of appendix A of part 60 shall be used to determine the HAP concentration of air exhaust streams.

(7) Test conditions and durations shall be as specified in paragraphs (b)(7)(i) through (b)(7)(v) of this section, as appropriate.

(i) Testing of process vents on equipment operating as part of a continuous process will consist of three l-hour runs. Gas stream volumetric flow rates shall be measured every 15 minutes during each 1-hour run. The HAP concentration shall be determined from samples collected in an integrated sample over the duration of each l-hour test run, or from grab samples collected simultaneously with the flow rate measurements (every 15 minutes). If an integrated sample is collected for laboratory analysis, the sampling rate shall be adjusted proportionally to reflect variations in flow rate. For continuous gas streams, the emission rate used to determine compliance shall be the average emission rate of the three test runs.

(ii) Testing of process vents on equipment where the flow of gaseous emissions is intermittent (batch operations) shall include testing for the worst-case episode or aggregated episodes in the batch cycle or cycles (in the event that equipment may be manifolded and vented through a common stack) or testing under normal conditions, provided that the operation of the device is limited to those conditions that existed during testing under representative worst-case or normal conditions. Testing shall be conducted at absolute worst-case conditions, representative worst-case conditions, hypothetical worst-case conditions, or normal conditions as required by paragraph (d)(3)(iii) of this section. Gas stream volumetric flow rates shall be measured at 15-minute intervals. The HAP or TOC concentration shall be determined from samples collected in an integrated sample over the duration of the test, or from grab samples collected simultaneously with the flow rate measurements (every 15 minutes). If an integrated sample is collected for laboratory analysis, the sampling rate

shall be adjusted proportionally to reflect variations in flow rate. The absolute worst-case, representative worst-case, or hypothetical worst-case conditions shall be characterized by the criteria presented in paragraphs (b)(7)(ii)(A), (B), and (C) of this section. In all cases, a site-specific plan shall be submitted to the administrator for approval prior to testing in accordance with § 63.7(c). The test plan shall include the emissions profile described in paragraph (b)(7)(iii) of this section.

(A) Absolute worst-case conditions are defined by any of the criteria presented in paragraphs (b)(7)(ii)(A)(1) through (3) of this section.

(*1*) The period in which the inlet to the control device will contain at least 50 percent of the maximum HAP load (in lb) capable of being vented to the control device over any 8 hour period. An emission profile as described in paragraph (b)(7)(iii) of this section shall be used to identify the 8-hour period that includes the maximum projected HAP load.

(*2*) A 1-hour period of time in which the inlet to the control device will contain the highest HAP mass loading rate, in lb/hr, capable of being vented to the control device. An emission profile as described in paragraph (b)(7)(iii) of this section shall be used to identify the 1-hour period of maximum HAP loading.

(*3*) If a condenser is used as a control device, absolute worst-case conditions shall represent a 1-hour period of time in which the gas stream capable of being vented to the condenser will require the maximum heat removal capacity, in Btu/hr, to cool the stream to a temperature that, upon calculation of HAP concentration, will yield the required removal efficiency for the process. The calculation of maximum heat load shall be based on the emission profile described in paragraph (b)(7)(iii) of this section and a concentration profile that will allow calculation of sensible and latent heat loads.

(B) Representative worst-case conditions are defined by any of the criteria presented in paragraph (b)(7)(ii)(A) (*1*) through (*2*) of this section. Representative worst-case conditions shall include the worst-case process as well as any other processes that are emitting to the control device during the test.

(*1*) A 1-hour period of time that contains the highest HAP mass loading rate, in lb/hr, from a single process;

(*2*) If a condenser is used as the control device, the 1-hour period of time in which the vent from a single process will require the maximum heat removal capacity, in BTU/hr, to cool the stream to a temperature that, upon calculation of HAP concentration, will yield the required removal efficiency for the process.

(C) Hypothetical worst-case conditions are simulated test conditions that, at a minimum, contain the highest total average hourly HAP load of emissions that would be predicted to be vented to the control device from the emissions profile described in paragraph (b)(7)(iii) of this section.

(iii) For batch operations, the owner or operator may choose to perform tests only during those periods of the worst-case conditions that the owner or operator selects to control as part of achieving the required emission reduction. The owner or operator must develop an emission profile for the vent to the control device, based on either process knowledge, engineering analyses, or test data collected, to identify the appropriate test conditions. The emission profile must include average HAP loading rate (in lb/hr) versus time for all emission episodes within processes that could contribute to the vent stack for a period of time that is sufficient to include all processes venting to the stack. Examples of information that could constitute process knowledge include calculations based on material balances, and process stoichiometry. Previous test results may be used provided the results are still relevant to the current process vent stream conditions. The average hourly HAP loading rate may be calculated by first dividing the HAP emissions from each episode by the duration of each episode, in hours, and selecting the highest hourly block average.

(iv) For testing of process vents of duration greater than 8 hours, the owner or operator is required to perform a maximum of 8 hours of testing. The test period must include the one hour period in which the highest HAP loading rate, in lb/hr, is predicted by the emission profile.

(v) For testing durations of greater than 1 hour, the emission rate from a single test run may be used to determine compliance. For testing durations less than or equal to 1 hour, testing shall include three 1-hour runs.

(8) For emission streams controlled using condensers, a direct measurement of condenser outlet gas temperature to be used in predicting upper concentration limits at saturated conditions is allowed in lieu of concentration measurements described in paragraph (b)(6) of this section.

(9) Wastewater analysis shall be conducted in accordance with paragraph (b)(9)(i) or (b)(9)(ii) of this section.

(i) Use the equations in paragraphs (b)(9)(i)(A) and (B) of this section to determine the total HAP concentration of a wastewater stream.

(A) The following equation shall be used to calculate the HAP concentration of an individually speciated HAP.

$$C_i = \left(C_c * \frac{MW}{24.055} * \frac{P_i}{760} * \frac{293}{T_i} * t * L * 10^3 \right) / M_s$$

Where:

C_i=HAP concentration of the individually-speciated organic HAP in the wastewater, parts per million by weight.

C_C=concentration of the organic HAP (i) in the gas stream, parts per million by volume on a dry basis

M_S=mass of sample, milligrams

MW=molecular weight of the organic HAP (i), grams per gram-mole

24.055=ideal gas molar volume at 293° Kelvin and 760 millimeters of mercury, liters per gram-mole

P_i=barometric pressure at the time of sample analysis, millimeters mercury absolute

760=reference or standard pressure, millimeters mercury absolute

293=reference or standard temperature, °Kelvin

T_i=sample gas temperature at the time of sample analysis, °Kelvin

t=actual purge time minutes

L=actual purge rate liters per minute

10^3=conversion factor, milligrams per gram

(B) Total HAP concentration can be determined by summing the HAP concentrations of all individually speciated organic HAP in the wastewater.

$$C_{stream} = \sum_{i=1}^{n} C_i$$

Where:

C_{stream}=total HAP concentration of wastewater stream
n=number of individual organic HAP (i) in the wastewater stream
C_i=HAP concentration of individual HAP (i) calculated according to the procedures in paragraph (b)(7)(i)(A) of this section

(ii) Use a test method or results from a test method that measures HAP concentrations in the wastewater, and that has been validated according to section 5.1 or 5.3 of Method 301 of 40 CFR part 63 appendix A.

(iii) Use Methods 624, 625, 1624, 1625, and 8270, and the alternative validation procedures presented in § 63.144.

(c) *Compliance with storage tank provisions.* The owner or operator of an affected storage tank shall demonstrate compliance with §§ 63.1252(b)(2) and 63.1252(b)(3)(i) and (ii), as applicable, by fulfilling the requirements of either paragraph (c)(1) or (c)(2) or (c)(3) of this section.

(1) To demonstrate compliance with the percent reduction requirement of § 63.1252(b)(2) or § 63.1252(b)(3) (i) or (ii), the mass rate of total HAP (E_i, E_o) shall be computed.

(i) The following equations shall be used:

$$E_i = K_2\left(\sum_{j=1}^{n} C_{ij}M_{ij}\right)Q_i$$

$$E_o = K_2\left(\sum_{j=1}^{n} C_{oj}M_{oj}\right)Q_o$$

Where:

C_{ij}, C_{oj}=concentration of sample component j of the gas stream at the inlet and outlet of the control device, respectively, dry basis, parts per million by volume
E_i, E_o=mass rate of total HAP at the inlet and outlet of the control device, respectively, dry basis, kilogram per hour
M_{ij}, M_{oj}=molecular weight of sample component j of the gas stream at the inlet and outlet of the control device, respectively, gram/gram-mole
Q_i, Q_o=flow rate of gas stream at the inlet and outlet of the control device, respectively, dry standard cubic meter per minute
K_2=constant, 2.494×10^{-6} (parts per million)$^{-1}$ (gram-mole per standard cubic meter) (kilogram/gram) (minute/hour), where standard temperature is 20°C

(ii) The percent reduction in total HAP shall be calculated as follows: where:

$$R = \frac{E_i - E_o}{E_i}(100)$$

Where:

R=control efficiency of control device, percent
E_i=mass rate of total HAP at the inlet to the control device as calculated under paragraph (c)(1)(i) of this section, kilograms organic HAP per hour
E_o=mass rate of total HAP at the outlet of the control device, as calculated under paragraph (c)(1)(i) of this section, kilograms organic HAP per hour

(iii) A performance test is not required to be conducted if the control device used to comply with § 63.1252(b) (storage tank provisions) is also used to comply with § 63.1252(c) (process vent provisions), and compliance with § 63.1252(c) has been demonstrated in accordance with paragraph (d)(2) of this section.

(2) To demonstrate compliance with the percent reduction requirement of § 63.1252(b)(2) or § 63.1252(b)(3)(i) or (ii), a design evaluation shall be prepared. The design evaluation shall include documentation demonstrating that the control device being used achieves the required control efficiency during reasonably expected maximum filling rate. This documentation is to include a description of the gas stream which enters the control device, including flow and organic HAP content under varying liquid level conditions, and the information specified in paragraphs (c)(2)(i) through (c)(2)(v) of this section, as applicable.

(i) If the control device receives vapors, gases or liquids, other than fuels, from emission points other than storage vessels subject to this subpart, the efficiency demonstration is to include consideration of all vapors, gases, and liquids, other than fuels, received by the control device.

(ii) If an enclosed combustion device with a minimum residence time of 0.5 seconds and a minimum temperature of 760°C is used to meet the emission reduction requirement specified in § 63.1252(b)(2)(i) (or (ii)), documentation that those conditions exist is sufficient to meet the requirements of paragraph (c)(2) of this section.

(iii) Except as provided in paragraph (c)(2)(ii) of this section, for thermal incinerators, the design evaluation shall include the autoignition temperature of the organic HAP, the flow rate of the organic HAP emission stream, the combustion temperature, and the residence time at the combustion temperature.

(iv) For carbon adsorbers, the design evaluation shall include the affinity of the organic HAP vapors for carbon, the amount of carbon in each bed, the number of beds, the humidity of the feed gases, the temperature of the feed gases, the flow rate of the organic HAP emission stream, the desorption schedule, the regeneration stream pressure or temperature, and the flow rate of the regeneration stream. For vacuum desorption, pressure drop shall be included.

(v) For condensers, the design evaluation shall include the final temperature of the organic HAP vapors, the type of condenser, and the design flow rate of the organic HAP emission stream.

(3) If the owner or operator of an affected source chooses to comply with the provisions of § 63.1252(b)(2) or § 63.1252(b)(3) by installing a floating roof, the owner or operator shall comply with the procedures described in 40 CFR 63.119(b), (c), (d), and 63.120.

(d) *Compliance with process vent provisions.* An owner or operator of an affected source complying with the process vent standards in § 63.1252(c) shall demonstrate compliance using the procedures described in paragraphs (d)(1) through (d)(4) of this section.

(1) Except as provided in paragraph (d)(4) of this section, compliance with the process vent standards in § 63.1252(c) shall be demonstrated using the procedures specified in paragraphs (d)(1)(i) through (v), as applicable.

(i) Compliance with § 63.1252(c)(2) is demonstrated when the controlled emissions of HAP from the sum of all process vents within a process that do not meet the criteria specified in § 63.1252(c)(4)(ii) is less than or equal to 2,000 pound per year. Controlled emissions of HAP shall be determined using the procedures described in paragraph (d)(3) of this section.

(ii) Compliance with § 63.1252(c)(3) is demonstrated when the annual uncontrolled HAP emissions from the sum of all process vents within a process that do not meet the criteria specified in § 63.1252(c)(4)(ii) is reduced by 93 percent. This demonstration shall be based on controlled emissions of HAP determined using the procedures described in paragraph (d)(3) of this section and uncontrolled emissions of HAP determined using the procedures described in paragraph (d)(2) of this section or by controlling the process vents using a device meeting the criteria specified in paragraph (d)(4) of this section.

(iii) Compliance with § 63.1252(c)(5) is demonstrated when the annual

uncontrolled HAP emissions from all process vents within a process is reduced by 98 percent, or when the sum of uncontrolled HAP emissions of all process vents within a process is less than or equal to 180 kg/yr (400 lb/yr). This demonstration shall be based on controlled emissions of HAP determined using the procedures described in paragraph (d)(3) of this section and uncontrolled emissions of HAP determined using the procedures described in paragraph (d)(2) of this section or by controlling the process vents using a device meeting the criteria specified in paragraph (d)(4) of this section.

(iv) Compliance with § 63.1252(c)(4) is demonstrated when the annual uncontrolled HAP emissions from each process vent meeting the requirements of § 63.1252(c)(4)(i) is reduced by 98 percent. This demonstration shall be based on controlled emissions of HAP determined using the procedures described in paragraph (d)(3) of this section and uncontrolled emissions of HAP determined using the procedures described in paragraph (d)(2) of this section or by controlling the process vents using a device meeting the criteria specified in paragraph (d)(4) of this section.

