ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 63

[AD–FRL–6135–6]

RIN–2060–AE83

National Emission Standards for Hazardous Air Pollutants for Source Categories: Pharmaceuticals Production

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action promulgates national emission standards for hazardous air pollutants (NESHAP) to reduce air emissions of hazardous air pollutants (HAP) from existing and new facilities that manufacture pharmaceutical products. The Agency intends that this promulgated rule will have a common technology basis with a rule promulgated this date under the Clean Water Act (CWA) and published elsewhere in this issue of the **Federal Register**; this will allow coordinated and cost effective compliance planning by the industry. The standards implement section 112 of the Clean Air Act (CAA) as amended in 1990. The standards apply to major source facilities which produce pharmaceutical products.

The major HAP emitted by facilities covered by this final rule include methylene chloride, methanol, toluene, and hydrogen chloride. Methylene chloride is considered to be a probable human carcinogen and the other pollutants can cause noncancer health effects in humans. The promulgated rule is estimated to reduce HAP emissions from existing facilities by 22,000 megagrams per year (Mg/yr) (24,000 tons per year [tons/yr]). It also reduces volatile organic compound (VOC) emissions.

DATES: This regulation is effective on September 21, 1998. The incorporation by reference of certain publications listed in the regulation is approved by the Director of the Office of the Federal Register as of September 21, 1998. See the **SUPPLEMENTARY INFORMATION** section concerning judicial review.

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

FOR FURTHER INFORMATION CONTACT: For information concerning the final CAA standard, contact Mr. Randy McDonald at (919) 541–5402, Organic Chemicals Group, Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. For further information concerning the CWA effluent limitation guidelines pretreatment standards and new source performance standards, contact Dr. Frank H. Hund, at (202) 260–7786, Engineering and Analysis Division (4303), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. For information concerning applicability and rule determinations, contact your State or local representative or the appropriate EPA regional representatives. For a listing of EPA regional contacts, see the following **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION: An electronic version of documents from the Office of Air and Radiation (OAR) are available through EPA's OAR Technology Transfer Network Web site (TTNWeb). The TTNWeb is a collection of related Web sites containing information about many areas of air pollution science, technology, regulation, measurement, and prevention. The TTNWeb is directly accessible from the Internet via the World Wide Web at the following address, ''http://www.epa.gov/ttn''. Electronic versions of this preamble and rule are located under the OAR Policy and Guidance Information Web site, ''http://www.epa.gov/ttn/oarpg/'', under the **Federal Register** Notices section. If more information on the TTNWeb is needed, contact the Systems Operator at (919) 541–5384.

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

Category	Regulated entities
Industry	• Facilities described by the SIC codes 2833 and 2834 and NAICS codes 32541 and 325412. • Producers of finaished dosage forms of drugs, for example, tablets, capsules, solutions, that contain an active ingredient generally, but not necessarily, in association with inactive ingredients. • Producers of components whose intended primary use is to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals.

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

Region I

NESHAP (MACT) Coordinator, U.S. EPA Region I, John F. Kennedy Federal Building, One Congress Street, Boston, MA 02203–001, (617) 565–3438

Region II

Umesh Dholakia, U.S. EPA Region II, 290 Broadway Street, New York, NY 10007–1866, (212) 637–4023 (Umesh), (212) 637–4065 (Yue-On)

Region III

Bernard Turlinski, U.S. EPA Region III, 841 Chestnut Building, Philadelphia, PA 19107, (215) 566–2150

Region IV

Lee Page, U.S. EPA Region IV, Atlanta Federal Center, 61 Forsyth Street SW, Atlanta, GA 30303–3104, (404) 562–9131

Region V

Bruce Varner, U.S. EPA Region V, 77 West Jackson Boulevard, Chicago, IL 60604–3507, (312) 886–6793

Region VI

Robert Todd, U.S. EPA Region VI, First Interstate Bank Tower @ Fountain Place, 1445 Ross Avenue, 12th Floor, Suite 1200, Dallas, TX 75202–2733, (214) 665–2156

Region VII

Richard Tripp, U.S. EPA Region VII, Air Toxics Coordinator, 726 Minnesota Avenue, Kansas City, KS 66101, (913) 551–7566

Region VIII

Ann Marie Patrie, U.S. EPA Region VIII, Air Toxics Coordinator, 999 18th Street, Suite 500, Denver, CO 80202–2466, (303) 312–6524

Region IX

Nahid Zoueshtiagh, U.S. EPA Region IX, Air Division-6, 75 Hawthorne Street, San Francisco, CA 94105, (415) 744–1261

Region X

Andrea Wullenweber, U.S. EPA Region X, Air Toxics Coordinator, 1200 Sixth Avenue, Seattle, WA 98101, (206) 553–8760

Judicial review. Under section 307(b)(1) of the Act, judicial review of NESHAP is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit within 60 days of today's publication of this final rule. Under section 307(b)(2) of the Act, the requirements that are the subject of today's notice may not be challenged later in civil or criminal proceedings brought by the EPA to enforce these requirements. The information presented in this preamble is organized as follows:

I. List of Source Categories

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

Production methods used in the manufacture of pharmaceutical products include both batch and continuous operations, although batch operations make up a majority of the processes. The sizes of the facilities range from those that make one product at the rate of several hundred kilograms per year (kg/yr) to those that produce numerous pharmaceutical products on the scale of thousands of kilograms (megagrams [Mg]) per year. Air emissions of HAP compounds originate from breathing and withdrawal losses from storage tanks, venting of process vessels, leaks from piping and equipment used to transfer HAP compounds (equipment leaks), and volatilization of HAP from wastewater streams. Pollutants emitted from the production processes include a range of organic compounds, including VOC and several specific HAP. Among the most prevalent are methylene chloride and methanol, which account for nearly 70 percent of all HAP emissions from this industry. Detailed information describing manufacturing processes and emissions can be found in the basis and purpose document located in Docket A–96–03, Item No. III–B–01.

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

II. Background

A. Summary of Considerations Made in Developing These Standards

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

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

Today's final rule gives existing affected sources 3 years from the date of promulgation to comply. This is the maximum amount of time allowed by the Act. New affected sources are required to comply with the standard upon startup.

Included in today's final rule are methods for determining initial compliance as well as monitoring, recordkeeping, and reporting requirements. All of these components are necessary to ensure that affected sources comply with the standards both initially and over time. However, the

EPA has made every effort to simplify the requirements in the final rule. In addition, EPA has significantly reduced the amount of cross-referencing to other rules included in today's final standards at the request of facilities affected by these standards.

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

Representatives from other interested EPA offices and programs, including State and regional environmental agency personnel, and representatives from industry participated in the regulatory development process as MACT partnership members. For example, Region II, acting as the lead, worked closely with the States of New York and New Jersey as well as the pharmaceutical industry in developing the pollution prevention alternative. The partnership members were given opportunities to review and comment on the regulation prior to proposal and had the opportunity to comment on the proposed standards and to provide additional information during the public comment period that followed proposal.

The standards were proposed in the **Federal Register** on April 2, 1997 [62 FR 15754]. The preamble to the proposed standards and the basis and purpose document (Docket Item III–B–01) described the rationale for the proposed standards. Public comments were solicited at the time of proposal. To provide interested persons the opportunity for oral presentation of data, views, or arguments concerning the proposed standards, a public hearing was offered at proposal. However, the public did not request a hearing and, therefore, one was not held. The public comment period was from April 2, 1997 to July 2, 1997. More than 40 letters were received during the comment period. Commenters included industry representatives and State agencies. The comments were carefully considered, and changes were made in the proposed standards when determined by the EPA to be appropriate. A detailed discussion of these comments and responses can be found in the promulgation background information document (BID) which is located in Docket No. A–96–03, Item V–B–01, which is referenced in the ADDRESSES section of this preamble. The promulgation BID (summary of comments and responses document) serves as the basis for the revisions that have been made to the standards between proposal and promulgation. Section VI of this preamble discusses these major changes.

B. Regulatory Background

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

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

In 1994, EPA promulgated National Emission Standards for Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks. Pharmaceutical processes, defined as processes that synthesize pharmaceutical intermediates or final products using carbon tetrachloride or methylene chloride as a reactant or process solvent, are subject to this rule. Today's final rule requires control of leaking components that are currently not subject to the Negotiated Regulation for Equipment Leaks, but that contain and/or transport HAP and are associated with processes in this source category. Today's rule also allows sources subject to the Negotiated Regulation to comply with the LDAR provisions of this rule.

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

The Clean Water Act (CWA) and a recent settlement agreement (see 59 FR 25869) require EPA to develop effluent limitations guidelines and standards regulations for the pharmaceutical manufacturing industry.

On May 2, 1995 at 60 FR 21592, the EPA proposed best available technology (BAT) economically achievable and new source performance standards (NSPS) regulations for 53 volatile and semivolatile organic pollutants of which 17 are HAP. The Agency also proposed pretreatment standards for existing sources (PSES) and performance standards for new sources (PSNS) for 45 volatile organic pollutants of which 16 are HAP. The technology basis for the volatile organic limitations were based on steam stripping and advanced biological treatment. The proposed NSPS and PSNS differed from BAT and PSES, respectively, in that they were based on steam stripping plus distillation.

In the April 2, 1997 proposal EPA indicated that it was considering changing the BAT technology basis to advanced biological treatment only. The EPA also described three options under consideration for setting PSES and PSNS to address HAP and non-HAP wastewater pollutant discharges not controlled by the MACT standards. Under the first option compliance with the MACT standards would constitute compliance with PSES and PSNS. Option 2 involved compliance with the MACT standards plus additional PSES based on the performance data base for the 1995 proposed PSES for all volatile organic pollutants except alcohols and related pollutants, and Option 3 was the same as Option 2 except the additional pollutants included alcohols and related pollutants.

On August 8, 1997, at 62 FR 42720, the EPA published a Notice of Availability (NOA) to allow public comment on the data received since the May 2, 1995 CWA proposal and to further develop and revise options for the control of volatile organic pollutant discharges presented in the April 2, 1997 MACT proposal. The EPA provided the results of an EPA sampling study designed to provide information concerning the pass-through analysis for water soluble organic pollutants such as methanol and provided a discussion thereafter of the final pass-through analysis that EPA would be performing with respect to these and other

pollutants. The EPA also presented revisions to the pretreatment options (Options 2 and 3) which were first suggested in the CWA section of the April 2, 1997 MACT proposal.

Elsewhere in today's **Federal Register** EPA is publishing final effluent limitation guideline and standards under the Clean Water Act for the pharmaceutical manufacturing point source category.

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

A. Source of Authority for NESHAP Development

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

B. Criteria for Development of NESHAP

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

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

IV. Summary of Promulgated Standards

A. Source Categories to be Regulated

Today's final rule regulates HAP emissions from pharmaceutical production facilities that are determined to be major sources. These standards apply to existing sources as well as new sources. The final standards for existing and new source are summarized in Table 1.

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TABLE 1.—STANDARDS FOR NEW AND EXISTING SOURCES

Emission point	New or existing?	Applicability		Requirement
		Applicability Level	Cutoff	
Process vents ...	New	Processes	>400 lb HAP/yr uncontrolled.	98 percent control or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit.
	Existing	Processes	≥2,000 lb HAP/yr controlled.	93 percent control or 2,000 lb HAP/yr or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit (if there are any vents in a process not manifolded to the control device, process must still meet 93 percent control); and 98 percent* for individual vents (within a process) meeting cutoff based on flow and emissions or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit.
Storage tanks ...	New and existing.	≥10,000 gal and <20,000 gal.	≥1.9 psia vapor pressure of liquid stored.	90 percent control or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit.
		≥20,000 gal	≥1.9 psia vapor pressure of liquid stored.	95 percent control or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit**
Wastewater	New and existing.	>Mg/yr total HAP load from all POD from PMPU.	≥1,300 ppm at POD of Table 2 HAP.	99 percent reduction of Table 2 HAP.
			≥5,200 ppmw at POD of total HAP load.	99 percent reduction of Table 2 HAP. 90 percent reduction of Table 3 HAP. 95 percent reduction of total HAP using biotreatment.
		>1 Mg/yr total HAP load from facility.	≥10,000 ppmw at POD of total HAP load.	99 percent reduction of Table 2 HAP. 90 percent reduction of Table 3 HAP. 95 percent reduction of total HAP using biotreatment.
	New	>1 Mg/yr total HAP load from all POD from PMPU.	≥110,000 ppmw at POD of Table 3 HAP.	99 percent reduction of Table 3 HAP and existing source requirements.

TABLE 1.—STANDARDS FOR NEW AND EXISTING SOURCES—Continued

Emission point	New or existing?	Applicability		Requirement
		Applicability Level	Cutoff	
Equipment leaks	New and existing.	All components in HAP service.		LDAR program.

*For process vents controlled to 93 percent prior to April 2, 1997, no additional control is required.
**For tanks controlled to 90 percent prior to April 2, 1997, no additional control is required.

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

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

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

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

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

C. Affected Sources

Emission points identified from pharmaceuticals production include process vents, equipment leaks, storage tanks, wastewater collection and treatment systems, and heat exchange systems. The affected source subject to this subpart is any pharmaceutical manufacturing operation, as defined in § 63.1251 of today's final rule, that meets the following criteria: (1) it manufactures a pharmaceutical product, as defined in § 63.1251; (2) it is located at a plant site that is a major source as defined in section 112(a) of the Act; and (3) it processes, uses, or produces HAP. Based on this definition of affected source, new sources are created by reconstructing existing sources, constructing new ''greenfield'' facilities, or constructing an addition to an existing source which is a dedicated pharmaceutical manufacturing process unit (PMPU) and exceeds 10 tons/yr of an individual HAP or 25 tons/yr of combined HAP. Reconfigurations of existing equipment do not constitute ''construction'' and therefore NSM would not be triggered under this circumstance. Therefore, a new affected source subject to this subpart is any affected source for which construction or reconstruction commenced after April 2, 1997, and the standard was applicable at the time of construction or reconstruction, or any PMPU that is dedicated to manufacturing a single product that has the potential to emit 10 tons per year of any one HAP or 25 tons per year of combined HAP, for which construction commenced after April 2, 1997.

The PMPU is defined according to the equipment used to make a pharmaceutical product. The PMPU also includes storage tanks that are associated with the process.

D. Storage Tank Provisions

Today's final standards require existing and new sources to control emissions from storage tanks having volumes greater than or equal to 38 cubic meters (m^3) (10,000 gallons), and storing material with a vapor pressure of greater than or equal to 13.1 kPa (1.9 psi). The final standards require that emissions from storage tanks with capacities greater than or equal to 38 m^3 (10,000 gallons) and less than 75 m^3 (20,000 gallons) be reduced by 90 percent. Emissions from storage tanks greater than or equal to 75 m^3 (20,000 gallons) must be reduced by 95 percent.

One of the following control systems can be applied to meet these requirements:

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

The final rule also includes an alternative standard for any storage tank vents that are routed to an add-on control device. Under the alternative standard, an owner or operator may choose to comply with a total organic compound (TOC) and hydrogen halide and halogen limit of 20 ppmv or less, measured prior to dilution and at the outlet of the control device. The alternative standard is discussed in more detail in sections IV.K and VI.G of this preamble and is included in § 63.1253(d) of the final rule. Today's final rule does not provide for vapor balancing systems to be used as an alternative means of control for storage tanks.

E. Process Vent Provisions

The MACT standard for most existing process vents was set at the floor level of control, which was determined to be 93 percent control. The final standards require existing sources to reduce emissions from the sum of all vents within a process to 900 kg/yr (2,000 pounds per year [lb/yr]), considering control, or meet an overall process control level of 93 percent. The 2,000 lb/yr compliance option is limited to seven processes per year per facility. Additionally, a regulatory alternative beyond the floor was selected that requires 98 percent control of some large emission vents. Individual process vents (manifolded or nonmanifolded) meeting the annual emissions and flow rate criteria are required to achieve 98 percent control, independent of the overall 93 percent requirement. (Those process vents achieving 93 percent control prior to April 2, 1997 are not required to meet the 98 percent control requirement.) The MACT standard for process vents at new sources was set at the floor level of control. The MACT floor was determined from the best controlled similar source and is based on the most stringent control level achieved for both chemical synthesis and formulation type processes. Today's final standards for new sources require 98 percent control of vents in a process that has uncontrolled emissions greater than 182 kg/yr (400 lb/yr).

An alternative standard for process vents was added to the final rule [see § 63.1254(c)]. Under the alternative standard, an owner or operator may choose to comply with a TOC and hydrogen halide and halogen limit of 20 ppmv or less, measured prior to dilution and at the outlet of the control device. If only a portion of the process vents associated with a process comply with the alternative standard, then the remaining process vents must be controlled to the levels required by the standards (e.g., 93 percent for the sum of remaining vents and/or 98 percent control of some individual vents for existing sources and 98 percent control of the sum of remaining vents for new sources).

The process vent and storage tank standards also contain provisions for complying in essentially the same manner as is described by the alternative standard—by routing streams to control devices achieving an outlet concentration of TOC and hydrogen halide and halogen limit of 20 ppmv or less, measured prior to dilution. These provisions differ from those described under the Alternative standard only in the monitoring options available.

F. Wastewater Provisions

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

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

The final standards require that air emissions from wastewater collection systems be suppressed and that wastewater is treated. Compliance is demonstrated by one of the following methods:

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

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

A de minimis HAP concentration and flow rate exemption was added to today's final rule. Streams containing less than 5 ppmw of partially soluble and/or soluble HAP and a total yearly load of 0.05 kg/yr of partially soluble and/or soluble HAP are not considered wastewater, and thus, are exempted from the wastewater provisions in today's final rule.

G. Equipment Leaks

Today's final rule contains revisions to the proposed equipment leak requirements that were originally based on subpart H (of the HON rule). The final rule primarily contains changes to the standards for valves and connectors in gas/vapor service and light liquid service. The standards for valves in gas/vapor service and in light liquid service were changed as follows: the requirement to implement a quality improvement program and all references to § 63.175 have been removed; an allowance for monitoring every 2 years for those processes with less than 0.25 percent leaking valves has been added; an allowance for valve subgrouping was also added; the equation used to determine the percent of leaking valves in a process was changed to eliminate the optional credit for valves removed, Vc; and the rolling average of leaking valves was revised so that it is calculated as an average of the last 3 monitoring periods for annual or biannual monitoring programs. The monitoring schedule for connectors in gas/vapor service and light liquid service was revised to allow for decreased monitoring for those components with the lowest leak rates. For leak rates less than 0.25, the monitoring frequency for connectors is

now once every 8 years. Finally, the equipment leak provisions were removed from appendix GGGA to Section 63.1255.

H. Pollution Prevention Alternative

Today's final standards include a pollution prevention (P2) alternative standard that meets the MACT floor for existing sources and can be implemented in lieu of meeting the requirements for existing process vents, storage tanks, wastewater streams and equipment leaks. The P2 alternative only applies to existing sources and includes two options which are shown in Table 2. Under option 1, owners or operators can satisfy the requirements for all emission source types associated with each pharmaceutical manufacturing process unit (PMPU) by demonstrating that the production-indexed consumption of HAP has decreased by at least 75 percent from a baseline set no earlier than the 1987 calendar year. The production indexed HAP consumption factor is expressed as kg HAP consumed/kg product produced. Under the second P2 option, owners or operators must demonstrate at least a 50 percent reduction in the production indexed HAP consumption factor, plus an additional amount of reduction in HAP emissions through the use of add-on controls, such that the overall reduction in HAP emissions is at least 75 percent from the baseline period.

TABLE 2.—ALTERNATIVE P2 STANDARD

Option	Description of P2 option
1	Demonstrate at least a 75 percent reduction in the kg consumption/kg production factor from a baseline period.
2	Demonstrate at least a 50 percent reduction in the kg/kg factor, plus an additional reduction from add-on control equivalent to at least a 75 percent overall reduction in the kg/kg factor from baseline.

The following restrictions also apply to the pollution prevention standards in today's final rule. For any reduction in the production-indexed HAP consumption factor that is achieved by reducing a HAP that is also a VOC, an equivalent reduction in the production-indexed VOC consumption factor is required. For any reduction in the production-indexed HAP consumption factor that is achieved by reducing a HAP that is not a VOC, the production-indexed VOC consumption factor may not be increased. Also, the final rule allows owners or operators of PMPU's that generate HAP emissions to qualify for the pollution prevention alternative, provided that the HAP emissions generated in the PMPU are reduced to the required levels for process vents, storage tanks, wastewater streams and equipment leaks specified in §§ 63.1252 through 63.1256 of today's final standards. The baseline production-indexed HAP and VOC consumption factors must be based on consumption and production values averaged over the time period from startup of the process until the present time (assuming the process has been in operation at least 1 full year), or the first 3 years of operation (beginning no earlier than 1987), whichever is the lesser time period. Processes that began operation after April 2, 1997 are not eligible for the P2 alternative.

Today's final standards also require owners and operators complying with the P2 standard to submit a P2 Demonstration Summary as part of the Precompliance Notification Report that describes how the P2 alternative will be applied at their facilities. The minimum data requirements for the P2 Demonstration Summary are listed in § 63.1257(f) of today's final rule.

I. Heat Exchange Provisions

Today's final standards for heat exchange systems are unchanged from proposal. Owners or operators must comply with the heat exchange provisions listed in the HON at § 63.104 with two exceptions: (1) the monitoring frequency shall be no less than quarterly, and (2) owners or operators of heat exchange systems that meet current good manufacturing practice (CGMP) requirements at 21 CFR part 211 may elect to use the physical integrity of the reactor as the surrogate indicator of heat exchange system around reactors.

J. Emissions Averaging Provisions

The emissions averaging provisions in today's final rule are unchanged from proposal. The final rule allows emissions averaging among process vents and among storage tanks at existing sources. Restrictions on the use of emissions averaging are listed in § 63.1252(d) of today's final rule and are essentially the same as those contained in the HON. The alternative standard (see following section K) is not to be included in the emissions averaging provisions and/or calculations.

K. Alternative Standard

For owners or operators of affected sources that treat emissions with an add-on control device, an alternative standard has been added under §§ 63.1253(d) (storage tanks) and 63.1254(c) (process vents). To comply with today's alternative standard(s), the control device must achieve an outlet, undiluted TOC concentration, as calibrated based on methane or the predominant HAP, of 20 ppmv or less and a hydrogen halide and halogen concentration of 20 ppmv or less, as demonstrated through the test methods and procedures in § 63.1257 and monitoring provisions in § 63.1258. The applicability level is the control unit and all sources vented to the control unit which is considered one regulated entity. Because the applicability of this standard is focused on the control device, this scenario is considered one regulated entity with regard to the number of violations that would apply if there is an exceedance of the 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet concentration limit(s). The remaining process vents within a process not controlled by the alternative standard must be controlled to the percent reduction required by the standards.

L. Test Methods and Compliance Procedures

To determine compliance with the percent reduction requirement for pharmaceutical process vents, uncontrolled and controlled emissions from all process vents within the process shall be quantified to demonstrate the appropriate overall reduction requirements (93 percent or 98 percent). For process vents controlled by devices handling less than 10 tons/yr, the owner or operator can either test or use calculational methodologies to determine the uncontrolled and controlled emission rates from individual process vents. For process vents controlled by devices handling more than 10 tons/yr, tests are required to determine the reduction efficiency of each device. Performance test provisions require testing under worst-case conditions, but the final rule provides flexibility in determining these worst-case conditions. Control devices that have previously been tested under conditions required by this standard and condensers are exempt from emissions testing. Testing is not required for devices used to control emission streams from storage or wastewater sources exclusively. However, if testing is conducted, then the same methods apply.

M. Monitoring Requirements

Monitoring is required in the final rule to determine whether a source is in compliance on an ongoing basis. This monitoring is done either by continuously measuring emission

reductions directly or by continuously measuring a site-specific operating parameter, the value of which is established by the owner or operator during the initial compliance determination. The operating parameter value is defined as a single point at either a minimum or maximum value established for a control device that, if achieved on a daily average or block average by itself or in combination with one or more other operating parameter values, determines that an owner or operator is complying with the applicable operating limits. These parameters are required to be monitored at 15-minute intervals throughout the operation of the control device for devices controlling greater than 1 tons/yr. For devices controlling streams totaling less than 1 ton/yr, only a site-specific periodic verification that the devices are operating as designed is required to demonstrate continuous compliance. Owners and operators must determine the most appropriate method of verification and propose this method to the Agency for approval in the precompliance report, which is due 6 months prior to the compliance date of the standard. The monitoring requirements apply to all control devices, even those used exclusively for storage tanks or wastewater sources.

N. Recordkeeping and Reporting Requirements

Table 1 to subpart GGG was revised to clarify the specific requirements of the final rule and the referenced requirements in the General Provisions. A summary column describing the requirements of each part of the General Provisions has been added to Table 1 and additional comments address wording issues and exceptions to the General Provisions language.

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

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

A. Air Impacts

Today's final standards will reduce HAP emissions from existing sources by 22,000 Mg/yr (24,000 tons/yr) from the baseline level, a reduction of 65 percent from baseline, and 75 percent from uncontrolled. These reductions also will occur if facilities elect to implement the alternative pollution prevention standard. Since many of the HAP emitted by the pharmaceutical industry are also VOC, today's final standards also will reduce VOC emissions.

B. Water and Solid Waste Impacts

Much of the steam stripping operations will result in recoverable material. However, the new source requirement for very rich, soluble HAP-containing wastewater is expected to generate solid waste. The EPA estimates that an average of 900 tons of solid waste per year per facility will be generated as a result of today's final standards. However, biological treatment is a possible means of compliance.

C. Energy Impacts

Today's final standards for the pharmaceuticals source category will require an additional energy usage of $2,400 \times 10^9$ British thermal units per year (Btu/yr).

D. Cost Impacts

The emission reductions required by this regulation can be achieved using one or more of several different techniques. To determine costs, certain control scenarios were assumed. The scenarios used in costing were judged to be the most feasible scenarios possible for meeting the requirements of the standards from a technical and cost standpoint. The total control cost includes the capital cost to install the control device, the costs involved in operating the control device, and costs associated with monitoring the device to ensure compliance. Monitoring costs include the cost to purchase and operate monitoring devices, as well as reporting and recordkeeping costs required to demonstrate compliance. Nationwide, the total annual cost of this standard to the industry for existing and new sources is approximately $64 million and $11 million, respectively (1998 dollars). To estimate these annual costs, capital costs were annualized over 10 years (with no delay for installation). (The annual costs presented in the preamble to the effluent limitations guidelines and standards are lower than the above costs because they are based on a longer annualization period. Costs for the effluent guidelines limitations and standards are annualized over 16 years (a 1-year installation period plus a 15-year project life). As a result, annual costs for existing sources in the preamble to the effluent limitations guidelines and standards (referred to as pretax annualized costs for the MACT standards rule for all facilities) are reported at $58.4 million.) The EPA believes that monitoring, reporting, and recordkeeping costs will be substantially reduced for those facilities that choose to comply with today's final rule through either the P2 option or the alternative standard of 20 ppm TOC and 20 ppm hydrogen halides and halogens.

E. Economic Impacts

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

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

VI. Major Comments and Changes to the Proposed Standards

In response to comments received on the proposed standards, changes have been made to the final standards. While some of these changes are clarifications designed to make EPA's intent clearer, many of them are significant changes to the requirements of the proposed standards. A summary of the substantive comments and/or changes made since proposal are described in the following sections. Detailed responses to public comments are included in the promulgation BID: Summary of Public Comments and Responses (Docket Item No. V-B–01). Additional information on the final standards is contained in the docket for this rulemaking (see ADDRESSES section of this preamble).

A. Applicability Provisions and Definitions

1. General Applicability: Definition of Pharmaceutical Product

At proposal, pharmaceutical product was defined as ''any material described by the Standard Industrial Classification (SIC) Code 283, or any other fermentation, biological or natural extraction, or chemical synthesis product regulated by the Food and Drug Administration, including components (excluding excipients) of pharmaceutical formulations, or intermediates used in the production of a pharmaceutical product.'' Many commenters stated that, based on the proposed definition of pharmaceutical product, the general applicability of the standard is too broad, ambiguous, and

appears to overlap with other MACT standards that cover the chemical industry. Comments on the definition of pharmaceutical product focused on the following four areas: (1) the use of Standard Industrial Classification (SIC) codes, (2) the scope of products regulated by the FDA, (3) the meaning of the term ''intermediates,'' and (4) the exclusion of specific products/processes.

Many commenters suggested that instead of referencing SIC code 283, the definition of pharmaceutical product should be narrowed to include only SIC codes 2833 and 2834 because facilities classified under these two SIC codes produce pharmaceuticals as their primary product, and were the source of information and data that formed the basis for the proposed rule. Two other commenters stated that the use of SIC codes or the new North American Industrial Classification System (NAICS) codes in defining pharmaceutical products was inappropriate because of the ambiguous nature of SIC and NAICS code applicability, and that instead of using SIC or NAICS codes, the definition should clearly describe the characteristics of the processes that are subject to the rule. One of the commenters also provided a recommended definition of pharmaceutical product based upon the definition of ''drug product'' already established by the Food and Drug Administration at 21 CFR 210.3 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs).

Many commenters stated that the inclusion of the phrase, ''regulated by the Food and Drug Administration'' should be deleted from the definition of pharmaceutical products because many nondrug products such as cosmetics, food additives, plastics (food contact films) and dietary supplements, are regulated by the FDA and could be interpreted as being pharmaceutical products based on the proposed definition of pharmaceutical product. However, another commenter requested that EPA expand the definition of pharmaceutical products to include products regulated by the U.S. Department of Agriculture (USDA) as well as the FDA because the pharmaceutical industry produces animal biologics using the same processes used to produce human biologics, and therefore, HAP emitted from the production of animal biologics also should be regulated as part of the pharmaceutical NESHAP.

Many commenters stated that the use of the term ''intermediates'' in the definition of pharmaceutical product was confusing and brings many unintended chemicals and processes into the pharmaceutical NESHAP; and therefore, the term should be either clarified or deleted from the definition of pharmaceutical product. One commenter stated that inclusion of the term, ''intermediate,'' in the definition of pharmaceutical product makes it unclear how far back in the manufacturing chain a regulated entity must look when determining applicability. Many commenters stated that operations that manufacture raw materials (such as acids and solvents) that are not precursors to active ingredients in pharmaceutical products should not be regulated as part of the pharmaceutical NESHAP. Several commenters stated that the rule should only apply to processes which produce materials which exclusively or primarily are used to make drug active ingredients. Another commenter stated that EPA needs to clarify that intermediates already regulated by the HON are excluded from the pharmaceutical NESHAP.

Four commenters requested that EPA specifically exclude certain ''nonpharmaceutical products'' from the definition of pharmaceutical product. One commenter expressed concern that due to the inclusion of SIC code 2835 and the phrase, ''regulated by the FDA,'' in the pharmaceutical product definition, equipment used to manufacture medical devices or substances used in the manufacture of medical devices could be subject to the pharmaceutical NESHAP instead of the miscellaneous organic NESHAP (MON). Therefore, the commenter requested that ''medical devices'' be specifically excluded from the definition of pharmaceutical product. A second commenter stated that the rule should not apply to specialty chemical manufacturers who occasionally engage in tolling a pharmaceutical intermediate. The commenter further stated that tolling of pharmaceutical intermediates could be driven overseas if U.S. specialty chemical opera tions require long lead times to identify MACT requirements, develop compliance systems, and amend title V requirements. A third commenter suggested that EPA exclude contract manufacturing from the pharmaceutical rule, and allow it to be covered by the MON. The fourth commenter requested that EPA specifically exclude ''color additives and other inactive ingredients'' from the definition of pharmaceutical product because the commenter interpreted EPA's exclusion of excipients from the definition of pharmaceutical product to mean that the pharmaceutical NESHAP was only intended to cover active ingredients. The fourth commenter also provided a definition of excipients developed by the International Pharmaceutical Excipients Council.

The EPA considered all of the above comments and revised the definition of pharmaceutical product based on these and other considerations. The rationale for the revised definition is presented below.

The EPA agrees with the commenters that SIC codes may be ambiguous, were not developed with environmental regula tion in mind, and may not reflect individual processes within a facility, and therefore, that the use of SIC codes to define pharmaceutical product may introduce unintended ambiguity into applicability determinations. Also, EPA believes that the use of the newer NAICS codes in defining applicability would result in the same problems with ambiguity and intended use. However, based on industry survey responses, EPA recognizes that facilities primarily claiming SIC codes 2833 and 2834 and/or NAICS codes 325411 and 325412 produce medicinals and pharmaceuticals as their primary products. Therefore, for the sake of clarity and consistent with the survey responses, EPA has retained the SIC Codes and added the NAICS codes in the definition of pharmaceutical product.

The EPA also agrees that the term ''regulated by FDA'' is also ambiguous. As noted by one commenter, in 21 CFR section 207.10(e), FDA exempts from registration and drug listing, ''manufacturers of harmless inactive ingredients that are excipients, coloring, flavorings, emulsifiers, lubricants, preservatives, or solvents that become components of drugs, and who otherwise would not be required to register under this part.'' The EPA agrees that some of the processes used to manufacture such substances were not intended for coverage by this rule, and that was the intent of including the phrase ''regulated by FDA'' in the definition of pharmaceutical product in the proposed rule. Based on the comments, EPA believes that a less ambiguous way to define pharmaceutical product would be to base it on definitions contained in 21 CFR 210.3 (Current Good Manufacturing Practice in Manufacturing, Processing, or Holding of Drugs; General) for drug product or active ingredient. These definitions capture formulation products as well as pharmaceutical active ingredients and their precursors.

The proposed rule also was intended to cover intermediates that are manufactured prior to the final processing steps in which a compound becomes a pharma ceutical product. However, EPA recognizes the difficulty associated with defining an intermediate, especially the point at which a chemical becomes associated with pharma ceutical manufacturing. Because the pharmaceutical industry is characterized by numerous processes that may be conducted prior to the actual synthesis and isolation of active ingredients, EPA rejects the notion that, in order to simplify applicability, only those processes yielding active ingredients should be covered by the rule. Rather, EPA agrees with the suggestion that the rule be based on the primary intended use of the materials manufactured. By defining applicability according to primary use as pharmaceutical products or as their precursors, intermediates that are further processed to become active ingredients or drug components are covered. Therefore, in order to clarify the boundaries of the coverage of such precursors or intermediates, the definition of process was changed in the final rule to clarify that the provisions of the subpart apply to materials whose ''primary use'' is as a pharmaceutical product or precursor.

The ''primary use'' approach also addresses the comment regarding the exclusion of contract manufacturing from the pharmaceutical rule. Simply put, contract manufacturers will be subject to this standard during periods when they manufacture a pharmaceutical product. To simplify the determination of applicability for facilities that conduct contract manufacturing, some commenters suggested that the rule apply to processes whose primary product is a pharmaceutical active ingredient. The concept of primary product has been used in past regulations (e.g., HON, P&R IV, etc.) and was not considered in the proposed rule because there was a conscious effort to disengage production equipment from products manufactured. Because the standards are process-based, the intent of the proposal was to cover the production of pharmaceutical products, regardless of what pieces of equipment were used to manufacture them in the course of a year. Conceptually, the primary product definition makes sense for process lines that can be used to manufacture more than one product. In the pharmaceutical manufacturing industry, however, process equipment is reconfigured such that the same pieces of equipment may not always be part of the same process line. Under the current concept of primary product that appears in other rules, it would still be difficult to determine the primary product of a nondedicated process, because not all the same equipment would be associated with the ''process.'' However, by reverting back to the concept of ''primary use,'' owners and operators can clearly delineate applicability based on the intended use of materials they manufacture, and not the equipment they are manufactured in.

The revised definition for pharmaceutical product in today's final rule borrows heavily from definitions contained in 21 CFR 210.3 (Current Good Manufacturing Practice in Manufacturing, Processing, or Holding of Drugs; General). The revised definition of pharmaceutical product and a new definition for primary use are shown below. Also, definitions for ''active ingredient,'' ''component,'' and ''excipient'' have been included in today's final rule.

Pharmaceutical product means: (1) any material described by the standard industrial classification (SIC) code 2833 or 2834; (2) any material whose manufacturing process is described by the north american industrial classification system (NAICS) code 325411 or 325412; (3) a finished dosage form of a drug, for example, a tablet, capsule, solution, etc., that contains an active ingredient generally, but not necessarily, in association with inactive ingredients; or (4) any component whose intended primary use is to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals (the term does not include excipients, but includes drug components such as raw starting materials or precursors that undergo chemical change or processing before they become active ingredients).

Primary use means the single largest use of a material.

For reasons described above and in response to related comments, the applicability language in § 63.1250(a) also has been changed in the final rule such that the rule only applies to those pharmaceutical manufacturing operations that meet the following criteria: (1) they manufacture a pharmaceutical product, as defined in section 63.1251, (2) they are located at a plant site that is a major source as defined in section 112(a) of the Act, and (3) they process, use, or produce HAP. The third criterion was included in response to one commenter's concern that, while the rule covers all processes at a facility which is determined to be major source, some processes at those major sources do not emit HAP. The commenter also stated that although this situation may not pose a significant compliance problem, the lack of an exclusion for these non-HAP emitting processes posed an unwarranted regulatory burden. The EPA agreed with the commenter, and modified the applicability of the rule as described above.

2. Definition of PMPU and Pharmaceutical Manufacturing Operations

The EPA received several comments on the proposed definitions of PMPU and pharmaceutical manufacturing operations. At proposal, PMPU was defined as ''any processing equipment assembled to process materials and manufacture a pharmaceutical product and associated storage tanks, waste-water management units, or components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used in the manufacturing of a pharmaceutical product.'' Pharmaceutical manufacturing operations were defined to ''include PMPU's and other processes and operations as well as associated equipment such as heat exchange systems that are located at a facility for the purpose of manufacturing pharmaceuticals.''

One commenter stated that having both ''pharmaceutical manufacturing operation'' and PMPU in the proposed rule was confusing and redundant. The commenter stated that by having both terms, the rule implies that the definition of PMPU does not cover all of the equipment to be regulated by subpart GGG. The commenter further stated that the inclusion of the phrase ''associated equipment'' in the pharmaceutical manufacturing operations definition was unclear because the definition of PMPU already covers ''associated'' equipment. The commenter also stated that heat exchangers were given as an example of ''associated equipment'' under the definition of pharmaceutical manufacturing operation, but not included as an example in the definition of PMPU. For these reasons, the commenter suggested that the definition of pharmaceutical manufacturing operation be deleted entirely, and that heat exchangers be added to the list of examples of ''associated equipment'' in the PMPU definition.

Two commenters stated that wastewater management units should not be included in the definition of PMPU. One commenter stated that wastewater management units are not subject to the standard, but instead are used to comply with the standard. This commenter also pointed out that neither the HON's definition of chemical manufacturing process unit (CMPU) nor the Polymers and Resin I NESHAP definition of elastomer product process unit (EPPU) includes wastewater management units. The commenter further stated that including wastewater management units in the definition of PMPU could be interpreted to require new source MACT at an existing wastewater management unit if a new, major, dedicated PMPU is built that will contribute wastewaters to that unit. Another commenter stated that packaging operations (e.g., ''placement of dose forms, such as tablets, into containers, and assembly, closure, and labeling of these containers'') are not pharmaceutical manufacturing operations, and thus, should be explicitly excluded from the definition of pharmaceutical manufacturing operations.

Many commenters stated that the definition of PMPU should be modified to make it clear that a PMPU is a group of equipment. These commenters were concerned that, as written, the definition of PMPU could be interpreted to mean that an individual piece of equipment constitutes a PMPU, and thus, the addition of a single piece of equipment to an existing dedicated process line could trigger new source MACT.

Many commenters stated that a PMPU should be identified by its primary product and suggested adding language to the definition that makes it clear that PMPU's manufacture pharmaceutical products as their primary product.

After consideration of the above comments on the definitions of pharmaceutical manufacturing operations and PMPU, EPA has decided to retain both terms, but with some modifications. The terms ''Pharmaceutical Manufacturing Operations'' and ''Pharmaceutical Manufacturing Process Unit (PMPU)'' were not intended in the proposed rule to refer to the same sources entirely. While the term ''Pharmaceutical Manufacturing Operations'' is the broadest term used in the rule and covers all emission sources within a given facility that are the direct or indirect result of pharmaceutical manufacturing, the term ''PMPU'' was intended to encompass each process unit within the facility and its associated equipment. Therefore, the pharmaceutical manufacturing operations encompasse all PMPU's at a given facility as well as equipment that is not included in individual PMPU's. In the proposed rule, the PMPU was used exclusively to define new source applicability in § 63.1250(c). In today's final rule, PMPU's also have replaced ''processes'' in the pollution prevention standard, and therefore, PMPU's serve several functions in the final rule. The PMPU also serves as the basis of the wastewater cutoffs for the standard, at 1 Mg/yr applicability HAP load per PMPU. The EPA believes that the broader term for pharmaceutical manufacturing operations is necessary to include sources that cannot be associated with single PMPU's.

By including wastewater management units in the definition of PMPU at proposal, EPA intended that all wastewater streams and residuals would be considered part of the PMPU. The EPA reviewed the definition of process and PMPU for consistency with the HON and other MACT standards. Wastewater management units are subject to the standard, but manage wastewater from several PMPU. However, wastewater generated in a PMPU is not specifically defined as part of the PMPU, but rather can be associated with it. This convention is analogous to process vent emissions; although they are not specifically identified as part of the PMPU, a PMPU may generate process vent emissions. In deciding whether the PMPU has the potential to emit 10 or 25 tons of HAP, all emissions from all sources associated with the PMPU, including process vents and wastewater, must be considered. Therefore, the definition of PMPU was modified to not specify wastewater streams, residuals, and wastewater management units, as part of the PMPU.