(v) Compliance with § 63.1252(c)(4)(ii) is demonstrated when the annual uncontrolled HAP emissions from each process vent meeting the requirements of § 63.1252(c)(4)(ii) is reduced by 93 percent. This demonstration shall be based on controlled emissions of HAP determined using the procedures described in paragraph (d)(3) of this section and uncontrolled emissions of HAP determined using the procedures described in paragraph (d)(2) of this section or by controlling the process vents using a device meeting the criteria specified in paragraph (d)(4) of this section.

(2) An owner or operator of an affected source complying with the emission limitation required by § 63.1252(c)(2), or emissions reductions specified in § 63.1252(c)(3), (c)(4), or (c)(5) of this subpart for each process vent within a process, shall calculate uncontrolled emissions according to the procedures described in paragraph (d)(2)(i) or (d)(2)(ii) of this section, as appropriate.

(i) Owners or operators shall determine uncontrolled emissions of HAP using measurements and/or calculations for each batch emission episode within each unit operation according to the engineering evaluation methodology in paragraphs (d)(2)(i)(A) through (d)(2)(i)(E) of this section. Individual HAP partial pressures in multicomponent systems shall be determined by the following methods: If the components are miscible in one another, use Raoult's law to calculate the partial pressures; if the solution is a dilute aqueous mixture, use Henry's law to calculate partial pressures; if Raoult's law or Henry's law are not appropriate or available, use experimentally obtained activity coefficients or models such as the group-contribution models, to predict activity coefficients, or assume the components of the system behave independently and use the summation of all vapor pressures from the HAP as the total HAP partial pressure. Chemical property data can be obtained from standard reference texts.

(A) Emissions from vapor displacement due to transfer of material shall be calculated according to equation (1):

$$E = \frac{(y_i)(V)(P_T)(MW)}{(R)(T)} \quad (1)$$

Where:

E = mass emission rate

y_i = saturated mole fraction of HAP in the vapor phase

V = volume of gas displaced from the vessel

R = ideal gas law constant

T = temperature of the vessel vapor space; absolute

P_T = pressure of the vessel vapor space

MW = molecular weight of the HAP

(B) Emissions from purging shall be calculated using equation (1), except that for purge flow rates greater than 100 standard cubic feet per minute (scfm), the mole fraction of HAP will be assumed to be 25 percent of the saturated value.

(C) Emissions caused by the heating of a vessel shall be calculated using the procedures in either paragraph (d)(2)(i)(C)(*1*), (C)(*2*), or (C)(*3*) of this section, as appropriate.

(*1*) If the final temperature to which the vessel contents is heated is lower than 50° K below the boiling point of the HAP in the vessel, then emissions shall be calculated using the equations (2) through (5) in paragraphs (d)(2)(i)(C)(*1*)(*i*) through (*iv*) of this section.

(*i*) The mass of HAP emitted per episode shall be calculated as follows:

$$E = \frac{\frac{\sum(P_i)_{T1}}{Pa_1} + \frac{\sum(P_i)_{T2}}{Pa_2}}{2} \times \Delta\eta \times MW_{HAP} \quad (2)$$

Where:

E = mass of HAP vapor displaced from the vessel being heated

$(P_i)T_n$ = partial pressure of each HAP in the vessel headspace at initial (n=1) and final (n=2) temperature

Pa_1 = initial gas pressure in the vessel

Pa_2 = final gas pressure

MW_{HAP} = the average molecular weight of HAP present in the vessel

(*ii*) The moles of gas displaced is represented by:

$$\Delta\eta = \frac{V}{R}\left[\left(\frac{Pa_1}{T_1}\right) - \left(\frac{Pa_2}{T_2}\right)\right] \quad (3)$$

Where:

$\Delta\eta$ = number of lb-moles of gas displaced

V = volume of free space in the vessel

R = ideal gas law constant

Pa_1 = initial gas pressure in the vessel

Pa_2 = final gas pressure

T_1 = initial temperature of vessel

T_2 = final temperature of vessel

(*iii*) The initial and final pressure of the noncondensable gas in the vessel shall be calculated according to the following equation:

$$Pa_n = P_{atm} - \Sigma(P_i)T_n \quad (4)$$

Where:

Pa_n = partial pressure of gas in the vessel headspace at initial (n=1) and final (n=2) temperature

P_{atm} = atmospheric pressure

$(P_i)T_n$ = partial pressure of each condensable volatile organic compound (including HAP) in the vessel headspace at the initial temperature (n=1) and final (n=2) temperature

(*iv*) The average molecular weight of HAP in the displaced gas shall be calculated as follows:

$$MW_{HAP} = \frac{\sum_{i=1}^{n} (\text{mass of HAP})_i}{\sum_{i=1}^{n} \frac{(\text{mass of HAP})_i}{(\text{HAP molecular weight})_i}} \quad (5)$$

where n is the number of different HAP compounds in the emission stream.

(*2*) If the vessel contents are heated to a temperature greater than 50°K below the boiling point, then emissions from the heating of a vessel shall be calculated as the sum of the emissions calculated in accordance with paragraphs (d)(2)(i) (C)(*2*)(*i*) and (C)(*2*)(*ii*) of this section.

(*i*) For the interval from the initial temperature to the temperature 50°K below the boiling point, emissions shall be calculated using Equation 2, where T_2 is the temperature 50°K below the boiling point.

(*ii*) For the interval from the temperature 50°K below the boiling point to the final temperature, emissions shall be calculated as the summation of emissions for each 5°K increment, where the emission for each increment shall be calculated using Equation 2.

(*A*) If the final temperature of the heatup is lower than 5°K below the boiling point, the final temperature for the last increment shall be the final temperature of the heatup, even if the last increment is less than 5°K.

(*B*) If the final temperature of the heatup is higher than 5°K below the boiling point, the final temperature for the last increment shall be the temperature 5°K below the boiling point, even if the last increment is less than 5°K.

(*C*) If the vessel contents are heated to the boiling point and the vessel is not operating with a process condenser, the final temperature for the final increment shall be the temperature 5°K below the boiling point, even if the last increment is less than 5°K.

(*3*) If the vessel is operating with a process condenser, and the vessel contents are heated to the boiling point, the primary condenser is considered part of the process. Emissions shall be calculated as the sum of Equation 2, which calculates emissions due to heating the vessel contents to the temperature of the gas exiting the condenser, and Equation 1, which calculates emissions due to the displacement of the remaining saturated noncondensable gas in the vessel. The final temperature in Equation 2 shall be set equal to the exit gas temperature of the process condenser. In Equation 1, V shall be set equal to the free space volume, and T_2 shall be set equal to the condenser exit gas temperature.

(*D*) Emissions from depressurization shall be calculated using the procedures in paragraphs (d)(2)(i) (D)(*1*) through (D)(*5*) of this section.

(*1*) The moles of HAP vapor initially in the vessel are calculated using the ideal gas law as follows:

$$n_{HAP} = \frac{(Y_{HAP})(V)(P_1)}{RT} \quad (6)$$

Where:

Y_{HAP} = mole fraction of HAP (the sum of the individual HAP fractions, ΣY_i)

V = free volume in the vessel being depressurized

P_1 = initial vessel pressure

R = gas constant

T = vessel temperature, absolute units

(*2*) The moles of noncondensable gas present initially in the vessel are calculated as follows:

$$n_1 = \frac{VP_{nc_1}}{RT} \quad (7)$$

Where:

V = free volume in the vessel being depressurized

P_{nc1} = initial partial pressure of the noncondensable gas, $P_1 - \Sigma P_i$

R = gas law constant, K

T = temperature, absolute units

(*3*) The moles of noncondensable gas present at the end of depressurization are calculated as follows:

$$n_2 = \frac{VP_{NC_2}}{RT} \quad (8)$$

Where:

V = free volume in the vessel being depressurized

P_{NC2} = Final partial pressure of the noncondensable gas, $P_2 - \Sigma P_i$

R = gas law constant

T = temperature, absolute

(*4*) The moles of HAP emitted during the depressurization are calculated by taking an approximation of the average ratio of moles of HAP to moles of noncondensable and multiplying by the total moles of noncondensables released during the depressurization, or:

$$\frac{\left(\frac{n_{HAP}}{n_1} + \frac{n_{HAP}}{n_2}\right)}{2}\left[n_2 - n_1\right] = n_{HAP} \quad (9)$$

Where:

n_{HAP} = moles of HAP emitted

(*5*) The moles of HAP emitted can be converted to a mass rate using the following equation:

$$\frac{n_{HAP} * MW_{HAP}}{t} = Er_{HAP} \quad (10)$$

Where:

Er_{voc} = emission rate of the HAP

MW_{voc} = molecular weight of the HAP

t = time of the depressurization

(E) Emissions from vacuum systems may be calculated if the air leakage rate is known or can be approximated, using the following equation:

$$E_r = MWs\frac{La}{29}\left(\frac{P_{system}}{P_{system} - P_i *} - 1\right) \quad (11)$$

Where:

E_r = rate of HAP emission, in lb/hr

P_{system} = absolute pressure of receiving vessel or ejector outlet conditions, if there is no receiver

P_i* = vapor pressure of the HAP at the receiver temperature, in mmHg

La = total air leak rate in the system, lb/hr

29 = molecular weight of air, lb/lbmole

(ii) For emission episodes in which the owner or operator can demonstrate that the methods in paragraph (d)(2)(i) of this section are not appropriate according to paragraph (d)(2)(iii) of this section, owners and operators shall calculate uncontrolled emissions by conducting an engineering assessment which includes, but is not limited to, the following:

(A) Previous test results provided the tests are representative of current operating practices at the process unit.

(B) Bench-scale or pilot-scale test data representative of the process under representative operating conditions.

(C) Maximum flow rate, HAP emission rate, concentration, or other relevant parameter specified or implied within a permit limit applicable to the process vent.

(D) Design analysis based on accepted chemical engineering principles, measurable process parameters, or

physical or chemical laws or properties. Examples of analytical methods include, but are not limited to:

(*1*) Use of material balances based on process stoichiometry to estimate maximum organic HAP concentrations,

(*2*) Estimation of maximum flow rate based on physical equipment design such as pump or blower capacities,

(*3*) Estimation of HAP concentrations based on saturation conditions.

(E) All data, assumptions, and procedures used in the engineering assessment shall be documented in accordance with § 63.1255(b). Data or other information supporting a finding that the emissions estimation equations are inappropriate shall be reported in the Notification of Compliance Status.

(iii) The emissions estimation equations in paragraph (d)(2)(i) of this section shall be considered inappropriate for estimating emissions for a given batch emissions episode if one or more of the criteria in paragraphs (d)(2)(iii)(A) and (d)(2)(iii)(B) of this section are met.

(A) Previous test data are available that show a greater than 20 percent discrepancy between the test value and the estimated value.

(B) The owner or operator can demonstrate to the Administrator through any other means that the emissions estimation equations are not appropriate for a given batch emissions episode.

(3) Owners and operators shall determine controlled emissions using measurements and/or calculations for each process vent using the control efficiency calculated from each device that controls process vents with total emissions of less than 10 tons per year, before control, according to the design evaluation described in paragraph (d)(3)(i) of this section, or using the emission estimation equations described in paragraph (d)(2) of this section, as appropriate. Owners and operators shall determine controlled emissions for each process vent using the control efficiency determined from each device that controls process vents with total emissions of greater than 10 tons per year, before control, by conducting a performance test on the control device as described in paragraphs (d)(3)(ii) through (iv) of this section, or by using the results of a previous performance test as described in paragraph (d)(5) of this section. Owners and operators are not required to conduct performance tests for devices described in paragraphs (d)(4) and (d)(5) of this section that control total emissions of greater than 10 tons per year, before control.

(i) The design evaluation shall include documentation demonstrating that the control device being used achieves the required control efficiency during the emission episodes in which it is functioning in reducing emissions. This documentation is to include a description of the gas stream which enters the control device, including flow and HAP concentration, and the information specified in paragraphs (c)(2)(i) through (c)(2)(v) of this section, as applicable.

(ii) 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 § 63.1253(b). Concentrations shall be calculated from the data obtained through emission testing according to the following procedures:

(A) The total HAP concentration (C_{HAP}) is the sum of the concentrations of the individual HAP and shall be computed for each run using the following equation:

$$C_{HAP} = \sum_{i=1}^{x} \frac{\left(\sum_{j=1}^{n} C_{ji} \right)}{x}$$

Where:

C_{HAP} = concentration of total HAP, dry basis, parts per million by volume

C_{ji} = concentration of individual HAP j of sample i, dry basis, parts per million by volume

n = number of HAP in the sample

x = number of samples in the sample run

(B) The concentration of total HAP shall be corrected to 3 percent oxygen if a combustion device is the control device. The emission rate correction factor for excess air, based on the integrated sampling and analysis procedures of Method 3B of 40 CFR part 60, appendix A shall be used to determine the oxygen concentration ($\%0_{2d}$). The samples shall be taken during the same time that the total HAP samples are taken. The concentration corrected to 3 percent oxygen (C_c) shall be computed as:

$$C_c = C_m \left(\frac{17.9}{20.9 - \%0_{2d}} \right)$$

where:

C_c=concentration of organic HAP corrected to 3 percent oxygen, dry basis, parts per million by volume

C_m=concentration of organic HAP, dry basis, parts per million by volume

$\%0_{2d}$=concentration of oxygen, dry basis, percent by volume

(iii) Performance testing shall be conducted under the following conditions:

(A) For all control devices, the owner or operator shall test over absolute or hypothetical worst-case conditions, or over normal conditions, provided the operation of the devices is limited to the conditions that existed during testing. For testing during normal conditions, test conditions and their corresponding operating limits shall be established in the precompliance report and characterized according to stream composition, temperature, and flowrate. The owner or operator must demonstrate in the precompliance report that emission stream conditions entering the control device shall be within the test conditions at all times.

(B) For thermal incinerators, the owner or operator may also choose to test over representative worst-case conditions; however, if the owner or operator chooses to test over representative worst-case conditions, the maximum allowable vent stream flowrate into the thermal incinerator is restricted to the level for which it was designed. The design basis of the incinerator shall be included as part of the Notification of Compliance Status.

(iv) The owner or operator may elect to conduct more than one performance test on the control device for the purpose of establishing operating conditions associated with a range of achievable control efficiencies.

(4) An owner or operator is not required to conduct a performance test when a control device specified in paragraphs (d)(4)(i) through (4)(iii) of this section is used to comply with the emission reductions required by § 63.1252(c)(4) or (c)(5) of this subpart.

(i) A boiler or process heater with a design heat input capacity of 44 megawatts or greater.

(ii) A boiler or process heater where the vent stream is introduced with the primary fuel or is used as the primary fuel.

(iii) A boiler or process heater burning hazardous waste for which the owner or operator:

(A) Has been issued a final permit under 40 CFR part 270 and complies with the requirements of 40 CFR part 266, subpart H, or

(B) Has certified compliance with the interim status requirements of 40 CFR part 266, subpart H.

(5) An owner or operator is not required to conduct a performance test for the following:

(i) Any control device for which a previous performance test was conducted, provided the test was conducted using the same procedures

specified in § 63.1253(b) of this subpart over conditions typical of the appropriate worst-case, as defined in paragraph (d)(3)(iii)(A) of this section, or typical of normal operations, as defined in paragraph (d)(3)(iii)(A) of this section and restricted to the conditions described therein. The results of the previous performance test shall be used to demonstrate compliance.

(ii) A condenser system that is equipped with a temperature sensor and recorder, such that the condenser exit gas temperature can be measured at 15-minute intervals when the condenser is functionning in cooling a vent stream. The condenser exit gas temperature shall be used to calculate removal efficiency of the condenser in demonstrating compliance.

(e) Compliance with wastewater provisions.

(1) An owner or operator of a wastewater stream shall comply with paragraphs (e)(1)(i) through (1)(iii) of this section in determining streams that are exempt from the control requirements of § 63.1252(d).

(i) Compliance is demonstrated when the concentration of partially soluble HAP is less than 1,300 ppmw at the POD, or the concentration of total HAP is less than 5,200 ppmw at the POD, as measured or estimated using one of the procedures described in paragraphs (e)(1)(i) (A) through (C) of this section.

(A) The concentration of partially soluble HAP, soluble HAP, or total HAP shall be measured using methods validated under the procedures described in paragraphs (b)(8)(ii) and (iii) of this section.

(B) The concentration of partially soluble HAP, soluble HAP, or total HAP shall be calculated based on knowledge of the process wastewater. The owner or operator shall provide sufficient information to document concentrations. Examples of information that could constitute such knowledge include material balances, records of chemical purchases, process stoichiometry, or previous test results provided the results are still representative of current operating practices at the process unit(s).

(C) The concentration of partially soluble HAP, soluble HAP, or total HAP shall be calculated based on bench scale or pilot-scale test data. The owner or operator shall provide sufficient information to demonstrate that the bench-scale or pilot-scale test concentration data are representative of actual HAP concentrations. The owner or operator shall also provide documentation describing the testing protocol, and the means by which sample variability and analytical variability were accounted for in the determination of HAP concentrations.

(ii) Compliance is demonstrated when the total HAP load calculated by summing the load from all POD's at a facility is less than 1 Mg/yr. The total wastewater load shall be calculated by converting the concentration of partially soluble HAP, soluble HAP, or total HAP, as appropriate from a concentration (ppmw), to a measure of the kg of HAP per liter of wastewater. The load shall be calculated by multiplying the kilograms of HAP per liter by the total liters of wastewater per year at the POD. The total liters of wastewater discharged per year shall be demonstrated through the records required by § 63.1255(b) of this subpart.

(iii) Compliance is demonstrated for each stream with a concentration exceeding 1,300 ppmw partially soluble HAP or 5,200 ppmw total HAP at the POD, but less than 10,000 ppmw total HAP at the POD, and the HAP load at the POD or the total HAP load calculated from summing the load from all POD's within a process is less than 1 Mg/yr. Concentrations may be measured or estimated using the procedures described in paragraphs (e)(1)(i)(A) through (C) of this section.

(2) Compliance with the control requirements of § 63.1252(d)(4) is demonstrated through the procedures outlined in §§ 63.145(b), 63.145(c), 63.145(d), 63.138(j) or 63.145(i) as appropriate.

(3) Compliance with the control device requirements for devices used to comply with the provisions in §§ 63.133 through 63.138 is demonstrated by compliance with the provisions of § 63.139(d).

(4) Compliance with the inspection requirements for vapor collection systems, closed vent systems, fixed roofs, covers, or enclosures is demonstrated by compliance with the provisions of § 63.148.

(5) Compliance with the inspection requirements for wastewater tanks, surface impoundments, containers, individual drain systems, and oil-water separators is demonstrated through the provisions of § 63.143.

(f) Pollution prevention alternative standard: The owner or operator shall demonstrate compliance with § 63.1252(h)(2) of this subpart using the procedures described in paragraph (f)(1) of this section. The owner or operator shall demonstrate compliance with § 63.1252(h)(3) of this subpart using the procedures described in paragraph (f)(2) of this section.

(1) Compliance is demonstrated when the annual kg/kg factor, calculated according to the procedure in paragraphs (f)(1)(i) and (iii) of this section, is reduced to a value equal to or less than 25 percent of the baseline factor calculated according to the procedure in paragraph (f)(1)(i) and (ii) of this section.

(i) The production-indexed HAP consumption factors shall be calculated by dividing annual consumption of total HAP by the annual production rate, per process. The production-indexed total VOC consumption factor shall be calculated by dividing annual consumption of total VOC by the annual production rate, per process.

(ii) The baseline factor is calculated from yearly production and consumption data for the first 12-month period of time for which data was available, to begin no earlier than January 1, 1987.

(iii) The annual factor is calculated on the following bases:

(A) For continuous processes, the annual factor shall be calculated every 30 days for the 12-month period preceding the 30th day (30-day rolling average).

(B) For batch processes, the annual factor shall be calculated every 10 batches for the 12-month period preceding the 10th batch (10-batch rolling average).

(2) Compliance is demonstrated when the requirements of paragraphs (f)(2)(i) through (iv) of this section are met.

(i) The annual kg/kg factor, calculated according to the procedure in paragraphs (f)(1)(i) and (f)(1)(iii) of this section, is reduced to a value equal to or less than 50 percent of the baseline factor calculated according to the procedure in paragraphs (f)(1)(i) and (f)(1)(ii) of this section.

(ii) The yearly reduction, in kg HAP/yr, associated with add-on controls that meet the criteria of §§ 63.1252(h)(3)(ii)(A) through (D), is equal to or greater than the mass of HAP calculated by the following equation:

$$[\text{kg}/\text{kg}]_b * .25 * [\text{kg produced}]_a = [\text{kg reduced}]_a$$

where:

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

$[kg\ produced]_a$ = the annual production rate, in kg/yr

$[kg\ reduced]_a$ = the annual reduction required by add-on controls, in kg/yr

(iii) Demonstration that the criteria in §§ 63.1252(h)(3)(ii)(A) through (D) are met shall be accomplished through a description of the control device and of the material streams entering and exiting the control device.

(iv) The annual reduction achieved by the add-on control shall be quantified using the methods described in § 63.1253(d).

(g) Planned maintenance: The owner or operator shall demonstrate compliance with the requirements of § 63.1252(b), and (c) of this subpart by including in each Periodic Report required by § 63.1256 of this subpart the periods of planned routine maintenance specified by date and time (planned routine maintenance of a control device, during which the control device does not meet the specifications of § 63.1252 of this subpart, as applicable, shall not exceed 240 hours per year).

(h) Compliance with storage tank provisions by using emissions averaging: An owner or operator with two or more affected storage tanks may demonstrate compliance with § 63.1252(b)(2) and § 63.1252(b)(3)(i) and (ii), as applicable, by fulfilling the requirements of paragraphs (h)(1) through (4) or paragraphs (h)(1), (2), (5) and (6) of this section, as appropriate.

(1) The owner or operator shall develop and submit for approval an Implementation Plan containing all the information required in § 63.1255(f) of this subpart 18 months prior to the compliance date of the standard. The Administrator shall have 60 days to approve or disapprove the emissions averaging plan after which time the plan shall be considered approved.

(2) The annual mass rate of total organic HAP (E_{Ti}, E_{To}) shall be calculated for each storage tank included in the emissions average using the requirements specified in either paragraph (c)(1) or (c)(2) or (c)(3) of this section.

(3) The following equations shall be used to calculate total HAP emissions for those tanks subject to § 63.1252(b)(1)(i):

$$E_{Ti} = \sum_{j=1}^{n} E_{ij}$$

$$E_{To} = \sum_{j=1}^{n} E_{oj}$$

where:

E_{ij} = yearly mass rate of total organic HAP at the inlet of the control device for tank j

E_{oj} = yearly mass rate of total organic HAP at the outlet of the control device for tank j

E_{Ti} = total yearly uncontrolled emissions

E_{To} = total yearly controlled emissions

n = number of tanks included in the emissions average

(4) The overall percent reduction efficiency shall be calculated as follows:

$$R = \frac{E_{Ti} - D\,E_{To}}{E_{Ti}}(100\%)$$

where:

R = overall percent reduction efficiency.

D = discount factor = 1.1 for all controlled storage tanks.

(5) The following equations shall be used to calculate total HAP emissions for those tanks subject to § 63.1252(b)(1)(ii):

$$E_{Ti} = \sum_{j=1}^{n} E_{ij}$$

$$E_{To} = \sum_{j=1}^{n} E_{oj}$$

Where:

E_{ij} = yearly mass rate of total organic HAP at the inlet of the control device for tank j

E_{oj} = yearly mass rate of total organic HAP at the outlet of the control device for tank j

E_{Ti} = total yearly uncontrolled emissions

E_{To} = total yearly controlled emissions

n = number of tanks included in the emissions average

(6) The overall percent reduction efficiency shall be calculated as follows:

$$R = \frac{E_{Ti} - D\,E_{To}}{E_{Ti}}(100\%)$$

Where:

R = overall percent reduction efficiency

D = discount factor = 1.1 for all controlled storage tanks

(i) Compliance with process vent provisions by using emissions averaging:

An owner or operator with two or more affected processes complying with § 63.1252(c) by using emissions averaging shall demonstrate compliance with paragraphs (i)(1), (2) and (3) of this section.

(1) The owner or operator shall develop and submit for approval an Implementation Plan 18 months prior to the compliance date of the standard containing all the information required in § 63.1255(f) of this subpart. The Administrator shall have 60 days to approve or disapprove the emissions averaging plan. The plan shall be considered approved if the administrator either approves the plan in writing, or fails to disapprove the plan in writing. The 60 day period shall begin when the administrator receives the request. If the request is denied, the owner or operator must still be in compliance with the standard by the compliance date.

(2) Owners or operators shall calculate uncontrolled and controlled emissions of HAP by using the methods specified in paragraph (d)(2) or (d)(3) of this section for each process included in the emissions average.

(i) The following equations shall be used to calculate total HAP emissions:

$$E_{TU} = \sum_{i=1}^{n} E_{Ui}$$

$$E_{TC} = \sum_{i=1}^{n} E_{Ci}$$

Where:

E_{Ui} = yearly uncontrolled emissions from process i

E_{Ci} = yearly controlled emissions for process i

E_{TU} = total yearly uncontrolled emissions

E_{TC} = total yearly controlled emissions

n = number of processes included in the emissions average

(3) The overall percent reduction efficiency shall be calculated as follows:

$$R = \frac{E_{TU} - D\,E_{TC}}{E_{TU}}(100\%)$$

Where:

R = overall percent reduction efficiency

D = discount factor = 1.1 for all controlled emission points

§ 63.1254 Monitoring requirements.

(a) The owner or operator of any existing, new, or reconstructed affected source shall provide evidence of continued compliance with the standard. During the initial compliance demonstration, maximum or minimum operating parameters, as appropriate, shall be established for emission sources that will indicate the source is in compliance. Test data, calculations, or information from the evaluation of the

control device design shall be used to establish the operating parameter. If the operating parameter to be established is a maximum and if performance testing has been required, the value of the parameter shall be the average of the maximum values from each of the three test runs. If the operating parameter to be established is a minimum and if performance testing has been required, the value of the parameter shall be the average of the minimum values from each of the three test runs. Parameter values for process vents from batch operations shall be determined as specified in paragraph (b)(1) and (2) of this section. The owner or operator shall operate processes and control devices within these parameters to ensure continued compliance with the standard. Monitoring parameters are specified for continuous process vent control scenarios in paragraphs (a)(1) through (7) of this section.

(1) For all control devices that are used to control process vent streams totaling less than 1 ton/yr HAP emissions, before control, monitoring shall consist of a periodic verification that the device is operating properly. This verification shall include, but not be limited to, a periodic demonstration that the unit is working as designed. This demonstration shall be included in the precompliance report, to be submitted 12 months prior to the compliance date of the standard.

(2) For affected sources using water scrubbers that are used to control process vent streams totaling greater than 1 ton/yr HAP, before controls, the owner or operator shall establish a minimum scrubber water flow rate as a site-specific operating parameter which must be measured and recorded every 15 minutes. The affected source will be considered to be out of compliance if the scrubber water flow rate, averaged over the operating day, is below the minimum value established during the initial compliance demonstration.

(3) For affected sources using condensers that are used to control process vent streams totaling greater than 1 ton/yr, before controls, the owner or operator shall establish the maximum condenser outlet gas temperature as a site-specific operating parameter which must be measured and recorded every 15 minutes. The affected source will be considered to be out of compliance if the condenser outlet gas temperature, averaged over the operating day, is greater than the maximum value established during the initial compliance demonstration.