Although EPA recognizes that rarely will one piece of equipment comprise a PMPU, the Agency disagrees with the commenters that a PMPU must always be defined as a group of equipment. The definition of PMPU in today's final rule, however, includes the term, ''process'' which is defined as a ''logical grouping of processing equipment which collectively function to produce a pharmaceutical product'' and ''may consist of one or more unit operations.'' However, a PMPU is not always associated with specific groupings of equipment associated with a given process. (See also section VI.A.3 of this preamble and § 63.1252 of the final rule for a complete definition of process.)

In response to suggestions that EPA define a PMPU by its primary product, the EPA has included a primary use concept in the definition of pharmaceutical product in the final rule as discussed previously in section VI.A.1, above. Based on the comments discussed above and related comments, the definitions of PMPU and pharmaceutical manufacturing operations in today's final rule are as follows:

Pharmaceutical manufacturing process unit (PMPU) means the process, as defined in this subpart, and any associated storage tanks, equipment identified in § 63.1252(f), and components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used in the manufacturing of a pharmaceutical product.

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

3. Definition of Process

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

Many commenters requested that the definition of process be clarified to indicate that Quality Assurance and Quality Control (QA/QC) laboratories are not considered part of the process. These commenters were concerned that, although it may be clear that QA/QC labs are not ''processing equipment'' or ''an activity or an operation used to produce a product,'' the words, ''or

other activity, operation,'' may lead to confusion as to whether QA/QC labs are part of the process. The commenters suggested that EPA explicitly exclude QA/QC labs from the definition of process because QA/QC laboratories emit insignificant quantities of HAP, and therefore, time-consuming nonapplicability demonstrations could be avoided.

Several commenters recommended that EPA include storage tanks in the definition of process so that sources that choose to comply using the pollution prevention alternative are not exempted from the storage tank requirements in § 63.1252(b) of the proposed rule. The commenters stated that emissions from storage tanks may be significant, and that sources should be required to comply with the storage tank standards under all circumstances.

Many commenters requested that EPA modify the definition of process to clarify how the process vent provisions will apply to formulation facilities. These commenters were concerned that the use of the term ''nondedicated'' in reference to formulation facilities results in confusion as to how to apply the standard. The commenters pointed out that, unlike equipment used in pharmaceutical chemical synthesis facilities, equipment in a formulation facility are only used to formulate products, and therefore, formulation facilities are ''dedicated'' to formulation operations. However, the commenters also pointed out that the equipment at the formulation facility is used to produce many different products, and therefore, is ''nondedicated.'' For these reasons, the commenters recommended that, for formulation operations, the term, ''nondedicated,'' be applied to the equipment within the facility and not the facility itself. The commenters also requested that for formulation operations, EPA limit the definition of process to formulation activities *within a contiguous area* (such as a formulation building or a contiguous area within a multipurpose building in which formulation takes place). The commenters cited examples where separate formulation operations are located at the same plant site, but are physically separate, and thus would require separate emission control systems.

Another commenter was concerned that use of the term ''nondedicated'' could be interpreted as including solvent recovery or formulation operations that process small quantities of pharmaceutical-related materials, but whose primary use is for a process subject to another MACT rule. The commenter recommended that this issue be resolved by (1) deleting the term ''nondedicated'' from the proposed definition of process, and (2) adding the phrase, ''whose primary use is associated with the manufacture of pharmaceutical products'' after the word ''operations'' in the last sentence of the proposed definition of process.

One commenter suggested that the phrase ''or isolated intermediate'' (used throughout the definition) be deleted because ''processes produce products,'' but ''*portions* of processes produce intermediates.'' The commenter further explained that although the product of one process may be used as a raw material in another process, the product serving as the raw material is not typically thought of as an intermediate.

The EPA has modified the definition of process in the final rule in response to the comments described above. The EPA agrees with the commenters that QA/QC laboratories are not part of the process, and the definition of process in the final rule excludes QA/QC laboratories.

To clarify EPA's intention that storage tanks be included as part of the pollution prevention alternative, and in response to the comments regarding the perceived exclusion of storage tanks from the P2 alternative, today's final rule includes storage tanks in the definition of PMPU and refers to PMPU's instead of ''processes'' in the pollution prevention provisions (see also section V.A.2 of this preamble—Definition of PMPU and Pharmaceutical Manufacturing Operations, and section VI.F—Pollution Prevention Alternative).

The EPA disagrees with the commenters who believe that the term, ''nondedicated,'' as applied to formulation facilities, should be applied to the equipment within the facility and not to the facility itself. As explained in section VI.A.1 of this preamble, the pharmaceutical NESHAP regulates processes, not equipment, and the concept of primary use is applied to the pharmaceutical product, not to the equipment used to manufacture the product. However, today's final rule clarifies the intent of the proposed rule with regard to formulation and solvent recovery operations: those operations occurring within a contiguous area are to be considered as single processes, regardless of the final product of that formulation or recovery operation.

The EPA agrees with the suggestions provided by one commenter to delete all references to ''isolated intermediate'' and has incorporated these comments into the definition of process in the final rule. Also, the definition of pharmaceutical product in the final rule (see section VI.A.1—General Applicability: Definition of Pharmaceutical Product) states that pharmaceutical product ''includes drug components such as raw starting materials or precursors that undergo chemical change or processing before they become active ingredients.'' Therefore, drug components such as raw materials and precursors, which are themselves products of processes, are defined as products, rather than ''intermediates,'' thus eliminating the need for the concept of ''intermediates'' (see also section VI.A.6—Definition of Isolated Intermediate).

For the reasons stated above, the definition of ''process'' in today's final rule is as follows:

Process means all equipment which collectively function to produce a pharmaceutical product. A process may consist of one or more unit operations. For the purposes of this subpart, process includes all or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a pharmaceutical product. Cleaning operations are considered part of the process. The holding of the pharmaceutical product in tanks or other holding equipment for more than 30 consecutive days, or transfer of the pharmaceutical product to containers for shipment, marks the end of a process, and the tanks are considered part of the PMPU that produced the stored material. When material from one unit operation is used as the feedstock for the production of two or more different pharmaceutical products, the unit operation is considered the endpoint of the process that produced the material, and the unit operations into which the material is routed mark the beginning of the other processes. Nondedicated recovery devices located within a contiguous area within the affected source are considered single processes. Nondedicated formulation operations occurring within a contiguous area are considered single processes. Quality Assurance and Quality Control laboratories are not considered part of any process.

The revised definition of process provided above clarifies when a process ends. The EPA selected 30 days as a reasonable period of time, beyond which, if a material has not been further processed or reacted, a process can be considered complete for the purposes of this subpart. Applicability determinations and control requirements would be more difficult without such a time frame. The definition of process is a key element of the rule because most of the

applicability and compliance determinations are based on the process, as a unit. Because of concerns that processes could be artificially divided into smaller portions of processes in order to meet the 2,000 lb/yr limit, EPA limited the number of processes per facility that can comply with the 2,000 lb/yr limit to seven per year. However, EPA also added that processes with very low emissions (less than 100 lb/yr HAP, uncontrolled) would not be counted as part of the seven process limit. These limitations and exemptions are currently under review and may be revised at a later time.

4. Definition of Process Vent

The EPA received several comments on the proposed definition of process vent, primarily related to the following two issues: (1) the establishment of a de minimis level or cutoff below which controls would not be required and (2) how the rule applies to process vents that are manifolded together. At proposal, process vent was defined as ''a vent from a unit operation through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Process vents do not include vents on storage tanks regulated under § 63.1252(b), vents on wastewater emission sources regulated under § 63.1252(d), or pieces of equipment regulated under § 63.1252(e).''

Many commenters requested that EPA modify the definition of process vent to exempt any vent that contains a gas stream with less than 50 ppmv HAP averaged over the unit operation. These commenters cited 40 CFR part 63.113(g) of the HON, which exempts vents with less than 50 ppmv from monitoring or any other provisions of sections 63.114 through 63.118. One of these commenters provided a cost analysis, using EPA's recently released biofilter cost model, for an existing fermentation operation, the emissions from which typically contain less than 50 ppmv methanol. The cost effectiveness of biofiltration for this scenario was estimated to be $27,000/Mg, with a percent control of 60 percent (i.e., from 50 ppmv to 20 ppmv, EPA's established practical limit of control), a value that the commenter stated was ''clearly unreasonable.'' The commenter further stated that for fermenter and fermenter preparation vents, a cutoff of 100 to 200 ppmv could be justified (as opposed to 50 ppmv) and requested that EPA consider such a cutoff.

Two commenters stated that the proposed definition of process vent implies that every process vent is connected to a single piece of unit operations equipment, which often is not the case at multiproduct, multibatch facilities. One of the commenters suggested that the definition include a statement indicating that ''multiproduct facilities having multiple production trains may have large numbers of process vents, which could discharge directly to the atmosphere; discharge through a dedicated control equipment; or which can be manifolded from many process units into a common header leading to a common control equipment.'' The other commenter stated that compliance with the process vent standards would be more difficult and expensive if the definition of process vent included the combined or commingled vents from several pieces of unit operations equipment, rather than just one piece of equipment. This commenter also questioned if standard industrial hygiene type exhaust pickups and general room ventilation exhaust points are meant to be included in the definition of process vents. The commenter pointed out that those types of systems may exhaust through a stack, which may be interpreted as being an emission point, but noted that some states do not consider these emission points for the purposes of Title V permits. The commenter stated that, if these emission points were not considered in developing the MACT floors, they should not be included as process vents, and requested clarification from EPA.

As explained in section VI.C of this preamble, the definition of process vent in today's final rule includes a de minimis cutoff for uncontrolled and undiluted vent streams of 50 ppmv HAP. Regarding multiple vents (from the same process) being manifolded together into a common header, the Agency considers the common header in this rule to be a single process vent, and has revised the definition of process vent to reflect this view. In response to one commenter's question about whether or not industrial hygiene exhausts and general room ventilation exhausts would meet the definition of process vent, these sources would not be considered process vents if they are under the 50 ppmv HAP cutoff. Based on the changes discussed above, the definition of process vent in the final rule is as follows:

Process vent means a vent from a unit operation or vents from multiple unit operations within a process that are manifolded together into a common header, through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Emission streams that are undiluted and uncontrolled containing less than 50 ppmv HAP, as determined through process knowledge, test data using Methods 18 of 40 CFR part 60, appendix A, or any other test method that has been validated according to the procedures in Method 301 or appendix A of this part, are not considered process vents. Process vents do not include vents on storage tanks regulated under § 63.1253, vents on wastewater emission sources regulated under § 63.1256, or pieces of equipment regulated under § 63.1255.

5. Definition of Process Condenser

The EPA received numerous comments on the proposed definition of process condenser. These comments primarily dealt with the dual role of condensers as both process condensers and air pollution control devices, and in which category recirculating condensation systems should be class ified. At proposal, process condenser was defined as ''a condenser whose primary purpose is to recover material as an integral part of a unit operation. The condenser must support vapor-to-liquid phase change for periods of source equipment operation that are above the boiling or bubble point of substances(s). Examples of process condensers include distillation condensers, reflux condensers, process condensers in line prior to the vacuum source, and process condensers used in stripping or flashing operations.''

Many commenters took issue with the phrase ''*integral part* of a unit operation'' and ''process condensers in line prior to the vacuum source.'' These commenters cited examples where it could be concluded that a condenser is not integral to a process because it does not perform any necessary process function. The commenters also stated that if there were two condensers in series prior to a vacuum source, and the first condenser effected a phase change, then the second condenser should be considered an air pollution control device, even though it is located ''prior to a vacuum source.''

Three commenters suggested that the intended use be considered when determining whether a condenser is a process condenser or an air pollution control device. Two of these commenters stated that, ''if the condenser is acting as a control unit, so

that its presence is intended to prevent chemicals from reaching the uncontrolled environment; if the materials collected are led towards management and disposal systems; and if the collected materials are in no way used, reused, nor sold for fuel value, then the condenser is serving as a control unit regardless of the fact that the bubble point is met or not at the source.'' The other commenter disagreed with the condition that to be a process condenser, the condenser must support a vapor-to-liquid phase change for periods of source equipment operation that are above the boiling or bubble point of the substance(s). This commenter pointed out that under the proposed definition, the same condenser will sometimes be a process condenser and sometimes an air pollution control device, and tracking when the condenser switches from one to the other would be burdensome. Therefore, the commenter recommended that the facility which operates the condenser (and knows the process best) be allowed to determine whether it is a process condenser or an air pollution control device.

Another commenter suggested that EPA distinguish between process condensers and condensers serving as air pollution control devices by including a specific temperature limit (i.e., 20°C) such that condensers that lower the temperature of the exit gas stream to a colder temperature would be considered air pollution control devices instead of process condensers.

Many commenters requested that EPA specifically address process condensers that belong to recirculating drying systems. Most commenters stated that condensers in recirculating drying systems should be considered pollution control devices. However, one commenter stated that recirculating condensation systems should be defined as neither process condensers nor air pollution control devices, but defined separately, with ''management systems to account for their pollution prevention effects to be worked out at a later date for the promulgated standard.'' The major concern of all of these commenters, however, was that under the proposed definition, the recirculating condensation systems would be considered process condensers, and thus, the uncontrolled emissions and resulting emissions reductions would be considerably lower than if the condenser was considered an air pollution control device. Even though these systems generate considerably lower emissions as compared to once-through systems, owners and operators could not take advantage of the high emission reductions in the process vent standard that requires 93 percent control or 2,000 lb/yr after control from the entire process.

The EPA disagrees with the suggestion that the owner or operator should be allowed to determine whether a condenser is a process condenser or an air pollution control device based on ''intended use.'' Because one of the formats of the process vent standard requires that a reduction from uncontrolled emissions be applied across a process (i.e., achieve a 93 percent reduction in emissions from the process), EPA is concerned about the opportunity for crediting reductions achieved by condensing boiling streams on other sources in the process. In fact, in requesting data from industry (which was later used to set the MACT floor), the MACT partnership specifically confirmed from responders that the data reported was based on the definition of process condenser as described in the proposed rule. Therefore, EPA has retained the intent of the proposed definition, but has made clarifying changes. The definition of process condenser in the final rule is as follows:

Process condenser means a condenser whose primary purpose is to recover material as an integral part of a process. The condenser must support a vapor-to-liquid phase change for periods of source equipment operation that are at or above the boiling or bubble point of substance(s) at the liquid surface. Examples of process condensers include distillation condensers, reflux condensers, and condensers used in stripping or flashing operations. In a series of condensers, all condensers up to and including the first condenser with an exit gas temperature below the boiling or bubble point of the substance(s) at the liquid surface are considered to be process condensers. All condensers in line prior to a vacuum source are included in this definition.

The EPA also rejects the suggestion to use 20°C as a temperature cutoff in determining whether a condenser is a process condenser or an air pollution control device. Because of the differences in the chemical and physical properties of substances used in the manufacture of pharmaceutical products, one temperature cannot be used to represent all processes; in some cases, a condenser operating at 20°C could actually be an air pollution control device and not a process condenser. Finally, EPA disagrees with the requests that condensers in recirculating drying systems be considered as pollution control devices or defined separately. Emissions from the recirculating drying systems only occur during periodic depressurizations, and these uncontrolled emissions may be low enough such that the process may be under the 2,000 lb/yr cutoff. Processes with recirculating drying systems also may be able to take advantage of the pollution prevention standard.

6. Definition of Isolated Intermediate

At proposal, isolated intermediate was defined as ''any intermediate that is removed from the process equipment for temporary or permanent storage or transferred to shipping containers.'' The concept of an intermediate was also included in the proposed definition of pharmaceutical product which contained a reference to ''intermediates used in the production of pharmaceutical products (see section VI.A.1 of this preamble). One commenter on the proposed rule stated that EPA should not use or define the term, ''isolated intermediate,'' in the pharmaceutical NESHAP. (The same commenter also stated that the term, ''isolated intermediate,'' should be removed from the definition of process [see also section VI.A.3—Definition of Process].) The commenter pointed out that the term is ''peculiar to the Toxic Substances Control Act (TSCA), where a long history of interpretation has been developed,'' and if EPA uses this same term in the pharmaceutical NESHAP, ''inconsistencies in interpretation will be inevitable.''

Many other commenters suggested that the definition of isolated intermediate be modified so that the physical removal of an intermediate from the process equipment is not required as a condition for meeting the definition of isolated intermediate. These commenters pointed out that, in some cases, an intermediate may remain in a storage tank or other retention equipment prior to being used in a different process step, and without ever being removed from either set of process equipment. The commenters further stated that the fact that retention tanks are used as separation lines as an alternative to storing the material in drums or separate containers ''is a matter of convenience.'' Therefore, the commenters recommended the following modified definition of isolated intermediate:

Isolated intermediate means any intermediate that is stored in storage tanks or other holding equipment for later use, or that is transferred to containers for shipment or storage.

After considering these and other related comments (see section VI.A.3 of this preamble), EPA has deleted the

term, ''isolated intermediate,'' from the definition of process to avoid confusion and emphasize that products are the end result of processes. Therefore, isolated intermediates are no longer defined or referred to in today's final rule. Also, the definition of process in the final rule incorporates the commenters' suggestion above regarding the fact that physical removal of the ''product'' from the process equipment should not be a required condition for meeting the definition of ''product.'' In addition, the definition of process in the final rule specifies when a process ''ends.''

7. Research and Development Facilities

Many commenters expressed support for the proposed definition of research and development facilities because it draws a clear distinction between activities related to manufacturing (which are covered under today's final pharmaceutical production NESHAP) and those related to research and development (which are not covered by today's final rule). The commenters further stated that such a clear distinction is necessary because pharmaceutical manufacturing operations and research and development activities are often located at the same site. Many commenters requested that EPA make it clear that pilot plants are not subject to the proposed pharmaceutical standards if they meet the definition of ''research and development facility.'' In determining whether an operation of facility constitutes a research and development facility, it is EPA's intention that owners and operators and implementing agencies should refer to the definition of research and development facility which appears in Section 112(c)(7) of the Clean Air Act, rather than relying on existing company designations or facility names. For example, if a pilot plant is collocated with pharmaceutical manufacturing operations that are subject to this subpart, and the pilot plant meets the criteria outlined in the definition of research and development facility, then the pilot plant would not be subject to this subpart.

Two commenters were concerned that the term ''de minimis,'' as it is used in the definition of research and development facility, was not defined in the proposed rule. One of the commenters stated that, without clarification (of de minimis) the definition will lead to exhaustive and potentially contentious negotiations between sources and regulatory agencies, and may result in inequitable exemption decisions at similar facilities located in different jurisdictions. The commenter also pointed out that some States have included more specific provisions, such as limiting the number of products produced, establishing maximum daily emission rates, or requiring segregation of the R&D activities from the production areas. Although EPA recognizes the concerns of the commenters, today's final rule does not establish a de minimis level for research and development facilities. The EPA does not have sufficient data to establish a de minimis level, and therefore, such determinations will have to be made by the applicable permitting authorities. Also, EPA is in the process of collecting background information on the various segments of research and development facilities nationwide and is considering development of a NESHAP for one or more of these segments in the future.

8. Consistency With Other Rules

The EPA received numerous comments regarding the potential for overlapping regulations. Commenters were strongly opposed to the idea of the same sources being subject to multiple regulations and asked EPA to clarify which regulations applied to pharmaceutical manufacturing operations.

The EPA has identified several potential areas in which today's final standards, the RCRA standards (subpart AA or CC), and/or subpart I of 40 CFR part 63 could apply to the same situation. To avoid inconsistent requirements, the EPA has tried to make the regulatory language as specific as possible as to which regulation(s) the owner or operator must comply with to satisfy the requirements of all regulatory programs. For example, if an air pollution control device is subject to the pharmaceuticals production NESHAP and RCRA requirements, § 63.1250(h)(2) of today's final rule states that the owner or operator may elect to comply with the monitoring, recordkeeping and reporting requirements of either rule, as long as they identify which rule's requirements they have selected in the Notification of Compliance Status report. However, if the owner/operator elects to go with RCRA requirements, there may be additional (minimal) reporting requirements.

Similarly, §§ 63.1250(h)(1), (3) and (h)(4) address overlap with other MACT standards, subpart Kb (the NSPS for organic liquid storage tanks), and subpart I (the negotiated regulation for equipment leaks). After the compliance date for today's final rule for pharmaceuticals production, an affected source subject to Subpart I is required to comply only with the provisions of today's final rule. For sources subject to other MACT standards and NSPS Kb, reporting requirements may be streamlined to the extent that the rules are consistent.

B. Storage Tank Provisions

The proposed and final standards for storage tanks with capacities greater than 20,000 gallons (i.e., reduce HAP emissions by at least 95 percent) represent a control level that is beyond the MACT floor. In deciding to go beyond the MACT floor, EPA determined that floating roof technology was less costly than condensers (which represented the MACT floor technology and 90 percent control) and resulted in greater emission reductions. Many commenters stated that the proposed requirements for storage tanks with capacities greater than or equal to 20,000 gallons represent an increase in stringency (beyond the MACT floor) without precedent. These commenters suggested that 90 percent control of HAP emissions was more appropriate and consistent with the storage tank provisions of similar rules (e.g., the HON and 40 CFR 60, Subpart Kb). The commenters also questioned EPA's assumption that floating roof technology could and would be used to reduce emissions from storage tanks, given the general lack of storage tanks at pharmaceutical manufacturing facilities that are fitted with floating roofs and the use of horizontal storage tanks (which cannot be fitted with floating roofs) at some facilities.

In addition, commenters requested that EPA include in the final rule: (1) an exemption for storage tanks emitting less than 500 lb/yr of HAP (an alternative that was considered and then dropped during the regulatory review .process), and (2) a provision that allows vapor balancing systems as an alternative means of control. The commenters reviewed what was gained by dropping the 500 lb/yr cutoff alternative and concluded that in the top 12 percent of storage tanks, the associated emissions that would not be controlled under the 500 lb/yr cutoff alternative are 2,710 lb/yr (or 150 lb/yr/tank). Based on an annualized cost of $142,500/yr (to control the 2,710 lb/yr), the commenters determined that the cost effectiveness of controlling the emissions from storage tanks with emissions less than 500 lb/yr would be $115,913/Mg. The commenters further stated that the EPA has authority under the law to establish de minimis provisions for exceptions from statutory directives when the benefits of regulation are significantly outweighed by the associated costs and other

burdens, and the 500 lb/yr cutoff alternative meets the criteria for establishing such a de minimis provision, especially considering the fact that the proposed storage tank provisions represent a control level above the MACT floor.

Many commenters stated that the rule should specify that vapor balancing systems meet the requirements of the storage tank provisions. The commenters stated that vapor balancing systems are effective, relatively easy to use, capable of achieving control efficiencies as high as 90 to 98 percent, and are accepted under other rules (both NSPS and NESHAP), and therefore, should be accepted in the pharmaceutical NESHAP. One commenter also pointed out that, when vapor balancing is used (i.e., the storage tank vapor space is routed to the truck), the source of pollution is the vapor content of the truck; however, when the storage tank is vented to a control device, there are two sources of pollution: the HAP vapor from the truck and secondary pollutants from the control device. The same commenter recommended that the State of New Jersey requirements for vapor control (7:27–16.4 VOC Transfer Operations, Other Than Gasoline) be incorporated into the storage tank provisions.

In response to the comments on the proposed storage tank provisions, today's final rule does not include provisions for vapor balancing of storage tanks. However, this issue will be addressed in the Organic Liquids distribution MACT standard. The MACT floor for storage tanks was determined to be 90 percent control of HAP from storage tanks and did not cover tank truck vapor. The EPA also considered the commenters' request for a 500 lb/yr cutoff, but rejected it because a sufficient number of small storage tanks in service at pharmaceutical manufacturing facilities are controlled, and the 500 lb/yr cutoff represents an alternative that is less stringent than the MACT floor, and thus, is not acceptable. The control level for storage tanks with capacities greater than or equal to 20,000 gallons in the final rule is the same as proposed level (i.e., 95 percent). As explained in the Basis and Purpose Document (see Docket A–96–03, Item No. III–B–01), EPA chose 95 percent control (as opposed to the MACT floor) for storage tanks greater than 20,000 gallons because floating roof technology has been demonstrated to achieve 95 percent control and is considerably less expensive than other technologies. Although floating roofs currently may not be in use on storage tanks in the pharmaceutical industry, EPA is not aware of any technical obstacles to their use, except in the case of horizontal tanks. Also, owners or operators still have the option of using add-on controls instead of floating roofs.

C. Process Vent Provisions

The EPA received numerous comments on the proposed standards for process vents. Comments focused on the following areas: (1) establishment of a concentration-based applicability cutoff, (2) implementation of the 98 percent control requirement, (3) new source MACT for process vents, and (4) compliance periods.

1. Applicability Cutoff

Many commenters suggested that EPA establish a concentration threshold below which an emission stream would not be considered a process vent, and thus would be exempt from further applicability determinations, control or monitoring requirements. The commenters recommended a de minimis concentration of 50 ppmv or 50 ppmw for process vents.

After consideration of the above recommendations and comments related to the alternative standard (see section VI.G of this preamble), EPA decided to establish a de minimis cutoff for process vents equal to 50 ppmv HAP, based on uncontrolled, undiluted emissions. The de minimis cutoff is incorporated into the definition of process vent, which states that uncontrolled, undiluted emission streams containing less than 50 ppmv HAP are not considered process vents.

2. Implementation of the 98 Percent Control Requirement

Today's final rule requires facilities to apply an equation in § 63.1254(a)(3) to determine if emissions from the process vent must be controlled by 98 percent as opposed to 93 percent. The applicability equation uses two variables, vent flow and yearly uncontrolled HAP emissions, to calculate a flow rate. The calculated flow rate is then compared to the process vent's actual flow rate, and if the actual flow rate is less than or equal to the calculated flow rate, the process vent requires 98 percent control. A number of commenters believe that the 98 percent control applicability equation should be deleted because it will create a significant recordkeeping burden, will be practically impossible to implement, and will significantly hamper operational flexibility.

The major concern noted by the commenters was that the applicability equation, though fairly straight-forward for dedicated single-product processes, is extremely difficult if not impossible to apply to multipurpose nondedicated processes. The commenters stated that, because nondedicated processes use individual pieces of equipment to make numerous products over the course of a year, the emission stream characteristics of the associated process vents will change depending on the product being manufactured, and thus, the recordkeeping requirements for a single process vent would be burdensome. The commenters also pointed out that a facility may have 200 to 300 individual process vents.

Another concern raised by the commenters was that a slight variance from forecasted production could result in a process vent previously required to control emissions by 93 percent to become subject to the 98 percent control requirement, and the affected facility would not have sufficient lead time to upgrade their control equipment from 93 to 98 percent. The commenters were concerned that such uncertainties will hamper operational flexibility because facilities will be forced to impose limitations on production to ensure that they will not trigger 98 percent control. The commenters also stated that applying the applicability equation to manifolded vents would further complicate matters because more sources emitted through the same vent will result in greater variability of vent stream characteristics.

The commenters also requested that if EPA retains the 98 percent control requirement for existing process vents in the final rule, that § 63.1252(c)(4) in the proposed rule be revised to clearly describe how to apply the 98 percent control applicability equation. Commenters noted that using the past actual annual HAP emissions versus projected annual HAP emissions in the applicability equation is an issue because the production of many products varies from year to year, and historical and forecasted annual HAP emission estimates may be very different. The commenters also were concerned that the proposed rule did not clearly establish how to determine the process vent's actual flow rate, which will be compared to the applicability equation's calculated flow rate. Finally, the commenters suggested that EPA specify that the applicability equation applies to individual pieces of equipment in a formulation facility. The commenters were concerned with how the applicability equation would be applied to nondedicated formulation facilities. The commenters pointed out that nondedicated formulation facilities often use multiple pieces of the same equipment to perform one operation

(e.g., six tray dryers), and not all of these pieces of equipment will be used to produce every product in the formulation facility (i.e., not all trays of the dryer are always used).

After considering the comments above, EPA decided to retain the 98 percent control requirement for existing process vents that meet the applicability criteria. (For those process vents already controlled to 93 percent prior to April 2, 1997, no additional control is necessary.) The applicability equation applies to individual process vents within a process; however today's final rule considers manifolded process vents within each process to constitute a single process vent. With the exception of formulation operations and recovery devices, the definition of process is based on the product manufactured, not the equipment used to manufacture it. Therefore, the determination of which vents require control to the 98 percent level for nondedicated process vents should be straightforward; namely, owners and operators need to anticipate the total uncontrolled HAP emissions per year from each vent from each process, and the average flow rate of the vent. The total uncontrolled emissions should be based on the potential number of batches per year that the facility can run for each process. Based on this projection, the owner or operator can decide whether to install or use an existing 98 percent control device or limit the number of batches to stay below the applicability threshold. Today's final rule also requires facilities to keep track of the number of batches of products they make each year to show that their number of batches is less than the number needed to trigger 98 percent.

In response to the commenters' request, the average flow rate has been clarified in the final rule to mean the weighted average flow rate of the emission events contributing to the process vent. For solvent recovery or formulation operations, the definition of process in today's final rule has been clarified to include all operations within a contiguous area; therefore, for these operations, a single process may be associated with several products. Like other processes, the application of the 98 percent control applicability equation should be based on individual process vents or manifolded vents. Thus, if each piece of equipment that is located at a formulation facility, considering processes by contiguous areas, has a separate vent, then the applicability equation is applied to each vent separately; however, if the vents from each piece of equipment are manifolded together, then they are treated as one process vent and the equation is applied to the aggregated flow.

As part of the rationale for retaining the 98 percent requirement, EPA notes that this level of control is imposed only on vents that have the potential to emit 25 tons/yr or more, on an uncontrolled basis. Secondly, the applicability equation is indexed on cost-effectiveness. Streams that are too dilute for cost effective control would not, per the equation, be required to be controlled. Third, process vents already controlled to levels of 93 percent or greater prior to April 2, 1997, would be grandfathered and not required to increase controls to 98 percent. The EPA believes that after these considerations are made, only very large streams that are cost effective to control to 98 percent will trigger the 98 percent control requirement.

3. New Source MACT for Process Vents

At proposal, new source MACT for process vents was set at 98 percent control for process vents with uncontrolled emissions greater than or equal to 400 lb/yr. The rationale for the 400 lb/yr cutoff (uncontrolled) was that it represented the smallest controlled process considered to be a similar source. Many commenters stated that the standard for new process vents should include a 2,000 lb/yr controlled emissions compliance alternative, because it is unreasonable and unwarranted to require vents with low HAP emissions to achieve 98 percent control. The commenters agreed with EPA's conclusion that 98 percent control represents the best controls in practice for certain sources; however, the commenters believe that the applicability cutoff for new source MACT for process vents is legally flawed because the cutoff did not consider two of the four process types in the industry (fermentation and extraction). The commenters also stated that the process on which the 400 lb/yr cutoff is based is not representative of the industry's processes because the process emits primarily one HAP (methanol) and is controlled by a dedicated scrubber and appears to be only a portion of a process based on the EPA's definition of process in the proposed rule. Citing other rules that set new source MACT as the average level of control achieved by sources using new source MACT control technology, the commenters performed an analysis of the MACT floor data base and determined that the average level of controlled emissions from the best-performing 12 plants was approximately 1,400 lb/yr. The commenters excluded two processes from their analysis that had uncontrolled emissions greater than 1 million lb/yr because these processes are much larger than the typical pharmaceutical manufacturing process and would skew the data. According to the commenters, if these two (larger) processes are included in the analysis, the average level of controlled emissions from the best-performing 12 plants would equal 6,400 lb/yr.

The EPA has reviewed the data used to set the MACT floor for process vents at new sources. Based on this review, the EPA has concluded that the data support the level of the proposed standard for new sources.

The EPA based the 98 percent control requirement on the 26 processes (under the proposed definition) at 7 plants in the data base that achieve or exceed this control level. These processes include dedicated and nondedicated formulation, chemical synthesis, and fermentation processes. The EPA has concluded that these processes are representative of the control challenges faced by the industry despite the fact that the data do not include an extraction process. The EPA has further concluded that the 98 percent control level achieved at the best controlled processes is applicable to all four process types.

The EPA does not believe that the variation in exhaust gas characteristics among the four types of processes in the industry is significant enough to warrant individual evaluation of achievable control levels. In any case, extraction processes are typically solvent-intensive, resulting in the highest average HAP concentration of the four types of processes. High HAP concentrations are conducive to high percent control levels.

The commenters suggested that the EPA adopt a 2,000 lb/yr actual emissions compliance alternative to account for variability within the industry. The commenters based this alternative on the average level of controlled emissions from 24 of the processes in the data base that achieve 98 percent control or greater. (The commenters excluded the other two processes in the data base because they were atypically large.) The EPA does not believe that the analysis presented by the commenters is an appropriate basis for a new source compliance alternative. First, while the commenters imply that the alternative is needed to account for variability in the control level that is achievable by the wide variety of pharmaceutical processes, the analysis does not address control efficiency at all. Because the commenters evaluated only processes that achieve at least 98

percent control, only variability in uncontrolled emissions truly figures into the analysis. Second, the alternative standard suggested by the commenters is not equivalent to the percent reduction standard and would result in greater total emissions of HAP from the industry. Finally, the EPA analyses cited as precedents address different situations and provide scant support for the commenters' analysis.

While the EPA has rejected the alternative standard suggested by the commenters, the final rule provides a 20 ppmv outlet concentration alternative to 98 percent control for process vents at new sources. This alternative addresses the primary impediment to achieving 98 percent control, i.e., low inlet concentration gas streams.

The EPA based the proposed applicability cutoff for new source process vents on the smallest representative process in the data base that achieves 98 percent control or greater. The commenters questioned whether this operation actually qualifies as an entire process under the proposed definition of ''process'' and whether the operation is representative of processes in the industry. Although the EPA continues to believe that the formulation operation selected as the basis for the proposed cutoff is a process under the proposed definition, it may not qualify as a process under the final definition because nondedicated formulation operations occurring within a contiguous area are now considered single processes. Consequently, the EPA has reanalyzed the data based on the final definition of ''process.'' In light of the new analysis, it is no longer relevant whether the process upon which the proposed cutoff was based is representative of the industry.

The new analysis was similar to the original analysis. After revising the data base of well-controlled sources to conform to the final definition of ''process,'' the EPA identified the smallest processes that are controlled by 98 percent or more. As in the previous analysis, formulation and chemical synthesis processes are the smallest processes. Two chemical synthesis processes, one emitting 85 lb/yr uncontrolled and another emitting 304 lb/yr uncontrolled, were identified as achieving control of 98 percent. Although these processes were reported as individual (single) processes, EPA summed emissions from both, since the product name listed for each was very similar, and EPA wanted to be conservative. The total uncontrolled emissions from the sum of these two processes is 390 lb/yr, which is the same level of emissions as the proposed cutoff. Therefore, the EPA has established in the final rule the new source process applicability cutoff of 400 lb/yr of uncontrolled HAP.

Despite the fact that no fermentation or extraction processes were among the smallest well-controlled processes, the EPA believes that the analysis is representative of the control capabilities of all process types. As discussed previously, the EPA has concluded that the gas streams generated by the four types of processes in this industry are similar enough that an individual analysis by process type is not warranted. Fermentation and extraction processes are typically much larger than formulation and chemical synthesis processes. Thus, the absence of fermentation and extraction processes in the list of the smallest well-controlled processes is the result of this size differential, not a difference in the control level that can be achieved. In fact, the average uncontrolled HAP concentration of fermentation and extraction process vents exceeds those of formulation and chemical synthesis process vents. Higher concentrations are more conducive to high percent control.

Practically speaking, new source MACT will apply to low HAP-emitting processes only at new facilities, where the minimum control requirement is 98 percent for all processes. (At existing sites, new source MACT will apply only to dedicated new PMPU's with a potential to emit 10 tons/yr of a single HAP or 25 tons/yr of all HAP combined.) Thus, sources will not be faced with the need to install 98 percent-efficient controls dedicated to small new processes, which could be very costly for a small amount of emission reduction. Instead, the EPA expects that sources will achieve the new source MACT standard using large control devices that treat multiple manifolded gas streams. Because this is the control situation most typically found for the small processes in EPA's data base of well-controlled sources, the EPA believes that the final rule's applicability cutoff accurately reflects what will be achievable at new sources in this industry.

4. Compliance Period

Several commenters stated that they support the proposed annual compliance period for process vents and noted the inconsistency with the daily continuous compliance provisions. If the final rule includes a shorter compliance period, the commenters have stated that either the standards must be adjusted to avoid an increase in stringency above the floor or a demonstration must be made that the increased stringency (i.e., going above the floor) is justified according to the requirements of the Clean Air Act. The EPA, in the final rule, has clarified the compliance period of the standard to be either on a 24-hour basis, or on a batch cycle or ''block'' basis. Additionally, compliance periods for emissions averaging are on a quarterly basis, while compliance periods for the P2 standard are on an annual basis, as calculated on a monthly or 10-batch rolling average. An annual compliance period for the standards was determined by EPA to be too difficult to implement. The annual compliance period implies that owners and operators could control processes to varying degrees during the course of a year, as long as the yearly percent reduction target could be met. While this format would offer flexibility to owners and operators that would want to change control strategies to accommodate production scheduling and operational changes, EPA believes that the demonstration of compliance over such an extended time period would result in delayed compliance determinations and the possibility for extended periods of violations. The EPA notes that the final rule offers some flexibility to owners and operators in addressing variability within the processes themselves by providing numerous compliance options. Therefore, EPA does not believe that by clarifying the final rule to reflect a daily compliance period, the stringency of the standard was increased.

D. Wastewater Provisions

1. MACT Floor

The EPA estimated that 101 pharmaceuticals facilities would be major sources subject to the rule. The MACT floor is based on available information about control levels at all of these sources. One commenter asserted that the applicability section of the proposed rule covers more types of facilities than those in the original MACT floor analysis, and thus the MACT floor should be recalculated. The EPA did not recalculate the MACT floor because, as noted in section VI.A.1 of this preamble, the applicability in the final rule is clarified to eliminate the likelihood that the rule would apply to types of facilities other than those represented in the 101 in the initial analysis.

2. DeMinimis Cutoff in Definition of Wastewater

The final rule includes de minimis cutoffs for determining if a water stream is wastewater. One commenter requested that HAP concentration and

flow rate cutoffs be added, as in the HON. The commenter contended that the burden to characterize streams with very small HAP loadings would be excessive without such cutoffs. For the final rule, EPA revised the definition of wastewater to include de minimis HAP cutoffs of 5 ppmw and 0.05 kg/yr, which is consistent with the HON. Although the owner or operator is given some flexibility in the methods used to characterize these streams, the Administrator may require the owner or operator to validate this information through sampling and analysis or other appropriate means.

3. Cross-References to the HON

The wastewater provisions in the proposed rule contained numerous cross-references to the wastewater provisions in §§ 63.132 through 63.148 of the HON. Many commenters requested that the applicable provisions from the HON be included in the final rule because the extensive cross-referencing made the proposed rule hard to understand and would likely be hard to implement. Some comments also noted that many cross references were not consistent with the most current version of the HON. To address these concerns, EPA decided to incorporate the applicable provisions from the HON in the final rule. These provisions include the emission suppression requirements from §§ 63.133 through 63.137, the control device requirements from § 63.139, the general procedures for determining compliance from § 63.145, many of the compliance options for treatment systems and control devices from §§ 63.138 and 63.145 (additional information about compliance options is provided in section VI.D.4), the inspection and monitoring provisions from §§ 63.143 and 63.148, the requirements for certain liquid streams in open systems within a PMPU from § 63.149, and the tables that are referenced from all of these sections.

4. Additional Treatment Options for Demonstrating Compliance

Several commenters requested that the rule include additional treatment options for demonstrating compliance. Some comments requested that all of the options in the HON be added to the rule. Other comments specifically requested that the rule allow treatment in RCRA units and that a concentration limit be developed for soluble HAP. In response to the comments, EPA included additional treatment options in the final rule that are consistent with the standards. All of the RCRA options from the HON were added because treatment in these units will meet the standards. A concentration option of 520 ppmw for soluble HAP was added because this level is consistent with the 90 percent reduction requirement for soluble HAP.

Four options from the HON were not added to the final rule. The design steam stripper option was not added because the available stripper designs that were used to estimate impacts have not been tested in the field. The percent mass removal/destruction option based on fraction removed (Fr) values was not added because the Fr values would be identical to the percent reduction option. The 1 Mg/yr option was not added because any facility with wastewater containing a load of total partially soluble and/or soluble HAP less than 1 Mg/yr would have no affected wastewater streams. The required mass removal options were not included because wastewater discharges from batch pharmaceutical processes are much more variable than those from continuous SOCMI processes; therefore, the required mass removal is likely to be different at any given time, and is not likely to correlate well with the actual mass removal in the treatment unit at a given time.