(4) For affected sources using carbon adsorbers that are used to control process vent streams totaling greater than 1 ton/yr, before controls, the owner or operator shall establish a maximum outlet HAP concentration as the site-specific operating parameter which must be measured and recorded every 15 minutes. The affected source will be considered to be out of compliance if the outlet HAP concentration, averaged over the operating day, is greater than the maximum value established during the initial compliance demonstration.

(5) For affected sources using flares that are used to control process vent streams totaling greater than 1 ton/yr, before controls, the presence of the pilot flame shall be monitored every 15 minutes. The affected source will be considered to be out of compliance upon loss of pilot flame.

(6) For each wastewater management unit, treatment process, or control device used to comply with §§ 63.138 and 63.139, the owner or operator shall comply with either paragraph (a)(6)(i) or (a)(6)(ii) of this section.

(i) The owner or operator shall monitor the parameters specified in Tables 11, 12, or 13 of subpart 63.

(ii) The owner or operator shall submit a request for approval to monitor alternative parameters according to the procedures specified in § 63.1256(a)(2)(i).

(7) For affected sources using combustion devices that are used to control process vents totaling greater than 1 ton/yr, before controls, the owner or operator shall monitor the temperature of the gases exiting the combustion chamber as the site-specific operating parameter which must be measured and recorded every 15 minutes. The affected sources will be considered to be out of compliance if the chamber temperature averaged over the operating day, is greater than the maximum value established during the initial compliance demonstration.

(b) The owner or operator of any existing, new, or reconstructed affected source that chooses to comply with the emission limit or emission reduction requirement for batch process vents and combined streams from process vents and storage tanks shall provide evidence of continued compliance with the standard. As part of the initial compliance demonstrations for batch process vents and storage tanks, test data, compliance calculations, or information from the control device design evaluation shall be used to establish a maximum or minimum level of a relevant operating parameter for each control device that the owner or operator selects to operate as part of achieving the required emission reduction or emission limitation. The owner or operator shall operate processes and control devices within these parameters to ensure continued compliance with the standard.

(1) For devices that are used to control batch process vent streams totaling less than 1 ton/yr HAP emissions, before control, monitoring shall consist of a periodic verification that the device is operating properly. This verification shall include, but not be limited to, a periodic demonstration that the unit is working as designed. This demonstration shall be included in the precompliance report, to be submitted 12 months prior to the compliance date of the standard.

(2) For batch process vents that are routed to a device that receives HAP in excess of 1 ton per year, before control, the level(s) shall be established in accordance with paragraphs (b)(2)(i) through (iv) of this section.

(i) If more than one batch emission episode or more than one portion of a batch emission episode has been selected to be controlled, a single level for the batch cycle(s) or process(es) shall be calculated from the initial compliance demonstration. The appropriate parameter shall be determined for the worst-case conditions, as determined in § 63.1253(b)(7)(ii) and (b)(7)(iii) selected to be controlled. The average parameter monitoring level for the cycle(s) or process(es) shall be based on the parameter value determined from the worst-case conditions.

(ii) Instead of establishing a single level for the batch cycle(s) or process(es), as described in paragraph (b)(2)(i) of this section, an owner or operator may establish separate levels for each batch emission episode, or portion thereof, selected to be controlled.

(iii) For devices controlling at least 10 tons per year for which a performance test is required, the owner or operator may establish the parametric monitoring level(s) based on the performance test supplemented by engineering assessments and manufacturer's recommendations. Performance testing is not required to be conducted over the entire range of expected parameter values. The rationale for the specific level for each parameter, including any data and calculations used to develop the level(s) and a description of why the level indicates proper operation of the control device shall be provided in the Precompliance report. The procedures specified in this section have not been approved by the Administrator and determination of the parametric monitoring level using these procedures is subject to review and approval by the Administrator.

(iv) For devices controlling at least 10 tons per year for which a performance test is conducted at routine conditions, the owner or operator shall establish the parametric monitoring level(s) at conditions of the test. The level(s) established shall be provided in the notification of compliance status report.

(3) If the sum of HAP emissions, before control, routed to the device is greater than 1 tons/yr, the appropriate parameter shall be monitored at 15-minute intervals for the entire period in which the control device is functioning in achieving required removals.

(4) Affected sources with condensers on process vents shall establish the maximum condenser outlet gas temperature as a site-specific operating parameter, which, except as provided in paragraph (b)(3) of this section, must be measured every 15 minutes or at least once for batch emission episodes less than 15 minutes in duration. The affected source will be considered to be out of compliance if the condenser outlet gas temperature, averaged over the operating day for each process is greater than the value established during the initial compliance demonstration.

(5) For affected sources using water scrubbers, the owner or operator shall establish a minimum scrubber water flow rate as a site-specific operating parameter which, except as provided in paragraph (b)(3) of this section, must be measured and recorded every 15 minutes, or at least once for batch emission episodes less than 15 minutes in duration. The affected source will be considered to be out of compliance if the scrubber water flow rate, averaged over the operating day for each process, is below the minimum flow rate established during the initial compliance demonstration.

(6) For affected sources using carbon adsorbers or having uncontrolled process vents, the owner or operator shall establish a maximum outlet HAP concentration as the site-specific operating parameter which, except as provided in paragraph (b)(3) of this section, must be measured and recorded every 15 minutes, or at least once for batch emission episodes of duration shorter than 15 minutes. The affected source will be considered to be out of compliance if the outlet HAP concentration, averaged over the operating day for each process, is greater than the value established during the initial compliance demonstration.

(7) For affected sources using flares, the presence of the pilot flame shall be monitored every 15 minutes, or at least once for batch emission episodes less than 15 minutes in duration. The affected source will be considered to be out of compliance upon loss of pilot flame.

(8) For affected sources using combustion devices, the temperature of the gases exiting the combustion chamber shall be monitored every 15 minutes, or at least once for episodes less than 15 minutes in duration. The affected source will be considered out of compliance if the combustion chamber temperature, averaged over the operating day for each process, is less than the value established during the initial compliance demonstration.

(c) An owner or operator may request approval to monitor parameters other than those required by paragraphs (a)(2) through (7) and paragraphs (b)(5) through (8) of this section. The request shall be submitted according to the procedures specified in § 63.8(f) of subpart A or included in the Precompliance report.

(d) Periods of time when monitoring measurements exceed the parameter values as well as periods of inadequate monitoring data do not constitute a violation if they occur during a startup, shutdown, or malfunction, and the facility follows its startup, shutdown, and malfunction plan.

(e) The owner or operator of any affected source complying with the requirements of appendix GGGA of this section shall meet the monitoring requirements described in the appendix.

(f) The owner or operator of any affected source that chooses to comply with the requirements of §§ 63.1252(h)(2) and (3) shall calculate rolling average values of kg HAP consumption per kg production and kg VOC consumption per kg production. The owner or operator will be considered out of compliance if either rolling average kg/kg factor exceeds the value established in § 63.1253(f)(1)(ii).

(g) Owners or operators of any affected source that chooses to comply with the requirements of § 63.1252(j) shall meet all monitoring requirements specified in § 63.1254 (a), (b), (c), and (d), as applicable, for all processes and storage tanks included in the emissions average.

§ 63.1255 Recordkeeping requirements.

(a) The owner or operator of any affected source shall keep records of daily values of equipment operating parameters specified to be monitored under § 63.1254, or specified by the Administrator. Records shall be kept in accordance with the requirements of applicable paragraphs of § 63.10 of subpart A of this part, as specified in the General Provisions applicability table of this subpart. The owner or operator shall keep records up-to-date and readily accessible.

(1) A daily (24-hour) average shall be calculated as the average of all values for a monitored parameter recorded during the operating day.

(2) The operating day shall be the period defined in the operating permit or the Notification of Compliance Status in § 63.9(h). It may be from midnight to midnight or another continuous 24-hour period.

(3) For every operating day in which the daily average value for an operating parameter is outside its established range, the owner or operator must keep records of each parameter value reading taken during the day on which the excursion occurred.

(4) For processes subject to § 63.1252(h), records shall be maintained of rolling average values of kg HAP/kg production and kg VOC/kg production.

(b) The owner or operator of any affected source that complies with the standards for process vents, storage tanks, and wastewater systems shall maintain up-to-date, readily accessible records of the following information to document that HAP emissions or HAP loadings (for wastewater) are below the limits specified in § 63.1252:

(1) The emissions per batch for each process.

(2) The wastewater concentrations per POD and process.

(3) The number of batches per year for each batch process.

(4) The operating hours per year for continuous processes.

(5) The number of tank turnovers per year.

(c) The owner or operator of any affected source implementing the leak detection and repair program specified in appendix A of this subpart, shall implement the recordkeeping requirements in appendix A to this subpart. All records shall be retained for a period of 5 years, in accordance with the requirements of 40 CFR 63.10(b)(1).

(d) For unit operations occurring more than once per day, exceedances of established parameter limits shall result in no more than one violation per operating day for each monitored item of equipment utilized in the unit operation.

(e) For certain items of monitored equipment used for more than one type of unit operation in the course of an operating day, exceedances shall result in no more than one violation per operating day, per item of monitored equipment, for each type of unit operation in which the item is in service.

(f) Owners or operators of any affected source that chooses to comply with the requirements of § 63.1252(j) shall maintain up-to-date records of the following information:

(1) An Implementation Plan which shall include in the plan, for all process vents and storage tanks included in each of the averages, the information listed in paragraphs (f)(1)(i) through (f)(1)(v) of this section.

(i) The identification of all process vents and storage tanks in each emissions average.

(ii) The uncontrolled and controlled emissions of HAP and the overall percent reduction efficiency as determined in §§ 63.1253(h) (1) through (6) or §§ 63.1253(i) (1) through (3) as applicable.

(iii) The calculations used to obtain the uncontrolled and controlled HAP emissions and the overall percent reduction efficiency.

(iv) The estimated values for all parameters required to be monitored under § 63.1254(g) for each process and storage tank included in an average. These parameter values, or as appropriate, limited ranges for parameter values, shall be specified as enforceable operating conditions for the operation of the process or storage tank. Changes to the parameters must be reported as required by § 63.1256(d).

(v) A statement that the compliance demonstration, monitoring, inspection, recordkeeping and reporting provisions in §§ 63.1253(h) and (i), § 63.1254(g), and § 63.1256(d) that are applicable to each emission point in the emissions average will be implemented beginning on the date of compliance.

(2) The Implementation Plan must demonstrate that the emissions from the processes and storage tanks proposed to be included in the average will not result in greater hazard or, at the option of the operating permit authority, greater risk to human health or the environment than if the processes and storage tanks were controlled according to the provisions in § 63.1252(b) or (c).

(i) This demonstration of hazard or risk equivalency shall be made to the satisfaction of the operating permit authority.

(*A*) The Administrator may require owners and operators to use specific methodologies and procedures for making a hazard or risk determination.

(*B*) The demonstration and approval of hazard or risk equivalency shall be made according to any guidance that the Administrator makes available for use or any other technically sound information or methods.

(ii) An emissions averaging plan that does not demonstrate hazard or risk equivalency to the satisfaction of the Administrator shall not be approved. The Administrator may require such adjustments to the emissions averaging plan as are necessary in order to ensure that the average will not result in greater hazard or risk to human health or the environment than would result if the emission points were controlled according to § 63.1252 (b) or (c).

(iii) A hazard or risk equivalency demonstration must:

(*A*) Be a quantitative, comparative chemical hazard or risk assessment;

(*B*) Account for differences between averaging and non-averaging options in chemical hazard or risk to human health or the environment; and

(*C*) Meet any requirements set by the Administrator for such demonstrations.

(3) Records as specified in paragraphs (a), (b) and (d) of this section.

(4) A calculation of the overall percent reduction efficiency as specified in § 63.1253(h) and (i) of this subpart for the last quarter and the prior four quarters.

§ 63.1256 Reporting requirements

(a) The owner or operator of any affected source that elects to comply with the emission limit or emission reduction requirements for process vents, storage tanks, and wastewater systems, shall comply with the reporting requirements of applicable paragraphs of 40 CFR 63.9 and 63.10, as specified in the General Provisions applicability table.

(1) The Notification of Compliance Status report required under § 63.9 shall be submitted within 150 days of the compliance date and shall include:

(i) The results of any applicability determinations, emission calculations, or analyses used to identify and quantify HAP emissions from applicable sources.

(ii) The results of emissions profiles, performance tests, engineering analyses, design evaluations, or calculations used to demonstrate compliance. For performance tests, results should include descriptions of sampling and analysis procedures and quality assurance procedures.

(iii) Descriptions of monitoring devices, monitoring frequencies, and the values of monitored parameters established during the initial compliance determinations, including data and calculations to support the levels established.

(2) The precompliance report shall be submitted 12 months prior to the compliance date of the standard. For new sources, the Precompliance report shall be submitted to the Administrator with the application for approval of construction or reconstruction. The Administrator shall have 60 days to approve or disapprove the plan. The plan shall be considered approved if the administrator either approves the plan in writing, or fails to disapprove the plan in writing. The 60 day period shall begin when the administrator receives the request. If the request is denied, the owner or operator must still be in compliance with the standard by the compliance date. The Precompliance report shall include:

(i) Requests for approval to use alternative monitoring parameters or requests to set monitoring parameters according to § 63.1254(b)(2)(iii).

(ii) Descriptions of how the control devices subject to §§ 63.1254(a)(1) and 63.1254(b)(1) will be checked to verify that they are operating as designed.

(iii) A description of test conditions and limits of operation for control devices tested under normal conditions, and the corresponding monitoring parameter values.

(b) The owner or operator shall also submit to the Administrator, as part of the quarterly excess emissions and continuous monitoring system performance report and summary report required by 40 CFR 63.10(e)(3), the following recorded information.

(1) Reports of monitoring data, including 15-minute monitoring values as well as daily average values of monitored parameters for all operating days when the average values were outside the ranges established in the Notification of Compliance Status or operating permit.

(2) Reports of the duration of periods when monitoring data is not collected for each excursion caused by insufficient monitoring data. An excursion means any of the two cases listed in paragraphs (b)(2)(i) or (b)(2)(ii) of this section. For a control device where multiple parameters are monitored, if one or more of the parameters meets the excursion criteria in paragraphs (a)(2)(i) or (a)(2)(ii) of this section, this is considered a single excursion for the control device.

(i) When the period of control device operation is 4 hours or greater in an operating day and monitoring data are insufficient to constitute a valid hour of data, as defined in paragraph (b)(2)(iii) of this section, for at least 75 percent of the operating hours.

(ii) When the period of control device operation is less than 4 hours in an operating day and more than one of the hours during the period of operation does not constitute a valid hour of data due to insufficient monitoring data.

(iii) Monitoring data are insufficient to constitute a valid hour of data, as

used in paragraphs (b)(2)(i) and (b)(2)(ii) of this section, if measured values are unavailable for any of the 15-minute periods within the hour.

(3) Whenever a process change, as defined in 40 CFR 63.115(e), is made that causes the emission rate from a de minimis emission point to become a process vent with an emission rate of 1 pound per year or greater, or a change in any of the information submitted in the Notification of Compliance Report, the owner or operator shall submit a report within 180 calendar days after the process change. The report may be submitted as part of the next summary report required under 40 CFR 63.10(e)(3). The report shall include:

(i) A description of the process change.

(ii) The results of the recalculation of the emission rate.

(iii) Revisions to any of the information reported in the original Notification of compliance under § 63.1256(a)(1).

(iv) Information required by the Notification of compliance under § 63.1256(a)(1) for changes involving the addition of processes or equipment.

(c) The owner or operator of any affected source implementing the leak detection and repair program specified in subpart H of this part, shall implement the reporting requirements in 40 CFR 63.182. Copies of all reports shall be retained as records for a period of 5 years, in accordance with the requirements of 40 CFR 63.10(b)(1).

(d) Owners or operators of any affected source that chooses to comply with the requirements of § 63.1252(j) shall submit all information as specified in § 63.1255(f) for each process or storage tank included in the emissions average. The owner or operator shall also submit to the administrator all information as specified in paragraph (b) of this section for each process or storage tank included in the emissions average.

(1) The reports must also include the information listed in paragraphs (c)(1)(i) through (c)(1)(iv) of this section:

(i) Any changes of the processes or storage tanks included in the average.

(ii) The calculation of the overall percent reduction efficiency for the reporting period.

(iii) Changes to the Implementation Plan which affect the calculation methodology of uncontrolled or controlled emissions or the hazard or risk equivalency determination.

(iv) Any changes to the parameters monitored according to § 63.1254(g).

(2) Every 4th quarter report shall include the results according to § 63.1255(f)(4) to demonstrate the emissions averaging provisions of §§ 63.1252(j), 63.1253(h) and (i), 63.1254(g), and 63.1255(f) are satisfied.

§ 63.1257 Delegation of authority [Reserved]

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

Reference to subpart A	Applies to subpart GGG	Comment
§ 63.1(a)(1)	Yes	Additional terms defined in § 63.1251.
§ 63.1(a)(2)	Yes	
§ 63.1(a)(3)	Yes	
§ 63.1(a)(4)	Yes	Subpart GGG specifies applicability of each paragraph in subpart A to subpart GGG.
§ 63.1(a)(5)	N/A	Reserved.
§ 63.1(a)(6)	Yes	
§ 63.1(a)(7)	Yes	
§ 63.1(a)(8)	No	Discusses State programs.
§ 63.1(a)(9)	N/A	Reserved.
§ 63.1(a)(10)	Yes	
§ 63.1(a)(11)	Yes	
§ 63.1(a)(12)–(14)	Yes	
§ 63.1(b)(1)	No	§ 63.1250 of subpart GGG specifies applicability.
§ 63.1(b)(2)	Yes	
§ 63.1(b)(3)	Yes	
§ 63.1(c)(1)	Yes	Subpart GGG specifies applicability of each paragraph in subpart A to sources subject to subpart GGG.
§ 63.1(c)(2)	No	Area sources are not subject to subpart GGG.
§ 63.1(c)(3)	N/A	Reserved.
§ 63.1(c)(4)	Yes	
§ 63.1(c)(5)	Yes	
§ 63.1(d)	N/A	Reserved.
§ 63.1(e)	Yes	
§ 63.2	Yes	Additional terms are defined in § 63.1251 of subpart GGG; when overlap between subparts A and GGG occurs, subpart GGG takes precedence.
§ 63.3	Yes	Other units used in subpart GGG are defined in that subpart.
§ 63.4(a)(1)–(3)	Yes	
§ 63.4(a)(4)	N/A	Reserved.
§ 63.4(a)(5)	Yes	
§ 63.4(b)	Yes	
§ 63.4(c)	Yes	
§ 63.5(a)	Yes	Except replace the terms ''source'' and ''stationary source'' in § 63.5(a)(1) of subpart A with ''affected source''.
§ 63.5(b)(1)	Yes	
§ 63.5(b)(2)	N/A	Reserved.
§ 63.5(b)(3)	Yes	
§ 63.5(b)(4)	Yes	
§ 63.5(b)(5)	Yes	
§ 63.5(b)(6)	Yes	
§ 63.5(c)	N/A	Reserved.
§ 63.5(d)(1)(i)	Yes	
§ 63.5(d)(1)(ii)	Yes	

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

Reference to subpart A	Applies to subpart GGG	Comment
§63.5(d) (1)(iii)	Yes	
§63.5(d)(2)	Yes	
§63.5(d)(3)–(4)	Yes	
§63.5(e)	Yes	
§63.5(f)(1)	Yes	Except replace ''source'' in §63.5(f)(1) of subpart A with ''affected source''.
§63.5(f)(2)	Yes	
§63.6(a)	Yes	
§63.6(b)(1)–(2)	No	Subpart GGG specifies compliance dates.
§63.6(b)(3)–(4)	Yes	
§63.6(b)(5)	Yes	
§63.6(b)(6)	N/A	Reserved.
§63.6(b)(7)	Yes	
§63.6(c)(1)–(2)	Yes	Except replace ''source'' in §63.6(c)(1)–(2) of subpart A with ''affected source''.
§63.6(c)(3)–(4)	N/A	Reserved.
§63.6(c)(5)	Yes	
§63.6(d)	N/A	Reserved.
§63.6(e)	Yes	
§63.6(f)(1)	Yes	
§63.6(f)(2)(i)–(ii)	Yes	
§63.6(f)(2)(iii)	Yes	
§63.6(f)(2)(iv)	Yes	
§63.6(f)(3)	Yes	
§63.6(g)	Yes	An alternative standard has been proposed; however, affected sources will have the opportunity to demonstrate other alternatives to the Administrator.
§63.6(h)	No	Subpart GGG does not contain any opacity or visible emissions standards.
§63.6(i)(1)	Yes	
§63.6(i)(2)	Yes	Except replace ''source'' in §63.6(2)(i) and (ii) of subpart A with ''affected source''.
§63.6(i)(3)	Yes	
§63.6(i)(4)(i)	Yes	
§63.6(i)(4)(ii)	Yes	
§63.6(i)(5)–(14)	Yes	
§63.6(i)(15)	N/A	Reserved.
§63.6(i)(16)	Yes	
§63.6(j)	Yes	
§63.7(a)(1)	Yes	Subpart GGG specifies required testing and compliance procedures.
§63.7(a)(2)(i)–(vi)	Yes	
§63.7(a)(2) (vii)–(viii)	N/A	Reserved.
§63.7(a)(2) (ix)	Yes	
§63.7(a)(3)	Yes	
§63.7(b)(1)	Yes	
§63.7(b)(2)	Yes	
§63.7(c)	Yes	
§63.7(d)	Yes	Except replace ''source'' in §63.7(d) of subpart A with ''affected source''.
§63.7(e)(1)	Yes	Subpart GGG also contains test methods specific to pharmaceutical sources.
§63.7(e)(2)	Yes	
§63.7(e)(3)	Yes	Subpart GGG specifies test methods and procedures.
§63.7(f)	Yes	
§63.7(g)(1)	Yes	
§63.7(g)(2)	N/A	Reserved.
§63.7(g)(3)	Yes	
§63.7(h)(1)–(2)	Yes	
§63.7(h)(3)(i)	Yes	
§63.7(h)(3) (ii)–(iii)	Yes	
§63.7(h)(4)–(5)	Yes	
§63.8(a)(1)	Yes	
§63.8(a)(2)	Yes	
§63.8(a)(3)	N/A	Reserved.
§63.8(a)(4)	Yes	
§63.8(b)(1)	Yes	
§63.8(b)(2)	No	Subpart GGG has CMS requirements.
§63.8(b)(3)	Yes	
§63.8(c)(1)(i)	Yes	
§63.8(c) (1)(ii)	Yes	
§63.8(c) (1)(iii)	Yes	
§63.8(c)(2)–(3)	Yes	
§63.8(c)(4)–(8)	No	Subpart GGG specifies monitoring frequencies.
§63.8(d)	Yes	
§63.8(e)	Yes	
§63.8(f)(1)	Yes	
§63.8(f)(2)	Yes	
§63.8(f)(3)	Yes	

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

Reference to subpart A	Applies to subpart GGG	Comment
§63.8(f)(4)	Yes	
§63.8(f)(5)	Yes	
§63.8(f)(6)	Yes	
§63.8(g)	Yes	
§63.9(a)	Yes	
§63.9(b)(1) (i)–(ii)	Yes	
§63.9(b) (1)(iii)	Yes	
§63.9(b)(2)	Yes	
§63.9(b)(3)	Yes	
§63.9(b)(4)	Yes	
§63.9(b)(5)	Yes	
§63.9(c)	Yes	
§63.9(d)	Yes	
§63.9(e)	No	
§63.9(f)	No	
§63.9(g)	No	
§63.9(h)(1)–(3)	Yes	
§63.9(h)(4)	N/A	Reserved.
§63.9(h)(5)–(6)	Yes	
§63.9(i)	Yes	
§63.9(j)	Yes	
§63.10(a)	Yes	
§63.10(b)(1)	Yes	
§63.10(b)(2)	No	Subpart GGG specifies recordkeeping requirements.
§63.10(b)(3)	Yes	
§63.10(c)(1)–(6)	Yes	
§63.10(c)(7)–(8)	Yes	
§63.10(c)(9)–(15)	Yes	
§63.10(d)(1)	Yes	Subpart GGG specifies performance test reporting requirements.
§63.10(d)(2)	Yes	Subpart GGG specifies performance test reporting requirements.
§63.10(d)(3)	No	
§63.10(d)(4)	Yes	
§63.10(d)(5)	Yes	
§63.10(e)(1)–(2)	Yes	
§63.10(e)(3)	Yes	
§63.10(e)(4)	Yes	
§63.10(f)	Yes	
§63.11–§63.15	Yes	

TABLE 2 TO SUBPART GGG.—PARTIALLY SOLUBLE HAP

Compound
1,1,1-Trichloroethane (methyl chloroform)
1,1,2,2-Tetrachloroethane
1,1,2-Trichloroethane
1,1-Dichloroethylene (vinylidene chloride)
1,2-Dibromoethane
1,2-Dichloroethane (ethylene dichloride)
1,2-Dichloropropane
1,3-Dichloropropene
2,4,5-Trichlorophenol
2-Butanone (mek)
2-Nitropropane
4-Methyl-2-pentanone (mibk)
Acetaldehyde
Acrolein
Acrylonitrile
Allyl chloride
Benzene
Benzyl chloride
Biphenyl
Bromoform (tribromomethane)
Bromomethane
Butadiene
Carbon disulfide
Chlorobenzene
Chloroethane (ethyl chloride)
Chloroform
Chloromethane

TABLE 2 TO SUBPART GGG.—PARTIALLY SOLUBLE HAP—Continued

Compound
Chloroprene
Cumene
Dichloroethyl ether
Dinitrophenol
Ethyl acrylate
Ethylbenzene
Ethylene oxide
Hexachlorobenzene
Hexachlorobutadiene
Hexachloroethane
Methyl methacrylate
Methyl-t-butyl ether
Methylene chloride
N,N-dimethylaniline
Naphthalene
Phosgene
Propionaldehyde
Propylene oxide
Styrene
Tetrachloroethene (perchloroethylene)
Tetrachloromethane (carbon tetrachloride)
Toluene
Trichlorobenzene (1,2,4-)
Trichloroethylene
Triethylamine
Trimethylpentane
Vinyl acetate
Vinyl chloride
Xylene (m)
Xylene (o)
Xylene (p)
N-hexane
P-dichlorobenzene

TABLE 3.—SOLUBLE HAP'S

Compound
1,1-Dimethylhydrazine
1,4-Dioxane
Acetonitrile
Acetophenone
Diethyl sulfate
Dimethyl sulfate
Dinitrotoluene
Epichlorohydrin
Ethylene glycol dimethyl ether
Ethylene glycol monobutyl ether acetate
Ethylene glycol monomethyl ether acetate
Isophorone
Methanol (methyl alcohol)
Nitrobenzene
Toluidene

Appendix A to Subpart GGG—Equipment Leaks

§ GGGA–1 General Equipment Leak Requirements

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

(b) After the compliance date for a process, equipment to which this subpart applies that are also subject to the provisions of:

(1) 40 CFR part 60 will be required to comply only with the provisions of this subpart.

(2) 40 CFR part 61 will be required to comply only with the provisions of this subpart.

(c) [Reserved]

(d) The provisions in § 63.1(a)(3) of subpart A of this part do not alter the provisions in paragraph (b) of this section.

(e) Lines and equipment not containing process fluids are not subject to the provisions of this appendix. Utilities, and other nonprocess lines, such as heating and cooling systems which do not combine their materials with those in the processes they serve, are not considered to be part of a process.