5. General Compliance Procedures

The proposed rule cross-referenced the specific procedures in the HON for determining compliance with the standards when using various types of treatment units (i.e., noncombustion, combustion, or biological), but the general procedures used to determine compliance that are applicable to any performance test (or design evaluation) were not cross-referenced. Several commenters requested that these general procedures also be included in the rule. Specifically, the commenters requested that the rule specify that: (1) performance tests be conducted under representative operating conditions, (2) treatment may be conducted using a series of treatment devices, (3) treatment may be conducted offsite or in onsite treatment units not owned by the source, and (4) any biological units in compliance with the standards need not be covered and vented. Commenters also requested that the rule include: (1) procedures for the preparation and installation of testing equipment and (2) requirements for compounds that do not need to be considered in performance tests or design evaluations. The final rule includes all of these provisions; however, clarification of two points is provided below.

Clarification of the provision for testing under representative operating conditions is provided because the commenters misinterpreted the meaning of this provision in the HON. This provision requires a facility to conduct a single performance test under representative operating conditions. If actual operating conditions vary, such that there are multiple representative operating conditions, the owner or operator must supplement the test results with modeling and/or engineering assessments to demonstrate that the standard is met over the entire range of operating conditions. Testing under representative operating conditions does not mean the standard is an average that may be exceeded under certain conditions.

A clarification of the provision that allows open biological treatment units to be uncovered is also provided. Except for enhanced biological treatment units used to treat certain wastewater streams, an owner or operator demonstrates compliance for open biological treatment units by conducting a performance test and following the procedures in appendix C of part 63. If these procedures show the fraction biodegraded meets or exceeds the applicable control level, the treatment unit need not be covered. An enhanced biological treatment unit that is used to treat wastewater containing soluble HAP and less than 50 ppmw of partially soluble HAP is exempt from the performance test requirements and need not be covered.

6. Default Biodegradation Rate for Methanol

One commenter urged EPA to revise the default methanol biodegradation rate constant that is used in Table 37 of subpart G of the HON because it cannot be scientifically supported with available data. Based on data from a number of studies, the commenter concluded that the rate in the proposed rule is low by a factor of 10 to 100. The commenter noted that the geometric mean of the rates from the available studies was 8.6 L/g MLVSS-hr, and the lower bound of the 90 percent confidence interval was 3.5 L/g MLVSS-hr. The commenter also cited data in the scientific literature that show hexachlorobenzene, chlorobenzene, nitrobenzene, and biphenol (other list 1 compounds) to be less biodegradable than methanol, whereas Table 37 of the HON shows methanol to be less biodegradable than the other compounds.

The data submitted by the commenter show considerable variability, but they also show the higher biodegradation rate constants tend to correspond with higher methanol concentrations in the wastewater. The EPA concluded that a

methanol biodegradation rate constant higher than the default is appropriate for pharmaceutical facilities that are direct dischargers because they tend to treat wastewater with higher methanol concentrations than indirect dischargers or facilities in other industries. The final rule allows these facilities to use a methanol biodegradation rate constant of 3.5 L/g MLVSS-hr, the lower bound of the 90 percent confidence interval; this is a conservative value that minimizes the likelihood that the biodegradation rate will be overestimated.

7. Maintenance Wastewater

The wastewater provisions apply to both process and maintenance wastewater. Commenters requested that maintenance wastewater provisions be less stringent than those for process wastewater, as in the HON. According to one commenter, the same conveyance systems and controls are not practical or cost effective for maintenance wastewater. The EPA did not change the maintenance wastewater provisions because maintenance wastewater is a potential source of significant emissions. Furthermore, procedures to estimate maintenance wastewater characteristics should be the same as those for most process wastewater because both consist of batch discharges.

8. Control Requirements for Wastewater Tanks

The rule requires that wastewater tanks have either a fixed roof or additional controls, depending on tank design and/or operating characteristics. A number of commenters expressed confusion over these provisions and offered their interpretations or preferences to clarify the provisions. Under the rule, wastewater tanks that have a capacity of less than 75 m^3, a capacity between 75 and 151 m^3 that contain material with a vapor pressure less than 13.1 kPa, or a capacity greater than or equal to 151 m^3 that contain material with a vapor pressure less than 5.2 kPa are required to have a fixed roof unless the wastewater in the tank is heated, treated with an exothermic reaction, or sparged. If any of these three conditions is not satisfied, the owner or operator must install a floating roof or use control techniques that achieve equivalent emission reductions. These provisions match those in the HON. The proposed rule also included an additional provision that caused the confusion for the commenters. The intent of the provision was to exempt wastewater tanks from the additional control provisions, but not the fixed roof requirement, if the owner or operator demonstrates that the total partially soluble and/or soluble HAP emissions from a fixed roof tank that is heated, treated with an exothermic reaction, or sparged are less than 5 percent higher than the emissions would be in the absence of these activities. This additional provision is rewritten in the final rule to improve clarity.

9. Compliance Requirements for Biological Treatment Units

The EPA received numerous comments on the initial compliance procedures and monitoring requirements for enhanced biological treatment units. Some commenters requested that compliance demonstrations be based on parameters related to soluble HAP removal, not general compliance with all NPDES permit limits; the commenters suggested monitoring for surrogate parameters like COD, BOD, and/or TSS. Some commenters stated that EPA's definition of significant noncompliance in appendix A of 40 CFR 123.45 should be used as the basis for defining acceptable enhanced biotreatment operation for both POTW's and direct dischargers. One commenter stated that compliance provisions should focus on the indirect discharger, not the POTW; for example, the indirect discharger should be in compliance with the pretreatment provisions in 40 CFR 403 and 439. Several commenters stated that the provision allowing discharge to an enhanced biological treatment unit at a POTW only if the indirect discharger demonstrates that less than 5 percent of the soluble HAP in the wastewater from the POD's is emitted from the municipal sewer system is unnecessary and burdensome.

The compliance procedures for biological treatment units are rewritten in the final rule for clarity, simplification, and as noted above, to eliminate cross-references to the HON. Because the changes are extensive, all of the compliance procedures and monitoring requirements for biological treatment units, not just the issues raised by the commenters, are summarized below.

Onsite or offsite biological treatment units may be used to comply with the standards for soluble HAP, and onsite biological treatment units may be used to comply with the standard for total soluble and partially soluble HAP. The compliance requirements vary depending on the concentration of partially soluble HAP in the wastewater, whether the treatment unit is open or closed, whether the biological treatment unit is enhanced, and whether the wastewater is treated onsite or offsite.

If wastewater containing soluble HAP and any concentration of partially soluble HAP is treated in an open, onsite biological treatment unit that does not meet the definition of an enhanced biological treatment unit, the owner or operator must conduct an initial performance test to determine the fraction biodegraded (f_{bio}) in the unit; the f_{bio} for the compounds may be calculated using any of the procedures in appendix C to 40 CFR part 63, except procedure 3 (inlet and outlet concentration measurements). As noted in section VI.D.5, the treatment unit may remain open if the fraction biodegraded meets or exceeds the level of the standard. For a closed biological treatment system, the owner or operator may follow the same procedure; alternatively, the owner or operator of a closed biological treatment unit may conduct either a design evaluation using procedure 3 or a performance test to determine the mass reduction of soluble HAP (or total soluble and partially soluble HAP) in the unit. Under the proposed rule, the owner or operator of open and closed biological treatment units would have been required to specify appropriate monitoring parameters in the Notification of Compliance Status Report, subject to approval of the permitting authority. Based on consideration of the comments, EPA decided to specify continuous monitoring requirements for TSS and BOD in the final rule. To be in compliance, the TSS and BOD concentrations must not exceed the TSS and BOD criteria in 40 CFR 439 more frequently than, or by amounts greater than, allowed by the noncompliance reporting criteria in 40 CFR 123.45, appendix A.

If wastewater containing soluble HAP and more than 50 ppmw of partially soluble HAP is treated in an onsite, enhanced biological treatment system, the compliance procedures are the same as described above, except that the f_{bio} for soluble compounds may be calculated using either the default for first order biodegradation constants or any of the procedures in appendix C of 40 CFR part 63. As noted in section VI.D.6, the owner or operator may use a biodegradation rate constant of 3.5 L/g MLVSS-hr for methanol. The owner or operator also must monitor for TSS and BOD as described above. In addition, to demonstrate continuous compliance with the 1 kg/m^3 level in the definition of enhanced biological treatment unit, the owner or operator must monitor the concentration of MLVSS.

If wastewater containing soluble HAP and less than 50 ppmw of partially soluble HAP is treated in an onsite, enhanced biological treatment unit, the owner or operator is exempt from the performance test requirement for the treatment unit. Monitoring for TSS, BOD, and biomass is required as described above.

Wastewater containing soluble HAP and less than 50 ppmw of partially soluble HAP may be transferred for offsite treatment or onsite treatment in a unit not owned by the source. Before the source may transfer such wastewater, the transferee must submit to EPA written certification that the transferee will manage and treat any affected wastewater or residuals in accordance with the requirements of the rule. The initial compliance procedures and monitoring requirements to show continuous compliance are the same as for similar onsite units treating the same wastewater. In response to the comments, EPA reexamined emissions from municipal sewer systems and determined that the major potential for emissions is from the headworks. Thus, if the wastewater is discharged to a POTW, the final rule requires the owner or operator to demonstrate that less than 5 percent of HAPs are lost. However, if the headworks at the POTW are covered, no such demonstration is required. The same emission suppression requirements apply if the wastewater is discharged for treatment in any other type of offsite treatment unit or onsite treatment unit not owned by the source.

10. Control Requirements for Individual Drain Systems

The rule requires emission suppression and control measures for all individual drain systems that manage affected wastewater or residuals onsite. Several commenters requested that EPA exempt individual drain systems from these requirements, and allow them to be vented to the atmosphere, if they either manage wastewater that contains only soluble HAP compounds and de minimis amounts of partially soluble HAP compounds or demonstrate that emissions from the individual drain system and associated wastewater tanks are less than 5 percent of the loading in the affected wastewater. The commenter's rationale for this request was that: (1) a PhRMA study of municipal sewers, which was submitted to EPA, showed the potential emissions from individual drain systems that manage wastewater containing primarily soluble HAP are low; (2) the control is not cost effective; and (3) emissions of combustion products would increase because facilities would meet the requirement with steam strippers or incinerators.

For wastewater, EPA determined that MACT consists of hard-piping to a steam stripper. Because this configuration was determined to be a reasonable MACT floor requirement, any alternative must achieve equivalent emission reductions. As in the HON, a covered individual drain system is considered equivalent to hard piping. Thus, EPA did not change the requirements for individual drain systems in the final rule.

E. Equipment Leak Provisions

Several commenters raised a number of issues related to equipment leaks and EPA's proposed requirements for the LDAR program developed for the pharmaceutical manufacturing industry. The proposed general equipment leak requirements were based on subpart H (from the HON rule) and included slight changes tailored for the pharmaceutical industry. Some commenters were confused by the requirements and others were concerned that some facilities will be subject to two different LDAR programs because some pharmaceutical manufacturing operations are already subject to subpart I (which requires compliance with subpart H of the HON for components at pharmaceutical production processes that use carbon tetrachloride or methylene chloride). Today's final rule clarifies EPA's intent that affected sources that are subject to today's final rule and subpart I of 40 CFR part 63 will no longer be required to comply with subpart I after the compliance dates for today's final rule. Many commenters argued that EPA is bound by the subpart I regulatory negotiation and therefore, is not allowed to expand the LDAR requirements to include any HAP other than carbon tetrachloride and methylene chloride. The Clean Air Act requires that EPA regulate all major sources of HAP. The regulatory negotiations conducted in the development of subpart I included only a certain fraction of components from the industry because that was the extent of information that EPA had at the time the negotiations were conducted. The Agency does not agree that the negotiated rule for equipment leaks precludes further regulation of equipment leaks for pharmaceutical manufacturing operations.

Some of the changes and assumptions made in estimating the uncontrolled emissions for the industry used in determining the proposed LDAR requirements were questioned by the commenters. A group of commenters disapproved of the Agency's revised method to estimate uncontrolled emissions using the uncontrolled SOCMI average emission factors. The commenters argued that none of the studies used in developing the SOCMI emission factors involved pharmaceutical manufacturing operations.

Commenters also questioned EPA's assumptions and data used in some of the LDAR cost calculations. In general, commenters stated that the actual cost-effectiveness value associated with the proposed LDAR program was much higher than EPA's estimate due to overestimated emission reductions and underestimated costs. In response to these comments, the Agency reviewed its cost analysis and recalculated the cost effectiveness of several LDAR programs. The most acceptable program, in terms of cost effectiveness, is based on requirements similar to those of other recent regulations for similar manufacturing industries and the provisions developed for the SOCMI Consolidated Air Rule (CAR) which is yet to be proposed. The most significant difference between the CAR equipment leaks subpart and the proposed equipment leaks provisions is the innovative approach taken in the CAR to monitoring valves and connectors for leaks.

The CAR program significantly reduces the amount of burden associated with monitoring these types of equipment for leaks without increasing the emissions of regulated pollutants to the environment. In calculating the impacts of requiring an LDAR program meeting the requirements of the CAR, EPA calculated monitoring costs based on established guidance and calculated uncontrolled emissions using initial leak frequencies reported from the industry. The details of this analysis are included in the project docket (A–96–03) as Item No. IV–B–5. The EPA, in reassessing industry leak data, addressed many of the concerns of the commenters relative to the inclusion or exclusion of specific data.

Using as a starting point leak data that was confirmed as initial survey data by PhRMA, EPA reviewed the data base and further defined the pool of data. Some data from PhRMA's compilation was revised to reflect reported leak definitions, also, some data was excluded based on the facility's explanation of frequency of monitoring and calculated leak rates and the conclusion that the leak rates did not indeed reflect initial monitoring data. The resulting initial leak rate data was

1.45 percent for valves, 6.88 percent for pumps, and 1.5 percent for connectors.

The subsequent leak rates are a critical parameter in calculating the overall cost effectiveness of any LDAR program. Limited data were available to determine the leak rates at pharmaceutical manufacturing frequencies after the application of LDAR. Therefore, EPA assumed that the equipment leak frequency occurrence rate after implementation of LDAR was equal to the performance levels required in the draft CAR, that repairs were 100 percent effective, and that there were no recurrences of leaks. For the CAR rule, where several performance levels and corresponding monitoring schedules are available, occurrence rates were based on the best performance levels and longest monitoring intervals available. For flanges and valves, this performance level is 0.25 percent leakers. The corresponding monitoring interval for flanges is once every 8 years; for valves, it is once every 2 years. For light liquid pumps there is no performance level specified, therefore it was assumed that the leak occurrence rate was equal to 50 percent of the initial leak frequency. Subsequent leak frequencies for the revised EPA analysis were estimated to be 0.25 percent for valves, 3.44 percent for pumps, and 0.25 percent for connectors.

Emission reductions for the program were estimated to be the difference between the uncontrolled emission rate, as calculated using the mass emission rate, in kg/hr-source, calculated from the Average Leak Rate (ALR) equations and initial leak data, and the controlled emission rate, calculated using the ALR equations and assumed subsequent leak frequencies. The controlled emission rate was based on one-half of the occurrence rate. This assumption was necessary to account for the average leak frequency over the entire monitoring cycle.

The EPA, in the revised analysis, also addressed concerns of the commenters related to specific cost items. In general, capital and annualized costs for monitoring instruments, data management systems, and actual monitoring are not unreasonable and fall within the costs quoted by vendors and LDAR contract services, based on recent inquiries by EPA. Therefore, EPA did not revise significantly any cost items used in the model facility analysis.

Based on this revised analysis, the Agency found that the cost effectiveness of the CAR LDAR program was approximately $1000/Mg HAP for a model pharmaceutical facility.

After consideration of the above comments, EPA revised the proposed leak detection and repair provisions to be consistent with the Agency's recent efforts toward consolidation of equipment leak requirements for air regulations, the increased focus on processes with leaking components, and a general lessening of monitoring and recordkeeping and reporting requirements for processes with nonleaking components. Most of the changes to the proposed rule involve the requirements for valves and connectors in gas/vapor service and in light liquid service. These changes include the addition of 2 year monitoring (instead of once every four quarters) for those processes with less than 0.25 percent leaking valves; extending the monitoring period for connectors with low leak rates; provisions for valve subgrouping; deletion of the quality improvement program implementation requirement and the credit for valves removed; and revisions to the calculations for determining the percentage of leaking valves. The Agency believes that the equipment leak requirements included in today's final rule greatly reduce the administrative burden associated with LDAR recordkeeping and reporting, and at the same time, result in a significant reduction in emissions.

F. Pollution Prevention Alternative

Many comments were received on the proposed pollution prevention alternative, primarily relating to the proposed restrictions to the use of this alternative and the lack of specific recordkeeping and reporting requirements. The following sections summarize the commenters' concerns regarding the proposed pollution prevention alternative, EPA's response to these concerns, and subsequent changes made in today's final rule.

1. Restrictions on the Pollution Prevention (P2) Alternative

At proposal, processes emitting HAP that are generated in the process were perceived by commenters as being prohibited from using the pollution prevention alternative. Many commenters stated that processes that generate HAP should be allowed to use the P2 alternative as long as these quantities were included in the analysis. These commenters also recommended that the rule provide a de minimis HAP generation cutoff below which facilities could use the P2 alternative. The EPA agrees with the commenters that PMPU's that generate HAP emissions should be eligible for the P2 standard, provided the HAP emissions generated by the PMPU are controlled to the required levels. Therefore, today's final rule clarifies that processes that generate HAP can use the P2 alternative, provided that the HAP emissions generated in the PMPU are controlled to the required levels for storage tanks, process vents, wastewater and equipment leaks in §§ 63.1253 through 63.1256 of today's final, and the remaining requirements of the P2 alternative are met. Because the final rule requires sources to account for HAP generated in the process, a de minimis HAP generation cutoff is not needed.

No increase in the production-indexed VOC consumption factor was allowed as the result of compliance with the P2 alternative at proposal. One commenter stated that the stipulation in the P2 alternative that does not allow for an increase in the VOC consumption factor as a result of a decrease in use of HAP is unfair. According to the commenter, this restriction will eliminate many solvent replacement projects. The example that the commenter used was a 100 percent reduction in the use of methylene chloride (a non-VOC HAP) by replacing this solvent with a water-based solvent that contains trace amounts of some VOC. This trace amount of VOC would result in an increase in the VOC consumption factor. The commenter further explained that HAP solvents generally tend to have more aggressive solvent properties than non-HAP, and thus, when replacing a HAP solvent with a non-HAP solvent, the result is generally lower yields, more extensive processing, or higher quantities of solvent used. The commenter suggested that an upper limit could be set on the increase in VOC consumption, and gave a ''conservative'' limit of two times the baseline production-indexed VOC consumption factor.

In developing the pollution prevention alternative, EPA's intention was to recognize those processes that have reduced or will reduce the amount of HAP solvents used in the manufacture of pharmaceutical products as viable alternatives to add-on controls. By preventing affected sources from increasing the production-indexed VOC consumption factor, EPA intended to prevent solvent substitutions that merely swapped HAP for VOC. After reviewing the proposed pollution prevention standards in light of commenters concerns, EPA realized that the proposed standards gave an unfair advantage to affected sources that use VOC-HAP solvents as opposed to non-VOC HAP solvents. As proposed, the rule did not allow affected sources using non-VOC HAP solvents to switch to

low-VOC solvents and still qualify under the pollution prevention alternative because of the automatic increase in the production-indexed VOC consumption factor. However, affected sources that use VOC-HAP solvents could switch to low-VOC solvents as long as the production-indexed VOC consumption factor did not increase. The EPA's intention in the final rule is that pollution prevention be accomplished through reductions in solvent usage as opposed to solvent substitution. However, the EPA realized that the proposed rule gave an unfair advantage to sources using VOC-HAP solvents as opposed to non-HAP solvents because the rule did not allow affected sources using non-VOC HAP solvents to switch to VOC solvents and still qualify under the pollution prevention alternative. After consideration of this concern, EPA changed the final rule to require an equivalent reduction in the production-indexed VOC consumption factor, if the reduction in the production-indexed HAP consumption factor is achieved by reducing a HAP that is also a VOC. If the reduction in the production-indexed HAP consumption factor is achieved by reducing HAP that is not VOC, the consumption-indexed VOC factor may not be increased. In making these changes to the final rule, EPA essentially eliminated the possibility of receiving credit, through the pollution prevention alternative, for substituting VOC for HAP.

For example, a given PMPU has established its baseline production-indexed consumption factors of 10 kg/kg HAP and 20 kg/kg VOC. The 10 kg/kg HAP factor is made up of 4 kg/kg methanol and 6 kg/kg methylene chloride. The 20 kg/kg VOC factor is made up of 16 kg/kg ethanol and 4 kg/kg methanol. In order to comply with the P2 alternative, the owner/operator would be required to reduce their 10 kg/kg HAP factor to 2.5 kg/kg. This could be accomplished in a number of ways. Even if all the methanol were eliminated, a reduction of 3.5 kg/kg methylene chloride would still be required to yield 2.5 kg/kg. In this case, the production-indexed VOC consumption factor would also be decreased by the 4 kg/kg MeOH to 16 kg/kg VOC; however, no additional reductions of the ethanol would be required.

Today's final rule also changes the time period over which the baseline production-indexed HAP and VOC consumption factors are determined. At proposal, baseline production indexed consumption factors were determined based on the average values for the first full year of operation (or the first year for which data are available). The final rule requires that the baseline production-indexed HAP and VOC consumption factors be determined based on consumption and production values that are averaged over the time period from startup of the process until the present time (assuming the process has been in operation at least 1 full year), or the first 3 years of operation, whichever is the lesser time period. The changes to the baseline averaging period were made to ensure the baseline production indexed HAP consumption factor reflected normal production.

Another restriction on the pollution prevention alternative that many commenters wanted removed was the exclusion of control devices that recycle material back to the process. A number of commenters stated that the proposed restrictions on the P2 alternative would exclude multiproduct (nondedicated) processes due to strict FDA and quality control restrictions on cross-contamination, which oppose attempts to reduce the amount of solvent consumed per kilogram of product. For this reason, the commenters suggested that the P2 alternative be modified to give multiple-product facilities greater opportunity to make use of this alternative. The specific modification suggested by the commenters includes allowing solvent that is ''returned to the economy'' to be considered as an alternative for multiproduct processes. The commenters noted that, for implementation purposes, the interested party (first user of the solvent) would need to demonstrate that the required fraction of solvent was transferred to another (second) user *as a raw material*, to be used *as is*, so that the second user will purchase that much less solvent. Under this approach, the consumption of HAP would be equivalent to the amount purchased minus the amount sold. Similarly, two commenters suggested that the P2 alternative should be revised to allow credit for in-process recycling in the calculation of HAP reduction from a process. Although EPA recognizes that multiple-product facilities may not be able to take advantage of the pollution prevention alternative, the type of program whereby one entity certifies the nature and amount of the recovered solvent usage by another entity would be difficult and burdensome to implement, and would require tracking and verifying the usage of the recovered solvent at the second entity. Also, when the recovered solvent is sold to the second entity, the first entity does not achieve any real emission reduction (i.e., reduction in solvent usage), but instead, takes credit for the assumed emission reduction that would occur at the second entity. Also, the second entity may not be a pharmaceutical manufacturing facility which would result in emission reductions being moved across source categories. For these reasons, the final rule does not allow credit for sale of recovered solvents in the P2 standard. Also, EPA disagrees with the commenters that suggest credits be given for in-process recycling because giving a source ''credit'' for in-process recycling would result in ''double-counting'' of the emission reduction. By recycling solvents, the owner or operator already has reduced the amount of solvent entering the process (i.e., the more that is recycled, the less that is purchased), so further credits due to recycling are not necessary. For the reasons given above, the restrictions on solvent recycling in the proposed rule remain unchanged in today's final rule.

2. P2 Demonstration Summary

The proposed rule in § 63.1255(a)(4) would have required sources that comply with the P2 alternative to maintain records of rolling average values of kg HAP/kg production and kg VOC/kg production. The proposed rule also specified how production-indexed HAP and VOC consumption factors should be calculated (i.e., by dividing annual consumption of total HAP or VOC by the annual production rate, per process) but did not require the owner or operator to explain how the reductions in production-indexed HAP consumption factors are achieved. Several commenters stated that EPA should develop data requirements necessary to substantiate compliance with the pollution prevention alternative. Two commenters suggested that the final rule require facilities to submit a ''P2 Demonstration Summary'' that briefly describes the pollution prevention methods that were used to achieve the reduction in HAP consumption. The commenters stated that information on the facility's P2 activities was necessary to verify that (1) the HAP consumption data are directly related, on a per process basis, to each process that is complying with the P2 alternative; and (2) the reduction in HAP consumption was achieved via pollution prevention methods that meet the Agency's definition of pollution prevention. These commenters also noted that, in order to provide adequate incentive for facilities to choose the pollution prevention alternative, the EPA should ensure that data requirements are reasonable and protect confidential chemical formulation data.

In response to the above comments, today's final rule requires owners and operators seeking to comply with the P2 alter native to submit a P2 Demonstration Summary that describes how the P2 alternative will be applied at their facilities. The P2 Demonstration Summary must be included in the facility's Precompliance Report, which is submitted 6 months prior to the compliance date. The minimum requirements of the P2 Demonstration Summary are listed in § 63.1257(f) of today's final rule. These data requirements include descriptions of how each facility measures and records HAP consumption and pharmaceutical product production on a daily, monthly, and annual basis, and appropriate documentation such as operator log sheets, copies of daily, monthly, and annual inventories of materials and products, shipment and purchase records, tank-specific charts for converting tank-level measurements to volume (e.g., gallons) of HAP or product, and temperature/density charts for converting tank volume measurements into weight measurements. Also, if a facility complying with the P2 standard uses the same HAP in more than one process, the owner or operator will be required to modify existing methods of tracking HAP consumption at the plant, if necessary, to ensure that HAP consumption can be measured for each PMPU, as opposed to facility-wide.

G. Alternative Standard

Commenters requested that EPA consider an alternative standard for facilities that treat HAP emissions with add-on control devices. Industry commenters stated that an alternative standard would be especially useful for facilities that use a common control device to treat aggregated emis sion streams. The commenters further stated the use of common dedicated control systems should be encouraged rather than discouraged for the following reasons: (1) the use of common controls will ultimately result in a greater emission reduction because processes that are not required to reduce emissions under the rule would be controlled as well; (2) the use of common controls may facilitate the streamlining of monitoring, performance testing, and recordkeeping requirements and as a result reduce the resource burdens on both industry and the enforcement agencies; (3) the use of common controls may make it easier to assure and assess compliance; and (4) common controls may ultimately be more energy-efficient and result in lower emissions of secondary pollutants since fewer control devices will be employed.

The Agency agrees with the commenters and decided for the above reasons to include an alternative standard for storage tanks and process vents that are equipped with add-on control devices in §§ 63.1253(d) and 63.1254(c), respectively. The Agency also agrees with the commenters' belief that there will be a number of facilities and State regulators that will benefit from a regulatory alternative that encourages aggregating and treating emissions with a state-of-the-art common control device. The alternative standard included in the final rule can be applied to individual process vents or storage tanks that have emissions that are controlled with add-on control devices or to storage tanks and/or process vents that are manifolded together prior to treatment in an end-of-line control device (or series of devices). The control device (or last control device in a series) must achieve an outlet, undiluted TOC concentration of 20 ppmv or less, as methane, or calibrated based on the predominant HAP. The control device must also achieve an outlet concentration of 20 ppmv or less hydrogen halides and halogens. The EPA considers this level of emissions the practical level of control for the technologies on which the standard is based. The requirement to correct for 3% O2 if supplemental combustion air is used is currently under review. This requirement may be revised at a later time.

To simplify applicability of the alternative, all process vent and storage tank emissions that are manifolded to a common control device are considered as one regulated entity under the alternative standard. Nonmanifolded vents are regulated under the rule as otherwise specified without taking credit for the manifolded portion of the process.

H. Testing and Compliance Demonstrations

1. Worst-Case Conditions for Testing

Extensive comments were received on the provisions for absolute or hypothetical worst-case testing contained in the proposed rule. Many commenters stated that the provisions are not workable, especially in batch facilities where multiple streams are routed to common control devices. In these situations, owners and operators might be required to cease production in order to simulate a hypothetical worst-case test for a given device, or would have to artificially affect production in order to align emission events for testing that would meet absolute worst-case conditions. Commenters emphasized that, in both situations, there are safety concerns associated with generating such conditions, as well as practical concerns.

One safety concern raised by the commenters related to both absolute and hypothetical worst-case testing is that the manifold systems designed to carry emission streams to control devices may not be sized to handle the absolute worst-case situation, which could lead to potentially explosive situations during absolute and hypothetical worst-case testing. Many commenters stated that sources often design and install manifold systems at a lower capacity than that of the control device itself to prevent such explosion potential.

The most common practical concern expressed was that the prediction of when worst-case conditions would be occurring would be very difficult, although many commenters stated that calculating the potential maximum inlet loading scenario for a control device used to control emissions from multiple batch processing vessels would be a difficult, but manageable, task. Many commenters suggested that fluctuations related to processing, including sudden changes in temperatures or operator, could shift the timing of emission events and render any predictions about the timing of specific events invalid. The commenters believe that, for devices controlling multiple streams from moderately complex facilities, absolute worst-case test conditions might never occur within the life of the facility, nor could they reasonably be predicted. Additionally, one commenter stated that an owner or operator might encounter difficulty in proving to a compliance inspector that the conditions of a test were, indeed, run at absolute worst case.

A practical concern with hypothetical worst case conditions raised by the commenters is that testing cannot be performed while an actual batch is being produced. Based on the commenters' past experiences, testing in some cases could result in a process shutdown for 2 weeks, resulting in serious production losses.

One commenter also stated that representative worst case will also result in timing uncertainties similar to those of the absolute worst-case situation, especially when the device is controlling a single process with numerous emission episodes.

For normal testing conditions, commenters believe that the restriction to operate within conditions that existed during the test should be dropped. They stated that, because the proposed

standards include an annual compliance period, the commenters argued that the control device will constantly see variably challenging conditions and therefore, should be allowed to operate under conditions that are outside the range of conditions encountered during testing. In order to alleviate the EPA's concerns that a test under normal conditions may not indicate a control device's performance under more challenging conditions, one commenter suggested that an additional requirement to provide a design evaluation under more challenging conditions be added. Many commenters also suggested that representative worst case should be revised to include all control devices, and should not be restricted to ''the level for which it was designed.'' Additionally, one commenter believes that EPA did not mean to impose this limit on representative testing conditions and would like EPA to make the appropriate language changes to reflect their intent. Lastly, several commenters expressed approval of testing under worst-case conditions, but would like the conditions to be more clearly defined.

The Agency's intent in requiring testing under worst case conditions is to document the reduction efficiency of the control device under its most challenging conditions. Subsequent to the initial compliance test, continuous monitoring of operating parameters established during the initial test is a reasonable measure of continuous compliance with the efficiency requirement under all conditions. Presumably, the control device should function as well or better under conditions that are not as challenging.

Many of the comments regarding worst-case testing conditions are related to the restrictive language defining the worst case challenge and the difficulty associated with developing a time-dependent emissions profile to identify the appropriate test period. In an effort to provide more flexibility to owners and operators regarding the identification of the proper testing conditions, EPA has redefined the worst case ''challenge'' to include challenging conditions that are not based on high HAP load. These conditions include cases where efficiencies are dependent on other characteristics of emission streams, including the characteristics of components and the operating principles of the devices. For example, in situations in which non-HAP VOC's are present, where the efficiency of a device is most challenged by dilute steam characteristics or where specific characteristics of the compounds create limitations on control efficiency. In sizing and estimating the regeneration requirement for a carbon adsorber, for example, all material in the emission stream entering the unit must be considered in estimating bed capacity. Likewise, a limiting factor in scrubber efficiency is the solubility or reactivity of components in the scrubbing liquor. These considerations must be made at the time of evaluation of the device for compliance with the rule.

For worst-case challenges that are based on loading of HAP, EPA has also expanded the language describing the development of the emission profile. The emissions profile can be developed based on the actual processing conditions at the facility, as proposed, in which all emission events that can contribute to the control device are identified and considered to determine the highest hourly HAP load from all events that can occur at the same time. However, in the final rule, other options for the emissions profile have been developed that consider the facility's limitations based on equipment or conveyance and capture systems. Owners and operators can develop emission profiles based on equipment, in which the highest hourly HAP-producing emission streams that possibly could enter the control device, considering the facility's available equipment and HAP materials, are identified as appropriate testing conditions. Also, owners and operators have the option to develop emission profiles based on limitations of the control device or conveyance system. For example, many manifolds are limited in flows and concentration limits by fans and LEL monitors. Conducting performance tests based on conditions approaching these limits is also an option provided in the rule.

The expanded language on emission profiles eliminates the need for allowing owners and operators to test at conditions that are less than the worst-case challenge. Therefore, language referring to testing under ''representative'' and ''normal'' conditions was deleted from the batch testing provisions. Additionally, the added flexibility associated describing worst case may alleviate commenter's concerns regarding loss of production time.

2. Expedited Test Methods

Many commenters stated that the test methods referenced in the proposal under § 63.1253(b) (1) through (6) will require modification, because the methods were developed for continuous processes. Based on the commenters' past experience, obtaining approval for modifications to test methods often takes 6 to 12 months. Therefore, the industry commenters would like for EPA to consider adding explicit language in the rule allowing for the use of alternative test methods and providing some mechanism for expedited approval.

Specific suggestions from the above commenters for expediting approval were to eliminate EPA's validation Method 301 in favor of a less burdensome method and to explicitly state that approval of minor modifications do not require Method 301 validation, or that approval of alternative test methods should not trigger the need for a title V permit revision.

In response to the above comments, the Agency believes that the provisions in the final rule that require a site-specific test plan be submitted prior to any testing suffice in providing a mechanism for the presentation of, and approval of, proposed modifications to EPA test methods. In general, Method 301 should be used as a validation method for completely new and different testing procedures and instruments that have not previously been reviewed by EPA. It is not the Agency's intent to require the use of Method 301 for minor modifications to test methods such as the relocation of sampling probes.

3. Use of Method 25A

One commenter stated that Method 25A should be used only after an accurate response factor has been determined. The final rule specifies the following test methods:

1. Method 18 for control efficiency in all situations.

2. Method 25 for control efficiency determination in combustion devices.

3. Method 25A for the 20 ppmv outlet TOC concentration standard.

4. Method 25A in control efficiency determinations in the situations described in the introductory paragraphs of Part 60, Appendix A, Method 25 (when direct measurement by FID is appropriate).

The importance of calibrating a FID reading obtained using Method 25A with respect to a certain compound (adjustment by response factor) depends on how the Method will be used to demonstrate compliance with the standard. In general, the EPA believes that an accurate response factor is necessary in cases where Method 25A is used to demonstrate control efficiency across a device where the composition of the stream may change, or in situations where multiple components, including non-HAP VOC's, are present. Because the relative proportion of

organic compounds may change across the control device, appropriate response factors are needed to accurately quantify TOC at the inlet and outlet of a control device. In addition, the final rule allows owners and operators the opportunity to demonstrate compliance at the outlet of a control device by measuring 20 ppmv TOC or less. The EPA has allowed owners and operators to calibrate the FID using methane or the predominant HAP expected in the emission stream. The use of methane as a calibration gas for the 20 ppmv TOC alternative standard is based on the response factor of methane because it is similar to response factors of HAP that are predominant in this industry, such as methylene chloride and methanol. The EPA intends with this requirement to minimize the burden of recalibration for various HAP constituents that may actually change over a given period of time.

4. Emission Profiles

Many commenters requested clarification of the methodology for developing an emissions profile, which was contained in § 63.1253(b)(iii) of the proposed rule. The commenters stated that the definition of emissions profile implies that sources must prepare a graph of HAP emissions versus time. However, because EPA included the language ''the average hourly HAP loading rate may be calculated by first dividing the HAP emissions from each episode by the duration of each episode, in hours, and selecting the highest average hourly block average'', the commenters thought that EPA's intent was not to profile emissions versus time, but rather to simply list each batch episode and the average hourly HAP emissions loading from each episode. Additionally, some commenters stated that the emission profile method seemed very complicated, and that personnel with operating experience can quickly determine the worst-case conditions for a control device without producing the extensive information required by the emissions profile. One commenter suggested changing the language of § 63.1253(b)(7)(iii)(A) by eliminating the phase ''must include,'' so that sources can have the option of discussing an alternative means of determining appropriate test conditions with the permitting authority.

The Agency's intent, when requiring the development of an emissions profile, is to determine the maximum HAP loading to a control device over time. Therefore, the rule requires that the emissions to the device be evaluated by plotting HAP emissions versus time. The EPA has not, in the final rule, changed the requirements for developing the emissions profile, although EPA did clarify the exact language in the final rule to address the commenter's concerns about the clarity of the requirement. Additionally, two other methods for developing the emission profile were provided in the final rule.

I. Equations

1. Use of Equations in 1978 CTG

As part of the procedure to demonstrate compliance with the emission reduction standard for process vents, the final rule requires the owner or operator to determine uncontrolled emissions from each vent. Equations to calculate emissions from certain unit operations are provided in the rule. Numerous commenters requested that the rule also allow the use of similar equations for the same unit operations that are presented in the 1978 CTG. The commenters stated that although the two procedures give different results, they are based on the same fundamental principles and neither gives better results. The commenters provided the following additional reasons for allowing use of the equations from the 1978 CTG: (1) the MACT floor was based on data from the industry, which were estimated using the procedures in the 1978 CTG, (2) sources are already using the procedures in the 1978 CTG to comply with other regulatory programs and would incur significant costs to invest in a program and data systems to develop and maintain a second method for estimating emissions, (3) maintaining two sets of emission estimates would make State review and compliance efforts complex and confusing, possibly leading to compliance actions for perceived violations of one estimate but not the other, and (4) the emission estimation equations in the rule are based on the 1994 ACT, which has not undergone public review and comment.

The EPA reevaluated the procedures for calculating uncontrolled emissions and concluded that except for two situations, the equations in both the 1978 CTG and the 1994 ACT documents give acceptable estimates of emissions for the purposes of this rule. Therefore, both sets of equations, except as noted below, are included in the final rule for existing sources. The two situations for which emission estimation procedures in the 1978 CTG are not acceptable for this rule are: (1) purging with streams that have high flow rates and (2) heating when the final temperature is higher than 10 K below the boiling point. The EPA believes this change mitigates the commenters concerns because the two situations where the 1978 CTG procedures are not allowed affect a small number of streams. Owners and operators will have to redo calculations for existing processes under these two conditions. In addition, the owner or operator will have to calculate uncontrolled emissions for those events that the owners/operators have only controlled emission estimates. This is because the 1978 CTG uses condenser temperature instead of vessel temperature. Details about the equations for purging and heating are provided in sections VI.I.2.b and VI.I.3.

2. Procedures to Estimate Emissions from Purging

a. *Equation.* The equation for purging was changed in the final rule because the term that accounts for the increase in flow rate due to the volatilization of HAP was inadvertently left out of the equation in the proposed rule (i.e., the purge flow rate needs to be multiplied by the ratio of the total pressure to the partial pressure of noncondensables at saturation). The revised equation is identical to the equation in the 1994 ACT and gives the same results as the equation in the 1978 CTG as long as the total pressure is equal to 760 mmHg.

b. *Saturation level for large purge streams.* The rule requires an owner or operator to assume a purge stream greater than 100 scfm is 25 percent saturated. One commenter believes the assumption that the vapor phase is 25 percent saturated rather than 100 percent saturated is merely a different assumption and is not based on better information. The commenter also stated that assuming streams are 100 percent saturated is more conservative because it will overestimate emissions, whereas the 25 percent assumption will sometimes overestimate and sometimes underestimate emissions.

The assumptions that purge streams with flow rates less than or equal to 100 scfm are 100 percent saturated, and that purge streams with flow rates greater than 100 scfm are 25 percent saturated, are based on modeling analyses that are described in the 1994 ACT. In the 1994 ACT, the mass transfer (of toluene) from the liquid to the purge stream was estimated using various correlations and a range of design and operating parameters. The correlations showed the purge streams, especially purge streams with high flow rates, were well below saturation for all but the most agitated vessels or vessels with very shallow head space. Assuming these large streams are completely saturated would result in significantly overestimated uncontrolled emissions.

Overestimating uncontrolled emissions leads to at least two problems. First, for a condenser, overestimating uncontrolled emissions means the control efficiency of the condenser will be overstated (and the condenser will operate at a higher temperature than is actually needed to meet the standard). A second problem with overestimating the uncontrolled emissions is that even if the control efficiency is being met (say with an incinerator), the quantity of emissions reductions would also be overestimated, which, if this stream were used in emissions averaging, would result in overestimation of credits. To mitigate these problems, EPA reviewed the results of the modeling analyses and selected values that while still conservative greatly reduce the potential amount of overestimation. The correlations showed that under all types of conditions, the degree of saturation declines rapidly with increases in purge flow rate up to about 100 scfm, and then nearly levels off; the ''knee'' of the curve was at about 100 scfm for every scenario. For all modeled scenarios, purge flow rates greater than 100 scfm were always less than 25 percent of saturation. Based on these results, the EPA believes that assuming purge streams with flow rates greater than 100 scfm are 25 percent saturated rather than 100 percent saturated results in a better estimate of emissions, more accurate operating parameters, and reasonable credits for emissions averaging. Thus, the requirement to assume purge streams with flow rates greater than 100 scfm are 25 percent saturated was retained in the final rule; but an owner or operator also may conduct an engineering assessment to show that another value is more appropriate.

3. Procedures to Estimate Emissions from Heating

a. *Heatup temperature within 50 K of boiling.* When the contents of a vessel are heated to a temperature within 50 K of boiling, the proposed rule would require the owner or operator to calculate emissions in increments. One increment covered the range from the initial vessel temperature to the temperature 50 K below the boiling point. The procedure then required estimates for each 5 K temperature range up to the final heatup temperature. One commenter believes calculating over 5 K increments is overly conservative. Other commenters believe the approach is an error because it differs from the approach in the 1994 ACT.

As noted in section VI.I.1, EPA is changing the rule to include the equations from the 1978 CTG and the 1994 ACT as well as the approach in the proposed rule for most heatup conditions at existing sources. In response to industry concerns, the EPA is also reducing the temperature cutoff from 50 to 10 K below the boiling point. The concept of a cap is retained because the procedures in the 1978 CTG and the 1994 ACT can greatly overestimate emissions when the final heatup temperature is close to the boiling point. The equation in the 1978 CTG estimates emissions assuming equilibrium at the temperature of a receiver (i.e., the equation uses a ratio of the condensables partial pressure to the noncondensables partial pressure at equilibrium). This procedure does not specify what equilibrium conditions should be used in the absence of a condenser. If the equilibrium partial pressures at the final heatup temperature are used, the equation overestimates emissions. The overestimate is most significant when the final heatup temperature is close to the boiling point because the partial pressures ratio (condensables to noncondensables) increases exponentially with increasing temperature, and goes to infinity as the temperature approaches the boiling point. Using the average of the ratios at the initial and final temperatures, as is done in the 1994 ACT, also can overestimate emissions. The EPA believes calculating emissions over the 5 K increments when the final heatup temperature is above the temperature 10 K below the boiling point is a reasonable compromise between the accuracy of the estimate and the effort needed to perform the calculation.

b. *Emissions From Process Condenser.* Under the proposed rule, if the contents of a vessel are heated to the boiling point and the vessel operates with a process condenser, the emissions would be calculated using both the heatup and displacement equations. One commenter noted that this procedure results in negative emissions. The EPA reevaluated this equation and determined that this result occurs only if the process condenser operates at a temperature lower than the initial temperature of the vessel. To correct this problem, the final rule states that either the heatup procedure in the 1978 CTG or a variation of this procedure is to be used. The variation allows the owner or operator to use a vapor-liquid equilibrium relationship other than Raoult's law and to use the actual system pressure rather than assuming the system is at atmospheric pressure. Both procedures are also applicable when the condenser temperature is higher than the initial temperature of the vessel.

4. Vapor-Liquid Equilibrium Relationships for Multicomponent Systems

To estimate emissions, the rule specifies that owners and operators assume one of four vapor-liquid equilibrium (VLE) relationships apply, depending on the system conditions. These relationships are: (1) Raoult's law, (2) Henry's law, (3) a VLE relationship based on the use of activity coefficients (obtained experimentally or from models) to correct for nonideality in the liquid phase, and (4) the assumption that components of the system behave independently so that the sum of all HAP vapor pressures is equal to the total HAP partial pressure. Once the applicable VLE relationship is established, the HAP partial pressure(s) can be determined and used in the applicable equation to estimate the HAP emissions.

Two commenters expressed concern about some of the VLE relationships that the rule requires for estimating emissions from multicomponent systems. The commenters concur with EPA that Raoult's law is appropriate for miscible systems. The commenters also acknowledged that use of Henry's law is generally more accurate that Raoult's law in predicting vapor mole fraction for mixtures below the solubility limit, but they stated that this approach is excessively difficult and unworkable because Henry's law constants are not available for many of the solvents and reagents used in the pharmaceuticals industry. Therefore, the commenters would prefer to use Raoult's law for these mixtures. For multicomponent systems in which the compounds are not miscible or are only partially miscible, the commenters opposed the use of equilibrium relationships based on activity coefficients because developing activity coefficients is burdensome. As an alternative, the commenters recommended using an approach in which each liquid phase is treated independently, and emissions from each phase are calculated separately.

The final rule clarifies EPA's intent regarding the use of vapor-liquid equilibrium relationships. If the components are miscible in one another, Raoult's law may be used when it is applicable. However, if a miscible solution is not well characterized by Raoult's law, activity coefficients must be used. For dilute aqueous mixtures, Henry's law must be used. The EPA rejects the commenter's argument to use

Raoult's law due to the lack of Henry's law constants; Table I of appendix C in 40 CFR 63 contains Henry's law constants at 25°C and 100°C for 125 of the most common organic HAP compounds. For HAP compounds that are not on the list, the owner or operator must estimate the Henry's law constant. For systems with multiple liquid phases, the owner or operator may either use activity coefficients or, as suggested by the commenter, assume the components behave independently and assume the HAP vapor pressures and partial pressures are equal.

5. Emission Estimation Equations Versus Engineering Assessments

The rule lists two conditions under which an owner or operator may conduct an engineering assessment to show that equations in the rule are not appropriate: (1) if available test data and the results of calculations using an equation differ by more than 20 percent and (2) if the owner or operator can demonstrate through any other means that the emission estimation equations are not appropriate for a given batch emissions episode. Several commenters stated that both conditions should be deleted from the rule. The commenters rationale for deleting the conditions shows the language in the proposed rule did not convey EPA's intent. As a result, the conditions are rewritten in the final rule for clarity, and additional clarification is provided in the following paragraphs of today's notice.

Batch emission episodes may be due to a unit operation that is described by an equation in the rule or to a unit operation that is not described by an equation in the rule. Estimating emissions using the applicable equation is always the standard approach for emissions episodes that are covered by an equation. However, an owner or operator also always has the opportunity to conduct an engineering assessment to demonstrate and get approval to use another emission estimation technique. The intent of the first condition is to indicate that an owner or operator could include such a discrepancy between test data and calculations in an engineering assessment and it would be considered evidence that the equation is not appropriate (provided, of course, that the permitting authority agrees that the test data were obtained under ''representative conditions''). The purpose of the second condition is to indicate that other information may also be used in the design evaluation as evidence that an equation is not appropriate. Again, the permitting authority would have to approve the use of any proposed alternative to the equation.

The conditions have nothing to do with estimating emissions for batch emissions episodes from unit operations that are not described by equations in the rule. For such emissions episodes, an owner or operator would be required to conduct an engineering assessment to show how emissions will be estimated.

6. Calculation of Controlled Emissions

Two commenters stated that the rule should allow the use of techniques in the 1978 CTG to calculate controlled emissions from a condenser. The commenters stated that the procedures in the proposed rule cannot be used because they specify the use of system temperature, whereas the correct technique, which is used in the 1978 CTG, is to use the exit gas temperature from the condenser. One commenter also stated that even when the equations in the rule and the 1978 CTG are identical, ''implementation differences'' cause the controlled emissions estimates to differ. To address the commenters' concerns, the final rule specifies both the applicable equation and any changes to the temperature or volume that are needed for calculating controlled emissions.

J. Monitoring Requirements

Many commenters objected to the use of monitoring parameters for the determination of a source's compliance status on a continuous basis. Their central issue, for many emission streams controlled in this industry (e.g., batch, nondedicated, possibly manifolded together and routed to common control), is that an exceedance of a parameter level, as measured on 15-minute intervals and averaged over a 24-hour basis, may not necessarily constitute a violation of the 93 percent control requirement for the process for the following reasons:

1. If the parameter is conservative, the device will operate above the required efficiency;

2. The loading on the control device may be less than the assumed loading used to set the parameter, so the device provides adequate control even though the parameter has not been attained;

3. The actual compounds in the emission streams may be easier to treat than those used to set the parameter; and

4. The excursion may occur when there are little or no HAP emissions from the process routed to the device.

The EPA had solicited comment on this issue, and at that time, had questioned why the industry couldn't set multiple parametric levels for control devices to account for different operating scenarios. The commenters countered that, especially in the case of manifolded, end-of-line devices, it is not possible to predict with precision what conditions will exist at any point in time. Rather than establishing, up-front, a complex ''grid'' of parameters that will serve all potential combinations of operating scenarios, they would want to set conservative parametric levels as a screening mechanism for determining whether or not emission limits might have been exceeded, with an option to evaluate actual parameter excursions on a case-by-case basis after exceedances had occurred to determine whether an emission limit was actually exceeded.

The commenters recommended that the rule provide that a parameter exceedance must be reported to the permitting authority, with the opportunity to rebut the presumption that the emission limit(s) have been exceeded. Other commenters suggested that sources be treated in a manner consistent with the Compliance Assurance Monitoring (CAM) rule, which provides only that an excursion of a monitored parameter is an indication that an emission standard may have been exceeded, but makes no automatic finding of a violation of that emission standard.

In general, EPA recognizes two basic approaches to assuring that control devices used by the owner or operator to achieve compliance are properly operated and maintained so that the owner or operator continues to achieve compliance with applicable requirements. One method is to establish monitoring as a method for directly determining continuous compliance with the applicable requirements. The Agency has adopted this approach in part 63 standards, and is committed to following this approach whenever appropriate in future rulemakings. Another approach is to establish monitoring for the purposes of documenting continued operation of the control devices that are designed to provide a reasonable assurance of compliance, indicating excursion from these ranges, and correcting problems creating excursions. This second approach is outlined in the CAM rule, which applies to sources that are not currently subject to part 63 standards.

When determining appropriate monitoring options, EPA considers the availability and feasibility of the following monitoring strategies in a ''top-down'' fashion: (1) CEMS for the actual HAP emitted, (2) CEMS for HAP surrogates, (3) monitoring operating parameters, and (4) work practice standards. In evaluating the use of

CEMS in this standard, monitoring of individual HAP species was not found to be reasonable or technically feasible for many streams. However, in the case of continuous monitoring of surrogates, continuous TOC monitoring is considered a more viable monitoring option and is provided for some instances in the rule. (See discussion on alternative standard and on monitoring for carbon bed systems.) Monitoring of control device operating parameters is considered appropriate for many other emission sources, and therefore, most of the other monitoring options provided in the final rule are based on parametric monitoring.

The EPA has considered the commenters' argument that an exceedance of a monitoring parameter is not necessarily an exceedance of an emission limit, especially as described in the generic situations provided above. In the first three situations, EPA believes that as long as the source is given the flexibility to select operating parameters, including the option retained from the proposed rule to allow the owner or operator to set multiple parameter levels for different operating conditions, then the burden is on the source to remain within the parameter or parameter(s).

To address the potential disparity between parameter limit exceedances and emission limit exceedances, the final rule contains two different types of continuous compliance violations. Where a source is using a CEMS to monitor compliance with the 20 ppmv alternative standard, an exceedance is defined as a violation of the emission limit. Similarly, because the exit gas temperature of a condenser is so closely correlated with emissions, a condenser temperature exceedance is considered a violation of the emission limit. Exceedances of other types of parameter limits are defined as violations of an operating limit, rather than violations of the emission limit.

In response to industry's preference to evaluate parameter levels after an exceedance of a conservative parameter level to determine whether an emission limit was exceeded (thereby eliminating the need for a complex grid of preset parameter levels), EPA believes that the establishment of compliance levels *prior* to operation of the device or process is imperative; otherwise, the constant opportunity for rebutting a violation of the standard would render the standard unenforceable. While EPA is sensitive to industry's need to minimize its compliance burden, EPA believes that the burden placed on State agencies to consider the amount of information that the rebuttable presumption option would encourage is not reasonable.

In response to the fourth generic situation described by industry, EPA has provided in the final rule, clarification of situations (no flow) when exceedances of preset parameters would not constitute a violation of the standard.

For reasons described above, EPA rejects the assertion that the parametric levels should not be used as a direct indicator of compliance. The EPA believes that conditions in the proposed rule which have been retained in the final rule including options for setting parameters, coupled with clarifying the averaging times for compliance determinations and establishing valid data criteria for monitored parameters should address concerns of commenters, while retaining the enforceability of the standard. The final rule provides options for presetting multiple parameter levels to account for variation in batch emission stream characteristics within emission sources (as proposed), and to account for variability in combined stream characteristics in manifolds.

The final rule provides owners and operators with the option of setting averaging times based on either a ''block'' of time suitable for the expected variations of emission stream characteristics from a batch process (determined by the owner or operator, with some restrictions), or a 24-hour basis (as proposed).

The final rule also provides owners and operators with an opportunity to verify compliance based on a review of operating logs during periods of exceedances. Exceedances will not constitute violations of subpart GGG during periods when a parameter has been set based on worst-case conditions, or other conditions that were not representative of the conditions in the device during the exceedance, if the owner or operator has predetermined other levels that ensure compliance with the standards for these representative periods. If predetermined levels were established, the owner or operator can also determine compliance for discrete streams in manifolds by referencing to these limits.

Additionally, monitored data obtained during periods in which no flow to the control device occur should not be considered valid; during such periods, the final rule allows for the exclusion of such data from the daily or block averages. The use of a flowmeter to identify and exclude such periods from compliance average is therefore required in the final rule, if they cannot otherwise be predicted.

K. Recordkeeping and Reporting Requirements

Issues related to the amount and type(s) of recordkeeping and reporting requirements that were included in the proposed rule were raised by commenters representing both industry and enforcement agencies. The pharmaceutical manufacturing industry involves a wide variety of processes, products, and resulting emissions. In order to demonstrate compliance with the necessary MACT requirements, detailed records are needed to have a reliable, documented record of how the source complied with the regulation. The EPA has made a concerted effort to reduce the recordkeeping requirements of the final pharmaceutical rule. The EPA recognizes that unnecessary recordkeeping and reporting requirements would burden both the affected source and EPA/State enforcement agencies and will continue to review requirements to identify and implement other possible streamlining measures.

The EPA has reviewed the recordkeeping and reporting requirements required by the proposed rule and has eliminated those areas where duplicative and inapplicable requirements were proposed. Most of these changes involved areas where the referenced General Provision requirements were not directly applicable to this industry. Clarifications and/or additional language have been added to tailor the recordkeeping and reporting requirements to the relevant data needs from pharmaceutical manufacturing operations. Table 1 in today's final regulation was modified to include a summary column describing the relevant information in each part of the General Provisions, and more information was added to better relate the requirements of the final rule and those in the General Provisions.

Comments on precompliance reporting were varied depending on the commenter's perspective and experience. Some commenters viewed the precompliance reporting requirements as burdensome and restrictive. One commenter stated that submittal dates for reports and notifications due prior to the compliance date are much too early, unnecessary, and can be counterproductive. Two commenters stated that the Precompliance Report should be due only 3 months prior to the compliance date. Other commenters argued that the ''early'' due date for the Precompliance Report is valuable because it provides a practical means of

ensuring that a source is aware of the upcoming deadline. One of the commenters also stated that the description of test conditions and limits of operation for control devices tested under normal conditions and the corresponding monitoring parameter values should be submitted as part of the Pretest Notification Report rather than with the Precompliance Report. In response, the Agency revised the submittal dates for the precompliance report and the emissions averaging implementation plan to 6 months prior to the compliance date. The Agency believes the final submittal dates and data requirements for the precompliance report are adequate to provide the enforcement agencies with sufficient time to review the information.

Some commenters also suggested that the use of alternative parameters be included in the precompliance report and that periodic testing be done to correlate actual emission rates to alternative parameters. The EPA response to this issue is addressed in section VI.L of this preamble.

One commenter suggested that sources be required to establish an effective environmental management system to eliminate much of the paperwork burden associated with the proposed recordkeeping and reporting requirements. The Agency believes an effective environmental management system can be used to comply with all the requirements of the final rule provided the system is based on meeting the MACT requirements in the final rule. Sources are free to submit an alternative compliance plan to the appropriate agency to review/approve in lieu of any or all recordkeeping or reporting requirements.

Commenters also raised issues related to data availability stating that the proposed requirements were unreasonable, impracticable, and more stringent than those for other industries. The Agency does not agree with these comments.

L. Permitting and Compliance Options/ Change Management Strategy

1. Proposal Comments Received

In the April 1997 proposal, the EPA solicited comment on the interaction of this standard with the title V operating permits program, implemented at 40 CFR part 70. In addition, the Agency requested comment on an approach which would incorporate by reference the Notification of Compliance Status Report (NOCSR) into a pharmaceutical manufacturing facility's title V permit. The EPA also solicited comment on the types of operational changes that would trigger revision of the operating permit under title V. However, in soliciting comment on these issues, the Agency did not propose to revise part 70 through the establishment or implementation of subpart GGG.

Commenters to the proposed subpart GGG raised several issues with respect to process changes at pharmaceutical facilities, which they claimed would result in a potentially unmanageable title V permit administrative process. The pharmaceutical industry produces a wide range of existing and new and/or improved products primarily through the use of nondedicated equipment operated in a batch production mode. Commenters were fearful that frequent changes in the use of existing equipment as well as the additions of new equipment at pharmaceutical facilities would require frequent revisions to the operating permits for these facilities. These commenters predicted that such permit revisions would result in delays in implementing process changes and cause significant new administrative burdens on the facility and permitting authority.

The preamble to the proposed rule described the NOCSR as the compliance ''blueprint'' for implementation of the standard, containing ''[a]ll information regarding documentation of the facility's compliance status with regard to the standard. . . .'' This information would include ''process descriptions, emissions estimates from those processes, control device performance documentation, and continuous compliance demonstration strategies, including monitoring.'' The EPA solicited comment on whether the NOCSR could be initially incorporated by reference into the title V permit and whether the permit could be revised as necessary through quarterly update reports. The proposal posited that only changes requiring site-specific approval (such as the use of a monitoring parameter that was not identified in the standard) would trigger some significant review action under title V. The Agency expressed the view that this approach would allow enough flexibility for sources to make operational changes as necessary as well as changes to operating and compliance procedures without additional approval, if the changes were straightforward, and would assure that the compliance plan for the facility would always be reasonably current.

Most commenters did not support an ongoing implementation strategy based on permit revision for operational changes, even if it could be streamlined. Several industry commenters strongly reiterated concerns about the potentially huge administrative problems associated with implementing subpart GGG within title V permits.

In particular, PHRMA recommended an approach under which facilities that have been issued a title V permit before subpart GGG is finalized would be required to apply for a minor permit modification (MPM) by the due date for the NOCSR. The suggested MPM application would include: (1) a list of applicable subpart GGG requirements that should be included in the permit itself (including a ''menu'' of applicable process vent, tank, and wastewater standards); (2) a requirement for the facility to submit a compliance plan that outlines the regulated entities within the affected source (such list should include the identification of regulated processes, process vents, tanks, and wastewater PODs; a determination as to which substantive standard applies to each; and a list of corresponding testing, monitoring, record keeping, and reporting requirements); (3) a requirement for the facility to update the plan when a compliance requirement changes; (4) a requirement to submit the plan to the permitting authority every 6 months; and (5) a requirement to operate in accordance with the plan. For facilities that have not been issued a title V permit until after subpart GGG is finalized, a facility's initial permit would be issued to include these five items. Facilities that trigger new source MACT would be required to apply for a significant permit modification (SPM) prior to implementing the triggering change. Under this approach, PHRMA believes that a source could make most changes at the affected facility without triggering a title V permit revision, provided the compliance plan was updated to indicate the new regulated entities and/ or new requirements that would result from the change, thus avoiding delay while ensuring that the part 70 requirements are satisfied through timely recording of the requirements applicable to the source.

Title V requires operating permits to assure compliance with all applicable requirements at a source, including a section 112 standard such as subpart GGG. An existing source subject to subpart GGG must include in its operating permit by the time of the standard's compliance date—the latest date by which most provisions of the standard would become applicable requirements at existing affected sources-sufficient permit terms and conditions to assure compliance with the standard. If a source's initial title V permit does not include terms to assure compliance with subpart GGG by the

compliance date, the permit must be revised to incorporate the standard not later than 18 months after the standard's promulgation. *See* CAA section 502(b)(9). This will ensure that subpart GGG is reflected in title V permits for pharmaceutical facilities by the time of the compliance date and as required by statute, since the compliance date for subpart GGG is up to 36 months after the standard's promulgation (see section 63.1250(f)(1). Consistent with section 502(b)(6) of the Act, however, if the standard is promulgated when fewer than 3 years remain on a major source's permit term, a permitting authority's program may reflect the option not to require revisions to the permit to incorporate the standard. The Act permits State programs to require revisions to the permit to incorporate the standard in such instances, however, so any sources with fewer than 3 years remaining on their permits upon the promulgation of today's action, should consult their State permitting program regulations to determine whether revision to their permits is necessary to incorporate subpart GGG.

The EPA does not believe that PHRMA's recommended permitting approach would ensure that operating permits for pharmaceutical facilities assure compliance with subpart GGG by the standard's compliance date and subsequently during the permit term. PHRMA recommends including basic permit content information—such as the identification of regulated emissions units and activities, and their associated compliance requirements—in an off-permit compliance plan, when such information is appropriately required in the permit. The proposal addressed this point by soliciting comment on the incorporation by reference into the facility's permit of the NOCSR. The EPA believes that it is possible to provide the flexibility sought by pharmaceutical manufacturers while maintaining Congress' intent that the title V permit contain all of the applicable Federal requirements. However, neither the proposal nor today's final rule purports to revise part 70 to accomplish this transfer of permit content from the permit to an off-permit compliance plan, and EPA does not believe that a MACT standard such as this is the appropriate vehicle to accomplish revisions to part 70. A separate rulemaking is currently underway to revise part 70, and features of today's approach may be adopted in that rulemaking.

Moreover, for facilities that have been issued a title V permit before the MACT is promulgated, PHRMA's recommended approach would not meet the requirement that these permits assure compliance with subpart GGG by the standard's compliance date. In addition, the approach would not satisfy section 502(b)(9)'s requirement that such permits be revised not later than 18 months after the promulgation of subpart GGG. PHRMA recommended that facilities that have been issued a title V permit before the MACT is promulgated be required only to apply for a MPM by the due date for the NOCSR. The due date for the NOCSR under subpart GGG can fall as late as 150 days after the compliance date, see section 63.1260(f), and the compliance date for existing sources is within 3 years after the promulgation date of the standard, see section 63.1250(f)(1). Finally, under section 70.7(e)(2)(iv), a permitting authority may have up to 90 days following receipt of a MPM application to issue an actual MPM reflecting subpart GGG.

Therefore, PHRMA's recommended approach would allow existing sources with title V permits to delay revisions to their permits to incorporate subpart GGG as long as 44 months—36 months plus 5 months plus 3 months—after promulgation of the standard, when section 502(b)(9) requires such revisions to be accomplished not later than 18 months after promulgation of the standard. In addition, of course, PHRMA's approach would not ensure that existing sources subject to subpart GGG have permits that assure compliance with the standard by the time of the standard's compliance date. For these reasons, EPA declines to adopt PHRMA's recommended approach in its entirety. However, as stated above, EPA believes the Agency can meet the industry's needs while complying with statutory obligations and Congressional intent.

The EPA agrees that some types of pharmaceutical operational changes may be subject to frequent title V revisions. As a result, the EPA met with industry representatives to clarify industry comments received on the proposal. In response, EPA developed a recommended approach for managing changes involving reconfigurations of existing equipment and the additions of certain new equipment subject to the pharmaceutical MACT through title V permits. This change management strategy in general adopts aspects of both the EPA proposal (e.g., to incorporate the NOCSR into the title V permit) and of industry suggestions for managing change made subsequent to the NOCSR.

2. Description of Recommended Approach

a. *General strategy for change management.* This notice presents an interpretation of the current regulations at 40 CFR part 70, for purposes of an experimental permitting approach under which title V operating permits may be designed to implement subpart GGG and provide operational flexibility without frequent permit revision. This approach represents EPA's current views on these issues and, while it may include various statements that permitting authorities or sources may take certain actions, these statements are made pursuant to EPA's preliminary interpretations and, thus, are not binding on any party as a matter of law. Only if EPA makes its interpretations final through rulemaking will they be binding as a matter of law. This means that States are not required to follow this approach in implementing subpart GGG through their operating permit programs, and EPA will fully and fairly consider all comments and petitions calling upon the Agency to object to permits that rely upon the change management strategy.

Nonetheless, the Agency encourages States to use the flexibility described in this preamble wherever they believe that the change management strategy will assure compliance with subpart GGG, while implementing the MACT standard in an efficient, streamlined fashion. The EPA intends to use this strategy where requested by a pharmaceutical facility and where the Agency would to be the permitting authority of jurisdiction under 40 CFR part 71.

It should also be noted that the described change management strategy is only tailored toward meeting the requirements of subpart GGG. Additional strategies are likely to be needed to address the consequences of a particular change relative to other relevant applicable requirements [e.g., minor or major new source review (NSR)], particularly when the change would cause an increase in the type or amount of air pollutants released.

Under EPA's interpretation, the Agency envisions that all title V permits implementing the pharmaceutical MACT will contain two principal structures: the incorporated pharmaceutical MACT standard and a detailed description of the array of process equipment, control devices, and initial operating conditions at the subject facility. In addition, the title V permit may contain a third structure implementing the change management strategy through prior approval of

reasonably anticipated alternative operating scenarios [see section 70.6(a)(9)].

First, as it must under title V and part 70, the title V permit will contain permit terms and conditions that incorporate subpart GGG. These permit terms will include the requirements of the MACT rule applicable to PMPUs and other equipment that comprise pharmaceutical manufacturing operations, including all requirements for identifying affected emissions sources and applicable emission standards, calculating emissions, demonstrating compliance (e.g. requirements for the operation of control devices), and for testing, monitoring, record keeping and reporting.

The second permit structure, from the NOCSR submitted by the source owner, shows current operations and how the source is complying at that time with all the relevant requirements of subpart GGG (which were incorporated as the first permit feature). Named and described in the permit are the specific processes in operation at the time of the NOCSR and all those that will be run during the term of the permit; the PMPUs and other regulated emissions equipment and activities associated with the pharmaceutical manufacturing operations; the linkages between identified emissions points and control devices used for compliance with the standard; and the linkages between the identified emissions points and their associated compliance obligations under subpart GGG. The calculations demonstrating compliance must be submitted by the source in support of these linkages.

The third permit structure addresses the management of frequent changes at pharmaceutical facilities subject to subpart GGG. This structure generally will allow permit revisions at pharmaceutical facilities to be avoided without sacrificing compliance assurance, in instances where reasonably anticipated alternative operating scenarios can be established in title V permits and supported with detailed operating logs (onsite records). If a source owner or operator can reasonably anticipate the type of changes and operating scenarios relative to the current operations defined by the NOCSR (i.e. the baseline operating scenario) that will use the equipment identified in the permit and will occur over the life of a title V permit, part 70 provides for the permitting of such changes through alternative operating scenarios. However, because equipment configurations at pharmaceutical facilities can change frequently (and without complete predictability) in response to product changeovers, new drug introductions, and process improvements, the allowed operating scenarios need to be constructed in the title V permit in a ''menu'' format.

Under the permit menu for subpart GGG, a pharmaceutical source will be able to vary its array of processes and control devices from the permitted baseline scenario without need for permit revision, provided that these ways have been preapproved as alternative operating scenarios. This could include shifting process equipment, adding replacement process equipment, eliminating equipment within the same process, or changing the type or amount of solvent in order to improve existing processes or to add new processes. These changes, however, must not exceed the capacity of the control and process equipment as set out in the permit, and must always comply with the permit and all applicable requirements. The Agency again notes that such changes occurring under the change management strategy are preapproved for subpart GGG purposes only and other actions and/or strategies are necessary where other applicable requirements are implicated by such changes.

The change management strategy also addresses the addition of new condensers and of new process equipment subject to subpart GGG. Condensers are the only new control devices currently that may be advance approved and only in limited circumstances (see section VI.L.2.b. *Additional Considerations*). Bringing new process equipment into service may be accomplished in two situations as a reasonably anticipated alternative operating scenario for purposes of subpart GGG, provided that the new equipment is preapproved in the permit and otherwise meets the requirements below.

The first situation involves the like-kind replacement of permitted process equipment which is functionally equivalent to and provides no greater production capacity than the equipment being retired. The replacement transaction, and identification of the new process equipment, must be recorded in the OSIL along with other information necessary to reflect the changed operating scenario. Because the new process equipment is replacing the retired equipment that was specifically identified in the permit, the new process equipment need not be specifically identified in the initial permit in order to be preapproved. The preapproval approach does not allow the substitution of new process equipment for permitted equipment that will remain in service elsewhere at the source.

The second situation involves the addition of process equipment which already exists on-site but is not in current service. In order to be approved for purposes of subpart GGG, this equipment must be specifically identified in the permit in terms of its type and capacity. The Agency notes that the authority to preapprove such process equipment in the permit is limited to equipment for which the owner or operator holds a reasonable expectation that the equipment will be called into service over the 5-year life of the title V permit. Because this category of equipment already exists at the facility, and will be specifically identified in the permit with its capacity and type listed for review by the permitting authority, EPA, and public, the Agency believes such equipment may not only replace permitted, retired equipment, but may also augment permitted equipment in service and thereby increase production capacity at the source.

In both of these situations, the additions of such equipment must meet all provisions of the permit governing their operation, including the requirement to stay within the approved capacity of the control device to which their emissions are routed. Other situations involving process equipment may not be preapproved and are subject to the notice procedures of section 70.4(b) or the permit revision procedures of section 70.7. Options under the current regulations are, however, expected to change (see section VI.L.3. *Legal Considerations* for discussion of anticipated treatment of subpart GGG requirements attaching to new emissions units under the upcoming part 70 revisions).

At the time a source wishes to undertake a change that could trigger different obligations under subpart GGG or its permit, the source will evaluate first whether the change is within the scope of an approved alternative operating scenario in the permit. If so, the source will select the appropriate compliance options from the alternatives approved in the permit and implement the change consistent with the terms of the permit governing such selection. The source would not be required by the permit to route emissions from specific process equipment only to the specific control devices that were linked to them in the initial detailed compliance baseline. Instead, the menu of alternative operating scenarios, described below, in conjunction with features of subpart

GGG will allow a source to shift to the compliance obligations governing the change and, where applicable, to select among the control devices at the facility that the permitting authority has approved as capable of achieving compliance.

The menu of alternative operating scenarios is a combination of the first permit structure discussed above (i.e., the requirements of subpart GGG) and some additional features. In particular, the menu consists of: (1) a description of the emissions sources (e.g., process vents, wastewater points of determination, storage tanks, and other regulated equipment components) subject to the pharmaceutical MACT; (2) the specific emission standard or standards that potentially apply to each source; (3) all control devices that have been approved by the permitting authority through performance tests or engineering analyses (as provided by subpart GGG) to comply with those standards; (4) the parameters to be monitored and data to be recorded specified for each control device, each process or equipment, as appropriate, as well as the monitored parameter values that indicate compliance (i.e., parameter trigger levels); and (5) the testing, record keeping and reporting provisions that are relevant to each type of process or emissions source.

Whether a change can be accommodated within a preapproved alternative operating scenario from the menu depends on certain boundary conditions governing such use. These boundaries primarily depend upon: (1) the performance capabilities and any capacity limitations on control devices as approved in the permit for compliance;[1] (2) whether subpart GGG's provisions governing that change are limited to replicable operating procedures (ROPs) for determining emissions and applicable emissions limits; (3) whether changed emissions fall within the performance limits of (1) above; and (4) whether the approved monitoring approach remains applicable. The ROPs must be capable of yielding the identical compliance assessment whether applied by the source, permitting authority, EPA or member of the public. That is, the results from using these procedures are the same regardless of who uses it and when. The ROPs must be scientifically credible and be based solely on nondiscretionary steps and on objective data (where data are required). These ROPs are contained either in the standard itself or established during the title V permitting process. Where the applicable subpart GGG requirement is not already such a procedure, but one that can be established during the permit process (see later discussion as to which require ments are eligible), then the source would propose it and the permitting authority would specifically need to approve it, including any limits on its use, during a title V permit process that is subject to EPA and public review.

Where a permit would contain the change management structure, the source's on-site documentation, as required by subpart GGG (section 63.1259(b)(9)), will include an up-to-date operating log for alternative operating scenarios, [also required by section 70.6(a)(9)(i)]. The on-site implementation log (OSIL) must record sufficient information to show the compliance obligations of each specific operating scenario in advance of its operation. Accordingly, the OSIL must include for each process: (1) a description of the process and the type of process equipment used; (2) an identification of related process vents and their associated emissions episodes and durations, wastewater PODs, and tanks; (3) the applicable control requirements of this subpart, including the level of required control; (4) the control or treatment devices used, as applicable, including a description of operating and/or testing conditions for any associated control device; (5) the process vents, wastewater PODs, and tanks (including those from other processes) that are simultaneously routed to the control or treatment device(s); (6) the applicable monitoring requirements of this subpart and any parametric level that assures compliance for all emissions routed to the control or treatment device; (7) calculations and engineering analyses required to demonstrate compliance; and (8) a verification that the operating conditions for any associated control or treatment device have not been exceeded and that any required calculations and engineering analyses have been performed.

The OSIL, in conjunction with and the information contained in the permit, monitoring records, and any other available information and belief formed after reasonable inquiry, will provide the basis for making annual compliance certifications under section 70.5(d). Moreover, this information will allow an enforcement authority to verify when processes were being operated, to identify which emissions points from each process were controlled and how, and to determine whether the control devices were operated at performance levels that assured compliance with subpart GGG. The permit would require the source to submit a quarterly report of the new operating scenarios contained in to the OSIL to the permitting authority and to certify to its truth, accuracy and completeness pursuant to section 70.5(d). For reporting purposes, a change to any of the elements defining an operating scenario (see above) which have not previously been reported, except for element (5) above, shall constitute a new operating scenario. The permit shall also require that monitoring data, including that relevant to the identified parameter trigger levels, be submitted semiannually (except that deviations must be reported promptly). The source or the permitting authorities would then make compliance information and the OSIL reports available to EPA or members of the public upon request, consistent with confidential business information protections.

In establishing alternative operating scenarios in a title V permit, the source would propose performance levels and operating limits for control devices to be used for compliance. Except for condensers (see section VI.L.2.b. *Additional Considerations*), sources would then demonstrate compliance using control devices operated to accommodate the range of anticipated emissions episodes [i.e., a worst-case scenario(s) as provided in section 63.1257(b)(8)(i)]. The source must provide to the permitting authority in the NOCSR control device testing information and results (or other prescribed documentation), and monitoring provisions with parameters to be monitored to show compliance with the rule. Establishing monitoring parameter levels correlated to the required emissions reduction (i.e., trigger levels for compliance) assures compliance for anticipated worst-case emissions. This provides a source with considerable flexibility since most, if not all, changes to the source are likely to fall within the permitted worst-case emissions boundary and would not trigger a permit revision.

In some situations, the source may wish to establish multiple trigger levels for the same monitored parameter within the normal operating range of an existing control device, each of which would assure compliance for different specifically defined emissions profiles. Thus, within the constraints of a control device's capacity, the title V permit may establish more than one enforceable

[1] **Note** that these limitations must include restrictions on the amount of HAPs and, where relevant, the type of HAPs which can be routed to the device. It may be necessary to include other restrictions, e.g., total organic compounds that define the capacity and the performance of the control device.

trigger level for an operating parameter to accommodate most common kinds of anticipated operations without the need for a permit revision. A ROP in the permit must be used to calculate the emissions profile of any proposed change and match the new emissions profile to the appropriate operating parameter trigger level that assures compliance with subpart GGG. For example, in a system with three separate trigger levels for the same parameter, which have been predetermined in the permit, assume that the projected emissions associated with a particular change would require the level of control corresponding to the second trigger level. As a result, the calculated emissions would exceed the emissions profile associated with the first cutoff (and its lower level of control), would correspond to the emissions profile covered by the second and meet its required parameter trigger level, and would not meet the emissions profile characteristics and not require the greater control associated with the third trigger level.

For sources employing the change management strategy, the permit shall provide that a violation of the ROPs, a violation of other conditions implementing the change management strategy, or a violation of the monitored parameter trigger levels (as applicable and recorded in the OSIL) would be a violation of the permit and of the control device trigger operating limit, and a violation of the emissions limit where specifically provided for by the standard (e.g., an exceedance of the outlet gas temperature for a condenser). The EPA notes that neither the change management strategy nor the OSIL can alter any obligations that the source has to comply with either the permit or the MACT standard itself. While permitting authorities may extend the permit shield in section 70.6(f) to the permit terms and conditions of each alternative operating scenario contained in the permit, assuming the State program has a permit shield provision, this permit shield may not be applied to the specific compliance-related changes which are only recorded by the source in its OSIL (see section VI.L.3. *Legal Considerations*). Like CAA section 502(b)(10) changes, most administrative permit amendments, and MPMs which do not undergo prior public review [*see* sections 70.4(b)(12)(i)(B), 70.7(d)(4) and 70.7(e)(2)(vi)], the part 70 permit shield may not extend to an OSIL or source determinations made pursuant to the change management approach that have failed to undergo prior EPA and public review. The source's compliance with those parameter levels recorded in the OSIL will not shield the source against challenges to the source's compliance with subpart GGG.

To illustrate the change management permitting strategy, suppose a pharmaceutical source undertakes a process improvement project that replaces two steps in an existing pharmaceutical process with one new step. This project results in the elimination of two existing process vents from the process and the addition of a new vent. No new equipment is involved. Further, suppose that subpart GGG requires the existing process and the proposed process change to meet the 93 percent reduction requirement for process vents, and the source opts to meet that limit by ducting all vents from the process to an existing thermal oxidizer. As a first step, the source owner/operator must determine whether and to what extent the previously established baseline emissions profile for the process will change. To do this, the owner/operator will calculate the uncontrolled emissions from the new vent using the equations provided in the MACT rule (and incorporated into the permit). The new process step involves the following emissions-related activities: vapor displacement (Equation 8 in section 63.1257(d)(2)(i)(A) of the rule), heating (Equations 10–17), and depressurization (Equations 18–29). In calculating emissions, the owner/operator must supply the physical characteristics from the process batch production procedures as inputs to the required equations. This description is the material used and the procedures followed exactly by the source to perform the process each time the specific product is produced. The process batch description includes details such as: the amount and type of raw materials to be used in each batch, the mixing and heating cycle durations, the final temperature of the heated ingredients, reflux rates, and the temperature of the reflux condenser.

Once the emissions from the new process step are calculated, the owner/operator adds these emissions to the previously documented emissions from the process and subtracts the emissions from the two process steps that were eliminated to determine the total emissions to be routed to the thermal oxidizer. A revised emissions profile for the process is now established. Next, the owner/operator must evaluate whether the thermal oxidizer still assures compliance with the 93 percent reduction requirement. Under the source's title V permit, the owner/operator will have calculated and documented (and the permitting authority would have approved) the worst-case emissions profile that could be accommodated by the thermal oxidizer. The owner/operator compares the emissions profile in the worst-case analysis with the improved process emissions. If the worst-case emissions profile will not be exceeded, the changed process will comply with the standard, and the existing title V permit does not have to be revised (unless required to assure compliance with applicable requirements other than those of subpart GGG). If a new worst-case scenario would be created by the change, a permit revision must be undertaken to determine whether the change can be made. In order to support the permit revision, the owner/operator will have to perform additional analysis or testing, as required by the MACT rule and/or the permitting authority, to show that the oxidizer has sufficient capacity to control the new scenario to meet subpart GGG. This may require a corresponding revision to the monitored parameter compliance trigger level in the permit as well.

As stated earlier, the owner/operator is required by the MACT rule to keep records of all calculations performed to support the process improvement change. Thus, the on-site records include results of calculations to determine emissions from the new process step and total emissions from the improved process, and the comparison of emissions from the improved process with the previously established worst-case emissions analysis. If the change can be made without permit revision, the owner/operator also is required to maintain records in the OSIL showing when the change was made and how the new vent is controlled. In addition, the permit must require that the source operate consistently with the calculations made for the operating scenario described in the OSIL. Such consistency, however, does not protect a source from violations of the standard, where the calculations are in error or otherwise fail to assure compliance with subpart GGG.

In the example presented above, the new process involves emissions-related activities that are covered by the ROPs contained in subpart GGG. However, some activities may not fall under operations for which equations have been provided in the standard. In many such cases, the change management strategy allows the source to submit for approval its proposed methodology for quantifying these emissions. Under this approach, the permitting authority would have the opportunity to evaluate the proposed methodology and, if

judged replicable, by the permitting authority—with EPA and public review, establish this methodology in the title V permit. The ROPs could be established in the permit only through the permit issuance, permit renewal, or significant permit modification process. Where they are approved and upon their incorporation into the permit, the source must then use these procedures, as applicable, to determine if subsequent changes qualify for advance approval without need for permit revision under the change management strategy. The EPA intends to issue additional guidance to inform the development, review, and approval of such ROPs during the permitting process.

For example, the MACT rule does not give exact procedures or formulae for calculating wastewater characteristics needed to determine control requirements. Instead, the rule states that HAP concentrations in wastewater are to be determined based on testing, knowledge of the wastewater stream (using a mass balance approach or one relying on published water solubility data), or bench-scale or pilot-scale testing (see section 63.1257(e)(1)). To explain the development of ROPs to address this requirement, a more specific situation must be described. Suppose that the process improvement project above includes an extraction that was not previously part of the process, resulting in a new wastewater stream which the owner/ operator wishes to treat using an existing steam stripper. In order to create the necessary ROP for determining the wastewater characteristics of streams, the owner/ operator must first establish a methodology to determine this for the baseline scenario. During the initial compliance demonstration/permitting process, the owner/operator in this example would do so by proposing to determine the concentration of a partially soluble HAP in the aqueous phase of an extraction when a single organic compound is present by assuming that the concentration will be at the maximum possible value based on the solubility value found in standard reference texts. This procedure, along with the batch description and the number of batches to be produced each year, provides a ROP for determining the characteristics of the extraction step wastewater stream (i.e., HAP concentration and annual HAP load). After approval by the permitting authority, the ROP can be used for new or modified extraction wastewater streams to characterize the stream and to determine whether the stream is subject to treatment under the MACT standard per § 63.1256(a)(1)(i). [Note that this ROP would apply only when a single organic compound is present. A separate ROP would have to be developed and applied in other cases.]