(f) The provisions of this appendix do not apply to bench-scale processes, regardless of whether the processes are located at the same plant site as a process subject to the provisions of this subpart.

(g) Each piece of equipment to which this appendix applies shall be identified such

that it can be distinguished readily from equipment that is not subject to this appendix. Identification of the equipment does not require physical tagging of the equipment. For example, the equipment may be identified on a plant site plan, in log entries, or by designation of process boundaries by some form of weatherproof identification. If changes are made to the affected source subject to the leak detection requirements, equipment identification for each type of component shall be updated, if needed, within 15 calendar days of the end of each monitoring period for that component.

(h) Equipment that is in vacuum service is excluded from the requirements of this appendix.

(i) Equipment that is in organic HAP service, but is in such service less than 300 hours per calendar year, is excluded from the requirements of this appendix if it is identified as required in § GGGA–8(j) of this appendix.

(j) When each leak is detected by visual, audible, or olfactory means, or by monitoring as described in 63.180 (b) or (c), the following requirements apply:

(1) A weatherproof and readily visible identification, marked with the equipment identification number, shall be attached to the leaking equipment.

(2) The identification on a valve or connector in light liquid or gas/vapor service may be removed after it has been monitored as specified in § GGGA–6(f)(3), § 63.174(e), and § 63.175(e)(7)(i)(D), and no leak has been detected during the follow-up monitoring.

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

§ GGGA–2 Definitions

Bench-scale batch process means a batch process (other than a research and development facility) that is capable of being located on a laboratory bench top. This bench-scale equipment will typically include reagent feed vessels, a small reactor and associated product separator, recovery and holding equipment. These processes are only capable of producing small quantities of product.

Closed-loop system means an enclosed system that returns process fluid to the process and is not vented to the atmosphere except through a closed-vent system.

Closed-purge system means a system or combination of system and portable containers, to capture purged liquids. Containers must be covered or closed when not being filled or emptied.

Connector means flanged, screwed, or other joined fittings used to connect two pipe lines or a pipe line and a piece of equipment. A common connector is a flange. Joined fittings welded completely around the circumference of the interface are not considered connectors for the purpose of this regulation. For the purpose of reporting and recordkeeping, connector means joined fittings that are not inaccessible, ceramic, or ceramic-lined as described in § GGGA–3(a)(7) and § GGGA–7(c).

Control device, for purposes of this appendix, means any equipment used for recovering or oxidizing organic hazardous air pollutant vapors. Such equipment includes, but is not limited to, absorbers, carbon adsorbers, condensers, flares, boilers, and process heaters.

Double block and bleed system means two block valves connected in series with a bleed valve or line that can vent the line between the two block valves.

Duct work means a conveyance system such as those commonly used for heating and ventilation systems. It is often made of sheet metal and often has sections connected by screws or crimping. Hard-piping is not ductwork.

Equipment, for purposes of this appendix, means each pump, compressor, agitator, pressure relief device, sampling connection system, open-ended valve or line, valve, connector, surge control vessel, bottoms receiver, and instrumentation system in organic hazardous air pollutant service; and any control devices or closed-vent systems required by this subpart.

First attempt at repair means to take action for the purpose of stopping or reducing leakage of organic material to the atmosphere.

Flow indicator means a device which indicates whether gas flow is, or whether the valve position would allow gas flow to be present, in a line.

In gas/vapor service means that a piece of equipment in organic hazardous air pollutant service contains a gas or vapor at operating conditions.

In heavy liquid service means that a piece of equipment in organic hazardous air pollutant service is not in gas/vapor service or in light liquid service.

In light liquid service means that a piece of equipment in organic hazardous air pollutant service contains a liquid that meets the following conditions:

1. The vapor pressure of one or more of the organic compounds is greater than 0.3 kilopascals at 20 °C;

2. The total concentration of the pure organic compounds constituents having a vapor pressure greater than 0.3 kilopascals at 20 °C is equal to or greater than 20 percent by weight of the total process stream; and

3. The fluid is a liquid at operating conditions.

(**Note:** Vapor pressures may be determined by the methods described in 40 CFR 60.485(e)(1).)

In liquid service means that a piece of equipment in organic hazardous air pollutant service is not in gas/vapor service.

In organic hazardous air pollutant or in organic HAP service means that a piece of equipment either contains or contacts a fluid (liquid or gas) that is at least 5 percent by weight of total organic HAP's as determined according to the provisions of § 63.180(d). The provisions of § 63.180(d) also specify how to determine that a piece of equipment is not in organic HAP service.

In vacuum service means that equipment is operating at an internal pressure which is at least 5 kilopascals below ambient pressure.

In-situ sampling systems means nonextractive samplers or in-line samplers.

Initial startup means the first time a new or reconstructed source begins production. Initial startup does not include operation solely for testing equipment. Initial startup does not include subsequent startups (as defined in this section) of processes following malfunctions or process shutdowns.

Instrumentation system means a group of equipment components used to condition and convey a sample of the process fluid to analyzers and instruments for the purpose of determining process operating conditions (e.g., composition, pressure, flow, etc.). Valves and connectors are the predominant type of equipment used in instrumentation systems; however, other types of equipment may also be included in these systems. Only valves nominally 0.5 inches and smaller, and connectors nominally 0.75 inches and smaller in diameter are considered instrumentation systems for the purposes of this subpart. Valves greater than nominally 0.5 inches and connectors greater than nominally 0.75 inches associated with instrumentation systems are not considered part of instrumentation systems and must be monitored individually.

Liquids dripping means any visible leakage from the seal including dripping, spraying, misting, clouding, and ice formation. Indications of liquid dripping include puddling or new stains that are indicative of an existing evaporated drip.

Nonrepairable means that it is technically infeasible to repair a piece of equipment from which a leak has been detected without a process shutdown.

Open-ended valve or line means any valve, except pressure relief valves, having one side of the valve seat in contact with process fluid and one side open to atmosphere, either directly or through open piping.

Plant site means all contiguous or adjoining property that is under common control, including properties that are separated only by a road or other public right-of-way. Common control includes properties that are owned, leased, or operated by the same entity, parent entity, subsidiary, or any combination thereof.

Pressure release means the emission of materials resulting from the system pressure being greater than the set pressure of the pressure relief device. This release can be one release or a series of releases over a short time period due to a malfunction in the process.

Pressure relief device or valve means a safety device used to prevent operating pressures from exceeding the maximum allowable working pressure of the process equipment. A common pressure relief device is a spring-loaded pressure relief valve. Devices that are actuated either by a pressure of less than or equal to 2.5 psig or by a vacuum are not pressure relief devices.

Process shutdown means a work practice or operational procedure that stops production from a process or part of a process during which it is technically feasible to clear process material from a process or part of a process consistent with safety constraints and during which repairs can be effected. An unscheduled work practice or operational procedure that stops production from a process or part of a process for less than 24 hours is not a process

shutdown. An unscheduled work practice or operational procedure that would stop production from a process or part of a process for a shorter period of time than would be required to clear the process or part of the process of materials and start up the process, and would result in greater emissions than delay of repair of leaking components until the next scheduled process shutdown, is not a process shutdown. The use of spare equipment and technically feasible bypassing of equipment without stopping production are not process shutdowns.

Repaired means that equipment is adjusted, or otherwise altered, to eliminate a leak as defined in the applicable sections of this appendix.

Sampling connection system means an assembly of equipment within a process unit used during periods of representative operation to take samples of the process fluid. Equipment used to take nonroutine grab samples is not considered a sampling connection system.

Sensor means a device that measures a physical quantity or the change in a physical quantity, such as temperature, pressure, flow rate, pH, or liquid level.

Set pressure means the pressure at which a properly operating pressure relief device begins to open to relieve atypical process system operating pressure.

Startup means the setting in operation of a piece of equipment or a control device that is subject to this subpart.

§ GGGA–3 References

(a) The owner or operator of a source subject to this appendix shall comply with the following sections of subpart H, except that references to § 63.160 and § 63.162 shall mean § GGGA–1 of this appendix; references to § 63.161 shall mean § GGGA–2 of this appendix; references to § 63.163 and § 63.173 shall mean § GGGA–4 of this appendix; references to § 63.167 shall mean § GGGA–5 of this appendix; references to § 63.168 shall mean § GGGA–6 of this appendix; references to § 63.170 shall be included in the requirements set forth in § 63.1252(c); references to § 63.171 shall mean § GGGA–3(a)(5) of this appendix; references to § 63.172 shall mean § GGGA–3(a)(6) of this appendix; references to § 63.181 shall mean § GGGA–8 of this appendix; and references to § 63.182 shall mean § GGGA–9 of this appendix. The term ''process unit'' as used in subpart H shall be considered to be defined the same as ''process'' for sources subject to this subpart GGG:

(1) § 63.164, Compressors;

(2) § 63.165, Pressure relief devices in gas/vapor service;

(3) § 63.166, Sampling connection systems;

(4) § 63.169, Pumps, valves, connectors, and agitators in heavy liquid service; instrumentation systems; and pressure relief devices in liquid service;

(5) § 63.171, Delay of repair, except

Section 63.171(a) shall be changed to read: Delay of repair of equipment for which leaks have been detected is allowed if one of the following conditions exist:

(i) § 63.171(a)(1) is added to read: The repair is technically infeasible without a process shutdown. Repair of this equipment shall occur by the end of the next scheduled process shutdown.

(ii) § 63.171(a)(2) is added to read: 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.

(6) § 63.172, Closed-vent systems and control devices, for closed-vent systems used to comply with this subpart, and for control devices used to comply with this appendix only, except

(i) § 63.172(k) and (l) shall not apply. Instead, references to these paragraphs shall mean § GGGA–7.

(ii) 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.

(7) § 63.174, Connectors, except

(i) § 63.174(f) and (g) shall not apply. Instead, references to these paragraphs shall mean § GGGA–7.

(ii) Days that the connector are not in organic HAP service shall not be considered part of the 3 month period in § 63.174(e).

(8) § 63.175, Quality improvement program for valves, except

(i) § 63.175(a) is changed to read: An owner or operator may elect to comply with one of the alternative quality improvement programs specified in paragraphs (d) and (e) of this section. The decision to use one of these alternative provisions to comply with the requirements of § 63.168(d)(1)(ii) of this subpart must be made during the second year of compliance for existing and new processes.

(ii) The ''start of Phase III'' shall mean the ''compliance date'' as specified in § 63.1250. The phrase ''of Phase III'' shall mean ''after the compliance date'' as specified in § 63.1250.

(9) § 63.176, Quality improvement program for pumps, except

(i) § 63.176(a) is changed to read: If, on a 1-year rolling average, the greater of either 10 percent of the pumps in a process (or affected source) or three pumps in a process (or affected source) leak, the owner or operator may elect to comply with the requirements of this section as specified. The decision to use this provision to comply with the requirements of § 63.163(d)(2) of this subpart must be made during the second year of compliance for existing and new processes.

(ii) § 63.176(a)(1) and (2), and (d)(8) shall not apply.

(10) § 63.177, Alternative means of emission limitation: General;

(11) § 63.178, Alternative means of emission limitation: Batch processes;

(12) § 63.179, Alternative means of emission limitation: Enclosed-vented process units;

(13) § 63.180, Test methods and procedures, except § 63.180(b)(4)(ii)(A–C) are replaced by (b)(4)(ii) that reads: A mixture of methane and air at 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 paragraph (b)(4)(iii) of this section.

§ GGGA–4 Standards: Pumps in Light Liquid Service and Agitators in Gas/Vapor Service and in Light Liquid Service

(a) The provisions of this section apply to each pump that is in light organic HAP liquid service, and to each agitator in organic HAP gas/vapor service or in light organic HAP liquid service.

(b)(1) Each pump and agitator subject to this section shall be monitored quarterly to detect leaks by the method specified in § 63.180(b) of this subpart, except as provided in § 63.177, § GGGA–7, and paragraphs (e) through (i) of this section.

(2) The instrument reading, as determined by the method as specified in § 63.180(b), that defines a leak is:

(i) For agitators, an instrument reading of 10,000 parts per million or greater.

(ii) For pumps, an instrument reading of 2,000 parts per million or greater.

(3) Each pump and agitator shall be checked by visual inspection each calendar week for indications of liquids dripping from the pump or agitator seal. If there are indications of liquids dripping from the seal, a leak is detected.

(c)(1) 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 (c)(3) of this section or § GGGA–3(a)(5) of this appendix.

(2) A first attempt at repair shall be made no later than 5 calendar days after the leak is detected. First attempts at repair include, but are not limited to, the following practices where practicable:

(i) Tightening of packing gland nuts.

(ii) Ensuring that the seal flush is operating at design pressure and temperature.

(d) For pumps:

(1) The owner or operator shall decide no later than the first monitoring period whether to calculate percent leaking pumps on a process basis or on an affected source-wide basis. Once the owner or operator has decided, all subsequent percent calculations shall be made on the same basis.

(2) If, calculated on a 1-year rolling average, the greater of either 10 percent of the pumps in a process or three pumps in a process leak, the owner or operator shall either:

(i) Monitor each pump once per month; or

(ii) Implement a quality improvement program for pumps that complies with the requirements of § 63.176 and monitor quarterly.

(3) The number of pumps at a process shall be the sum of all the pumps in organic HAP service, except that pumps found leaking in a continuous process within 1 quarter after startup of the pump shall not count in the percent leaking pumps calculation for that one monitoring period only.

(4) Percent leaking pumps shall be determined by the following equation:

$$\%P_L=[(P_L-P_S)/(P_T-P_S)]\times 100$$

Where:

$\%P_L$=Percent leaking pumps
P_L=Number of pumps found leaking as determined through quarterly monitoring as required in paragraphs (b)(1) and (b)(2) of this section.
P_T=Total pumps in organic HAP service, including those meeting the criteria in paragraphs (e) and (f) of this section.
P_S=Number of pumps leaking within 1 quarter of startup during the current monitoring period.