In addition to this procedure, the owner/operator must also establish a replicable procedure to compare the wastewater characteristics associated with a change to the worst-case capabilities of the treatment unit. Accordingly, the appropriate operating parameter and the trigger level necessary to assure compliance with the standard must be established in the permit. The owner/operator may wish to establish more than one such trigger level to allow steam stripper operating parameters to be varied according to the ability of the treatment unit to treat different streams being routed to it. In this example, assume that an existing process at the facility uses methyl ethyl ketone (MEK) and generates an affected wastewater stream with 125,000 ppm MEK (based on the published solubility of MEK in water). Published data show that the Henry's Law Constant for MEK is 4.36×10^{-5} atm/gmole/m^3. Assume further that the initial steam stripper compliance demonstration for MEK removal indicated that a liquid/vapor (L/V) ratio of 12.7 and an average steam feed of 2,900 pounds per hour (not to fall below an instantaneous minimum of 2,300 pounds per hour) are required to achieve compliance.

Next, assume that a second existing process at the facility uses N,N-Dimethylanaline (DMA) and generates an affected wastewater stream with 16,000 ppm (based on the published water solubility for DMA). Published data show that the Henry's Law Constant for DMA is 1.75×10^{-5} atm/gmole/m^3. Assume further that the initial steam stripper compliance demonstration for DMA removal indicated that an L/V ratio of 10.0 and an average steam feed of 3,100 pounds per hour (not to fall below an instantaneous minimum of 2,400 pounds per hour) are required to achieve compliance.

The Henry's Law Constant is a measure of the partition of a compound between air and water (i.e., the ''strippability'' of the compound). Thus, based on the compliance demonstration results above, the owner/operator could propose, and the permitting authority approve, the conditions below for inclusion in the title V operating permit to assure compliance with subpart GGG for new and modified wastewater streams routed to the steam stripper. Note that these conditions would apply only to partially soluble HAPs with Henry's Law Constants equal to or greater than that of DMA. Other provisions would have to be made for soluble HAPs and for partially soluble HAPs with lower Henry's Law Constants, or the source would have to undertake a permit revision to address new streams containing HAPs of these types.

1. When the steam stripping unit is receiving wastewater containing one or more partially soluble HAP (and no soluble HAPs) and the lowest Henry's Law Constant for any of the HAPs is greater than or equal to 1.75×10^{-5} atm/gmole/m^3 but less than 4.36×10^{-5} atm/gmole/m^3, the stripper will maintain a maximum L/V ratio of 10.0 and an average steam feed of 3,100 pounds per hour (not to fall below an instantaneous minimum of 2,400 pounds per hour).

2. When the steam stripping unit is receiving wastewater containing one or more partially soluble HAP (and no soluble HAPs) and the lowest Henry's Law Constant for any of the HAPs is greater than or equal to 4.36×10^{-5} atm/gmole/m^3, the stripper will maintain a maximum L/V ratio of 12.7 and an average steam feed of 2,900 pounds per hour (not to fall below an instantaneous minimum 2,300 pounds per hour).

To illustrate the change management strategy for the wastewater requirements, assume in this example that a new extraction step will use methylene chloride which is listed as a partially soluble HAP in Table 2 of subpart GGG. Using the operating procedure already approved in the title V permit, the owner/operator determines that the new extraction step will generate a wastewater stream with 20,000 ppm methylene chloride (based on the published solubility of methylene chloride in water) and an annual load of more than 1 Megagram per year (based on the process ''recipe'' and maximum possible production rate or as limited by permit conditions). Thus, the new wastewater stream is subject to treatment under the MACT standard pursuant to section 63.1256(a)(1)(i)(A). Published data show that the Henry's Law Constant for methylene chloride is 2.68×10^{-3} atm/gmole/m^3. Since the Henry's Law Constant is greater than 4.36×10^{-5} atm/gmole/m^3, this stream can be discharged to the existing steam stripper provided the stripper is operated within the operating parameter trigger level established in the permit [i.e., maintaining a maximum L/V ratio of 12.7 and an average steam feed of 2,900 pounds per hour (not to fall below an instantaneous minimum of 2,300 pounds per hour)].

Based on this analysis, the new extraction step can be controlled by the steam stripper to assure compliance with the MACT standard and the change can be instituted without a permit revision. The owner/operator shall maintain in the on-site log records of all the procedures used (including the characterization of the new wastewater stream, the determination that the stream is subject to treatment under subpart GGG, and the comparison with the stripper's two-level Henry's Law Constant cutoffs) and the process and treatment unit parameters needed to verify ongoing compliance (including when the process change was instituted, when the modified process is in operation, how the wastewater stream is controlled, and the L/V ratio and average steam feed rate for the stripper). Moreover, the permit shall require the recordation in the log of additional applicability and compliance information, as necessary to assure compliance with subpart GGG.

b. *Additional considerations.* Additional options are available to permitting authorities designing flexible title V permits to accommodate, without permit revision, emissions changes controlled by a condenser. Instead of requiring that all changes affecting emissions must meet the MACT standard under constant operation of an existing condenser at worst-case conditions, a permitting authority may issue permits where the condenser may be operated at different temperatures correlated to actual emissions profiles. Permits (through their terms which incorporate subpart GGG) will already contain the replicable means to calculate emissions profiles for process changes and the condenser exit temperatures required to control them. The Agency may explore development of similar approaches for other control devices, but recognizes that any such approaches before being incorporated into the permit would have to: (1) be calibrated in the field for a particular site; (2) meet rigorous tests to demonstrate scientific credibility, replicability, and practical usage; (3) ultimately assure compliance with subpart GGG and all other relevant applicable requirements; and (4) be evaluated by EPA to determine whether such an approach is possible for other control devices.

New control devices are, in general, not preapproved and their operational limits must be the subject of a permit revision which incorporates this information into the title V permit. The Agency, based on its ongoing efforts to assure compliance, has found that the proposed new control devices must be subject to a prior site-specific evaluation by a reviewing authority in order to assure that the control device is adequately sized and that reasonable assumptions were used related to its performance. This general limitation is not related to change management except where the addition of new productive capacity (e.g., a new process using new process equipment) would require control capacity beyond that previously approved in the permit. Currently, the only exception to this limitation under the change management strategy involves the preapproval of certain new condensers. Here the permitting authority may advance approve new condensers but only to the extent that they are like-kind replacements for those currently approved in the permit or are specifically identified from an inventory of preapproved, existing (but not currently in-service) devices at the facility.

With respect to Leak Detection and Repair (LDAR) work practice standards under subpart GGG, changing to a new process or modifying an existing one would not affect the content of the title V permit. These LDAR requirements apply broadly across a site as a work practice standard to the fugitive emissions of many types of equipment components at a facility. This equipment typically includes pumps, pressure relief devices, valves, and connectors, which typically number in the thousands at pharmaceutical facilities. The individual components subject to the LDAR requirements do not need to be specifically listed in a facility's title V permit.[2]

Instead, the title V permit shall contain a general identification in the title V permit of the equipment covered and the associated compliance obligations that will suffice to assure compliance with the LDAR requirements. Accordingly, a separate up-to-date list of affected equipment components must be maintained as required by the extensive LDAR record keeping provisions. Given that no specific list of components is required in the permit, and the permit shall comprehensively cover the equipment component types subject to LDAR requirements, the content of the permit will be unaffected by changes to such components that occur in the course of introducing a new process or modifying an existing one.

Finally, the promulgated rule features alternative standards for any process vent and storage tank emissions sources that are ducted to control devices. These alternative standards require achieving a specific total organic carbon (TOC) concentration of 20 ppmv and a concentration of hydrogen halides and halogens of 20 ppmv from the outlet of control devices. Sources using these alternative compliance options are likely to reduce significantly (particularly where a single control device services multiple processes using nondedicated equipment) the required record keeping and reporting and to simplify the change management strategy. For example, a source could specify processes (which do not emit hydrogen halides or halogens), each of which vents to a carbon adsorption bed documented to achieve 20 ppmv TOC. In this case, several of the permit elements implementing the previously described change management strategy could be eliminated (e.g., provisions related to the menu of compliance options and suitable control devices, and the monitoring of parameter values), and much of the record keeping could be reduced to tracking which processes are routed to the common control device and monitoring TOC outlet concentrations to show compliance with the 20 ppmv standard. However, other monitoring and record keeping requirements (e.g., flow rate maximum through the control equipment) may be needed in the permit to address periodic monitoring or compliance assurance monitoring and non-MACT applicable requirements (e.g., minor NSR) which limit the total atmospheric loading from the source.

3. Legal Considerations

The management of change strategies set forth in this preamble represent the Agency's effort to devise an innovative approach to deal with the frequent process changes that take place at pharmaceutical manufacturing facilities without the need for equally frequent revisions to their permits. The strategies rely upon a number of factors (see section VI.L.4. *Supporting Rationale for Recommended Strategy*) that, while perhaps not unique in this industry and

[2] The rule's LDAR provisions apply to significant numbers of emissions units, and typically do not involve different emissions control levels for equipment components subject to LDAR requirements. The LDAR requirements typically are written as a set of work practice standards that either apply to a piece of equipment or do not apply. To ensure that an affected source properly identifies those pieces of equipment subject to the LDAR requirements under subpart GGG, the regulation is including a requirement to maintain a separate list of affected equipment components within the LDAR recordkeeping provisions. For these reasons, and because the LDAR requirements apply to so many equipment components at pharmaceutical facilities, the Agency believes it is appropriate not to require the individual components to be specifically listed in the title V permit for these facilities.

in subpart GGG, are specific to it, and the Agency is uncertain whether and to what extent they may have application in other contexts. These factors underlie the Agency's present belief that the change management strategy in its practical application will assure compliance with subpart GGG through title V permits, and satisfy the objectives of part 70 and title V of the Act.

This approach is frankly an experimental one. Although EPA believes that the legal interpretations upon which the Agency is relying are consistent with the Clean Air Act and existing regulations, some aspects of this approach strike out in new and untried directions. In effect, EPA is conducting a pilot program to demonstrate whether permits that allow changes under subpart GGG can be made: (1) without permit revision or 7-day advance notification under section 502(b)(10); (2) based on the source's application of clear, simple definitions and ROPs; and (3) while contemporaneously being recorded in detailed operating logs. The EPA will therefore be testing its belief that such an approach will be practicably enforceable, will assure compliance with the standard-obtaining the emissions reductions required by the standard, and will satisfy the objectives of title V of the Act.

The 40 CFR parts 70 and 71 provide for the establishment in title V operating permits of terms and conditions for reasonably anticipated operating scenarios at a source.[3] A source may then preapprove alternative operating scenarios in its permit and switch among these scenarios in response to operational demands, without obtaining a permit revision to account for the previously approved new operating scenarios and their different applicable requirements. All title V permits, including those implementing alternative scenarios, must contain terms and conditions sufficient to assure that each operating scenario will comply with all applicable requirements and will meet the requirements of part 70. Pursuant to section 70.6(a)(9), the source must identify such scenarios in its permit application and the permitting authority must approve the scenarios for inclusion in the permit. The permit terms and conditions necessary to implement the alternative operating scenarios must also require the source to record contemporaneously in an on-site log the scenario under which it is operating, upon changing from one scenario to another. The contemporaneous record of the present operating scenario that the source maintains on-site serves to document for important inspection and enforcement purposes that the source is in compliance with the source's permit terms and conditions.

The determination of when alternative scenarios are ''reasonably anticipated'' and would meet the requirements of section 70.6(a)(9) is not amenable to a rigid legal formula that can dictate through general guidance what types of permit terms and conditions will ensure that a source's future operations comply with these requirements. Instead, there must be legal and practical considerations that inform this determination within EPA's reasonably broad discretion to do so. The Agency has identified certain preliminary legal boundary considerations and conditions for implementing reasonably anticipated operating scenarios to meet subpart GGG, pending further experience with pilot projects and permits and further guidance or rulemaking on the subject.

The structure and nature of title V permitting will determine how permit terms and conditions may be developed to reasonably anticipate alternative operating scenarios. The part 70 regulations govern the content requirements for permit applications and permits in section 70.5 and 70.6, respectively, and these sections will govern how reasonably anticipated alternative operating scenarios must be addressed in permit applications and permits as well. For example, all part 70 permit applications must contain information ''for each emissions unit at a part 70 source,'' which includes a description of the source's processes and products for each alternate scenario identified by the source [sections 70.5(c) and (c)(2)]. Section 70.6(a)(9) in turn makes clear that a source must identify in its application each reasonably anticipated operating scenario for which it intends to include permit terms and conditions.

Along the same lines, section 70.6 requires that all part 70 permits include emissions limitations and standards, monitoring, record keeping, reporting, compliance and other requirements to assure compliance with all applicable requirements. Section 70.6(a)(9) again makes clear that the permit terms and conditions governing alternative scenarios must meet these requirements. Applicable requirements generally fix a source's compliance obligations on an emissions unit or activity, control equipment, process, or combination thereof. Permitting alternative scenarios requires the ability to reasonably anticipate future emissions units, future operational details, and the compliance obligations under each applicable requirement associated with each operational state, as necessary to assure compliance with each applicable requirement.

The permit terms and conditions governing each alternative operating scenario must assure compliance with all part 70 and applicable requirements at all times. This means that the permit terms and conditions must assure compliance with all relevant requirements at the time of initial permit issuance and at the time that changes to alternative operating scenarios are undertaken in the future. Upon a source's change from one operating scenario to another, the terms and conditions of the permit must continue to fully and accurately reflect the source's compliance obligations under all requirements applicable to the change. If a source changes to an operating scenario that was not provided for in its permit, or if a change undertaken by a source triggers compliance obligations that are not fully and accurately reflected in the permit, then the source would be subject to the permit revision, permit reopening, or section 70.4(b) notification provisions, as applicable, under the part 70 regulations prior to making the change.

The permitting of established operating scenarios at a part 70 source that are fully known, identified and expected is straightforward. Such situations are accounted for in part 70 permits through terms and conditions that specify the emissions units and activities, provide required citations to applicable requirements, and supply the additional range of permit provisions required in a complete title V permit. Reflecting current equipment and activities, existing operating configurations, and presently applicable regulatory requirements, these operating scenarios present no difficulty to incorporating into an operating permit sufficient terms to meet the permit content requirements of part 70.

The preapproval and permitting of reasonably anticipated alternative operating scenarios is somewhat different in that their associated emissions units and activities, operational configurations, and applicable requirements may not be known with the same specificity as

[3] Because part 71 addresses alternative operating scenarios in the same fashion as part 70, the Agency believes that part 71 is equally amenable to the management of change approach described in this section. For ease of discussion, this section will refer to the relevant provisions of part 70 in discussing the management of change approach. The EPA intends, however, that the part 70 discussions in this section should have equal force and application to the corresponding provisions of part 71.

previously established operating scenarios. Nonetheless, in order to be included in the permit as alternative operating scenarios, the source must provide sufficient specificity for those scenarios to allow the permitting authority to determine the applicable requirement(s) and establish permit terms and conditions assuring compliance with those applicable requirements and the requirements of part 70. The EPA believes that it is a reasonable interpretation of section 70.6(a)(9) to require only that permit terms and conditions reasonably anticipate the emissions units and activities, operational configurations, compliance obligations, and other relevant information associated with each alternative operating scenario, so long as the permit terms and conditions assure compliance with relevant applicable requirements at all times. Conversely, there may be new or different requirements that attach to an operating scenario at the time that the source changes to that scenario, or other material differences from the permitted operating scenario may have arisen, such that the change and its regulatory requirements are not covered by the permit. If the permit does not reflect those requirements because they were not previously established, then the source, as provided for under the part 70 regulation, must account for all requirements applicable to that operating scenario, whether through a permit revision or advance notification or in response to a permit reopening.

The permit terms needed to approve alternative operating scenarios to assure compliance with all applicable requirements and to be reasonably anticipated may, in general, be expected to vary by source category, the different types of emissions units and operating scenarios present at sources, and the inherent uncertainty of predicting future operating conditions and market demands. In particular, the authorizing permit limits might vary based on several factors which primarily include, but are not necessarily limited to: the types and specific terms of the applicable requirement(s); the complexity of the facility; whether the type or quantity of emissions will change widely; whether different pollution control devices will be needed; the ability of the permitting authority to develop practicably enforceable permit terms for alternative scenarios and to define the limitations of the control and monitoring approaches; the potential for future technology advances (where such advances are linked to the nature of the applicable requirements); and the presence of discretion in determining the applicability and/or the compliance status of the change. These factors are not always present, are often interdependent, and can range widely in their ability to affect whether compliance with the applicable requirements can be assured and whether operating scenarios can be reasonably anticipated.

Because permit terms and conditions for reasonably anticipated operating scenarios implementing subpart GGG will be based in part upon ROPs that are designed to yield site-specific compliance details at the time of a change, EPA believes these procedures must be capable of yielding the identical compliance details, such as compliance triggers for monitored control device parameters, whether applied by the source, permitting authority, EPA or member of the public. Thus, the permit terms and conditions which incorporate such procedures will produce predictable and certain compliance results at the time of a change.

The EPA is testing this approach to determine in practice the appropriateness of allowing pharmaceutical facilities to determine the specific compliance obligation(s) under subpart GGG that apply to a particular process change through reliance on the standard's ROPs and ROPs that gained earlier approval through the permitting process. The form of the ROPs in subpart GGG and the nature of pharmaceutical manufacturing operations, in conjunction with the other safeguards and features of the change management strategy, are central to the Agency's willingness to conduct this pilot strategy here.

A source's compliance with permit terms and conditions for reasonably anticipated operating scenarios based upon properly implementing ROPs derived from subpart GGG will be ''deemed'' compliance with the applicable requirement for section 70.6(f)'s permit shield only to the extent that the source applies the procedures correctly. While permitting authorities may extend the permit shield to the permit terms and conditions of each alternate operating scenario implementing subpart GGG, assuming the State program has a permit shield provision and assuming it is applied in the permit consistent with section 70.6(f), part 70's permit shield may not extend to on-site implementation logs required by section 70.6(a)(9)(i). Like section 502(b)(10) changes, most administrative permit amendments, and MPMs that do not undergo prior public review [*see* sections 70.4(b)(12)(i)(B), 70.7(d)(4) and 70.7(e)(2)(vi)], the part 70 permit shield may not extend to an implementation log that has failed to undergo prior public review. Nor may the shield extend to the outcomes of ROP equations, applicability or nonapplicability determinations, or other compliance determinations recorded only in the OSIL. While a source will be required to use the implementation log to follow compliance triggers that implement the permit and one or more applicable requirements, the permit shield is not available to deem the source's compliance with those compliance triggers to be compliance with the permit or the applicable requirement.

In addition to permitting authority review, part 70 permits are subject to public and EPA review to ensure that the permit terms and conditions assure compliance with all applicable requirements and the requirements of part 70. An essential consideration in determining whether permit terms and conditions reasonably anticipate operating scenarios is whether the permit provides sufficient information and opportunity for the public and EPA to determine and comment in a meaningful fashion whether the terms and conditions of reasonably anticipated operating scenarios meet, and will continue to meet, all applicable requirements (including those of subpart GGG) and part 70 requirements.

Permit terms and conditions reflecting alternative operating scenarios, like all part 70 permit terms and conditions, are subject to the possibility of EPA objection and public petition under section 505(b) of the Act. In addition, operating permits are subject to the possibility of reopening by permitting authorities or EPA under sections 502(b)(5) and 505(e) of the Act. Permit terms and conditions of alternative operating scenarios that fail to reasonably anticipate future operating scenarios, emissions units and activities, and their associated compliance obligations may be subject to EPA objection, public petition, or reopening for cause. Failure by permitting authorities to submit information necessary for the public and EPA to review proposed permits adequately constitutes grounds for an EPA objection under section 70.8(c)(3)(ii), but information necessary for the review of alternative operating scenarios should be guided by the principle that permit terms and conditions must reasonably, but not perfectly, anticipate alternative operating scenarios. (Note, however, that the permit and any alternative

operating scenarios must fully and accurately govern changes that a source believes to be pre-approved at the time of the change, or else the part 70 permit revision, permit reopening, or 502(b)(10) notification provisions, as applicable, must be followed prior to making the change.)

Section 70.6(a)(9) affords permitting authorities the latitude to impose permit terms and conditions to assure that alternative operating scenarios meet all applicable requirements and the requirements of part 70. Such terms and conditions may go beyond compliance obligations strictly incorporated from applicable requirements being implemented pursuant to the alternative scenario. For example, in order to assure compliance with an applicable requirement or part 70, a permitting authority may determine that it is necessary to impose additional safeguards for alternative scenarios, such as requiring new emissions units or emissions units operating under different scenarios to be routed to a common, existing control device with preapproved capacities and operating parameter limitations. A permit might also require additional monitoring, record keeping, or reporting, or require that the source undertake a permit revision should future changes deviate materially from the reasonably anticipated scenarios in a manner that jeopardizes the permit's ability to meet all part 70 and applicable requirements. Finally, the permitting authority may require additional details and compliance information in the source's on-site log to ensure that the record of the source's current operating scenario, in conjunction with the permit terms and conditions, assures compliance with all requirements in a manner that serves important compliance, inspection, and enforcement purposes. If the permitting authority determines that these additional safeguards are necessary for an alternative operating scenario to assure compliance with one or more applicable requirements, the permitting authority need not approve the alternative scenario in the permit without such measures.

The preceding legal considerations apply in general to alternative operating scenarios implementing subpart GGG. It is also important to distinguish further among categories of alternative operating scenarios, on the basis of whether new versus existing process equipment or control devices are involved, and on the basis of the specificity of the equipment identification, operational configurations, and linkages to applicable requirements in the permit. Of the three categories of alternative operating scenarios described below, the Agency is prepared to test the appropriateness of the second and third approaches under section 70.6(a)(9) for purposes of implementing subpart GGG.

First, there are alternative operating scenarios for existing emissions units and activities at a part 70 source, covering specifically identified operational states or configurations for specified emissions units. In its simplest form, this category is exemplified by an emissions unit such as a fossil fuel-fired boiler that has two fuel burning options, which are each subject to a different applicable requirement with different monitoring obligations. The task of reasonably anticipating the terms and conditions of an alternative operating scenario such as this is furthered by the relative ease of specifying the emissions unit and its activities, operational configurations and conditions, and associated applicable requirements. A source's past operating experience as well as future operational certainty, founded upon existing emissions units and activities, will make permitting of such alternative scenarios more like the task of permitting a source's current operating scenario.

The second category of alternative operating scenario, being tested to implement subpart GGG, covers the combination and reconfiguration of existing emissions units and control devices in alternative operational states and configurations that are not specifically identified in the permit. As described in greater detail in section VI.L.2.a *General Strategy for Change Management*, a permit menu of alternative operating scenarios may be constructed to govern only the subpart GGG compliance obligations of process equipment and control devices specifically identified in the permit. If a change to an alternative operating scenario preapproved in a permit menu involves only the reconfiguration of existing, permitted emissions units or control devices, and the change remains within the capacity of an approved control device to which it is routed; if subpart GGG's provisions governing that change are limited to ROPs; and if the other criteria of the change management strategy are satisfied (including the contemporaneous recordation of compliance information in the OSIL), then EPA is willing to test whether such an approach will assure compliance with subpart GGG through title V permitting. While this approach will not specify future applicability determinations and establish the specific compliance obligations of particular process configurations to the same degree as the first category of alternative operating scenarios, EPA anticipates that the approach will nonetheless assure compliance with subpart GGG and otherwise meet the requirements of part 70.

The third category of alternative operating scenario, again tested in this pilot permitting approach to subpart GGG, covers new emissions units and condensers that are not in service at the time the operating scenario is established in the permit, but that may be preapproved (with respect to subpart GGG requirements) in two circumstances only. First, the permit may preapprove future like-kind emissions units or condensers that will replace retired emissions units or condensers without increasing permitted capacity. Second, the permit may preapprove specifically identified, on-site surplus processing equipment that may replace retired equipment or augment in-service equipment by increasing production capacity. The Agency believes that it is a viable interpretation of the existing section 70.6(a)(9) to allow alternative operating scenarios implementing today's standard to include permit terms and conditions approving in advance these categories and usages of new emissions units and condensers that will be subject to subpart GGG, if they meet the criteria discussed earlier in section L.2.a.

The EPA, in August 1994, proposed to allow use of the concept of alternative operating scenarios under section 70.6(a)(9) to provide advance approval to construct and operate new or modified units subject to NSR and section 112(g) (referred to as ''advance NSR''). (59 FR 44460, 44472, Aug. 29, 1994). Under this proposal, advance NSR would have allowed permitting authorities to establish the applicable NSR or section 112(g) requirements before a reasonably anticipated project or class of projects was constructed or modified, and then include that project's requirements in the part 70 permit for the facility. As a result, the project would be ''preapproved'' by the permitting authority, without the need for a later part 70 permit revision since the part 70 permit would already contain the relevant construction and operation requirements for the project.

In August 1995, EPA further clarified its advance NSR proposal by proposing to add a definition of advance NSR to section 70.2, and by explaining that, in EPA's view, a change subject to an advance approval scenario would not be a change under section 502(b)(10) of the Act (60 FR 45530, 45544–45, Aug. 31, 1995). Rather, it would constitute a

switch to an alternative operating scenario under section 70.6(a)(9). As the 1995 preamble noted, this interpretation would have two advantages. First, it would allow the use of advance NSR for title I modifications, and avoid the limitation that changes made under section 502(b)(10) cannot be title I modifications. Second, and more important, the 7-day advance notification under section 502(b)(10) which attaches to each change made under that section would not apply to changes under the advance NSR approval. Consequently, where the State operating permit program allows for advance approval, and the permitting authority approves an alternative scenario containing advance approval, the part 70 permit could allow a source to make the approved change without an advance notice or a part 70 permit revision.

Although the Agency has not finalized revisions to the part 70 regulations to adopt the proposed amendments to sections 70.2 and 70.6(a)(9) discussed above, the Agency is prepared to interpret the existing part 70 regulations for purposes of the change management strategy for subpart GGG approach to enable alternative operating scenarios to encompass advance approvals in the limited manner described in this notice. In other words, for purposes of the approach described in this section, EPA believes that it is a reasonable interpretation of existing section 70.6(a)(9) to cover the advance approval of the categories of new process equipment and condensers described in this notice, within the scope of alternative operating scenarios that may be included in part 70 permits. The concept of ''reasonably anticipated operating scenarios'' is expansive enough to encompass not only existing equipment that may operate under a different operating scenario reasonably anticipated to occur, but also to encompass new equipment that replaces permitted equipment (without increasing permitted capacity), and new surplus equipment that is on-site and specifically identified and pre-approved in the permit.

The Agency is prepared to advance these interpretations under the current regulations prior to any final action on the part 70 revisions that might adopt the proposed amendments, for purposes of implementing subpart GGG through the pilot approach for the change management strategy described herein. This interpretation may not be relied upon for purposes of implementing applicable requirements other than subpart GGG through title V permits. The EPA may extend this interpretation to other applicable requirements, however, in the context of an individual permitting pilot project in order to facilitate the development and evaluation of the change management strategy, along with other flexible permitting opportunities, for the pharmaceutical industry. The policies set forth in this section are intended solely as guidance for purposes of implementing subpart GGG, do not represent final Agency action, and cannot be relied upon to create any rights enforceable by any party.

Other changes that a pharmaceutical facility undertakes that implicate subpart GGG requirements and that are not preapproved in the permit through the change management strategy or ordinary alternative operating scenarios, must be accounted for through part 70's permit revision or section 70.4(b)(12) or (b)(14) notice procedures, as appropriate. Such changes would include, but are not necessarily limited to: changes among permitted, in-service equipment involving subpart GGG's provisions governing the change that are not limited to ROPs; changes that would exceed the performance capabilities or capacity limitations of approved control devices; changes involving the addition of new emissions units or control devices (including any control device other than condensers) that have not been approved pursuant to the categories discussed in section L.2.a; and other changes that are not otherwise preapproved in the permit. Finally, of course, changes that implicate applicable requirements other than or in addition to subpart GGG must be addressed in the manner required by the part 70 regulations.

In the proposed revisions to part 70 in August 1995, 60 FR 45530, EPA proposed an expeditious permit revision process for the incorporation of requirements that would not need source-specific tailoring. The process was referred to as ''notice-and-go,'' since the source could operate the change as soon as it submitted a notice to the permitting authority, and would not need to wait for review or approval of the change by the permitting authority. The EPA further elaborated on the concept in a **Federal Register** notice announcing the availability of its May 14, 1997 draft final revisions to part 70, published on June 3, 1997, 62 FR 30289, where the process was called ''notice-only.''

As currently envisioned, the process would be available for changes that are: (1) subject to requirements taken directly from the applicable requirement; (2) where there is no creation of any source-specific requirements; and (3) the permitting authority allows the change to take place without the need for its review or approval. For example, incorporation into the permit of a compliance option specified in a MACT standard would be eligible for notice-only procedures, but the establishment of source-specific parameter ranges for monitoring the performance of a control device would not be eligible. The installation of a degreasing unit subject to the halogenated solvent cleaning MACT standard under subpart T of Part 63 would also be eligible, if the facility elects to meet the standard through one or more of the compliance options specified in the MACT standard. This change would be eligible for the notice-only process because the permit terms that apply to the change would be taken straight from the underlying requirement, and there would be no need to add monitoring requirements.

In the May 1997 draft, EPA would have required the source to certify compliance in the notice with all applicable requirements that apply to the change (in the case of subpart GGG, for example, a new unit being added). This certification requirement helps offset the lack of review by the permit authority prior to operation of the change, since a source making a false certification would be subject to penalties, or to criminal fines in the case of a knowing violation. There would also be no permit shield available for ''notice-only'' changes, so if a source failed to identify one or more requirements that apply to a new unit, the requirements are nonetheless applicable, and the source would be liable for any violations of applicable requirements to which the change is subject.

The Agency anticipates that the notice-only category of the third tier of the part 70 revisions, if adopted as presently conceived, would accommodate the application of subpart GGG requirements to new process equipment and control devices through part 70 permit revisions. Part 70 permits implementing subpart GGG through the management of change approach described in today's notice likely will have established source-specific requirements for existing control devices in the initial permit. The purpose of the notice-only procedures would be to revise the permit so as to identify new process equipment or control devices being added at the source, and to match up relevant permit requirements that apply to the new units. As noted at the outset of this section, however, it still may be

necessary to address the consequences of a particular change relative to other relevant applicable requirements that may attach to that change. Thus, changes must be evaluated under the part 70 permit revisions to determine what level of permit revision might be required to address other regulatory consequences of the change.

4. Supporting Rationale for Recommended Strategy

a. *Overview.* The EPA has initiated this pilot permitting strategy for subpart GGG based upon a preliminary view that the recommended approach will satisfy section 70.6(a)(9)'s expectations for ''reasonably anticipated'' alternative operating scenarios, and comport with title V's mandate that operating permits assure compliance with applicable requirements. In general, the Agency believes the change management strategy meets these criteria by relying upon the basic design and provisions of subpart GGG; the additional requirements under the policy for permits to contain terms that assure the proper identification and compliance of all alternative operating scenarios covered by the strategy; and the title V permit issuance, significant permit modification, or renewal processes, along with quarterly reporting to permitting authorities, to afford meaningful opportunities for the permitting authority, EPA, and the public to review the strategy proposed by a source, and oversee its implementation, for a particular location.

Notwithstanding these provisions and protections, the Agency is recommending that permitting authorities use the change management strategy only on a trial basis, and only with respect to subpart GGG. The EPA notes that the need to match that changes in emissions correctly to their applicable subpart GGG requirements is central to the purpose of section 70.6(a)(9). As a critical first step, certain key definitions (e.g., process vent, process) and other rule provisions must be interpreted by EPA or the permitting authority in the permit process before applying the relevant ROPs. The ROPs then objectively size and sort emissions changes relative to their subpart GGG obligations and assure compliance in part by routing the new emissions, as appropriate, to a control device with sufficient capacity. Use of these definitions and regulatory provisions could be open to interpretive disputes and misapplication of the standard. However, due to several factors (including the homogeneity of process equipment in the industry, the high accuracy with which emissions resulting from changes can be characterized, the existence of ROPs for determining emissions and the effects of emissions controls, and the validation of a source's use of the relevant definitions, regulatory provisions, and ROPs during the title V permit process), EPA believes that there is a sufficiently low probability that sources will make errors in applying these definitions and provisions during the implementation of the change management strategy. Accordingly, the Agency will determine on the basis of empirical results whether this strategy needs additional protections, whether it is an appropriate approach to permitting, and/or whether and on what basis it can be made available to a broader range of sources and standards.

b. *Detailed Rationale.* Subpart GGG is a process-based standard which has been carefully designed to provide the framework needed by the change management strategy to establish the preapproved family of alternative operating scenarios for reconfiguration of existing process equipment and to define the compliance obligations of operating scenarios involving the addition of certain new process equipment. This framework is defined primarily from three types of features found in subpart GGG. In total, these three features establish a means for demonstrating continuous compliance that must be repeatedly applied for process and operational changes at the source.

The first feature is comprised of requirements relating to the use of equations to estimate emissions from various pharmaceutical operations. These equations provide the ability to characterize a process or operational change's effect on emissions in a replicable and accurate fashion. The equations incorporate proven chemical and physical principles such as the Ideal Gas Law and Raoult's Law, and have previously been approved by the Agency (most recently in MACT standards for the Polymers and Resins Industry, subparts U and JJJ of 40 CFR part 63). Upon their incorporation into the permit and approval by the permitting authority, a source must use these equations to determine applicability of the standard and to demonstrate initial compliance with it. Subsequently, the source must use the equations to determine the emissions from changes in operations together with those from ongoing operations. Anyone using the level of emissions predicted from these equations would then determine in exactly the same objective fashion how to maintain compliance with subpart GGG while manufacturing different intermediate or final products.

The second feature providing flexibility is the requirement that control devices be designed to accommodate reasonable worst-case operating scenarios without need for revised operating parameters or operating conditions. This means that most changes that affect emissions can be handled by the devices. In all cases, compliance assurance is achieved by virtue of the requirement to compare the emissions profile associated with the change with the worst-case operation approved for the relevant control device(s) and to require a permit revision where the changed operation would present a need for greater control.

The third feature of the rule that facilitates operating changes is the record keeping requirements. In the OSIL, as described earlier (see section VI.L.2.a. *General Strategy for Change Management*) sources must keep a precise log of the operation of batches, the occurrence of any process or operational changes and associated changes in emissions, the requirements of subpart GGG contemporaneously applicable to each process under its new operational state, and the controls used to comply with these requirements. The information required by the permit, together with on-site records and the required calculations for the sizing of emissions sources and the sorting of changes relative to their subpart GGG requirements allows an inspector to determine initially and for any subsequent time period which activities from a listed process require control and the level of control that is required for each.

The rule enables the company's basic framework for the change management strategy to be incorporated into the title V permit. In addition, other permit terms are needed to assure that an appropriately useful scope of alternative scenarios can be reasonably anticipated and preapproved to meet section 70.6(a)(9) and that the compliance obligations of certain new process equipment (i.e., like-kind replacements and on-site surplus equipment identified in the permit) can be defined. The first of these terms applies to operations that are not covered by ROPs as taken directly from the requirements in subpart GGG. Previous discussions of ROPs have alluded to two types, those that are included in detail in subpart GGG and those that are established in the title V permitting process to meet subpart GGG. The latter category is necessary because of the compliance flexibility that subpart GGG contains.

For the methodology that the source proposes to receive the status of a permit-required ROP for purposes of the change management strategy, the permitting authority must determine that the methodology is scientifically credible and is objectively replicable. The bottom line is that the ROP must be a procedure based solely on nondiscretionary steps and on objective data (where data are required) to accomplish these steps. Accordingly, the results from using these procedures are the same regardless of who uses them and when. Where the permitting authority preapproves ROPs, the permit shall require the source to use them over the defined range of similar operations (unless, of course, the source wishes to obtain approval of a different method under the permit revision process). The EPA would like to stress that the ROPs are only an important part of the compliance process established by following the standard and are not an alternative standard, monitoring, or test method.

Section 504 (a) of the Act provides the legal basis for establishing ROPs during the permit process. This section requires that title V permits contain emissions limits/ standards and other terms as needed to assure compliance with applicable requirements. In its White Paper Number Two issued in March 1996, EPA stated that title V permits pursuant to section 504(a) may contain terms which are not necessarily the terms of a particular applicable requirement, provided that such terms assure compliance with this requirement. (see section II.A.2.d. and II.A.5.) The Agency believes that this same authority also supports development of a methodology as a ROP during the title V permit process, provided that its development is consistent with the provisions of the applicable requirement, following the methodology would provide the same degree of compliance assurance as would following the applicable requirement directly, and sufficient procedural safeguards are followed in its establishment.

Subpart GGG is consistent with establishing such methodologies. For example, it empowers the permitting authority to review and approve, as appropriate, a source's proposed emissions estimating procedures for operations not covered by the standard's equations. In addition, as part of the initial compliance determination process laid out in subpart GGG, the source is required to provide the specifics of its calculations and engineering analysis procedures to the permitting authority as a matter of course. Subject to certain boundary conditions on its applicability and use, the specific source proposal can often be extended into a methodology to address future qualifying changes.

The EPA is testing whether reliance on this approach also provides equivalent compliance assurance to that provided from a case-by-case review implemented for the same change by the permitting authority. In the absence of the change management strategy, the permitting authority would evaluate the procedures used by the source each time a change was to be made. Thus, the permitting authority would be called upon to make the same judgements in either case; only the timing and frequency of the review and approval process would change. In the context of the strategy, the permitting authority and the source simply agree ahead of time on the replicable procedures that are to be used for a range of changes.

Finally, by requiring that the approval to take place during permit issuance, permit renewal, or significant permit modification, the change management strategy ensures that adequate oversight by the public and EPA occurs. This determination and approval by the permitting authority must take place during a process in which EPA and the public are afforded the opportunity to review and comment on the methodology and upon its initial use. The EPA requires that the streamlining process contained in its White Paper Number Two issued March 1996 be used to accomplish this review (including the submittal of the demonstration to EPA while a complete application containing the demonstration is otherwise submitted to the permitting authority). Application of the methodology and its outcomes must also be reflected in the OSIL. Verification of its use as well as the supporting calculations and analyses will be included (consistent with confidential business information protections) as part of the quarterly OSIL report describing changes since the last report. This report shall be submitted to the permitting authority on a quarterly basis and be made available to the public and EPA.

It should be noted that subpart GGG, while not specifying enough details to make some procedures replicable, typically does include guidance on what will be required. For example, the standard allows sources to demonstrate compliance for small control devices using a design evaluation and specifies for each type of control device the factors that must be included in this evaluation. This guidance facilitates the permitting authority's review of the design evaluation that the source subsequently submits. Thus, in many cases, the standard provides the target for the design of a ROP, but leaves the details to be proposed by the source and approved by the permitting authority.

While the mentioned ROPs should enable the vast majority of expected changes to be preapproved in the title V permit with respect to compliance with the MACT standard, some exceptions do exist. Changes governed by MACT provisions which are affected by any meaningful subjective judgments cannot be preapproved. This would include all procedures which are not replicable as contained in subpart GGG and are not otherwise approved during the permit issuance or revision process to be ROPs. In addition, certain requirements apply in a very event-specific fashion and cannot be preapproved without a precise advance understanding of a particular change. The EPA has already identified some requirements and procedures in the final MACT rule that cannot be relied upon or developed as ROPs, and thus may not be employed under the change management strategy.

For example, for any process unit complying with the pollution prevention alternative standard, an owner/operator must establish baseline production-indexed HAP consumption factors from which to apply the 75 percent consumption reduction requirement. Such baseline factors are determined from historical information, and the acceptability of the value depends on which historical years are selected to represent the baseline and on the methods used for the involved material balance around the process unit. It is highly probable that each baseline consumption factor demonstration will encompass unique, process-specific information and methodologies that significantly affect the final value of the factor. With that in mind, the Agency feels that generic preapproval is not possible for changes whereby existing process units switch from complying with individual emission standards on emissions sources (such as a 93 percent reduction requirement for process vents) to complying with the pollution prevention alternative standard. It is appropriate that the permit revision process be used for making such changes.

An additional category not eligible for conversion to ROPs consists of determinations or approvals which have not been delegated to the permitting authority and must be submitted to EPA for approval. For example, the Administrator must review and approve, as appropriate, any source

proposal for an alternative emissions limit or test method. Such reviews cannot therefore be addressed in advance by a ROP defined by the permitting authority.

The Agency has preliminarily reviewed the requirements of subpart GGG in the context of defining which of them contain: (1) ROPs as written; (2) requirements that can be established during the permit process as a ROP; and (3) requirements which are ineligible for developing such procedures. Tables 3, 4, and 5 follow which describe this initial categorization. The EPA expects to address this subject more in its implementation guidance for subpart GGG.

TABLE 3.—PROCEDURES THAT ARE REPLICABLE AS WRITTEN IN SUBPART GGG

Procedure	40 CFR part 63 citation
Calculating uncontrolled emissions from process vents—equations for eight types of operations	63.1257(d)(2)(i)(A) through (H).
Calculating controlled emissions from process vents discharged through a condenser—equations for eight types of operations.	63.1257(d)(3)(i)(B) (*1*) through (*8*).
Equations for determining whether an existing vent is subject to 98% control	63.1254(a)(3)(i).
EPA performance test methods and calculations	63.1257(a)(2), (a)(3), (b)(1) through (8), and (b)(10)(i) through (iii).

TABLE 4.—POTENTIALLY REPLICABLE OPERATING PROCEDURES THAT CAN BE ESTABLISHED THROUGH PERMITTING WHERE APPROVED BY PERMITTING AUTHORITY, AND SUBJECT TO REVIEW BY EPA AND THE PUBLIC

Procedure	40 CFR part 63 citation
Evaluation of an air pollution control device capability for new scenario (not subject to testing)	63.1257(b)(8)(ii).
Establishing the emissions profile for inlet to control device	63.1257(a)(i).
Determining uncontrolled process vent emissions from an operation not covered by the eight equations in subpart GGG.	63.1257(d)(2)(ii).
Determining whether a new/modified process vent is within the worst-case emissions approved for a control device.	None.
Determining annual HAP load in a wastewater stream	63.1257(e)(1)(iii).
Determining annual average HAP concentration in a wastewater stream	63.1257(e)(1)(ii).
Identification of wastewater streams that require control	63.1256(a)(1).
Evaluation of wastewater treatment unit capability for new scenario	63.1257(e)(2)(ii).
Demonstrating that wastewater tank emissions are increased no more than 5 percent by heating, treating with an exothermic reaction, or sparging.	63.1256(b)(1).
Determining storage tank design capacity	63.1253(a) (1) and (2).
Maximum true vapor pressure for determining storage tank applicability	63.1251.
Methodology for determining individual HAP partial pressures in nonstandard situations	63.1257(d)(2)(i).
Emissions averaging compliance alternative	63.1252(d).
Pollution prevention compliance alternative	63.1252(e).
Demonstrating that an equation in the rule is not appropriate in a specific case for an operation covered by one of the eight equations.	63.1257(d)(2)(ii).
Demonstrating alternative test methods or emissions limits (or any other determinations which the Administrator has not delegated).	63.1261.

The recommended approach for permits also assures that alternative operating scenarios are reasonably anticipated for the reconfigurations of permit-listed equipment by requiring the initial detailed linkages among processes, vents, PODs, tanks, control obligations, and eligible controls contained in the NOCSR to be incorporated into the permit. This incorporation of the baseline operation serves to define an important benchmark from which to anticipate similar, but different future operating scenarios using the same equipment.

The Agency believes that the more general description of equipment within each particular alternative operating scenario in the menu may be appropriate under the particular design of the pharmaceutical MACT standard. That is, a description of process equipment in less detail can be justified here where the determination of process emissions is clear and a highly effective control approach is used, which is also versatile and effective enough to accommodate a wide range of inlet loadings (and the range is documented and specified on permits). Thus, a conservative approach to emissions reduction (e.g., most devices would operate as if the worst-case scenario were occurring), coupled with a replicable, objective basis (i.e., a required ROP for emissions calculation) to assure that each new change in operation is no more demanding on the control device than the previously established worst case, inherently allows more flexibility under which to ''anticipate'' a family of alternative operating scenarios.

One potential weakness of the change management strategy is that, before the mentioned ROPs can be relied upon to establish compliance obligations and to assure compliance with them, the strategy depends on the correct application of certain key definitions (e.g., process vent, process) and other regulatory provisions when a change in emissions occurs. Although EPA has carefully designed these definitions to be clear in their meaning, interpretive disputes could still conceivably arise. The Agency believes for several reasons, however, that there is an extremely low probability for such disputes to occur and that the change management strategy should assure compliance with subpart GGG.

First, the industry, in its basic operations and how subpart GGG definitions will apply to them, is relatively well known. While this assertion may appear to run counter to previous statements regarding the constantly changing processes and equipment configurations that characterize much of the industry, in actuality, the process steps that make up

the wide range of processes in the industry are confined to a relatively limited number of different chemical engineering unit operations. Thus, while the number of process steps, their order, and the specific conditions of each (e.g., temperature, solvents, etc.) may vary widely from process to process, the individual steps are basic, standard unit operations. The chemical engineering principles that govern these unit operations (and their air and wastewater emissions) are well understood. In addition, the FDA independently requires processes to be well defined which limits further any variations in definitional interpretations.

In addition to the significant protections that these inherent safeguards and the OSIL provide, the probability of misinterpreting the use of a particular definition is further reduced during the permit action that establishes the change management strategy. As mentioned, the initial linkages among processes, vents, PODs, tanks, control obligations, and eligible controls contained in the NOCSR would be incorporated into the title V permit to establish the baseline scenario from which to envision future changes. This incorporation also serves to demonstrate an appropriate working knowledge with the key definitions governing the applicability of subpart GGG. More importantly, the permitting authority must specifically approve the source's use of these definitions and this approval is subject to review by EPA and the public. The result will be that the source and the permitting authority will have a well validated common understanding of how these definitions work and how to apply them to future changes.

The recommended approach also fulfills the need to provide adequate review opportunities. In the permit issuance process, the permitting authority, EPA, and the public all have an opportunity to review how the current source operations would comply with the standard and how the proposed permit conditions establish alternative operating scenarios to manage changes occurring with respect to this compliance baseline. In particular, these groups will have the opportunity to review the operating boundaries to assure equal or greater controllability of other emissions profiles and to determine any further need to add specific operational constraints to safeguard against overloading the particular control device(s), for example, or additional permit terms or descriptions in order to assure compliance with the standard. The alternative operating scenarios as described in the permit must reasonably anticipate reconfigurations of existing emissions units and activities and the additions of certain other preapproved equipment and must contain the associated compliance obligations for these changes under subpart GGG, in order to afford permitting authorities, EPA and the public meaningful opportunity to ensure that the permit's alternative scenarios assure compliance with the MACT standard. To provide an ongoing opportunity to understand which alternative operating scenarios have been operated by the source and the specific corresponding compliance obligations that apply, the permit shall require quarterly transmission of the OSIL changes to the permitting authority, which shall make copies available to the public and EPA upon request.

The Agency is considering whether and to what extent the change management strategy for implementing subpart GGG might also be appropriate for other sources and applicable requirements. Preliminarily, EPA believes that the recommended permitting approach for subpart GGG will be essentially limited to the pharmaceutical and other similar batch chemical industries but it could be extended to industries subject to other emission standards to the extent that EPA believes the same level of compliance assurance associated with the change management strategy described for subpart GGG would be achieved. The EPA expects to evaluate other situations individually, using the mentioned factors and other considerations as appropriate. Affected parties are encouraged to comment on the adequacy of other EPA rulemakings (including those for other MACT standards), to address issues related to the change management strategy where similar needs for operational flexibility potentially exist. Certainly, the same legal constraints together with several situation specific factors (such as those involving the replicability of operating procedures contained in, or derived from, the applicable requirements, the potential for misapplication of the standard, the expectation for detailed descriptions and emissions reduction from the applicable requirement itself for subject equipment, and the ability of the control and monitoring approaches to accommodate changes) would again be relevant to defining whether a strategy for such applicable requirements based on alternative operating scenarios is possible under section 70.6(a)(9).

The EPA believes that the change management strategy should presumptively be limited to the pharmaceutical MACT, since other standards do not initially appear to produce equivalent opportunities to create alternative operating scenarios under such a strategy. The most limiting element is the ability to predict accurately, using relatively simple, repeatable procedures, the effect a particular change has on emissions and compliance obligations. In the pharmaceutical industry, it is possible to do so in an extremely accurate fashion since HAP emissions nearly exclusively result from nonreactant solvent use. It may be more difficult, for example, to predict the effect of process changes in chemical manufacturing industries other than pharmaceutical manufacturing. Changes in these industries often involve complex reaction theory and reaction kinetics and other factors, which must be applied individually to the specific situation at hand to determine how HAP emissions will change. For most changes, it would be difficult to distill these chemical dynamics into an equation that would predict emissions variations for a source's process changes accurately. Without an accurate ROP, the applicable permit revision process would be necessary to reevaluate compliance under the change.

As previously mentioned, the Agency's decision whether to extend the availability of a change management strategy similar to that for subpart GGG to other standards will also depend on the empirical results achieved from implementing subpart GGG through such a strategy. In particular, EPA expects to learn whether and how frequently interpretive disputes result from using the blend of definitions and approved ROPs relied upon to carry out the change management strategy and how to develop permit terms that establish and implement ROPs.

Finally, the Agency supports the testing of the recommended subpart GGG strategy since it is consistent with the Agency's program objectives to reinvent regulations, to eliminate delays and paperwork burdens, and to implement more efficiently the title V program. The development of the recommended approach benefited to a significant extent through the activities of a permitting pilot project which EPA initiated with the Environmental Quality Board of Puerto Rico and Merck Corporation. Considering the implementation of subpart GGG through title V permits in the context of this project has been extremely valuable in defining the type and frequency of

anticipated operational changes and evaluating the appropriate permit content to assure compliance for these changes. The Agency is grateful to the participants in this Reinvention project and expects that its final results (in the form of more detailed guidance and/or model permit conditions) will be useful to others seeking to implement subpart GGG.

VII. Technical Amendment to 40 CFR Part 9

In compliance with the Paperwork Reduction Act (PRA), this technical correction amends the table that lists the Office of Management and Budget (OMB) control numbers issued under the RPA for this final rule.

The EPA is today amending the table in 40 CFR part 9 (Section 9.1) of currently approved information collection request (ICR) control numbers issued by OMB for various regulation. The affected regulations are codified at 40 CFR part 63 subpart GGG, sections 63.1259 and 63.1260 (recordkeeping and reporting requirements, respectively). The OMB control (tracking) number for this final rule is 2060–0358. The EPA will continue to present OMB control numbers in a consolidated table format to be codified in 40 CFR part 9 of the Agency's regulations, and in each CFR volume containing EPA regulations. The table lists the section numbers with reporting and recordkeeping requirements, and the current OMB control numbers. The listing of the OMB control numbers and their subsequent codification in the CFR satisfy the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and OMB's implementing regulations at 5 CFR part 1320.

This ICR was previously subject to public notice and comment prior to OMB approval. As a result, EPA finds that there is ''good cause'' under section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)) to amend this table without prior notice and comment. Due to the technical nature of the table, further notice and comment would be necessary.

VIII. Administrative Requirements

A. Docket

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

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

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

B. Executive Order 12866

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

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

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

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

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

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

C. Enhancing the Intergovernmental Partnership Under Executive Order 12875

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

D. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq* and has assigned OMB control No. 2060–0358. An information collection request (ICR) document has been prepared by EPA (ICR No. 1781.01), and a copy may be obtained from Sandy Farmer, Regulatory Information Division, U.S. Environmental Protection Agency (Mail Code 2137), 401 M Street SW., Washington, DC 20460, or by calling 202–260–2740.

The EPA is required under section 112(d) of the Clean Air Act to regulate emissions of HAPs listed in section 112(b). The requested information is needed as part of the overall compliance and enforcement program. The ICR requires that pharmaceuticals production facilities retain records of control device monitoring or HAP emissions calculations records at facilities for a period of 5 years, which is consistent with the General Provisions to 40 CFR part 63 and the permit requirements under 40 CFR part 70. All sources subject to this rule will be required to obtain operating permits either through the State-approved permitting program or, if one does not exist, in accordance with the provisions of 40 CFR part 71, when promulgated.

The public reporting burden for this collection of information is estimated to average 4,800 hours per respondent for the first year and 2,600 hours per respondent for each of the second and third years. It is also estimated that there are approximately 100 facilities that are likely respondents. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of

information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. The EPA is amending Table 9.1 in 40 CFR part 9 of currently approved ICR control numbers issued by OMB for various regulations to list the information requirements contained in this final rule.

E. Regulatory Flexibility Act

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

The EPA analyzed the potential impact of the rule on small entities and determined that only 16 of 56 pharmaceutical producing firms are small entities—not a substantial number of entities. Of these 16 firms, only 4 will experience an increase in costs as a result of the promulgation of today's rule that are greater than 1 percent of revenues. Therefore, the Agency did not prepare an initial regulatory flexibility analysis.

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

F. Unfunded Mandates

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

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

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

H. National Technology Transfer and Advancement Act (NTTAA)

Under section 12(d) of the National Technology Transfer and Advancement Act (''NTTAA)'', the Agency is required to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. Where available and potentially applicable voluntary consensus standards are not used by EPA, the Act requires the Agency to provide Congress, through the Office of Management and Budget, an explanation of the reasons for not using such standards.

The Agency does not believe that this Notice addresses any technical standards subject to the NTTAA.

I. Executive Order 13045

The Executive Order 13045 applies to any rule that EPA determines (1) ''economically significant'' as defined under Executive Order 12866, and (2) the environmental health or safety risk addressed by the rule has a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children; and National Emission Standards for Hazardous Air Pollutants Pharmaceuticals Production—explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is not subject to Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it does not involve decisions on environmental health risks or safety risks that may disproportionately affect children.

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 63

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

Dated: July 30, 1998.

Carol M. Browner,

Administrator.

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

PART 9—[AMENDED]

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

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

2. Section 9.1 is amended by adding in numerical order a new entry to the table under the indicated heading to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
National Emission Standards for Hazardous Air Pollutants for Source Categories.[3]	
* * * * *	
63.1259–63.1260	2060–0314
* * * * *	

[3] The ICR's referenced in this section of the table encompass the applicable general provisions contained in the 40 CFR part 63, subpart A, which are not independent information collection requirements.

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PART 63—[AMENDED]

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

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

4. Section 63.14 is amended by adding paragraphs (b)(19) and (c)(3) to read as follows:

§ 63.14 Incorporations by reference.

* * * * *

(b) * * *

(19) ASTM D2879–97, Standard Test Method for Vapor Pressure-Temperature Relationship and Initial Decomposition Temperature of Liquids by Isoteniscope, IBR approved for § 63.1251 of subpart GGG of this part.

(c) * * *

(3) API Manual of Petroleum Measurement Specifications (MPMS) Chapter 19.2, Evaporative Loss From Floating-Roof Tanks (formerly API Publications 2517 and 2519), First Edition, April 1997, IBR approved for § 63.1251 of subpart GGG of this part.

* * * * *

5. Part 63 is amended by adding a new subpart GGG to read as follows:

Subpart GGG—National Emission Standards for Pharmaceuticals Production

Sec.

§ 63.1250 Applicability.

(a) *Definition of affected source.* The affected source subject to this subpart is the pharmaceutical manufacturing operation, as defined in § 63.1251. Except as specified in paragraph (d) of this section, the provisions of this subpart apply to pharmaceutical manufacturing operations that meet the criteria specified in paragraphs (a)(1) through (a)(3) of this section as follows:

(1) Manufacture a pharmaceutical product, as defined in § 63.1251;

(2) Are located at a plant site that is a major source as defined in section 112(a) of the Act; and

(3) Process, use, or produce HAP.

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

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

(d) *Processes exempted from the affected source.* The provisions of this subpart do not apply to research and development facilities.

(e) *Storage tank ownership determination.* The owner or operator shall follow the procedures specified in paragraphs (e)(1) through (e)(5) of this section to determine to which PMPU a storage tank shall belong.

(1) If a storage tank is dedicated to a single PMPU, the storage tank shall belong to that PMPU.

(2) If a storage tank is shared among PMPU's, then the storage tank shall belong to that PMPU located on the same plant site as the storage tank that has the greatest annual volume input into or output from the storage tank (i.e., said PMPU has the predominant use of the storage tank).

(3) If predominant use cannot be determined for a storage tank that is shared among PMPU's and if one of those PMPU's is subject to this subpart, the storage tank shall belong to said PMPU.

(4) If the predominant use of a storage tank varies from year to year, then predominant use shall be determined based on the utilization that occurred during the year preceding September 21, 1998 for existing affected sources. For new affected sources, predominant use will be based on the first year after initial startup. The determination of predominant use shall be reported in the Notification of Compliance Status required by § 63.1260(f). If the predominant use changes, the redetermination of predominant use

shall be reported in the next Periodic Report.

(5) If the storage tank begins receiving material from (or sending material to) another PMPU; or ceases to receive material from (or send material to) a PMPU; or if the applicability of this subpart to a storage tank has been determined according to the provisions of paragraphs (e)(1) through (4) of this section and there is a significant change in the use of the storage tank that could reasonably change the predominant use, the owner or operator shall reevaluate the applicability of this subpart to the storage tank, and report such changes to EPA in the next Periodic report.

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

(1) An owner or operator of an existing affected source must comply with the provisions of this subpart within 3 years after September 21, 1998.

(2) An owner or operator of a new or reconstructed affected source must comply with the provisions of this subpart on September 21, 1998 or upon startup, whichever is later.

(3) Notwithstanding the requirements of paragraphs (f)(1) and (2) of this section, a new source which commences construction or reconstruction after April 2, 1997 and before September 21, 1998 shall not be required to comply with such promulgated standard until 3 years after September 21, 1998 if:

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

(ii) The owner or operator complies with the standard as proposed during the 3-year period immediately after September 21, 1998.

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

(i) For purposes of this subpart, a request for an extension shall be submitted no later than 120 days prior to the compliance dates specified in paragraphs (f)(1) through (3) of this section, except as provided in paragraph (f)(4)(ii) of this section. The dates specified in § 63.6(i) for submittal of requests for extensions shall not apply to sources subject to this subpart.

(ii) An owner or operator may submit a compliance extension request after the date specified in paragraph (f)(4)(i) of this section provided the need for the compliance extension arose after that date and before the otherwise applicable compliance date, and the need arose due to circumstances beyond reasonable control of the owner or operator. This request shall include the data described in § 63.6(i)(6)(i)(A), (B), (C), and (D).

(g) *Applicability of this subpart except during periods of startup, shutdown, and malfunction.* (1) Each provision set forth in this subpart shall apply at all times except that emission limitations shall not apply during periods of: startup; shutdown; and malfunction, if the startup, shutdown, and malfunction precludes the ability of a particular emission point of an affected source to comply with one or more specific emission limitations to which it is subject and the owner or operator follows the provisions for periods of startup, shutdown, and malfunction, as specified in §§ 63.1259(a)(3) and 63.1260(i). Startup, shutdown, and malfunction are defined in § 63.1251.

(2) The provisions set forth in § 63.1255 of this subpart shall apply at all times except during periods of nonoperation of the PMPU (or specific portion thereof) in which the lines are drained and depressurized resulting in the cessation of the emissions to which § 63.1255 of this subpart applies.

(3) The owner or operator shall not shut down items of equipment that are required or utilized for compliance with the emissions limitations of this subpart during times when emissions (or, where applicable, wastewater streams or residuals) are being routed to such items of equipment, if the shutdown would contravene emissions limitations of this subpart applicable to such items of equipment. This paragraph does not apply if the item of equipment is malfunctioning, or if the owner or operator must shut down the equipment to avoid damage due to a malfunction of the PMPU or portion thereof.

(4) During startups, shutdowns, and malfunctions when the emissions limitations of this subpart do not apply pursuant to paragraphs (g)(1) through (3) of this section, the owner or operator shall implement, to the extent reasonably available, measures to prevent or minimize excess emissions to the extent practical. For purposes of this paragraph, ''excess emissions'' means emissions in excess of those that would have occurred if there were no startup, shutdown, or malfunction and the owner or operator complied with the relevant provisions of this subpart. The measures to be taken shall be identified in the applicable startup, shutdown, and malfunction plan, and may include, but are not limited to, air pollution control technologies, work practices, pollution prevention, monitoring, and/or changes in the manner of operation of the source. Back-up control devices are not required, but may be used if available.

(h) *Consistency with other regulations.* (1) *Consistency with other MACT standards.* After the compliance dates specified in this section, an affected source subject to the provisions of this subpart that is also subject to the provisions of any other subpart of 40 CFR part 63 may elect, to the extent the subparts are consistent, which subpart under which to maintain records and report to EPA. The affected source shall identify in the Notification of Compliance Status report required by § 63.1260(f) under which authority such records will be maintained.

(2) *Consistency with 40 CFR parts 264 and 265, subparts AA, BB, and/or CC.* After the compliance dates specified in this section, if any affected source subject to this subpart is also subject to monitoring, recordkeeping, and reporting requirements in 40 CFR part 264, subpart AA, BB, or CC, or is subject to monitoring and recordkeeping requirements in 40 CFR part 265, subpart AA, BB, or CC and the owner or operator complies with the periodic reporting requirements under 40 CFR part 264, subpart AA, BB, or CC that would apply to the device if the facility had final-permitted status, the owner or operator may elect to comply either with the monitoring, recordkeeping, and reporting requirements of this subpart, or with the monitoring, recordkeeping, and reporting requirements in 40 CFR parts 264 and/or 265, as described in this paragraph, which shall constitute compliance with the monitoring, record keeping, and reporting requirements of this subpart. If the owner or operator elects to comply with the monitoring, recordkeeping, and reporting requirements in 40 CFR parts 264 and/or 265, the owner or operator shall report all information required by § 63.1260(g). The owner or operator shall identify in the Notification of Compliance Status required by § 63.1260(f) the monitoring, recordkeeping, and reporting authority under which the owner or operator will comply.

(3) *Consistency with 40 CFR 60.112b.* After the compliance dates specified in this section, a storage tank controlled with a floating roof and in compliance with the provisions of 40 CFR 60.112b, subpart Kb, constitutes compliance with the provisions of this subpart GGG. A storage tank with a fixed roof, closed vent system, and control device in compliance with the provisions of 40 CFR 60.112b, subpart Kb must comply with the monitoring, recordkeeping, and reporting provisions of this subpart GGG. The owner or operator shall identify in the Notification of Compliance Status report required by

§ 63.1260(f) which tanks are in compliance with subpart Kb.

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

(5) *Consistency with other regulations for wastewater.* After the compliance dates specified in this section, the owner or operator of an affected wastewater that is also subject to provisions in 40 CFR parts 260 through 272 shall comply with the more stringent control requirements (e.g., waste management units, numerical treatment standards, etc.) and the more stringent testing, monitoring, recording, and recordkeeping requirements that overlap between the provisions of this subpart and the provisions of 40 CFR parts 260 through 272. The owner or operator shall keep a record of the information used to determine which requirements were the most stringent and shall submit this information if requested by the Administrator.

(i) For the purposes of establishing whether a person is in violation of this subpart, nothing in this subpart shall preclude the use of any credible evidence or information relevant to whether a source would have been in compliance with applicable requirements.

§ 63.1251 Definitions.

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

Active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the pharmaceutical product and be present in the pharmaceutical product in a modified form intended to furnish the specified activity or effect.

Actual HAP emissions means the HAP emitted to the atmosphere from either uncontrolled or controlled emission points.

Air pollution control device or Control device means equipment installed on a process vent, storage tank, wastewater treatment exhaust stack, or combination thereof that reduces the mass of HAP emitted to the air. The equipment may consist of an individual device or a series of devices. Examples include, but are not limited to, incinerators, carbon adsorption units, condensers, flares, boilers, process heaters, and gas absorbers. Process condensers are not considered air pollution control devices or control devices.

Annual average concentration, as used in the wastewater provisions, means the annual average concentration as determined according to the procedures specified in § 63.1257(e)(1).

Automated monitoring and recording system means any means of measuring values of monitored parameters and creating a hard copy or computer record of the measured values that does not require manual reading of monitoring instruments and manual transcription of data values. Automated monitoring and recording systems include, but are not limited to, computerized systems and strip charts.

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

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

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

Block means a time period that comprises a single batch.

Cleaning operation means routine rinsing, washing, or boil-off of equipment in batch operations between batches.

Closed biological treatment process means a tank or surface impoundment where biological treatment occurs and air emissions from the treatment process are routed to either a control device by means of a closed-vent system or by means of hard-piping. The tank or surface impoundment has a fixed roof, as defined in this section, or a floating flexible membrane cover that meets the requirements specified in § 63.1256(c).

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

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

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

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

Component means any ingredient for use in the manufacture of a drug product, including those that may not appear in such drug product.

Connector means flanged, screwed, or other joined fittings used to connect two pipe lines or a pipe line and a piece of equipment. A common connector is a flange. Joined fittings welded completely around the circumference of the interface are not considered connectors for the purpose of this regulation. For the purpose of reporting and recordkeeping, connector means joined fittings that are not inaccessible, ceramic, or ceramic-lined as described in § 63.1255(b)(1)(vii) and § 63.1255(f)(3).

Construction means the onsite fabrication, erection, or installation of an affected source or a PMPU.

Consumption means the quantity of HAP entering a process that is not used as reactant (makeup). If the same HAP component is generated in the process

as well as added as makeup, consumption shall include the quantity generated in the process, as calculated assuming 100 theoretical conversion. The quantity of material used as reactant is the theoretical amount needed assuming a 100 percent stoichiometric conversion. Makeup is the net amount of material that must be added to the process to replenish losses.

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

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

Continuous recorder means a data recording device that either records an instantaneous data value at least once every 15 minutes or records 15-minute or more frequent block average values.

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

Control device, for purposes of this § 63.1255, means any equipment used for recovering or oxidizing organic hazardous air pollutant vapors. Such equipment includes, but is not limited to, absorbers, carbon adsorbers, condensers, flares, boilers, and process heaters.

Controlled HAP emissions means the quantity of HAP discharged to the atmosphere from an air pollution control device.

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

Dedicated PMPU means a PMPU that is composed of equipment that is used to manufacture the same product for a continuous period of 6 months or greater. The PMPU includes any shared storage tank(s) that are determined to belong to the PMPU according to the procedures in § 63.1250(e).

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

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

Enhanced biological treatment system or enhanced biological treatment process means an aerated, thoroughly mixed treatment unit(s) that contains biomass suspended in water followed by a clarifier that removes biomass from the treated water and recycles recovered biomass to the aeration unit. The mixed liquor volatile suspended solids (biomass) is greater than 1 kilogram per cubic meter throughout each aeration unit. The biomass is suspended and aerated in the water of the aeration unit(s) by either submerged air flow or mechanical agitation. A thoroughly mixed treatment unit is a unit that is designed and operated to approach or achieve uniform biomass distribution and organic compound concentration throughout the aeration unit by quickly dispersing the recycled biomass and the wastewater entering the unit.

Equipment, for purposes of § 63.1255, means each pump, compressor, agitator, pressure relief device, sampling connection system, open-ended valve or line, valve, connector, and instrumentation system in organic hazardous air pollutant service; and any control devices or closed-vent systems required by this subpart.

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

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

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

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

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

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

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

Formulation means the process of mixing, blending, or diluting one or more active or inert ingredients with one or more active or inert ingredients, without an intended chemical reaction, to obtain a pharmaceutical dosage form. Formulation operations include mixing, compounding, blending, and tablet coating.

Group of processes means all of the equipment associated with processes in a building, processing area, or facility-wide. For a dedicated process, a group of processes may consist of a single process.

Halogen atoms mean atoms of chlorine or fluorine.

Halogenated compounds means organic HAP compounds that contain halogen atoms.

Halogenated vent stream or Halogenated stream means a process, storage tank, or waste management unit vent determined to have a concentration of halogenated compounds of greater than 20 ppmv, as determined through process knowledge, test results using Method 18 of 40 CFR part 60, appendix A, or test results using any other test method that has been validated according to the procedures in Method 301 of appendix A of this part.

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

Hydrogen halides and halogens means hydrogen chloride (HCl), chlorine (Cl^2), and hydrogen fluoride (HF).

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

In heavy liquid service means that a piece of equipment in organic

hazardous air pollutant service is not in gas/vapor service or in light liquid service.

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

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

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

(3) The fluid is a liquid at operating conditions. (Note: Vapor pressures may be determined by the methods described in 40 CFR 60.485(e)(1).)

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

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

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

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

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

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

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

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

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

Large control device means a control device that controls process vents with total emissions of greater than or equal to 10 tons of HAP per year, before control.

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

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

Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, emissions monitoring equipment, process equipment, or a process to operate in a normal or usual manner. Failures that are caused all or in part by poor maintenance or careless operation are not malfunctions.

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

(1) In accordance with methods described in Chapter 19.2 of the American Petroleum Institute's Manual of Petroleum Measurement Standards, Evaporative Loss From Floating-Roof Tanks (incorporated by reference as specified in § 63.14); or

(2) As obtained from standard reference texts; or

(3) As determined by the American Society for Testing and Materials Method D2879–97, Test Method for Vapor Pressure-Temperature Relationship and Initial Decomposition Temperature of Liquids by Isoteniscope (incorporated by reference as specified in § 63.14); or

(4) Any other method approved by the Administrator.

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

Nondedicated formulation operations means equipment used to formulate numerous products.

Nondedicated recovery device(s) means a recovery device that receives material from more than one PMPU.

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

Open biological treatment process means a biological treatment process that is not a closed biological treatment process as defined in this section.

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

Operating scenario for the purposes of reporting and recordkeeping, means any specific operation of a PMPU and includes for each process:

(1) A description of the process and the type of process equipment used;

(2) An identification of related process vents and their associated emissions episodes and durations, wastewater PODs, and storage tanks;

(3) The applicable control requirements of this subpart, including the level of required control;

(4) The control or treatment devices used, as applicable, including a

description of operating and/or testing conditions for any associated control device;

(5) The process vents, wastewater PODs, and storage tanks (including those from other processes) that are simultaneously routed to the control or treatment device(s);

(6) The applicable monitoring requirements of this subpart and any parametric level that assures compliance for all emissions routed to the control or treatment device;

(7) Calculations and engineering analyses required to demonstrate compliance; and

(8) A verification that the operating conditions for any associated control or treatment device have not been exceeded and that any required calculations and engineering analyses have been performed. For reporting purposes, a change to any of these elements not previously reported, except for paragraph (5) of this definition, shall constitute a new operating scenario.

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

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

Pharmaceutical manufacturing process unit (PMPU) means the process, as defined in this subpart, and any associated storage tanks, equipment identified in § 63.1252(f), and components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used in the manufacturing of a pharmaceutical product.

Pharmaceutical product means:

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

(2) Any material whose manufacturing process is described by north american industrial classification system (NAICS) code 325411 or 325412;

(3) A finished dosage form of a drug, for example, a tablet, capsule, solution, etc., that contains an active ingredient generally, but not necessarily, in association with inactive ingredients; or

(4) Any component whose intended primary use is to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals (the term does not include excipients, but includes drug components such as raw starting materials or precursors that undergo chemical change or processing before they become active ingredients).

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

Point of determination (POD) means the point where a wastewater stream exits the process, storage tank, or last recovery device. If soluble and/or partially soluble HAP compounds are not recovered from water before discharge, the discharge point from the process equipment or storage tank is a POD. If water streams are routed to a recovery device, the discharge from the recovery device is a POD. There can be more than 1 POD per process or PMPU.

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

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

Primary use means the single largest use of a material.

Process means all equipment which collectively function to produce a pharmaceutical product. A process may consist of one or more unit operations. For the purposes of this subpart, process includes all or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a pharmaceutical product. Cleaning operations conducted are considered part of the process. The holding of the pharmaceutical product in tanks or other holding equipment for more than 30 consecutive days, or transfer of the pharmaceutical product to containers for shipment, marks the end of a process, and the tanks are considered part of the PMPU that produced the stored material. When material from one unit operation is used as the feedstock for the production of two or more different pharmaceutical products, the unit operation is considered the endpoint of the process that produced the material, and the unit operations into which the material is routed mark the beginning of the other processes. Nondedicated recovery devices located within a contiguous area within the affected source are considered single processes. Nondedicated formulation operations occurring within a contiguous area are considered a single process that is used to formulate numerous materials and/or products. Quality Assurance and Quality Control laboratories are not considered part of any process.

Process condenser means a condenser whose primary purpose is to recover material as an integral part of a process. The condenser must support a vapor-to-liquid phase change for periods of source equipment operation that are at or above the boiling or bubble point of substance(s) at the liquid surface. Examples of process condensers include distillation condensers, reflux condensers, and condensers used in stripping or flashing operations. In a series of condensers, all condensers up to and including the first condenser with an exit gas temperature below the boiling or bubble point of the substance(s) at the liquid surface are considered to be process condensers. All condensers in line prior to a vacuum source are included in this definition.

Process shutdown means a work practice or operational procedure that stops production from a process or part of a process during which it is technically feasible to clear process material from a process or part of a process consistent with safety constraints and during which repairs can be effected. An unscheduled work practice or operational procedure that stops production from a process or part of a process for less than 24 hours is not a process shutdown. An unscheduled work practice or operational procedure that would stop production from a process or part of a process for a shorter period of time than would be required to clear the process or part of the process of materials and start up the process, and would result in greater emissions than delay of repair of leaking components until the next scheduled process shutdown, is not a process shutdown. The use of spare equipment and technically feasible bypassing of equipment without stopping production are not process shutdowns.

Process tank means a tank that is used to collect material discharged from a feedstock storage tank or unit operation

within the process and transfer this material to another unit operation within the process or to a product storage tank. Surge control vessels and bottoms receivers that fit these conditions are considered process tanks.

Process vent means a vent from a unit operation or vents from multiple unit operations within a process that are manifolded together into a common header, through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Emission streams that are undiluted and uncontrolled containing less than 50 ppmv HAP, as determined through process knowledge that no HAP are present in the emission stream or using an engineering assessment as discussed in § 63.1257(d)(2)(ii), test data using Methods 18 of 40 CFR part 60, appendix A, or any other test method that has been validated according to the procedures in Method 301 of appendix A of this part, are not considered process vents. Process vents do not include vents on storage tanks regulated under § 63.1253, vents on wastewater emission sources regulated under § 63.1256, or pieces of equipment regulated under § 63.1255.

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

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

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

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

Recovery device, as used in the wastewater provisions, means an individual unit of equipment used for the purpose of recovering chemicals for fuel value (i.e., net positive heating value), use, reuse, or for sale for fuel value, use or reuse. Examples of equipment that may be recovery devices include organic removal devices such as decanters, strippers, or thin-film evaporation units. To be a recovery device, a decanter and any other equipment based on the operating principle of gravity separation must receive only two-phase liquid streams.

Repaired means that equipment is adjusted, or otherwise altered, to eliminate a leak as defined in the applicable sections of § 63.1255.

Research and development facility means any stationary source whose primary purpose is to conduct research and development into new processes and products, where such source is operated under the close supervision of technically trained personnel, and is not engaged in the manufacture of products for commercial sale in commerce, except in a de minimis manner.

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

Safety device means a closure device such as a pressure relief valve, frangible disc, fusible plug, or any other type of device which functions exclusively to prevent physical damage or permanent deformation to a unit or its air emission control equipment by venting gases or vapors directly to the atmosphere during unsafe conditions resulting from an unplanned, accidental, or emergency event. For the purposes of this subpart, a safety device is not used for routine venting of gases or vapors from the vapor headspace underneath a cover such as during filling of the unit or to adjust the pressure in this vapor headspace in response to normal daily diurnal ambient temperature fluctuations. A safety device is designed to remain in a closed position during normal operations and open only when the internal pressure, or another relevant parameter, exceeds the device threshold setting applicable to the air emission control equipment as determined by the owner or operator based on manufacturer recommendations, applicable regulations, fire protection and prevention codes, standard engineering codes and practices, or other requirements for the safe handling of flammable, combustible, explosive, reactive, or hazardous materials.

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

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

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

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

Shutdown means the cessation of operation of a PMPU or an individual piece of equipment required or used to comply with this part or for emptying and degassing storage tanks. Shutdown occurs for purposes including but not limited to: periodic maintenance, replacement of equipment, or repair. Shutdown does not apply to routine batch operations or the rinsing or washing of equipment in batch operations between batches.

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

Small control device means a control device that controls process vents with total emissions of less than 10 tons of HAP per year, before control.

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

Startup means the first time a new or reconstructed source begins production, or, for new equipment added, including equipment used to comply with this subpart, the first time the equipment is put into operation, or for the introduction of a new product/process, the first time the product or process is run in equipment. As used in § 63.1255, startup means the setting in operation of

a piece of equipment or a control device that is subject to this subpart.

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

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

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

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

(4) Wastewater storage tanks; and

(5) Process tanks.

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

Total organic compounds (TOC) means those compounds measured according to the procedures of Method 18 or Method 25A, 40 CFR part 60, appendix A.

Treatment process means a specific technique that removes or destroys the organics in a wastewater or residual stream such as a steam stripping unit, thin-film evaporation unit, waste incinerator, biological treatment unit, or any other process applied to wastewater streams or residuals to comply with § 63.1256. Most treatment processes are conducted in tanks. Treatment processes are a subset of waste management units.

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

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

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

Volatile organic compounds (VOC) means those materials defined in 40 CFR 51.100.

Waste management unit means the equipment, structure(s),and or devices used to convey, store, treat, or dispose of wastewater streams or residuals. Examples of waste management units include wastewater tanks, air flotation units, surface impoundments, containers, oil-water or organic-water separators, individual drain systems, biological wastewater treatment units, waste incinerators, and organic removal devices such as steam and air stripper units, and thin film evaporation units. If such equipment is used for recovery then it is part of a pharmaceutical process and is not a waste management unit.

Wastewater means any portion of an individual wastewater stream or any aggregation of wastewater streams.

Wastewater stream means water that is discarded from a PMPU through a single POD, that contains an annual average concentration of partially soluble and/or soluble HAP compounds of at least 5 parts per million by weight and a load of at least 0.05 kg/yr, and that is not exempted by the provisions of § 63.1256(a)(3). For the purposes of this subpart, noncontact cooling water is not considered a wastewater stream. Wastewater streams are generated by both process operations and maintenance activities.

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

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

§ 63.1252 Standards: General.

Each owner or operator of any affected source subject to the provisions of this subpart shall control HAP emissions to the level specified in this section on and after the compliance dates specified in § 63.1250(f). Compliance with the emission limits may be demonstrated initially through the provisions of § 63.1257 (Test methods and compliance procedures) and continuously through the provisions of § 63.1258 (Monitoring requirements).

(a) *Opening of a safety device.* Opening of a safety device, as defined in § 63.1251, is allowed at any time conditions require it to do so to avoid unsafe conditions.

(b) *Closed-vent systems.* The owner or operator of a closed-vent system that contains bypass lines that could divert a vent stream away from a control device used to comply with the requirements in §§ 63.1253, 63.1254, and 63.1256 shall comply with the requirements of Table 4 to this subpart and paragraph (b)(1) or (2) of this section. Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and pressure relief valves needed for safety purposes are not subject to this paragraph.

(1) Install, calibrate, maintain, and operate a flow indicator that determines whether vent stream flow is present at least once every 15 minutes. Records shall be maintained as specified in § 63.1259(i)(6)(i). The flow indicator shall be installed at the entrance to any bypass line that could divert the vent stream away from the control device to the atmosphere; or

(2) Secure the bypass line valve in the closed position with a car seal or lock and key type configuration. A visual inspection of the seal or closure mechanism shall be performed at least once every month to ensure that the valve is maintained in the closed position and the vent stream is not diverted through the bypass line. Records shall be maintained as specified in § 63.1259(i)(6)(ii).

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

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

§ 63.104, except that the monitoring frequency shall be no less than quarterly.

(2) For identifying leaking equipment, the owner or operator of heat exchange systems on equipment which meet current good manufacturing practice (CGMP) requirements of 21 CFR part 211 may elect to use the physical integrity of the reactor as the surrogate indicator of heat exchange system leaks around the reactor.

(d) *Emissions averaging provisions.* Except as specified in paragraphs (d)(1) through (5) of this section, owners or operators of storage tanks or processes subject to the provisions of §§ 63.1253 and 63.1254 may choose to comply by using emissions averaging requirements specified in § 63.1257(g) or (h) for any storage tank or process.

(1) A State may prohibit averaging of HAP emissions and require the owner or operator of an existing source to comply with the provisions in §§ 63.1253 and 63.1254.

(2) Only emission sources subject to the requirements of § 63.1253(b)(1) and (c)(1) or § 63.1254(a)(2), (a)(3)(ii)(A) or (a)(3)(iii) may be included in any averaging group.

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

(4) Processes and storage tanks already controlled on or before November 15, 1990 may not be included in an emissions averaging group, except where the level of control is increased after November 15, 1990. In these cases, the uncontrolled emissions shall be the controlled emissions as calculated on November 15, 1990 for the purpose of determining the uncontrolled emissions as specified in § 63.1257(g) and (h).

(5) Emission points controlled to comply with a State or Federal rule other than this subpart may not be included in an emission averaging group, unless the level of control has been increased after November 15, 1990 above what is required by the other State or Federal rule. Only the control above what is required by the other State or Federal rule will be credited. However, if an emission point has been used to generate emissions averaging credit in an approved emissions average, and the point is subsequently made subject to a State or Federal rule other than this subpart, the point can continue to generate emissions averaging credit for the purpose of complying with the previously approved average.

(6) Not more than 20 processes subject to § 63.1254(a)(2)(i), 20 storage tanks subject to § 63.1253(b)(1), and 20 storage tanks subject to § 63.1253(c)(1)(i) at an affected source may be included in an emissions averaging group.

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

(8) Compliance with the emissions standards in § 63.1254(a)(2) shall be satisfied when the annual percent reduction efficiency is greater than or equal to 93 percent, as demonstrated using the test methods and compliance procedures specified in § 63.1257(h).