(e) Each pump or agitator equipped with a dual mechanical seal system that includes a barrier fluid system is exempt from the requirements of paragraphs (a) through (d) of this section, provided the following requirements are met:

(1) Each dual mechanical seal system is:

(i) Operated with the barrier fluid at a pressure that is at all times greater than the pump/agitator stuffing box pressure; or

(ii) Equipped with a barrier fluid degassing reservoir that is connected by a closed-vent system to a control device that complies with the requirements of § GGGA–3(a)(6); or

(iii) Equipped with a closed-loop system that purges the barrier fluid into a process stream.

(2) The barrier fluid is not in light liquid service.

(3) Each barrier fluid system is equipped with a sensor that will detect failure of the seal system, the barrier fluid system, or both.

(4) Each pump/agitator is checked by visual inspection each calendar week for indications of liquids dripping from the pump/agitator seal.

(i) If there are indications of liquids dripping from the pump/agitator seal at the time of the weekly inspection, the pump/agitator shall be monitored as specified in § 63.180(b) to determine if there is a leak of organic HAP in the barrier fluid.

(ii) If an instrument reading of 2,000 parts per million or greater is measured for pumps, or 10,000 parts per million or greater is measured for agitators, a leak is detected.

(5) Each sensor as described in paragraph (e)(3) of this section is observed daily or is equipped with an alarm unless the pump is located within the boundary of an unmanned plant site.

(6)(i) The owner or operator determines, based on design considerations and operating experience, criteria applicable to the presence and frequency of drips and to the sensor that indicates failure of the seal system, the barrier fluid system, or both.

(ii) If indications of liquids dripping from the pump/agitator seal exceed the criteria established in paragraph (e)(6)(i) of this section, or if, based on the criteria established in paragraph (e)(6)(i) of this section, the sensor indicates failure of the seal system, the barrier fluid system, or both, a leak is detected.

(iii) 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 § GGGA–3(a)(5) of this appendix.

(iv) A first attempt at repair shall be made no later than 5 calendar days after each leak is detected.

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

(g) 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 § GGGA–3(a)(6) is exempt from the requirements of paragraphs (b) through (e) of this section.

(h) Any pump/agitator that is located within the boundary of an unmanned plant site is exempt from the weekly visual inspection requirement of paragraphs (b)(3) and (e)(4) of this section, and the daily requirements of paragraph (e)(5) of this section, provided that each pump/agitator is visually inspected as often as practicable and at least monthly.

(i) If more than 90 percent of the pumps at a process meet the criteria in either paragraph (e) or (f) of this section, the process is exempt from the requirements of paragraph (d) of this section.

§ GGGA–5 Standards: Open-Ended Valves or Lines

(a)(1) Each open-ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve, except as provided in § 63.177 and paragraph (d) of this section.

(2) 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.

(b) Each open-ended valve or line equipped with a second valve shall be operated in a manner such that the valve on the process fluid end is closed before the second valve is closed.

(c) When a double block and bleed system is being used, the bleed valve or line may remain open during operations that require venting the line between the block valves but shall comply with paragraph (a) of this section at all other times.

(d) Open-ended valves or lines in an emergency shutdown system which are designed to open automatically in the event of a process upset are exempt from the requirements of paragraphs (a), (b) and (c) of this section.

(e) Open-ended valves or lines containing materials which would autocatalytically polymerize or, would prevent an explosion, serious overpressure, or other safety hazard if capped or equipped with a double block and bleed system as specified in paragraphs (a) through (c) of this section are exempt from the requirements of paragraph (a) through (c) of this section.

§ GGGA–6 Standards: Valves in Gas/Vapor Service and in Light Liquid Service

(a) The provisions of this section apply to valves that are either in gas organic HAP service or in light liquid organic HAP service.

(1) For existing and new affected sources, all valves subject to this section shall be monitored, except as provided in § 63.177 and § GGGA–7, by no later than 1 year after the compliance date.

(b) The owner or operator of a source subject to this appendix shall monitor all valves, except as provided in § 63.177 and § GGGA–7, at the intervals specified in paragraph (d) of this section and shall comply with all other provisions of this section, except as provided in § GGGA–3(a)(5), § 63.178, and § 63.179.

(1) The valves shall be monitored to detect leaks by the method specified in § 63.180(b).

(2) An instrument reading of 500 parts per million or greater defines a leak.

(c) [Reserved]

(d) After conducting the initial survey required in paragraph (a)(1) of this section, the owner or operator shall monitor valves for leaks at the intervals specified below:

(1) At processes with 2 percent or greater leaking valves, calculated according to paragraph (e) of this section, the owner or operator shall either:

(i) Monitor each valve once per month; or

(ii) Implement a quality improvement program for valves that complies with the requirements of § 63.175(d) or (e) and monitor quarterly.

(2) At processes with less than 2 percent leaking valves, the owner or operator shall monitor each valve once each quarter, except as provided in paragraphs (d)(3) and (d)(4) of this section.

(3) At processes with less than 1 percent leaking valves, the owner or operator may elect to monitor each valve once every 2 quarters.

(4) At processes with less than 0.5 percent leaking valves, the owner or operator may elect to monitor each valve once every 4 quarters.

(e)(1) Percent leaking valves at a process shall be determined by the following equation:

$$\%V_L=[V_L/(V_T+V_C)]\times 100$$

Where:

$\%V_L$=Percent leaking valves.
V_L=Number of valves found leaking excluding nonrepairables as provided in paragraph (e)(3)(i) of this section.
V_T=Total valves monitored, in a monitoring period excluding valves monitored as required by (f)(3) of this section.
V_C=Optional credit for removed valves=0.67×net number (i.e., total removed-total added) of valves in organic HAP service removed from process after the effective date for existing processes, and after the date of initial startup for new sources. If credits are not taken, then V_C=0.

(2) For use in determining monitoring frequency, as specified in paragraph (d) of this section, the percent leaking valves shall be calculated as a rolling average of two consecutive monitoring periods for monthly, quarterly, or semiannual monitoring programs; and as an average of any three out of four consecutive monitoring periods for annual monitoring programs.

(3)(i) Nonrepairable valves shall be included in the calculation of percent leaking valves the first time the valve is identified as leaking and nonrepairable and as required to

comply with paragraph (e)(3)(ii) of this section. Otherwise, a number of nonrepairable valves (identified and included in the percent leaking calculation in a previous period) up to a maximum of 1 percent of the total number of valves in organic HAP service at a process may be excluded from calculation of percent leaking valves for subsequent monitoring periods.

(ii) If the number of nonrepairable valves exceeds 1 percent of the total number of valves in organic HAP service at a process, the number of nonrepairable valves exceeding 1 percent of the total number of valves in organic HAP service shall be included in the calculation of percent leaking valves.

(f)(1) When a leak is detected, it shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in § GGGA–3(a)(5) of this appendix.

(2) A first attempt at repair shall be made no later than 5 calendar days after each leak is detected.

(3) When a leak is repaired, the valve shall be monitored at least once within the first 3 months after its repair. Days that the valve are not in organic HAP service shall not be considered part of this 3-month period.

(g) First attempts at repair include, but are not limited to, the following practices where practicable:

(1) Tightening of bonnet bolts,

(2) Replacement of bonnet bolts,

(3) Tightening of packing gland nuts, and

(4) Injection of lubricant into lubricated packing.

(h) Any equipment located at a plant site with fewer than 250 valves in organic HAP service in the affected source is exempt from the requirements for monthly monitoring and a quality improvement program specified in paragraph (d)(1) of this section. Instead, the owner or operator shall monitor each valve in organic HAP service for leaks once each quarter, or comply with paragraphs (d)(3) or (d)(4) of this section.

§ GGGA–7 Unsafe To Monitor, Difficult To Monitor, and Inaccessible Equipment

(a) Equipment subject to this appendix shall not be required to comply with the monitoring requirements of this appendix if it meets the definition of difficult to monitor or unsafe to monitor as specified in paragraphs (b) or (c) of this section. Agitators and connectors will also be subject to the inaccessible to monitor requirements in paragraph (d) of this section. Specific paragraphs that will no longer apply to such equipment are as follows:

(1) For pumps and agitators, §§ GGGA–4 (b), (c), and (d) shall not apply.

(2) For valves, § GGGA–6 (b), (c), (d), (e), and (f) shall not apply.

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

(4) For connectors, § 63.174 (b), (c), (d), and (e) shall not apply.

(b) Equipment that is designated, as described in § GGGA–8(b)(7) of this appendix, as unsafe-to-monitor is subject to the exemptions of paragraph (a) of this section if:

(1) The owner or operator of the equipment determines that it is unsafe to monitor because monitoring personnel would be exposed to an immediate danger as a consequence of complying with the paragraphs referenced in (a)(1) through (4) of this section.

(2) The owner or operator has 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.

(c) Equipment that is designated, as described in § GGG–8(b)(7) of this appendix, as difficult to monitor is subject to the exemptions of paragraph (a) of this section if:

(1) The owner or operator of the equipment determines that the equipment cannot be monitored without elevating the monitoring personnel more than 2 meters above a support surface or it is not accessible at anytime in a safe manner;

(2) The process unit within which the equipment is located is an existing source or the owner or operator designates less than 3 percent of the total number of valves in a new source as difficult to monitor; and

(3) The owner or operator of the equipment follows a written plan that requires monitoring of the equipment at least once per calendar year.

(d) Agitators and connectors designated as inaccessible are subject to the exemptions of paragraph (a) of this section if:

(1) The equipment is inaccessible because it is:

(i) Buried;

(ii) Insulated in a manner that prevents access to the equipment by a monitor probe;

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

(iv) 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;

(v) 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.

(2) For pumps, agitators, and valves, the process within which the equipment is located is an existing source or the owner or operator designates less than 3 percent of the total number of components of that type (e.g., pumps, agitators, or valves) in a new source as inaccessible; and

(3) If any inaccessible equipment 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 § GGGA–8 of this appendix.

§ GGGA–8 Recordkeeping Requirements

(a) An owner or operator of more than one process subject to the provisions of this appendix may comply with the recordkeeping requirements for these processes in one recordkeeping system if the system identifies with each record the program being implemented (e.g., quarterly monitoring, quality improvement) for each type of equipment. All records and information required by this section shall be maintained in a manner that can be readily accessed at the plant site. This could include physically locating the records at the plant site or accessing the records from a central location by computer at the plant site.

(b) Except as provided in paragraph (e) of this section and in paragraph GGGA–1(i), the following information pertaining to all equipment subject to the requirements in this appendix shall be recorded:

(1)(i) A list of identification numbers for equipment (except connectors exempt from monitoring and recordkeeping identified in § 63.174 and instrumentation systems) subject to the requirements of this appendix. Equipment need not be individually identified if all equipment in a designated area or length of pipe subject to the provisions of this appendix are identified as a group, and the number of components of each type of equipment (pumps, valves, etc.) subject is indicated. The list for each type of equipment shall be complete no later than the completion of the initial survey required for that component. The list of identification numbers shall be updated, if needed, to incorporate equipment changes within 15 calendar days of the completion of each monitoring survey for the type of equipment component monitored.

(ii) A schedule for monitoring connectors subject to the provisions of § 63.174(a) and valves subject to the provisions of § GGGA–6(d) of this appendix.

(iii) Physical tagging of the equipment to indicate that it is in organic HAP service is not required. Equipment subject to the provisions of this appendix may be identified on a plant site plan, in log entries, or by other appropriate methods.

(2)(i) A list of identification numbers for equipment that the owner or operator elects to equip with a closed-vent system and control device, under the provisions of § GGGA–4(g), § 63.164(h), or § 63.165(c).

(ii) A list of identification numbers for compressors that the owner or operator elects to designate as operating with an instrument reading of less than 500 parts per million above background, under the provisions of § 63.164(i).

(3)(i) A list of identification numbers for pressure relief devices subject to the provisions in § 63.165(a).

(ii) A list of identification numbers for pressure relief devices equipped with rupture disks, under the provisions of § 63.165(d).

(4) Identification of instrumentation systems subject to the provisions of this appendix. Individual components in an instrumentation system need not be identified.

(5) The owner or operator may develop a written procedure that identifies the conditions that justify a delay of repair. The written procedures may be included as part of the startup/shutdown/malfunction plan, required by § 63.6(e)(3), for the source or may be part of a separate document that is maintained at the plant site. In such cases, reasons for delay of repair may be documented by citing the relevant sections of the written procedure.

(6) The following information shall be recorded for each dual mechanical seal system:

(i) Design criteria required in §§ GGGA–4(e)(6)(i) and 63.164(e)(2), and an explanation of the design criteria; and

(ii) Any changes to these criteria and the reasons for the changes.

(7) The following information pertaining to all equipment subject to the requirements of § GGGA–7, and all equipment subject to the requirements of § GGGA–3(a)(5)(iii) shall be recorded:

(i) Identification of equipment designated as unsafe to monitor, difficult to monitor, or inaccessible and the plan for monitoring or inspecting this equipment.

(8)(i) A list of valves removed from and added to the process, as described in § GGGA–6(e)(1) of this appendix, if the net credits for removed valves is expected to be used.

(ii) A list of connectors removed from and added to the process, as described in § 63.174(i)(1), and documentation of the integrity of the weld for any removed connectors, as required in § 63.174(j). This is not required unless the net credits for removed connectors is expected to be used.

(9) For batch processes that the owner or operator elects to monitor as provided under § 63.178(c), a list of equipment added to batch product processes since the last monitoring period required in §§ 63.178(c)(3)(ii) and (3)(iii). This list must be completed for each type of equipment within 15 calendar days of the completion of the each monitoring survey for the type of equipment monitored.

(c) For visual inspections of equipment subject to the provisions of this appendix (e.g., §§ GGGA–4(b)(3), GGGA–4(e)(4)(i)), the owner or operator shall document that the inspection was conducted and the date of the inspection. The owner or operator shall maintain records as specified in paragraph (d) of this section for leaking equipment identified in this inspection, except as provided in paragraph (e) of this section. These records shall be retained for 2 years.