(e) *Pollution prevention alternative.* Except as provided in paragraph (e)(1) of this section, owners and operators may choose to meet the pollution prevention alternative requirement specified in either paragraph (e)(2) or (3) of this section for any PMPU, in lieu of the requirements specified in §§ 63.1253, 63.1254, 63.1255, and 63.1256. Compliance with paragraphs (e)(2) and (3) of this section shall be demonstrated through the procedures in § 63.1257(f).

(1) The HAP that are generated in the PMPU that are not part of the production-indexed consumption factor must be controlled according to the requirements of §§ 63.1253, 63.1254, 63.1255, and 63.1256. The HAP that are generated as a result of combustion control of emissions must be controlled according to the requirements of paragraph (g) of this section.

(2) The production-indexed HAP consumption factor (kg HAP consumed/kg produced) shall be reduced by at least 75 percent from a 3 year average baseline established no earlier than the 1987 calendar year, or for the time period from startup of the process until the present in which the PMPU was operational and data are available, whichever is the lesser time period. If a time period less than 3 years is used to set the baseline, the data must represent at least 1 year's worth of data. For any reduction in the HAP factor achieved by reducing a HAP that is also a VOC, an equivalent reduction in the VOC factor is also required. For any reduction in the HAP factor that is achieved by reducing a HAP that is not a VOC, the VOC factor may not be increased.

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

(i) The production-indexed HAP consumption factor (kg HAP consumed/kg produced) shall be reduced by at least 50 percent from a 3-year average baseline established no earlier than the 1987 calendar year, or for the time period from startup of the process until the present in which the PMPU was operational and data are available, whichever is less. If a time period less than 3 years is used to set the baseline, the data must represent at least 1 year's worth of data. For any reduction in the HAP factor achieved by reducing a HAP that is also a VOC, an equivalent reduction in the VOC factor is also required. For any reduction in the HAP factor that is achieved by reducing a HAP that is not a VOC, the VOC factor may not be increased.

(ii) The total PMPU HAP emissions shall be reduced by an amount, in kg/yr, that, when divided by the annual production rate, in kg/yr, and added to the reduction of the production-indexed HAP consumption factor, in kg/kg, yields a value of at least 75 percent of the average baseline HAP production-indexed consumption factor established according to paragraph (e)(3)(i) of this section according to the equation provided in § 63.1257(f)(2)(ii)(A). The total PMPU VOC emissions shall be reduced by an amount calculated according to the equation provided in § 63.1257(f)(2)(ii)(B). The annual reduction in HAP and VOC air emissions must be due to the use of the following control devices:

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

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

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

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

(f) *Control requirements for certain liquid streams in open systems within a PMPU.* (1) The owner or operator shall comply with the provisions of Table 5 of this subpart, for each item of equipment meeting all the criteria specified in paragraphs (f)(2) through (4) and either paragraph (f)(5)(i) or (ii) of this section.

(2) The item of equipment is of a type identified in Table 5 of this subpart;

(3) The item of equipment is part of a PMPU, as defined in § 63.1251;

(4) The item of equipment is controlled less stringently than in Table

5 of this subpart and the item of equipment is not otherwise exempt from controls by the provisions of this subpart or subpart A of this part; and

(5) The item of equipment:

(i) Is a drain, drain hub, manhole, lift station, trench, pipe, or oil/water separator that conveys water with an annual average concentration greater than or equal to 1,300 parts per million by weight (ppmw) of partially soluble HAP compounds; or an annual average concentration greater than or equal to 5,200 ppmw of partially soluble and/or soluble HAP compounds. The annual average concentration shall be determined according to the procedures in § 63.1257(e)(1)(ii).

(ii) Is a tank that receives one or more streams that contain water with an annual average concentration greater than or equal to 1,300 ppmw of partially soluble HAP compounds, or greater than or equal to 5,200 ppmw of total partially soluble and/or soluble HAP compounds. The owner or operator of the source shall determine the average concentration of the stream at the inlet to the tank and according to the procedures in § 63.1257(e)(1)(ii).

(g) *Control requirements for halogenated vent streams that are controlled by combustion devices.* If a combustion device is used to comply with the provisions of §§ 63.1253 (storage tanks), 63.1254 (process vents), 63.1256(h) (wastewater vent streams) for a halogenated vent stream, then the vent stream shall be ducted to a halogen reduction device such as, but not limited to, a scrubber, before it is discharged to the atmosphere. The halogen reduction device must reduce emissions by the amounts specified in either paragraph (g)(1) or (2) of this section.

(1) A halogen reduction device after the combustion control device must reduce overall emissions of hydrogen halides and halogens, as defined in § 63.1251, by 95 percent or to a concentration less than or equal to 20 ppmv.

(2) A halogen reduction device located before the combustion control device must reduce the halogen atom content of the vent stream to a concentration less than or equal to 20 ppmv.

§ 63.1253 Standards: Storage tanks.

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

(1) A storage tank with a design capacity greater than or equal to 38 m^3 (10,000 gallons [gal]) but less than 75 m^3 (20,000 gal), and storing a liquid for which the maximum true vapor pressure of total HAP is greater than or equal to 13.1 kPa (1.9 psia).

(2) A storage tank with a design capacity greater than or equal to 75 m^3 (20,000 gal) storing a liquid for which the maximum true vapor pressure of total HAP is greater than or equal to 13.1 kPa (1.9 psia).

(b) The owner or operator of a storage tank shall equip the affected storage tank with either a fixed roof with internal floating roof, an external floating roof, an external floating roof converted to an internal floating roof, or a closed-vent system meeting the conditions of § 63.1252(b) with a control device that meets any of the following conditions:

(1) Reduces inlet emissions of total HAP by 90 percent by weight or greater;

(2) Is an enclosed combustion device that provides a minimum residence time of 0.5 seconds at a minimum temperature of 760° C;

(3) Is a flare that meets the requirements of § 63.11(b); or

(4) Is a control device specified in § 63.1257(a)(4).

(c) The owner or operator of a storage tank shall equip the affected storage tank with either a fixed roof with internal floating roof, an external floating roof, an external floating roof converted to an internal floating roof, or a closed-vent system meeting the conditions of § 63.1252(b) with a control device that meets any of the following conditions:

(1) Reduces inlet emissions of total HAP as specified in paragraph (c)(1) (i) or (ii) of this section:

(i) By 95 percent by weight or greater; or (ii) If the owner or operator can demonstrate that a control device installed on a storage tank on or before April 2, 1997 is designed to reduce inlet emissions of total HAP by greater than or equal to 90 percent by weight but less than 95 percent by weight, then the control device is required to be operated to reduce inlet emissions of total HAP by 90 percent or greater.

(2) Is an enclosed combustion device that provides a minimum residence time of 0.5 seconds at a minimum temperature of 760° C;

(3) Is a flare that meets the requirements of § 63.11(b); or

(4) Is a control device specified in § 63.1257(a)(4).

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

(e) *Planned routine maintenance.* The specifications and requirements in paragraphs (b) through (d) of this section for control devices do not apply during periods of planned routine maintenance. Periods of planned routine maintenance of the control devices, during which the control device does not meet the specifications of paragraphs (b) through (d) of this section, as applicable, shall not exceed 240 hours per year.

§ 63.1254 Standards: Process vents.

(a) *Existing sources.* Except as provided in paragraph (c) of this section, the owner or operator of an existing affected source must control the collection of all gas streams originating from processes subject to this standard so as to comply with the requirements in paragraph (a)(1) or the requirements of paragraphs (a)(2) and (a)(3) of this section. If any vent within a process meets the criteria of paragraph (a)(3)(i) of this section, the owner or operator must comply with the provisions in paragraphs (a)(2) and (a)(3) for that process. The requirements of paragraphs (a) (1) and (2) of this section apply to all process vents within a process, as a group, and do not apply to individual vents. An owner or operator may switch from compliance with paragraph (a)(1) of this section to compliance with paragraphs (a) (2) and (3) of this section only after at least 1 year of operation in compliance with paragraph (a)(1) of this section. An owner or operator may switch from compliance with paragraphs (a) (2) and (3) of this section to compliance with paragraph (a)(1) of this section at any time. Notification of such a change in the compliance method shall be reported according to the procedures in § 63.1260(h) of this subpart. Compliance with the required

emission limits or reductions in paragraphs (a) (1) through (3) of this section may be demonstrated using the initial compliance procedures described in § 63.1257(d) and the monitoring requirements described in § 63.1258.

(1) Except for processes with a vent that meets the conditions in paragraph (a)(3)(i) of this section, actual HAP emissions shall not exceed 900 kilograms (kg) per year [2,000 pounds per year] from the sum of all process vents within a process.

(i) Except as provided in paragraph (a)(1)(ii) of this section, the owner or operator is limited to 7 processes in any 365-day period that can be selected to comply with paragraph (a)(1) of this section.

(ii) The owner or operator may exclude processes with less than 100 lb/yr HAP, on an uncontrolled basis, from the 7-process limit described in paragraph (a)(1)(i) of this section.

(2) Uncontrolled HAP emissions from the sum of all process vents within a process that do not meet the conditions in paragraph (a)(3)(i) of this section or are not controlled according to any of the requirements of paragraphs (a)(2)(i), (a)(2)(ii), (a)(2)(iii), or (c) of this section shall be reduced by 93 percent or greater by weight.

(i) To outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens;

(ii) By a flare that meets the requirements of § 63.11(b); or (iii) By a control device specified in § 63.1257(a)(4).

(3) Except as provided in paragraph (a)(3)(iii) of this section, uncontrolled HAP emissions from each process vent that meets the conditions in paragraph (a)(3)(i) of this section shall be reduced as specified in paragraph (a)(3)(ii) of this section.

(i) Uncontrolled HAP emissions from a process vent shall be reduced as specified in paragraph (a)(3)(ii) if the vent meets either of the criteria described in paragraph (a)(3)(i) (A) or (B) of this section:

(A) The flow-weighted average flowrate calculated using Equation 1 of this subpart is less than or equal to the flowrate calculated using Equation 2 of this subpart.

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

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

Where:

FR_a = flow-weighted average flowrate for the vent, scfm

D_i = duration of each emission event, min

FR_i = flowrate of each emission event, scfm

n = number of emission events

FR = flowrate, scfm

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

(B) As an alternative to the criteria described in paragraph (a)(3)(i)(A) of this section, uncontrolled HAP emissions from a process vent shall be reduced or controlled as specified in paragraph (a)(3)(ii) of this section if the process vent meets the criteria specified in paragraphs (a)(3)(i)(B)(*1*) and (*2*) of this section or the criteria specified in paragraphs (a)(3)(i)(B)(*1*) and (*3*) of this section.

(*1*) Uncontrolled HAP emissions from the process vent exceed 25 tons per year.

(*2*) The flow-weighted average flowrate for the vent, as calculated in Equation 1 of this section, is less than or equal to 100 scfm.

(*3*) The flow weighted average is greater than 100 scfm and less than or equal to the flowrate calculated using Equation 2 of this section.

(ii) Uncontrolled HAP emissions shall be reduced:

(A) By 98 percent by weight or greater; or

(B) To outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens; or

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

(D) By a control device specified in § 63.1257(a)(4).

(iii) If the owner or operator can demonstrate that a control device, installed on a process vent that meets the conditions of paragraph (a)(3)(i) of this section on or before April 2, 1997, was designed to reduce uncontrolled HAP emissions of total HAP by greater than or equal to 93 percent by weight, but less than 98 percent by weight, then the control device is required to be operated to reduce inlet emissions of total HAP by 93 percent by weight or greater.

(b) *New sources.* Uncontrolled HAP emissions from the sum of all process vents within a process at a new affected source that are not controlled according to any of the requirements of paragraphs (b)(1), (2), or (3) of this section or paragraph (c) of this section shall be reduced by 98 percent or greater by weight if the uncontrolled HAP emissions from the sum of all process vents within a process is greater than 180 kg/yr (400 lb/yr). Compliance with the required emission limit or reduction is demonstrated using the initial compliance procedures in § 63.1257(d) and the monitoring requirements described in § 63.1258.

(1) To outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens;

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

(3) By a control device specified in § 63.1257(a)(4).

(c) As an alternative standard, the owner or operator of an existing or new affected source may comply with the process vent standards by routing all vents from a process to a control device achieving an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 20 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 20 ppmv or less. Any process vents within a process that are not routed to this control device must be controlled in accordance with the provisions of paragraphs (a)(2),(a)(3), and (b) of this section, as applicable. Compliance with the outlet concentrations shall be determined by the initial compliance procedures described in § 63.1257(d)(1)(iv) and the continuous emission monitoring requirements described in § 63.1258(b)(5).

§ 63.1255 Standards: Equipment leaks.

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

(2) *Consistency with other regulations.* After the compliance date for a process, equipment subject to both this section and either of the following will be required to comply only with the provisions of this subpart:

(i) 40 CFR part 60.

(ii) 40 CFR part 61.

(3) [Reserved]

(4) The provisions in § 63.1(a)(3) of subpart A of this part do not alter the provisions in paragraph (a)(2) of this section.

(5) Lines and equipment not containing process fluids are not subject

to the provisions of this section. Utilities, and other nonprocess lines, such as heating and cooling systems which do not combine their materials with those in the processes they serve, are not considered to be part of a process.

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

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

(8) Equipment that is in vacuum service is excluded from the requirements of this section.

(9) Equipment that is in organic HAP service, but is in such service less than 300 hours per calendar year, is excluded from the requirements of this section if it is identified as required in paragraph (g)(9) of this section.

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

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

(ii) The identification on a valve or connector in light liquid or gas/vapor service may be removed after it has been monitored as specified in paragraph (e)(7)(iii) of this section and § 63.174(e), and no leak has been detected during the follow-up monitoring.

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

(b) *References.* (1) The owner or operator of a source subject to this section shall comply with the following sections of subpart H, except for § 63.160, § 63.161, § 63.162, § 63.163, § 63.167, § 63.168, § 63.170, § 63.171, § 63.172, § 63.173, § 63.181, and § 63.182 of this subpart. In place of § 63.160 and § 63.162, the owner or operator shall comply with paragraph (a) of this section; in place of § 63.161, the owner or operator shall comply with § 63.1251 of this subpart; in place of § 63.163 and § 63.173, the owner or operator shall comply with paragraph (c) of this section; in place of § 63.167, the owner or operator shall comply with paragraph (d) of this section; in place of § 63.168, the owner or operator shall comply with paragraph (e) of this section; in place of § 63.170, the owner or operator shall comply with § 63.1254 of this subpart; in place of § 63.171, the owner or operator shall comply with paragraph (b)(1)(v) of this section; in place of § 63.172, the owner or operator shall comply with paragraph (b)(1)(vi) of this section; in place of § 63.181, the owner or operator shall comply with paragraph (g) of this section; in place of § 63.182, the owner or operator shall comply with paragraph (h) of this section. The term ''process unit'' as used in subpart H shall be considered to be defined the same as ''group of processes'' for sources subject to this subpart GGG.

(i) Section 63.164, Compressors;

(ii) Section 63.165, Pressure relief devices in gas/vapor service;

(iii) Section 63.166, Sampling connection systems;

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

(v) Section 63.171, Delay of repair, shall apply except § 63.171(a) shall not apply. Instead, delay of repair of equipment for which leaks have been detected is allowed if one of the following conditions exist:

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

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

(vi) Section 63.172, Closed-vent systems and control devices, for closed-vent systems used to comply with this subpart, and for control devices used to comply with this section only, except

(A) Sections 63.172(k) and (l) shall not apply. In place of § 63.172(k) and (l), the owner or operator shall comply with paragraph (f) of this section.

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

(vii) Section 63.174, Connectors, except:

(A) Sections 63.174(f) and (g) shall not apply. In place of § 63.174(f) and (g), the owner or operator shall comply with paragraph (f) of this section.

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

(C) Section 63.174(b)(3)(ii) shall not apply. Instead, if the percent leaking connectors in the process unit was less than 0.5 percent, but equal to or greater than 0.25 percent, during the last required monitoring period, monitoring shall be performed once every 4 years. An owner or operator may comply with the requirements of this paragraph by monitoring at least 40 percent of the connectors in the first 2 years and the remainder of the connectors within the next 2 years. The percent leaking connectors will be calculated for the total of all monitoring performed during the 4 year period.

(D) Section 63.174(b)(3)(iv) shall not apply. Instead, the owner or operator shall increase the monitoring frequency to once every 2 years for the next monitoring period if leaking connectors comprise at least 0.5 percent but less than 1.0 percent of the connectors monitored within the 4 years specified in paragraph (b)(1)(vii)(C) of this section or the first 4 years specified in § 63.174(b)(3)(iii). At the end of that 2 year monitoring period, the owner or operator shall monitor once per year while the percent leaking connectors is greater than or equal to 0.5 percent; if the percent leaking connectors is less than 0.5 percent, the owner or operator may return to monitoring once every 4 years or may monitor in accordance with § 63.174(b)(3)(iii), if appropriate.

(E) Section 63.174(b)(3)(v) shall not apply. Instead, if an owner or operator complying with the requirements of paragraph (b)(1)(vii)(C) and (D) of this section or § 63.174 (b)(3)(iii) for a group of processes determines that 1 percent or greater of the connectors are leaking, the owner or operator shall increase the monitoring frequency to one time per year. The owner or operator may again elect to use the provisions of paragraphs (b)(1)(vii)(C) or (D) of this section after a monitoring period in which less than

0.5 percent of the connectors are determined to be leaking.

(F) Section 63.174(b)(3)(iii) shall not apply. Instead, monitoring shall be required once every 8 years, if the percent leaking connectors in the process unit was less than 0.25 percent during the last required monitoring period. An owner or operator shall monitor at least 50 percent of the connectors in the first 4 years and the remainder of the connectors within the next 4 years. If the percent leaking connectors in the first 4 years is equal to or greater than 0.35 percent, the monitoring program shall revert at that time to the appropriate monitoring frequency specified in paragraphs (b)(1)(vii)(C), (D), or (E) of this section.

(viii) Section 63.177, Alternative means of emission limitation: General;

(ix) Section 63.178, Alternative means of emission limitation: Batch processes, except that § 63.178(b), requirements for pressure testing, shall apply to all processes, not just batch processes;

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

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

(2) [Reserved]

(c) *Standards for Pumps in Light Liquid Service and Agitators in Gas/Vapor Service and in Light Liquid Service.* (1) The provisions of this section apply to each pump that is in light organic HAP liquid service, and to each agitator in organic HAP gas/vapor service or in light organic HAP liquid service.

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

(ii) *Leak definition.* The instrument reading, as determined by the method as specified in § 63.180(b), that defines a leak is:

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

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

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

(3) *Repair provisions.* (i) When a leak is detected, it shall be repaired as soon as practicable, but not later than 15 calendar days after it is detected, except as provided in paragraph (b)(1)(v) of this section.

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

(A) Tightening of packing gland nuts.

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

(4) *Calculation of percent leakers.* (i) The owner or operator shall decide no later than the end of the first monitoring period what groups of processes will be developed. Once the owner or operator has decided, all subsequent percent calculations shall be made on the same basis.

(ii) If, calculated on a 1 year rolling average, the greater of either 10 percent or three of the pumps in a group of processes leak, the owner or operator shall monitor each pump once per month.

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

(iv) Percent leaking pumps shall be determined by the following Equation 3:

$$\%P_L = [(P_L — P_S)/(P_T — P_S)] \times 100 \quad \text{(Eq. 3)}$$

Where:

$\%P_L$ = percent leaking pumps

P_L = number of pumps found leaking as determined through quarterly monitoring as required in paragraphs (c)(2)(i) and (c)(2)(ii) of this section.

P_T = total pumps in organic HAP service, including those meeting the criteria in paragraphs (c)(5) and (c)(6) of this section

PS = number of pumps in a continuous process leaking within 1 quarter of startup during the current monitoring period

(5) *Exemptions.* Each pump or agitator equipped with a dual mechanical seal system that includes a barrier fluid system is exempt from the requirements of paragraphs (c)(1) through (c)(4)(iii) of this section, provided the following requirements are met:

(i) Each dual mechanical seal system is:

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

(B) Equipped with a barrier fluid degassing reservoir that is connected by a closed-vent system to a control device that complies with the requirements of paragraph (b)(1)(vi) of this section; or

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

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

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

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

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

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

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

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

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

(C) When a leak is detected, it shall be repaired as soon as practicable, but not later than 15 calendar days after it is detected, except as provided in paragraph (b)(1)(v) of this section.

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

(6) Any pump/agitator that is designed with no externally actuated

shaft penetrating the pump/agitator housing is exempt from the requirements of paragraphs (c)(1) through (c)(4) of this section, except for the requirements of paragraph (c)(2)(iii) and, for pumps, paragraph (c)(4)(iv).

(7) Any pump/agitator equipped with a closed-vent system capable of capturing and transporting any leakage from the seal or seals back to the process or to a control device that complies with the requirements of paragraph (b)(1)(vi) of this section is exempt from the requirements of paragraphs (c)(2) through (c)(5) of this section.

(8) Any pump/agitator that is located within the boundary of an unmanned plant site is exempt from the weekly visual inspection requirement of paragraphs (c)(2)(iii) and (c)(5)(iv) of this section, and the daily requirements of paragraph (c)(5)(v) of this section, provided that each pump/agitator is visually inspected as often as practicable and at least monthly.

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

(d) *Standards: Open-Ended Valves or Lines.* (1)(i) Each open-ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve, except as provided in § 63.177 and paragraphs (d)(4) through (6) of this section.

(ii) The cap, blind flange, plug, or second valve shall seal the open end at all times except during operations requiring process fluid flow through the open-ended valve or line, or during maintenance or repair. The cap, blind flange, plug, or second valve shall be in place within 1 hour of cessation of operations requiring process fluid flow through the open-ended valve or line, or within 1 hour of cessation of maintenance or repair.

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

(3) When a double block and bleed system is being used, the bleed valve or line may remain open during operations that require venting the line between the block valves but shall comply with paragraph (d)(1) of this section at all other times.

(4) Open-ended valves or lines in an emergency shutdown system which are designed to open automatically in the event of a process upset are exempt from the requirements of paragraphs (d)(1) through (d)(3) of this section.

(5) Open-ended valves or lines containing materials which would autocatalytically polymerize are exempt from the requirements of paragraphs (d)(1) through (d)(3) of this section.

(6) Open-ended valves or lines containing materials which could cause an explosion, serious overpressure, or other safety hazard if capped or equipped with a double block and bleed system as specified in paragraphs (d)(1) through (d)(3) of this section are exempt from the requirements of paragraphs (d)(1) through (d)(3) of this section.

(e) *Standards: Valves in Gas/Vapor Service and in Light Liquid Service.* (1) The provisions of this section apply to valves that are either in gas organic HAP service or in light liquid organic HAP service.

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

(3) *Monitoring.* The owner or operator of a source subject to this section shall monitor all valves, except as provided in paragraph (f) of this section and in § 63.177, at the intervals specified in paragraph (e)(4) of this section and shall comply with all other provisions of this section, except as provided in paragraph (b)(1)(v) of this section, § 63.178, and § 63.179.

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

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

(4) *Subsequent monitoring frequencies.* After conducting the initial survey required in paragraph (e)(2) of this section, the owner or operator shall monitor valves for leaks at the intervals specified below:

(i) For a group of processes with 2 percent or greater leaking valves, calculated according to paragraph (e)(6) of this section, the owner or operator shall monitor each valve once per month, except as specified in paragraph (e)(9) of this section.

(ii) For a group of processes with less than 2 percent leaking valves, the owner or operator shall monitor each valve once each quarter, except as provided in paragraphs (e)(4)(iii) through (e)(4)(v) of this section.

(iii) For a group of processes with less than 1 percent leaking valves, the owner or operator may elect to monitor each valve once every 2 quarters.

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

(v) For a group of processes with less than 0.25 percent leaking valves, the owner or operator may elect to monitor each valve once every 2 years.

(5) *Calculation of percent leakers.* For a group of processes to which this subpart applies, an owner or operator may choose to subdivide the valves in the applicable group of processes and apply the provisions of paragraph (e)(4) of this section to each subgroup. If the owner or operator elects to subdivide the valves in the applicable group of processes, then the provisions of paragraphs (e)(5)(i) through (e)(5)(viii) of this section apply.

(i) The overall performance of total valves in the applicable group of processes must be less than 2 percent leaking valves, as detected according to paragraphs (e)(3) (i) and (ii) of this section and as calculated according to paragraphs (e)(6) (ii) and (iii) of this section.

(ii) The initial assignment or subsequent reassignment of valves to subgroups shall be governed by the provisions of paragraphs (e)(5)(ii) (A) through (C) of this section.

(A) The owner or operator shall determine which valves are assigned to each subgroup. Valves with less than 1 year of monitoring data or valves not monitored within the last 12 months must be placed initially into the most frequently monitored subgroup until at least 1 year of monitoring data has been obtained.

(B) Any valve or group of valves can be reassigned from a less frequently monitored subgroup to a more frequently monitored subgroup provided that the valves to be reassigned were monitored during the most recent monitoring period for the less frequently monitored subgroup. The monitoring results must be included with the less frequently monitored subgroup's monitoring event and associated next percent leaking valves calculation for that group.

(C) Any valve or group of valves can be reassigned from a more frequently monitored subgroup to a less frequently monitored subgroup provided that the valves to be reassigned have not leaked for the period of the less frequently monitored subgroup (e.g., for the last 12 months, if the valve or group of valves is to be reassigned to a subgroup being monitored annually). Nonrepairable valves may not be reassigned to a less frequently monitored subgroup.

(iii) The owner or operator shall determine every 6 months if the overall performance of total valves in the applicable group of processes is less than 2 percent leaking valves and so indicate the performance in the next periodic report. If the overall performance of total valves in the

applicable group of processes is 2 percent leaking valves or greater, the owner or operator shall revert to the program required in paragraphs (e)(2) through (e)(4) of this section. The overall performance of total valves in the applicable group of processes shall be calculated as a weighted average of the percent leaking valves of each subgroup according to the following Equation 4:

$$\%V_{LO} = \frac{\sum_{i=1}^{n}(\%V_{Li} \times V_i)}{\sum_{i=1}^{n} V_i} \qquad \text{(Eq. 4)}$$

where:

$\%V_{LO}$ = overall performance of total valves in the applicable process or group of processes

$\%V_{Li}$ = percent leaking valves in subgroup I, most recent value calculated according to the procedures in paragraphs (e)(6) (ii) and (iii) of this section

V_i = number of valves in subgroup I

n = number of subgroups

(iv) *Records.* In addition to records required by paragraph (g) of this section, the owner or operator shall maintain records specified in paragraphs (e)(5)(iv)(A) through (D) of this section.

(A) Which valves are assigned to each subgroup,

(B) Monitoring results and calculations made for each subgroup for each monitoring period,

(C) Which valves are reassigned and when they were reassigned, and

(D) The results of the semiannual overall performance calculation required in paragraph (e)(5)(iii) of this section.

(v) The owner or operator shall notify the Administrator no later than 30 days prior to the beginning of the next monitoring period of the decision to subgroup valves. The notification shall identify the participating processes and the valves assigned to each subgroup.

(vi) *Semiannual reports.* In addition to the information required by paragraph (h)(3) of this section, the owner or operator shall submit in the periodic reports the information specified in paragraphs (e)(5)(vi)(A) and (B) of this section.

(A) Valve reassignments occurring during the reporting period, and

(B) Results of the semiannual overall performance calculation required by paragraph (e)(5)(iii) of this section.

(vii) To determine the monitoring frequency for each subgroup, the calculation procedures of paragraph (e)(6)(iii) of this section shall be used.

(viii) Except for the overall performance calculations required by paragraphs (e)(5)(i) and (e)(5)(iii) of this section, each subgroup shall be treated as if it were a process for the purposes of applying the provisions of this section.

(6)(i) The owner or operator shall decide no later than the implementation date of this subpart or upon revision of an operating permit how to group the processes. Once the owner or operator has decided, all subsequent percentage calculations shall be made on the same basis.

(ii) Percent leaking valves for each group of processes or subgroup shall be determined by the following Equation 5:

$$\%V_L = [V_L/V_T] \times 100 \qquad \text{(Eq. 5)}$$

Where:

$\%V_L$ = percent leaking valves

V_L = number of valves found leaking excluding nonrepairables as provided in paragraph (e)(6)(iv)(A) of this section

V_T = total valves monitored, in a monitoring period excluding valves monitored as required by (e)(7)(iii) of this section

(iii) When determining monitoring frequency for each group of processes or subgroup subject to monthly, quarterly, or semiannual monitoring frequencies, the percent leaking valves shall be the arithmetic average of the percent leaking valves from the last two monitoring periods. When determining monitoring frequency for each group of processes or subgroup subject to annual or biennial (once every 2 years) monitoring frequencies, the percent leaking valves shall be the arithmetic average of the percent leaking valves from the last three monitoring periods.

(iv)(A) Nonrepairable valves shall be included in the calculation of percent leaking valves the first time the valve is identified as leaking and nonrepairable and as required to comply with paragraph (e)(6)(iv)(B) of this section. Otherwise, a number of nonrepairable valves (identified and included in the percent leaking calculation in a previous period) up to a maximum of 1 percent of the total number of valves in organic HAP service at a process may be excluded from calculation of percent leaking valves for subsequent monitoring periods.

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

(7) *Repair provisions.* (i) When a leak is detected, it shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in paragraph (b)(1)(v) of this section.

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

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

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

(i) Tightening of bonnet bolts,

(ii) Replacement of bonnet bolts,

(iii) Tightening of packing gland nuts, and

(iv) Injection of lubricant into lubricated packing.

(9) Any equipment located at a plant site with fewer than 250 valves in organic HAP service in the affected source is exempt from the requirements for monthly monitoring specified in paragraph (e)(4)(i) of this section. Instead, the owner or operator shall monitor each valve in organic HAP service for leaks once each quarter, or comply with paragraphs (e)(4)(iii) or (e)(4)(iv) of this section.

(f) *Unsafe to Monitor, Difficult to Monitor, and Inaccessible Equipment.* (1) Equipment that is designated as unsafe to monitor, difficult to monitor, or inaccessible is exempt from the monitoring requirements specified in paragraphs (f)(1)(i) through (iv) of this section provided the owner or operator meets the requirements specified in paragraph (f)(2), (f)(3), or (f)(4) of this section, as applicable. Ceramic or ceramic-lined connectors are subject to the same requirements as inaccessible connectors.

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

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

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

(iv) For connectors, § 63.174(b) through (e) do not apply.

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

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

(3) *Equipment that is difficult to monitor.* (i) Equipment may be designated as difficult to monitor if the owner or operator determines that the equipment cannot be monitored without elevating the monitoring personnel more than 2 meters above a support surface or it is not accessible at anytime in a safe manner;

(ii) At an existing source, any equipment within a group of processes that meets the criteria of paragraph (f)(3)(i) of this section may be designated as difficult to monitor. At a new affected source, an owner or operator may designate no more than 3 percent of each type of equipment as difficult to monitor.

(iii) The owner or operator of equipment designated as difficult to monitor must follow a written plan that requires monitoring of the equipment at least once per calendar year.

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

(A) Buried;

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

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

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

(E) Not able to be accessed at any time in a safe manner to perform monitoring. Unsafe access includes, but is not limited to, the use of a wheeled scissor-lift on unstable or uneven terrain, the use of a motorized man-lift basket in areas where an ignition potential exists, or access would require near proximity to hazards such as electrical lines, or would risk damage to equipment.

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

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

(g) *Recordkeeping Requirements.* (1) An owner or operator of more than one group of processes subject to the provisions of this section may comply with the recordkeeping requirements for the groups of processes in one recordkeeping system if the system identifies with each record the program being implemented (e.g., quarterly monitoring) for each type of equipment. All records and information required by this section shall be maintained in a manner that can be readily accessed at the plant site. This could include physically locating the records at the plant site or accessing the records from a central location by computer at the plant site.

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

(i)(A) A list of identification numbers for equipment (except connectors that are not subject to paragraph (f) of this section and instrumentation systems) subject to the requirements of this section. Connectors, except those subject to paragraph (f) of this section, need not be individually identified if all connectors in a designated area or length of pipe subject to the provisions of this section are identified as a group, and the number of subject connectors is indicated. The list for each type of equipment shall be completed no later than the completion of the initial survey required for that component. The list of identification numbers shall be updated, if needed, to incorporate equipment changes within 15 calendar days of the completion of each monitoring survey for the type of equipment component monitored.

(B) A schedule for monitoring connectors subject to the provisions of § 63.174(a) and valves subject to the provisions of paragraph (e)(4) of this section.

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

(ii)(A) A list of identification numbers for equipment that the owner or operator elects to equip with a closed-vent system and control device, under the provisions of paragraph (c)(7) of this section, § 63.164(h), or § 63.165(c).

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

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

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

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

(v) The owner or operator may develop a written procedure that identifies the conditions that justify a delay of repair. The written procedures may be included as part of the startup/shutdown/malfunction plan, required by § 63.1260(i), for the source or may be part of a separate document that is maintained at the plant site. Reasons for delay of repair may be documented by citing the relevant sections of the written procedure.

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

(A) Design criteria required by paragraph (c)(5)(vi)(A) of this section and § 63.164(e)(2), and an explanation of the design criteria; and

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

(vii) A list of equipment designated as unsafe to monitor, difficult to monitor, or inaccessible under paragraphs (f) or (b)(1)(v)(B) of this section and a copy of the plan for monitoring or inspecting this equipment.

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

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

(3) *Records of visual inspections.* For visual inspections of equipment subject to the provisions of paragraphs (c)(2)(iii) and (c)(5)(iv)(A) of this section, the

owner or operator shall document that the inspection was conducted and the date of the inspection. The owner or operator shall maintain records as specified in paragraph (g)(4) of this section for leaking equipment identified in this inspection, except as provided in paragraph (g)(5) of this section. These records shall be retained for 2 years.

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

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

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

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

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

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

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

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

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

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

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

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

(ix) Copies of the periodic reports as specified in paragraph (h)(3) of this section, if records are not maintained on a computerized data base capable of generating summary reports from the records.

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

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

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

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

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

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

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

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

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

(C) The reason for the delay of repair.

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

(E) The date of successful repair.

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

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

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

(7) *Records for closed-vent systems.* The owner or operator shall maintain records of the information specified in paragraphs (g)(7)(i) through (g)(7)(iii) of this section for closed-vent systems and control devices subject to the provisions of paragraph (b)(1)(vi) of this section. The records specified in paragraph (g)(7)(i) of this section shall be retained for the life of the equipment. The records specified in paragraphs (g)(7)(ii) and (g)(7)(iii) of this section shall be retained for 2 years.

(i) The design specifications and performance demonstrations specified in paragraphs (g)(7)(i)(A) through (g)(7)(i)(D) of this section.

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

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

(C) The flare design (i.e., steam assisted, air assisted, or nonassisted) and the results of the compliance demonstration required by § 63.11(b).

(D) A description of the parameter or parameters monitored, as required in paragraph (b)(1)(vi) of this section, to ensure that control devices are operated and maintained in conformance with their design and an explanation of why that parameter (or parameters) was selected for the monitoring.

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

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

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

(C) Dates and durations of startups and shutdowns of control devices required in paragraph (c)(7) of this section and §§ 63.164 through 63.166.

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

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

(B) For each inspection conducted in accordance with the provisions of § 63.172(f)(1) or (f)(2) during which leaks were detected, the information specified in paragraph (g)(4) of this section shall be recorded.

(8) *Records for components in heavy liquid service.* Information, data, and analysis used to determine that a piece of equipment or process is in heavy liquid service shall be recorded. Such a determination shall include an analysis or demonstration that the process fluids do not meet the criteria of ''in light liquid or gas service.'' Examples of information that could document this include, but are not limited to, records of chemicals purchased for the process, analyses of process stream composition, engineering calculations, or process knowledge.

(9) *Records of exempt components.* Identification, either by list, location (area or group) of equipment in organic HAP service less than 300 hours per year subject to the provisions of this section.

(10) *Records of alternative means of compliance determination.* Owners and operators choosing to comply with the requirements of § 63.179 shall maintain the following records:

(i) Identification of the process(es) and the organic HAP they handle.

(ii) A schematic of the process, enclosure, and closed-vent system.

(iii) A description of the system used to create a negative pressure in the enclosure to ensure that all emissions are routed to the control device.

(h) *Reporting Requirements.*

(1) Each owner or operator of a source subject to this section shall submit the reports listed in paragraphs (h)(1)(i) through (ii) of this section.

(i) A Notification of Compliance Status Report described in paragraph (h)(2) of this section,

(ii) Periodic Reports described in paragraph (h)(3) of this section, and

(2) *Notification of compliance report.* Each owner or operator of a source subject to this section shall submit the information specified in paragraphs (h)(2)(i) through (iii) of this section in the Notification of Compliance Status Report described in § 63.1260(f).

(i) The notification shall provide the information listed in paragraphs (h)(2)(i)(A) through (C) of this section for each process subject to the requirements of paragraphs (b) through (g) of this section.

(A) Process group identification.

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

(C) Method of compliance with the standard (for example, ''monthly leak detection and repair'' or ''equipped with dual mechanical seals'').

(ii) The notification shall provide the information listed in paragraphs (h)(2)(ii)(A) and (B) of this section for each process subject to the requirements of paragraph (b)(1)(ix) of this section and § 63.178(b).

(A) Products or product codes subject to the provisions of this section, and

(B) Planned schedule for pressure testing when equipment is configured for production of products subject to the provisions of this section.

(iii) The notification shall provide the information listed in paragraphs (h)(2)(iii)(A) and (B) of this section for each process subject to the requirements in § 63.179.

(A) Process identification.

(B) A description of the system used to create a negative pressure in the enclosure and the control device used to comply with the requirements of paragraph (b)(1)(vi) of this section.

(iv) Any change in the information submitted under paragraph (h) of this section shall be provided to the Administrator as a part of subsequent Periodic Reports. Section 63.9(j) shall not apply to the Notification of Compliance Status Report described in this paragraph (h)(2) of this section.

(3) *Periodic reports.* The owner or operator of a source subject to this section shall submit Periodic Reports.

(i) A report containing the information in paragraphs (h)(3)(ii), (h)(3)(iii), and (h)(3)(iv) of this section shall be submitted semiannually starting 6 months after the Notification of Compliance Status Report, as required in paragraph (h)(2) of this section. The first periodic report shall cover the first 6 months after the compliance date specified in § 63.1250(e). Each subsequent periodic report shall cover the 6 month period following the preceding period.

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

(A) The number of valves for which leaks were detected as described in paragraph (e)(3) of this section, the percent leakers, and the total number of valves monitored;

(B) The number of valves for which leaks were not repaired as required in paragraph (e)(7) of this section, identifying the number of those that are determined nonrepairable;

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

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

(E) The number of compressors for which leaks were detected as described in § 63.164(f);

(F) The number of compressors for which leaks were not repaired as required in § 63.164(g);

(G) The number of connectors for which leaks were detected as described in § 63.174(a), the percent of connectors leaking, and the total number of connectors monitored;

(H) The number of connectors for which leaks were not repaired as required in § 63.174(d), identifying the number of those that are determined nonrepairable;

(I) The facts that explain any delay of repairs and, where appropriate, why a process shutdown was technically infeasible.

(J) The results of all monitoring to show compliance with §§ 63.164(i), 63.165(a), and 63.172(f) conducted within the semiannual reporting period.

(K) If applicable, the initiation of a monthly monitoring program under either paragraph (c)(4)(ii) or paragraph (e)(4)(i) of this section.

(L) If applicable, notification of a change in connector monitoring alternatives as described in § 63.174(c)(1).

(iii) For owners or operators electing to meet the requirements of § 63.178(b), the report shall include the information listed in paragraphs (h)(3)(iii)(A) through (E) of this paragraph for each process.

(A) Product process equipment train identification;

(B) The number of pressure tests conducted;

(C) The number of pressure tests where the equipment train failed either the retest or two consecutive pressure tests;

(D) The facts that explain any delay of repairs; and

(E) The results of all monitoring to determine compliance with § 63.172(f) of subpart H.

(iv) Any revisions to items reported in earlier Notification of Compliance

Status Report, if the method of compliance has changed since the last report or any other changes to the information reported has occurred.

§ 63.1256 Standards: Wastewater.

(a) *General.* Each owner or operator of any affected source (existing or new) shall comply with the general wastewater requirements in paragraphs (a)(1) and (2) of this section.

(1) *Identify wastewater that requires control.* For each POD, the owner or operator shall comply with the requirements in either paragraph (a)(1)(i), or (ii) of this section to determine whether a wastewater stream is an affected wastewater stream that requires control for soluble and/or partially soluble HAP compounds or to designate the wastewater stream as an affected wastewater stream, respectively. The owner or operator may use a combination of the approaches in paragraphs (a)(1)(i) and (ii) of this section for different affected wastewater generated at the source. The owner or operator shall also comply with the requirements for multiphase discharges in paragraph (a)(4) of this section. Wastewater identified in paragraph (a)(3) of this section is exempt from the provisions of this subpart.

(i) *Determine characteristics of a wastewater stream.* At new and existing sources, a wastewater stream is an affected wastewater stream if the annual average concentration and annual load exceed any of the criteria specified in paragraph (a)(1)(i)(A) through (C) of this section. At new sources, a wastewater stream is subject to additional control requirements if the annual average concentration and annual load exceed the criteria specified in paragraphs (a)(1)(i)(D) of this section. The owner or operator shall comply with the provisions of § 63.1257(e)(1) to determine the annual average concentrations and annual load of partially soluble and soluble HAP compounds.