(d) When each leak is detected as specified in §§ GGGA–4 and 63.164; §§ GGGA–6 and 63.169; and §§ 63.172 and 63.174 of this subpart, the following information shall be recorded and kept for 2 years:

(1) The instrument and the equipment identification number and the operator name, initials, or identification number.

(2) The date the leak was detected and the date of first attempt to repair the leak.

(3) The date of successful repair of the leak.

(4) If postrepair monitoring is required, maximum instrument reading measured by Method 21 of 40 CFR part 60, appendix A after it is successfully repaired or determined to be nonrepairable.

(5) ''Repair delayed'' and the reason for the delay if a leak is not repaired within 15 calendar days after discovery of the leak.

(i) The owner or operator may develop a written procedure that identifies the conditions that justify a delay of repair. In such cases, reasons for delay of repair may be documented by citing the relevant sections of the written procedure.

(ii) If delay of repair was caused by depletion of stocked parts, there must be documentation that the spare parts were sufficiently stocked onsite before depletion and the reason for depletion.

(6) If repairs were delayed, dates of process shutdowns that occur while the equipment is unrepaired.

(7)(i) If the alternative in § 63.174(c)(1)(ii) is not in use for the monitoring period, identification, either by list, location (area or grouping), or tagging of connectors disturbed since the last monitoring period required in § 63.174(b), as described in § 63.174(c)(1).

(ii) The date and results of follow-up monitoring as required in § 63.174(c). If identification of disturbed connectors is made by location, then all connectors within the designated location shall be monitored.

(8) The date and results of the monitoring required in § 63.178(c)(3)(i) for equipment added to a batch process since the last monitoring period required in §§ 63.178(c)(3)(ii) and (c)(3)(iii). If no leaking equipment is found in this monitoring, the owner or operator shall record that the inspection was performed. Records of the actual monitoring results are not required.

(9) Copies of the periodic reports as specified in § GGGA–9(d) of this appendix, if records are not maintained on a computerized data base capable of generating summary reports from the records.

(e) The owner or operator of a batch product process who elects to pressure test the batch product process equipment train to demonstrate compliance with this appendix is exempt from the requirements of paragraphs (b), (c), (d), and (f) of this section. Instead, the owner or operator shall maintain records of the following information:

1(1) The identification of each product, or product code, produced during the calendar year. It is not necessary to identify individual items of equipment in a batch product process equipment train.

(2) Records demonstrating the proportion of the time during the calendar year the equipment is in use in a batch process that is subject to the provisions of this subpart. Examples of suitable documentation are records of time in use for individual pieces of equipment or average time in use for the process unit. These records are not required if the owner or operator does not adjust monitoring frequency by the time in use, as provided in § 63.178(c)(3)(iii).

(3) Physical tagging of the equipment to identify that it is in organic HAP service and subject to the provisions of this appendix is not required. Equipment in a batch product process subject to the provisions of this appendix may be identified on a plant site plan, in log entries, or by other appropriate methods.

(4) The dates of each pressure test required in § 63.178(b), the test pressure, and the pressure drop observed during the test.

(5) Records of any visible, audible, or olfactory evidence of fluid loss.

(6) When a batch product process equipment train does not pass two consecutive pressure tests, the following information shall be recorded in a log and kept for 2 years:

(i) The date of each pressure test and the date of each leak repair attempt.

(ii) Repair methods applied in each attempt to repair the leak.

(iii) The reason for the delay of repair.

(iv) The expected date for delivery of the replacement equipment and the actual date of delivery of the replacement equipment.

(v) The date of successful repair.

(f) The dates and results of each compliance test required for compressors subject to the provisions in § 63.164(i) and the dates and results of the monitoring following a pressure release for each pressure relief device subject to the provisions in §§ 63.165(a) and (b). The results shall include:

(1) The background level measured during each compliance test.

(2) The maximum instrument reading measured at each piece of equipment during each compliance test.

(g) The owner or operator shall maintain records of the information specified in paragraphs (g)(1) through (g)(3) of this section for closed-vent systems and control devices subject to the provisions of § GGGA–3(a)(6). The records specified in paragraph (g)(1) of this section shall be retained for the life of the equipment. The records specified in paragraphs (g)(2) and (g)(3) of this section shall be retained for 2 years.

(1) The design specifications and performance demonstrations specified in paragraphs (g)(1)(i) through (g)(1)(iv) of this section.

(i) Detailed schematics, design specifications of the control device, and piping and instrumentation diagrams.

(ii) The dates and descriptions of any changes in the design specifications.

(iii) The flare design (i.e., steam-assisted, air assisted, or nonassisted) and the results of the compliance demonstration required by § 63.11(b) of subpart A of this part.

(iv) A description of the parameter or parameters monitored, as required in § GGGA–3(a)(6)(e), to ensure that control devices are operated and maintained in conformance with their design and an explanation of why that parameter (or parameters) was selected for the monitoring.

(2) Records of operation of closed-vent systems and control devices.

(i) Dates and durations when the closed-vent systems and control devices required in § GGGA–4 and §§ 63.164 through 63.166 are not operated as designed as indicated by the monitored parameters, including periods when a flare pilot light system does not have a flame.

(ii) Dates and durations during which the monitoring system or monitoring device is inoperative.

(iii) Dates and durations of startups and shutdowns of control devices required in § GGGA–4 and §§ 63.164 through 63.166.

(3) Records of inspections of closed-vent systems subject to the provisions of § 63.172.

(i) For each inspection conducted in accordance with the provisions of § 63.172(f)(1) or (f)(2) during which no leaks were detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected.

(ii) For each inspection conducted in accordance with the provisions of § 63.172(f)(1) or (f)(2) during which leaks

were detected, the information specified in paragraph (d) of this section shall be recorded.

(h) Each owner or operator of equipment subject to the requirements of §§ 63.175 and 63.176 shall maintain the records specified in paragraphs (h)(1) through (h)(9) of this section for the period of the quality improvement program for the equipment.

(1) For owners or operators who elect to use a reasonable further progress quality improvement program, as specified in § 63.175(d):

(i) All data required in § 63.175(d)(2).

(ii) The percent leaking valves observed each quarter and the rolling average percent reduction observed in each quarter.

(iii) The beginning and ending dates while meeting the requirements of § 63.175(d).

(2) For owners or operators who elect to use a quality improvement program of technology review and improvement, as specified in § 63.175(e):

(i) All data required in § 63.175(e)(2).

(ii) The percent leaking valves observed each quarter.

(iii) Documentation of all inspections conducted under the requirements of § 63.175(e)(4), and any recommendations for design or specification changes to reduce leak frequency.

(iv) The beginning and ending dates while meeting the requirements of § 63.175(e).

(3) For owners or operators who elect to use the pump quality improvement program as specified in § 63.176:

(i) All data required in § 63.176(d)(2).

(ii) The rolling average percent leaking pumps.

(iii) Documentation of all inspections conducted under the requirements of § 63.176(d)(4), and any recommendations for design or specification changes to reduce leak frequency.

(iv) The beginning and ending dates while meeting the requirements of § 63.176(d).

(4) If a leak is not repaired within 15 calendar days after discovery of the leak, the reason for the delay and the expected date of successful repair.

(5) Records of all analyses required in §§ 63.175(e) and 63.176(d). The records will include the following:

(i) A list identifying areas associated with poorer than average performance and the associated service characteristics of the stream, the operating conditions and maintenance practices.

(ii) The reasons for rejecting specific candidate superior emission performing valve or pump technology from performance trials.

(iii) The list of candidate superior emission performing valve or pump technologies, and documentation of the performance trial program items required under §§ 63.175(e)(6)(iii) and 63.176(d)(6)(iii).

(iv) The beginning date and duration of performance trials of each candidate superior emission performing technology.

(6) All records documenting the quality assurance program for valves or pumps as specified in §§ 63.175(e)(7) and 63.176(d)(7).

(7) Records indicating that all valves or pumps replaced or modified during the period of the quality improvement program are in compliance with the quality assurance requirements in § 63.175(e)(7) and § 63.176(d)(7).

(8) Records documenting compliance with the 20 percent or greater annual replacement rate for pumps as specified in § 63.176(d)(8).

(9) If exempted by § 63.175(e)(6)(v) or § 63.176(d)(6)(v), information and data to show the corporation has fewer than 100 employees, including employees providing professional and technical contracted services.

(i) Information, data, and analysis used to determine that a piece of equipment or process is in heavy liquid service shall be recorded. Such a determination shall include an analysis or demonstration that the process fluids do not meet the criteria of ''in light liquid or gas service.'' Examples of information that could document this include, but are not limited to, records of chemicals purchased for the process, analyses of process stream composition, engineering calculations, or process knowledge.

(j) Identification, either by list, location (area or group) of equipment in organic HAP service less than 300 hours per year subject to the provisions of this appendix.

(k) Owners and operators choosing to comply with the requirements of § 63.179 shall maintain the following records:

(1) Identification of the process(es) and the organic HAP's they handle.

(2) A schematic of the process, enclosure, and closed-vent system.

(3) A description of the system used to create a negative pressure in the enclosure to ensure that all emissions are routed to the control device.

§ GGGA–9 Reporting Requirements

(a) Each owner or operator of a source subject to this appendix shall submit the reports listed in paragraphs (a)(1) through (a)(5) of this section. Owners or operators requesting an extension of compliance shall also submit a report as described in § 63.6 of subpart A.

(1) An Initial Notification as described in § 63.9 of subpart A, and

(2) A Notification of Compliance Status described in paragraph (c) of this section,

(3) Periodic Reports described in paragraph (d) of this section, and

(4) [Reserved]

(5) [Reserved]

(b) Each owner or operator of a source subject to this appendix shall submit a Notification of Compliance Status within 90 days after the compliance dates specified in § 63.1250(e).

(1) The notification shall provide the information listed in paragraphs (b)(1)(i) through (b)(1)(iii) of this section for each process subject to the requirements of §§ GGGA–3 through GGGA–8 of this appendix.

(i) Process identification.

(ii) Approximate number of each equipment type (e.g., valves, pumps) in organic HAP service, excluding equipment in vacuum service.

(iii) Method of compliance with the standard (for example, ''monthly leak detection and repair'' or ''equipped with dual mechanical seals'').

(2) The notification shall provide the information listed in paragraphs (b)(2)(i) and (b)(2)(ii) of this section for each process subject to the requirements of § 63.178(b).

(i) Batch products or product codes subject to the provisions of this appendix, and

(ii) Planned schedule for pressure testing when equipment is configured for production of products subject to the provisions of this appendix.

(3) The notification shall provide the information listed in paragraphs (b)(3)(i) and (b)(3)(ii) of this section for each process subject to the requirements in § 63.179.

(i) Process identification.

(ii) A description of the system used to create a negative pressure in the enclosure and the control device used to comply with the requirements of § GGGA–3(a)(6).

(4) Any change in the information submitted under this paragraph (b) shall be provided to the Administrator as a part of subsequent Periodic Reports. Section 63.9(j) shall not apply to the Notification of Compliance Status described in this paragraph (b).

(c) The owner or operator of a source subject to this appendix shall submit Periodic Reports.

(1) A report containing the information in paragraphs (c)(2), (c)(3), and (c)(4) of this section shall be submitted semiannually starting 6 months after the Notification of Compliance Status, as required in paragraph (b) of this section. The first periodic report shall cover the first 6 months after the compliance date specified in § 63.1250(e). Each subsequent periodic report shall cover the 6 month period following the preceding period.

(2) For equipment complying with the provisions of §§ GGGA–3 through GGGA–8 of this appendix, the summary information listed in paragraphs (i) through (xii) of this paragraph for each monitoring period during the 6-month period.

(i) The number of valves for which leaks were detected as described in § GGGA–6(b) of this appendix, the percent leakers, and the total number of valves monitored;

(ii) The number of valves for which leaks were not repaired as required in § GGGA–6(f) of this appendix, identifying the number of those that are determined nonrepairable;

(iii) The number of pumps and agitators for which leaks were detected as described in § GGGA–4(b) of this appendix, the percent leakers, and the total number of pumps and agitators monitored;

(iv) The number of pumps and agitators for which leaks were not repaired as required in § GGGA–4(c) of this appendix;

(v) The number of compressors for which leaks were detected as described in § 63.164(f);

(vi) The number of compressors for which leaks were not repaired as required in § 63.164(g);

(vii) The number of connectors for which leaks were detected as described in § 63.174(a), the percent of connectors leaking, and the total number of connectors monitored;

(viii) The number of connectors for which leaks were not repaired as required in § 63.174(d), identifying the number of those that are determined nonrepairable;

(ix) The facts that explain any delay of repairs and, where appropriate, why a process shutdown was technically infeasible.

(x) The results of all monitoring to show compliance with §§ 63.164(i), 63.165(a), and 63.172(f) conducted within the semiannual reporting period.

(xi) If applicable, the initiation of a monthly monitoring program under either §§ GGGA4–(d)(2)(i) or GGGA–6(d)(1)(i) of this appendix, or a quality improvement program under either § 63.175 or 63.176.

(xii) If applicable, notification of a change in connector monitoring alternatives as described in § 63.174(c)(1).

(3) For owners or operators electing to meet the requirements of § 63.178(b), the report shall include the information listed in paragraphs (i) through (v) of this paragraph for each process.

(i) Batch product process equipment train identification;

(ii) The number of pressure tests conducted;

(iii) The number of pressure tests where the equipment train failed either the retest or two consecutive pressure tests;

(iv) The facts that explain any delay of repairs; and

(v) The results of all monitoring to determine compliance with § 63.172(f) of this subpart.

(4) Any revisions to items reported in earlier Notification of Compliance Status, if the method of compliance has changed since the last report or any other changes to the information reported has occurred.

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