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

(B) The wastewater stream contains partially soluble and/or soluble HAP compounds at an annual average concentration of 5,200 ppmw, and the total soluble and partially soluble HAP load in all wastewater from the PMPU exceeds 1 Mg/yr.

(C) The wastewater stream contains partially soluble and/or soluble HAP at an annual average concentration of greater than 10,000 ppmw, and the total partially soluble and/or soluble HAP load in all wastewater from the affected source is greater than 1 Mg/yr.

(D) The wastewater stream contains soluble HAP compounds at an annual average concentration greater than 110,000 ppmw, and the total soluble and partially soluble HAP load in all wastewater from the PMPU exceeds 1 Mg/yr.

(ii) *Designate wastewater as affected wastewater.* For existing sources, the owner or operator may elect to designate wastewater streams as meeting the criteria of either paragraphs (a)(1)(i)(A),(B), or (C) of this section. For new sources, the owner or operator may elect to designate wastewater streams meeting the criterion in paragraph (a)(1)(i)(D) or for wastewater known to contain no soluble HAP, as meeting the criterion in paragraph (a)(1)(i)(A) of this section. For designated wastewater the procedures specified in paragraphs (a)(1)(ii)(A) and (B) of this section shall be followed, except as specified in paragraphs (g)(8)(i), (g)(9)(i), and (g)(10) of this section. The owner or operator is not required to determine the annual average concentration or load for each designated wastewater stream for the purposes of this section.

(A) From the POD for the wastewater stream that is designated as an affected wastewater stream to the location where the owner or operator elects to designate such wastewater stream as an affected wastewater stream, the owner or operator shall comply with all applicable emission suppression requirements specified in paragraphs (b) through (f) of this section.

(B) From the location where the owner or operator designates a wastewater stream as an affected wastewater stream, such wastewater stream shall be managed in accordance with all applicable emission suppression requirements specified in paragraphs (b) through (f) of this section and with the treatment requirements in paragraph (g) of this section.

(iii) *Scrubber Effluent.* Effluent from a water scrubber that has been used to control Table 2 HAP-containing vent streams that are controlled in order to meet the process vent requirements in § 63.1254 of this subpart is considered an affected wastewater stream.

(2) *Requirements for affected wastewater.* (i) An owner or operator of a facility shall comply with the applicable requirements for wastewater tanks, surface impoundments, containers, individual drain systems, and oil/water separators as specified in paragraphs (b) through (f) of this section, except as provided in paragraph (g)(3) of this section.

(ii) Comply with the applicable requirements for control of soluble and partially soluble compounds as specified in paragraph (g) of this section. Alternatively, the owner or operator may elect to comply with the treatment provisions specified in paragraph (a)(5) of this section.

(iii) Comply with the applicable monitoring and inspection requirements specified in § 63.1258.

(iv) Comply with the applicable recordkeeping and reporting requirements specified in §§ 63.1259 and 63.1260.

(3) *Exempt wastewater.* The following wastewaters are not subject to the wastewater provisions of this part:

(i) Stormwater from segregated sewers;

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

(iii) Spills; and

(iv) Water from safety showers.

(4) *Requirements for multiphase discharges.* The owner or operator shall not discharge a separate phase that can be isolated through gravity separation from the aqueous phase to a waste management or treatment unit, unless the stream is discharged to a treatment unit in compliance with paragraph (g)(13) of this section.

(5) *Offsite treatment or onsite treatment not owned or operated by the source.* The owner or operator may elect to transfer affected wastewater streams that contain less than 50 ppmw of partially soluble HAP or a residual removed from such affected wastewater to an onsite treatment operation not owned or operated by the owner or operator of the source generating the wastewater or residual, or to an offsite treatment operation, provided that the waste management units up to the activated sludge unit are covered or the owner or operator demonstrates that less than 5 percent of the total soluble HAP is emitted from the these units.

(i) The owner or operator transferring the wastewater or residual shall:

(A) Comply with the provisions specified in paragraphs (b) through (f) of this section for each waste management unit that receives or manages affected wastewater or a residual removed from affected wastewater prior to shipment or transport.

(B) Include a notice with each shipment or transport of affected wastewater or residual removed from affected wastewater. The notice shall state that the affected wastewater or residual contains organic HAP that are to be treated in accordance with the

provisions of this subpart. When the transport is continuous or ongoing (for example, discharge to a publicly-owned treatment works), the notice shall be submitted to the treatment operator initially and whenever there is a change in the required treatment. The owner or operator shall keep a record of the notice in accordance with § 63.1259(g).

(ii) The owner or operator may not transfer the affected wastewater or residual unless the transferee has submitted to the EPA a written certification that the transferee will manage and treat any affected wastewater or residual removed from affected wastewater received from a source subject to the requirements of this subpart in accordance with the requirements of either:

(A) Paragraphs (b) through (i) of this section; or

(B) Subpart D of this part if alternative emission limitations have been granted the transferor in accordance with those provisions; or

(C) Section 63.6(g).

(iii) The certifying entity may revoke the written certification by sending a written statement to the EPA and the owner or operator giving at least 90 days notice that the certifying entity is rescinding acceptance of responsibility for compliance with the regulatory provisions listed in this paragraph. Upon expiration of the notice period, the owner or operator may not transfer the wastewater stream or residual to the treatment operation.

(iv) By providing this written certification to the EPA, the certifying entity accepts responsibility for compliance with the regulatory provisions listed in paragraph (a)(5)(ii) of this section with respect to any shipment of wastewater or residual covered by the written certification. Failure to abide by any of those provisions with respect to such shipments may result in enforcement action by the EPA against the certifying entity in accordance with the enforcement provisions applicable to violations of these provisions by owners or operators of sources.

(v) Written certifications and revocation statements, to the EPA from the transferees of wastewater or residuals shall be signed by the responsible official of the certifying entity, provide the name and address of the certifying entity, and be sent to the appropriate EPA Regional Office at the addresses listed in § 63.13. Such written certifications are not transferable by the treater.

(b) *Wastewater tanks.* For each wastewater tank that receives, manages, or treats affected wastewater or a residual removed from affected wastewater, the owner or operator shall comply with the requirements of either paragraph (b)(1) or (2) of this section as specified in Table 6 of this subpart.

(1) The owner or operator shall operate and maintain a fixed roof except when the contents of the wastewater tank are heated, treated by means of an exothermic reaction, or sparged, during which time the owner or operator shall comply with the requirements specified in paragraph (b)(2) of this section. For the purposes of this paragraph, the requirements of paragraph (b)(2) of this section are satisfied by operating and maintaining a fixed roof if the owner or operator demonstrates that the total soluble and partially soluble HAP emissions from the wastewater tank are no more than 5 percent higher than the emissions would be if the contents of the wastewater tank were not heated, treated by an exothermic reaction, or sparged.

(2) The owner or operator shall comply with the requirements in paragraphs (b)(3) through (9) of this section and shall operate and maintain one of the emission control techniques listed in paragraphs (b)(2)(i) through (iii) of this section.

(i) A fixed roof and a closed-vent system that routes the organic HAP vapors vented from the wastewater tank to a control device; or

(ii) A fixed roof and an internal floating roof that meets the requirements specified in § 63.119(b), with the differences noted in § 63.1257(c)(3)(i) through (iii) for the purposes of this subpart; or

(iii) An external floating roof that meets the requirements specified in §§ 63.119(c), 63.120(b)(5), and 63.120(b)(6), with the differences noted in § 63.1257(c)(3)(i) through (v) for the purposes of this subpart.

(3) If the owner or operator elects to comply with the requirements of paragraph (b)(2)(i) of this section, the fixed roof shall meet the requirements of paragraph (b)(3)(i) of this section, the control device shall meet the requirements of paragraph (b)(3)(ii) of this section, and the closed-vent system shall meet the requirements of paragraph (b)(3)(iii) of this section.

(i) The fixed roof shall meet the following requirements:

(A) Except as provided in paragraph (b)(3)(iv) of this section, the fixed roof and all openings (e.g., access hatches, sampling ports, and gauge wells) shall be maintained in accordance with the requirements specified in § 63.1258(h).

(B) Each opening shall be maintained in a closed position (e.g., covered by a lid) at all times that the wastewater tank contains affected wastewater or residual removed from affected wastewater except when it is necessary to use the opening for wastewater sampling, removal, or for equipment inspection, maintenance, or repair.

(ii) The control device shall be designed, operated, and inspected in accordance with the requirements of paragraph (h) of this section.

(iii) Except as provided in paragraph (b)(3)(iv) of this section, the closed-vent system shall be inspected in accordance with the requirements of § 63.1258(h).

(iv) For any fixed roof tank and closed-vent system that is operated and maintained under negative pressure, the owner or operator is not required to comply with the requirements specified in § 63.1258(h).

(4) If the owner or operator elects to comply with the requirements of paragraph (b)(2)(ii) of this section, the floating roof shall be inspected according to the procedures specified in § 63.120(a)(2) and (3), with the differences noted in § 63.1257(c)(3)(iv) for the purposes of this subpart.

(5) Except as provided in paragraph (b)(6) of this section, if the owner or operator elects to comply with the requirements of paragraph (b)(2)(iii) of this section, seal gaps shall be measured according to the procedures specified in § 63.120(b)(2)(i) through (b)(4) and the wastewater tank shall be inspected to determine compliance with § 63.120(b)(5) and (6) according to the schedule specified in § 63.120(b)(1)(i) through (iii).

(6) If the owner or operator determines that it is unsafe to perform the seal gap measurements specified in § 63.120(b)(2)(i) through (b)(4) or to inspect the wastewater tank to determine compliance with § 63.120(b)(5) and (6) because the floating roof appears to be structurally unsound and poses an imminent or potential danger to inspecting personnel, the owner or operator shall comply with the requirements in either paragraph (b)(6)(i) or (ii) of this section.

(ii) The owner or operator shall empty and remove the wastewater tank from service within 45 calendar days of determining that the roof is unsafe. If the wastewater tank cannot be emptied within 45 calendar days, the owner or operator may utilize up to two extensions of up to 30 additional calendar days each. Documentation of a decision to utilize an extension shall include an explanation of why it was unsafe to perform the inspection or seal gap measurement, shall document that alternate storage capacity is unavailable, and shall specify a schedule of actions that will ensure that the wastewater

tank will be emptied as soon as possible.

(7) Except as provided in paragraph (b)(6) of this section, each wastewater tank shall be inspected initially, and semiannually thereafter, for improper work practices in accordance with § 63.1258(g). For wastewater tanks, improper work practice includes, but is not limited to, leaving open any access door or other opening when such door or opening is not in use.

(8) Except as provided in paragraph (b)(6) of this section, each wastewater tank shall be inspected for control equipment failures as defined in paragraph (b)(8)(i) of this section according to the schedule in paragraphs (b)(8)(ii) and (iii) of this section in accordance with § 63.1258(g).

(i) Control equipment failures for wastewater tanks include, but are not limited to, the conditions specified in paragraphs (b)(8)(i)(A) through (I) of this section.

(A) The floating roof is not resting on either the surface of the liquid or on the leg supports.

(B) There is stored liquid on the floating roof.

(C) A rim seal is detached from the floating roof.

(D) There are holes, tears, cracks or gaps in the rim seal or seal fabric of the floating roof.

(E) There are visible gaps between the seal of an internal floating roof and the wall of the wastewater tank.

(F) There are gaps between the metallic shoe seal or the liquid mounted primary seal of an external floating roof and the wall of the wastewater tank that exceed 212 square centimeters per meter of tank diameter or the width of any portion of any gap between the primary seal and the tank wall exceeds 3.81 centimeters.

(G) There are gaps between the secondary seal of an external floating roof and the wall of the wastewater tank that exceed 21.2 square centimeters per meter of tank diameter or the width of any portion of any gap between the secondary seal and the tank wall exceeds 1.27 centimeters.

(H) Where a metallic shoe seal is used on an external floating roof, one end of the metallic shoe does not extend into the stored liquid or one end of the metallic shoe does not extend a minimum vertical distance of 61 centimeters above the surface of the stored liquid.

(I) A gasket, joint, lid, cover, or door has a crack or gap, or is broken.

(ii) The owner or operator shall inspect for the control equipment failures in paragraphs (b)(8)(i)(A) through (H) according to the schedule specified in paragraphs (b)(4) and (5) of this section.

(iii) The owner or operator shall inspect for the control equipment failures in paragraph (b)(8)(i)(I) of this section initially, and semiannually thereafter.

(9) Except as provided in paragraph (i) of this section, when an improper work practice or a control equipment failure is identified, first efforts at repair shall be made no later than 5 calendar days after identification and repair shall be completed within 45 calendar days after identification. If a failure that is detected during inspections required by this section cannot be repaired within 45 calendar days and if the tank cannot be emptied within 45 calendar days, the owner or operator may utilize up to two extensions of up to 30 additional calendar days each. Documentation of a decision to utilize an extension shall include a description of the failure, shall document that alternate storage capacity is unavailable, and shall specify a schedule of actions that will ensure that the control equipment will be repaired or the tank will be emptied as soon as practical.

(c) *Surface impoundments.* For each surface impoundment that receives, manages, or treats affected wastewater or a residual removed from affected wastewater, the owner or operator shall comply with the requirements of paragraphs (c)(1), (2), and (3) of this section.

(1) The owner or operator shall operate and maintain on each surface impoundment either a cover (e.g., air-supported structure or rigid cover) and a closed-vent system that routes the organic hazardous air pollutants vapors vented from the surface impoundment to a control device in accordance with paragraphs (c)(1)(i), (iii), (iv), and (v) of this section, or a floating flexible membrane cover as specified in paragraph (c)(1)(ii) of this section.

(i) The cover and all openings shall meet the following requirements:

(A) Except as provided in paragraph (c)(1)(iv) of this section, the cover and all openings (e.g., access hatches, sampling ports, and gauge wells) shall be maintained in accordance with the requirements specified in § 63.1258(h).

(B) Each opening shall be maintained in a closed position (e.g., covered by a lid) at all times that affected wastewater or residual removed from affected wastewater is in the surface impoundment except when it is necessary to use the opening for sampling, removal, or for equipment inspection, maintenance, or repair.

(C) The cover shall be used at all times that affected wastewater or residual removed from affected wastewater is in the surface impoundment except during removal of treatment residuals in accordance with 40 CFR 268.4 or closure of the surface impoundment in accordance with 40 CFR 264.228.

(ii) Floating flexible membrane covers shall meet the requirements specified in paragraphs (c)(1)(ii)(A) through (F) of this section.

(A) The floating flexible cover shall be designed to float on the liquid surface during normal operations, and to form a continuous barrier over the entire surface area of the liquid.

(B) The cover shall be fabricated from a synthetic membrane material that is either:

(*1*) High density polyethylene (HDPE) with a thickness no less than 2.5 millimeters (100 mils); or

(*2*) A material or a composite of different materials determined to have both organic permeability properties that are equivalent to those of the material listed in paragraph (c)(1)(ii)(B)(*1*) of this section, and chemical and physical properties that maintain the material integrity for the intended service life of the material.

(C) The cover shall be installed in a manner such that there are no visible cracks, holes, gaps, or other open spaces between cover section seams or between the interface of the cover edge and its foundation mountings.

(D) Except as provided for in paragraph (c)(1)(ii)(E) of this section, each opening in the floating membrane cover shall be equipped with a closure device designed to operate such that when the closure device is secured in the closed position there are no visible cracks, holes, gaps, or other open spaces in the closure device or between the perimeter of the cover opening and the closure device.

(E) The floating membrane cover may be equipped with one or more emergency cover drains for removal of stormwater. Each emergency cover drain shall be equipped with a slotted membrane fabric cover that covers at least 90 percent of the area of the opening or a flexible fabric sleeve seal.

(F) The closure devices shall be made of suitable materials that will minimize exposure of organic HAP to the atmosphere, to the extent practical, and will maintain the integrity of the equipment throughout its intended service life. Factors to be considered in designing the closure devices shall include: the effects of any contact with the liquid and its vapor managed in the surface impoundment; the effects of outdoor exposure to wind, moisture, and sunlight; and the operating

practices used for the surface impoundment on which the floating membrane cover is installed.

(G) Whenever affected wastewater or residual from affected wastewater is in the surface impoundment, the floating membrane cover shall float on the liquid and each closure device shall be secured in the closed position. Opening of closure devices or removal of the cover is allowed to provide access to the surface impoundment for performing routine inspection, maintenance, or other activities needed for normal operations and/or to remove accumulated sludge or other residues from the bottom of surface impoundment. Openings shall be maintained in accordance with § 63.1258(h).

(iii) The control device shall be designed, operated, and inspected in accordance with paragraph (h) of this section.

(iv) Except as provided in paragraph (c)(1)(v) of this section, the closed-vent system shall be inspected in accordance with § 63.1258(h).

(v) For any cover and closed-vent system that is operated and maintained under negative pressure, the owner or operator is not required to comply with the requirements specified in § 63.1258(h).

(2) Each surface impoundment shall be inspected initially, and semiannually thereafter, for improper work practices and control equipment failures in accordance with § 63.1258(g).

(i) For surface impoundments, improper work practice includes, but is not limited to, leaving open any access hatch or other opening when such hatch or opening is not in use.

(ii) For surface impoundments, control equipment failure includes, but is not limited to, any time a joint, lid, cover, or door has a crack or gap, or is broken.

(3) Except as provided in paragraph (i) of this section, when an improper work practice or a control equipment failure is identified, first efforts at repair shall be made no later than 5 calendar days after identification and repair shall be completed within 45 calendar days after identification.

(d) *Containers.* For each container that receives, manages, or treats affected wastewater or a residual removed from affected wastewater, the owner or operator shall comply with the requirements of paragraphs (d)(1) through (5) of this section.

(1) The owner or operator shall operate and maintain a cover on each container used to handle, transfer, or store affected wastewater or a residual removed from affected wastewater in accordance with the following requirements:

(i) Except as provided in paragraph (d)(3)(iv) of this section, if the capacity of the container is greater than 0.42 m^3, the cover and all openings (e.g., bungs, hatches, sampling ports, and pressure relief devices) shall be maintained in accordance with the requirements specified in § 63.1258(h).

(ii) If the capacity of the container is less than or equal to 0.42 m^3, the owner or operator shall comply with either paragraph (d)(1)(ii)(A) or (B) of this section.

(A) The container must meet existing Department of Transportation specifications and testing requirements under 49 CFR part 178; or

(B) Except as provided in paragraph (d)(3)(iv) of this section, the cover and all openings shall be maintained without leaks as specified in § 63.1258(h).

(iii) The cover and all openings shall be maintained in a closed position (e.g., covered by a lid) at all times that affected wastewater or a residual removed from affected wastewater is in the container except when it is necessary to use the opening for filling, removal, inspection, sampling, or pressure relief events related to safety considerations.

(2) For containers with a capacity greater than or equal to 0.42 m^3, either a submerged fill pipe shall be used when a container is being filled by pumping with affected wastewater or a residual removed from affected wastewater or the container shall be located within an enclosure with a closed-vent system that routes the organic HAP vapors vented from the container to a control device.

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

(ii) The cover shall remain in place and all openings shall be maintained in a closed position except for those openings required for the submerged fill pipe and for venting of the container to prevent physical damage or permanent deformation of the container or cover.

(3) During treatment of affected wastewater or a residual removed from affected wastewater, including aeration, thermal or other treatment, in a container, whenever it is necessary for the container to be open, the container shall be located within an enclosure with a closed-vent system that routes the organic HAP vapors vented from the container to a control device.

(i) Except as provided in paragraph (d)(3)(iv) of this section, the enclosure and all openings (e.g., doors, hatches) shall be maintained in accordance with the requirements specified in § 63.1258(h).

(ii) The control device shall be designed, operated, and inspected in accordance with paragraph (h) of this section.

(iii) Except as provided in paragraph (d)(3)(iv) of this section, the closed-vent system shall be inspected in accordance with § 63.1258(h).

(iv) For any enclosure and closed-vent system that is operated and maintained under negative pressure, the owner or operator is not required to comply with the requirements specified in § 63.1258(h).

(4) Each container shall be inspected initially, and semiannually thereafter, for improper work practices and control equipment failures in accordance with § 63.1258(g).

(i) For containers, improper work practice includes, but is not limited to, leaving open any access hatch or other opening when such hatch or opening is not in use.

(ii) For containers, control equipment failure includes, but is not limited to, any time a cover or door has a gap or crack, or is broken.

(5) Except as provided in paragraph (i) of this section, when an improper work practice or a control equipment failure is identified, first efforts at repair shall be made no later than 5 calendar days after identification and repair shall be completed within 15 calendar days after identification.

(e) *Individual drain systems.* For each individual drain system that receives or manages affected wastewater or a residual removed from affected wastewater, the owner or operator shall comply with the requirements of paragraphs (e) (1), (2), and (3) or with paragraphs (e) (4), (5), and (6) of this section.

(1) If the owner or operator elects to comply with this paragraph, the owner or operator shall operate and maintain on each opening in the individual drain system a cover and if vented, route the vapors to a process or through a closed-vent system to a control device. The owner or operator shall comply with the requirements of paragraphs (e)(1) (i) through (v) of this section.

(i) The cover and all openings shall meet the following requirements:

(A) Except as provided in paragraph (e)(1)(iv) of this section, the cover and all openings (e.g., access hatches, sampling ports) shall be maintained in accordance with the requirements specified in § 63.1258(h).

(B) The cover and all openings shall be maintained in a closed position at all

times that affected wastewater or a residual removed from affected wastewater is in the drain system except when it is necessary to use the opening for sampling or removal, or for equipment inspection, maintenance, or repair.

(ii) The control device shall be designed, operated, and inspected in accordance with paragraph (h) of this section.

(iii) Except as provided in paragraph (e)(1)(iv) of this section, the closed-vent system shall be inspected in accordance with § 63.1258(h).

(iv) For any cover and closed-vent system that is operated and maintained under negative pressure, the owner or operator is not required to comply with the requirements specified in § 63.1258(h).

(v) The individual drain system shall be designed and operated to segregate the vapors within the system from other drain systems and the atmosphere.

(2) Each individual drain system shall be inspected initially, and semiannually thereafter, for improper work practices and control equipment failures, in accordance with § 63.1258(g).

(i) For individual drain systems, improper work practice includes, but is not limited to, leaving open any access hatch or other opening when such hatch or opening is not in use for sampling or removal, or for equipment inspection, maintenance, or repair.

(ii) For individual drain systems, control equipment failure includes, but is not limited to, any time a joint, lid, cover, or door has a gap or crack, or is broken.

(3) Except as provided in paragraph (i) of this section, when an improper work practice or a control equipment failure is identified, first efforts at repair shall be made no later than 5 calendar days after identification and repair shall be completed within 15 calendar days after identification.

(4) If the owner or operator elects to comply with this paragraph, the owner or operator shall comply with the requirements in paragraphs (e)(4) (i) through (iii) of this section:

(i) Each drain shall be equipped with water seal controls or a tightly fitting cap or plug. The owner or operator shall comply with paragraphs (e)(4)(i)(A) and (B) of this section.

(A) For each drain equipped with a water seal, the owner or operator shall ensure that the water seal is maintained. For example, a flow-monitoring device indicating positive flow from a main to a branch water line supplying a trap or water being continuously dripped into the trap by a hose could be used to verify flow of water to the trap. Visual observation is also an acceptable alternative.

(B) If a water seal is used on a drain receiving affected wastewater, the owner or operator shall either extend the pipe discharging the wastewater below the liquid surface in the water seal of the receiving drain, or install a flexible shield (or other enclosure which restricts wind motion across the open area between the pipe and the drain) that encloses the space between the pipe discharging the wastewater to the drain receiving the wastewater. (Water seals which are used on hubs receiving wastewater that is not subject to the provisions of this subpart for the purpose of eliminating cross ventilation to drains carrying affected wastewater are not required to have a flexible cap or extended subsurface discharging pipe.)

(ii) Each junction box shall be equipped with a tightly fitting solid cover (i.e., no visible gaps, cracks, or holes) which shall be kept in place at all times except during inspection and maintenance. If the junction box is vented, the owner or operator shall comply with the requirements in paragraph (e)(4)(ii) (A) or (B) of this section.

(A) The junction box shall be vented to a process or through a closed-vent system to a control device. The closed-vent system shall be inspected in accordance with the requirements of § 63.1258(h) and the control device shall be designed, operated, and inspected in accordance with the requirements of paragraph (h) of this section.

(B) If the junction box is filled and emptied by gravity flow (i.e., there is no pump) or is operated with no more than slight fluctuations in the liquid level, the owner or operator may vent the junction box to the atmosphere provided that the junction box complies with the requirements in paragraphs (e)(4)(ii)(B) (*1*) and (*2*) of this section.

(*1*) The vent pipe shall be at least 90 centimeters in length and no greater than 10.2 centimeters in nominal inside diameter.

(*2*) Water seals shall be installed and maintained at the wastewater entrance(s) to or exit from the junction box restricting ventilation in the individual drain system and between components in the individual drain system. The owner or operator shall demonstrate (e.g., by visual inspection or smoke test) upon request by the Administrator that the junction box water seal is properly designed and restricts ventilation.

(iii) Each sewer line shall not be open to the atmosphere and shall be covered or enclosed in a manner so as to have no visible gaps or cracks in joints, seals, or other emission interfaces. (Note: This provision applies to sewers located inside and outside of buildings.)

(5) Equipment used to comply with paragraphs (e)(4) (i), (ii), or (iii) of this section shall be inspected as follows:

(i) Each drain using a tightly fitting cap or plug shall be visually inspected initially, and semiannually thereafter, to ensure caps or plugs are in place and that there are no gaps, cracks, or other holes in the cap or plug.

(ii) Each junction box shall be visually inspected initially, and semiannually thereafter, to ensure that there are no gaps, cracks, or other holes in the cover.

(iii) The unburied portion of each sewer line shall be visually inspected initially, and semiannually thereafter, for indication of cracks or gaps that could result in air emissions.

(6) Except as provided in paragraph (i) of this section, when a gap, hole, or crack is identified in a joint or cover, first efforts at repair shall be made no later than 5 calendar days after identification, and repair shall be completed within 15 calendar days after identification.

(f) *Oil-water separators.* For each oil-water separator that receives, manages, or treats affected wastewater or a residual removed from affected wastewater, the owner or operator shall comply with the requirements of paragraphs (f)(1) through (6) of this section.

(1) The owner or operator shall maintain one of the following:

(i) A fixed roof and a closed-vent system that routes the organic HAP vapors vented from the oil-water separator to a control device. The fixed roof, closed-vent system, and control device shall meet the requirements specified in paragraph (f)(2) of this section;

(ii) A floating roof that meets the requirements in 40 CFR 60.693–2(a)(1)(i), (a)(1)(ii), (a)(2), (a)(3), and (a)(4). For portions of the oil-water separator where it is infeasible to construct and operate a floating roof, such as over the weir mechanism, the owner or operator shall operate and maintain a fixed roof, closed-vent system, and control device that meet the requirements specified in paragraph (f)(2) of this section.

(2) A fixed roof shall meet the requirements of paragraph (f)(2)(i) of this section, a control device shall meet the requirements of paragraph (f)(2)(ii) of this section, and a closed-vent system shall meet the requirements of (f)(2)(iii) of this section.

(i) The fixed roof shall meet the following requirements:

(A) Except as provided in (f)(2)(iv) of this section, the fixed roof and all openings (e.g., access hatches, sampling ports, and gauge wells) shall be maintained in accordance with the requirements specified in § 63.1258(h).

(B) Each opening shall be maintained in a closed, sealed position (e.g., covered by a lid that is gasketed and latched) at all times that the oil-water separator contains affected wastewater or a residual removed from affected wastewater except when it is necessary to use the opening for sampling or removal, or for equipment inspection, maintenance, or repair.

(ii) The control device shall be designed, operated, and inspected in accordance with the requirements of paragraph (h) of this section.

(iii) Except as provided in paragraph (f)(2)(iv) of this section, the closed-vent system shall be inspected in accordance with the requirements of § 63.1258(h).

(iv) For any fixed-roof and closed-vent system that is operated and maintained under negative pressure, the owner or operator is not required to comply with the requirements of § 63.1258(h).

(3) If the owner or operator elects to comply with the requirements of paragraph (f)(1)(ii) of this section, seal gaps shall be measured according to the procedures specified in 40 CFR part 60, subpart QQQ § 60.696(d)(1) and the schedule specified in paragraphs (f)(3)(i) and (ii) of this section.

(i) Measurement of primary seal gaps shall be performed within 60 calendar days after installation of the floating roof and introduction of affected wastewater or a residual removed from affected wastewater and once every 5 years thereafter.

(ii) Measurement of secondary seal gaps shall be performed within 60 calendar days after installation of the floating roof and introduction of affected wastewater or a residual removed from affected wastewater and once every year thereafter.

(4) Each oil-water separator shall be inspected initially, and semiannually thereafter, for improper work practices in accordance with § 63.1258(g). For oil-water separators, improper work practice includes, but is not limited to, leaving open or ungasketed any access door or other opening when such door or opening is not in use.

(5) Each oil-water separator shall be inspected for control equipment failures as defined in paragraph (f)(5)(i) of this section according to the schedule specified in paragraphs (f)(5)(ii) and (iii) of this section.

(i) For oil-water separators, control equipment failure includes, but is not limited to, the conditions specified in paragraphs (f)(5)(i)(A) through (G) of this section.

(A) The floating roof is not resting on either the surface of the liquid or on the leg supports.

(B) There is stored liquid on the floating roof.

(C) A rim seal is detached from the floating roof.

(D) There are holes, tears, or other open spaces in the rim seal or seal fabric of the floating roof.

(E) There are gaps between the primary seal and the separator wall that exceed 67 square centimeters per meter of separator wall perimeter or the width of any portion of any gap between the primary seal and the separator wall exceeds 3.8 centimeters.

(F) There are gaps between the secondary seal and the separator wall that exceed 6.7 square centimeters per meter of separator wall perimeter or the width of any portion of any gap between the secondary seal and the separator wall exceeds 1.3 centimeters.

(G) A gasket, joint, lid, cover, or door has a gap or crack, or is broken.

(ii) The owner or operator shall inspect for the control equipment failures in paragraphs (f)(5)(i)(A) through (F) according to the schedule specified in paragraph (f)(3) of this section.

(iii) The owner or operator shall inspect for control equipment failures in paragraph (f)(5)(i)(G) of this section initially, and semiannually thereafter.

(6) Except as provided in paragraph (i) of this section, when an improper work practice or a control equipment failure is identified, first efforts at repair shall be made no later than 5 calendar days after identification and repair shall be completed within 45 calendar days after identification.

(g) *Performance standards for treatment processes managing wastewater and/or residuals removed from wastewater.* This section specifies the performance standards for treating affected wastewater. The owner or operator shall comply with the requirements as specified in paragraphs (g)(1) through (6) of this section. Where multiple compliance options are provided, the options may be used in combination for different wastewater and/or for different compounds (e.g., soluble versus partially soluble compounds) in the same wastewater, except where otherwise provided in this section. Once affected wastewater or a residual removed from affected wastewater has been treated in accordance with this subpart, it is no longer subject to the requirements of this subpart.

(1) *Existing source.* For a wastewater stream at an existing source that exceeds or is designated to exceed the concentration and load criteria in paragraph (a)(1)(i)(A) of this section, the owner or operator shall comply with a control option in paragraph (g)(8) of this section. For a wastewater stream at an existing source that exceeds the concentration and load criteria in either paragraph (a)(1)(i)(B) or (C) of this section, the owner or operator shall comply with a control option in paragraph (g)(8) of this section and a control option in paragraph (g)(9) of this section. As an alternative to the control options in paragraphs (g)(8) and (g)(9) of this section, the owner or operator may comply with a control option in either paragraph (g)(10), (11) or (13) of this section, as applicable.

(2) *New source.* For a wastewater stream at a new source that exceeds or is designated to exceed the concentration and load criteria in paragraph (a)(1)(i)(A) of this section, the owner or operator shall comply with a control option in paragraph (g)(8) of this section. For wastewater at a new source that exceeds the concentration and load criteria in either paragraph (a)(1)(i)(B) or (C) of this section, but does not exceed the criteria in paragraph (a)(1)(i)(D) of this section, the owner or operator shall comply with a control option in paragraph (g)(8) of this section and a control option in paragraph (g)(9) of this section. As an alternative to the control options in paragraphs (g)(8) and/or (9) of this section, the owner or operator may comply with a control option in either paragraph (g)(10), (11), or (13) of this section, as applicable. For a wastewater stream at a new source that exceeds or is designated to exceed the concentration and load criteria in paragraph (a)(1)(i)(D) of this section, the owner or operator shall comply with a control option in paragraph (g)(12) or (13) of this section.

(3) *Biological treatment processes.* Biological treatment processes in compliance with this section may be either open or closed biological treatment processes as defined in § 63.1251. An open biological treatment process in compliance with this section need not be covered and vented to a control device. An open or a closed biological treatment process in compliance with this section and using § 63.1257(e)(2)(iii)(E) or (F) to demonstrate compliance is not subject to the requirements of paragraphs (b) and (c) of this section. A closed biological treatment process in compliance with this section and using § 63.1257(e)(2)(iii)(G) to demonstrate compliance shall comply with the

requirements of paragraphs (b) and (c) of this section. Waste management units upstream of an open or closed biological treatment process shall meet the requirements of paragraphs (b) through (f) of this section, as applicable.

(4) *Performance tests and design evaluations.* If the Resource Conservation and Recovery Act (RCRA) option [paragraph (g)(13) of this section] or the enhanced biological treatment process for soluble HAP compounds option [paragraph (g)(10) of this section] is selected to comply with this section, neither a design evaluation nor a performance test is required. For any other nonbiological treatment process, and for closed biological treatment processes as defined in § 63.1251, the owner or operator shall conduct either a design evaluation as specified in § 63.1257(e)(2)(ii) or performance test as specified in § 63.1257(e)(2)(iii). For each open biological treatment process as defined in § 63.1251, the owner or operator shall conduct a performance test as specified in § 63.1257(e)(2)(iii)(E) or (F).

(5) *Control device requirements.* When gases are vented from the treatment process, the owner or operator shall comply with the applicable control device requirements specified in paragraph (h) of this section and § 63.1257(e)(3), and the applicable leak inspection provisions specified in § 63.1258(h). This requirement is in addition to the requirements for treatment systems specified in paragraphs (g)(8) through (14) of this section. This requirement does not apply to any open biological treatment process that meets the mass removal requirements.

(6) *Residuals: general.* When residuals result from treating affected wastewater, the owner or operator shall comply with the requirements for residuals specified in paragraph (g)(14) of this section.

(*7) Treatment using a series of treatment processes.* In all cases where the wastewater provisions in this subpart allow or require the use of a treatment process or control device to comply with emissions limitations, the owner or operator may use multiple treatment processes or control devices, respectively. For combinations of treatment processes where the wastewater stream is conveyed by hard-piping, the owner or operator shall comply with either the requirements of paragraph (g)(7)(i) or (ii) of this section. For combinations of treatment processes where the wastewater stream is not conveyed by hard-piping, the owner or operator shall comply with the requirements of paragraph (g)(7)(ii) of this section. For combinations of control devices, the owner or operator shall comply with the requirements of paragraph (g)(7)(i) of this section.

(i) *Compliance across the combination of all treatment units or control devices in series.* (A) For combinations of treatment processes, the wastewater stream shall be conveyed by hard-piping between the treatment processes. For combinations of control devices, the vented gas stream shall be conveyed by hard-piping between the control devices.

(B) For combinations of treatment processes, each treatment process shall meet the applicable requirements of paragraphs (b) through (f) of this section, except as provided in paragraph (g)(3) of this section.

(C) The owner or operator shall identify, and keep a record of, the combination of treatment processes or of control devices, including identification of the first and last treatment process or control device. The owner or operator shall include this information as part of the treatment process description reported in the Notification of Compliance Status.

(D) The performance test or design evaluation shall determine compliance across the combination of treatment processes or control devices. If a performance test is conducted, the ''inlet'' shall be the point at which the wastewater stream or residual enters the first treatment process, or the vented gas stream enters the first control device. The ''outlet'' shall be the point at which the treated wastewater stream exits the last treatment process, or the vented gas stream exits the last control device.

(ii) *Compliance across individual units.* (A) For combinations of treatment processes, each treatment process shall meet the applicable requirements of paragraphs (b) through (f) of this section except as provided in paragraph (g)(3) of this section.

(B) The owner or operator shall identify, and keep a record of, the combination of treatment processes, including identification of the first and last treatment process. The owner or operator shall include this information as part of the treatment process description reported in the Notification of Compliance Status report.

(C) The owner or operator shall determine the mass removed or destroyed by each treatment process. The performance test or design evaluation shall determine compliance for the combination of treatment processes by adding together the mass removed or destroyed by each treatment process and determine the overall control efficiency of the treatment system.

(8) *Control options: Wastewater containing partially soluble HAP compounds.* The owner or operator shall comply with either paragraph (g)(8)(i) or (ii) of this section for the control of partially soluble HAP compounds at new or existing sources.

(i) *50 ppmw concentration option.* The owner or operator shall comply with paragraphs (g)(8)(i)(A) and (B) of this section.

(A) Reduce, by removal or destruction, the concentration of total partially soluble HAP compounds to a level less than 50 ppmw as determined by the procedures specified in § 63.1257(e)(2)(iii)(B).

(B) This option shall not be used when the treatment process is a biological treatment process. This option shall not be used when the wastewater is designated as an affected wastewater as specified in paragraph (a)(1)(ii) of this section. Dilution shall not be used to achieve compliance with this option.

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

(9) *Control options: Wastewater containing soluble HAP compounds.* The owner or operator shall comply with either paragraph (g)(9)(i) or (ii) of this section for the control of soluble HAP compounds at new or existing sources.

(i) *520 ppmw concentration option.* The owner or operator shall comply with paragraphs (g)(9)(i)(A) and (B) of this section.

(A) Reduce, by removal or destruction, the concentration of total soluble HAP compounds to a level less than 520 ppmw as determined in the procedures specified in § 63.1257(e)(2)(iii)(B).

(B) This option shall not be used when the treatment process is a biological treatment process. This option shall not be used when the wastewater is designated as an affected wastewater as specified in paragraph (a)(1)(ii) of this section. Dilution shall not be used to achieve compliance with this option.

(ii) *Percent mass removal/destruction option.* The owner or operator shall reduce, by removal or destruction, the mass of total soluble HAP by 90 percent

or more. The removal/destruction efficiency shall be determined by the procedures in § 63.1257(e)(2)(iii)(C), for noncombustion, nonbiological treatment processes; § 63.1257(e)(2)(iii)(D), for combustion processes; and § 63.1257(e)(2)(iii)(F) or (G) for biological treatment processes.

(10) *Control option: Enhanced biotreatment for wastewater containing soluble HAP.* The owner or operator may elect to treat affected wastewater streams containing soluble HAP and less than 50 ppmw partially soluble HAP in an enhanced biological treatment system, as defined in § 63.1251. This option shall not be used when the wastewater is designated as an affected wastewater as specified in paragraph (a)(1)(ii) of this section. These treatment processes are exempt from the design evaluation or performance tests requirements specified in paragraph (g)(4) of this section.

(11) *95-percent mass reduction option, for biological treatment processes.* The owner or operator of a new or existing source using biological treatment for any affected wastewater shall reduce the mass of total soluble and partially soluble HAP sent to that biological treatment unit by at least 95 percent. All wastewater as defined in § 63.1251 entering such a biological treatment unit from PMPU's subject to this subpart shall be included in the demonstration of the 95-percent mass removal. The owner or operator shall comply with paragraphs (g)(11)(i) through (iv) of this section.

(i) Except as provided in paragraph (g)(11)(iv) of this section, the owner or operator shall ensure that all wastewater from PMPU's subject to this subpart entering a biological treatment unit are treated to destroy at least 95-percent total mass of all soluble and partially soluble HAP compounds.

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

(iii) For each treatment process or waste management unit that receives, manages, or treats wastewater subject to this paragraph, from the POD to the biological treatment unit, the owner or operator shall comply with paragraphs (b) through (f) of this section for control of air emissions. When complying with this paragraph, the term affected wastewater in paragraphs (b) through (f) of this section shall mean all wastewater from PMPU's, not just affected wastewater.

(iv) If wastewater is in compliance with the requirements in paragraph (g)(8), (9), or (12) of this section before entering the biological treatment unit, the hazardous air pollutants mass of that wastewater is not required to be included in the total mass flow rate entering the biological treatment unit for the purpose of demonstrating compliance.

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

(13) *Treatment in a RCRA unit option.* The owner or operator shall treat the affected wastewater or residual in a unit identified in, and complying with, paragraph (g)(13)(i), (ii), or (iii) of this section. These units are exempt from the design evaluation or performance tests requirements specified in paragraph (g)(4) of this section and § 63.1257(e)(2), and from the monitoring requirements specified in paragraph (a)(2)(iii) of this section, as well as recordkeeping and reporting requirements associated with monitoring and performance tests.

(i) The wastewater or residual is discharged to a hazardous waste incinerator for which the owner or operator has been issued a final permit under 40 CFR part 270 and complies with the requirements of 40 CFR part 264, subpart O, or has certified compliance with the interim status requirements of 40 CFR part 265, subpart O;

(ii) The wastewater or residual is discharged to a process heater or boiler burning hazardous waste for which the owner or operator:

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

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

(iii) The wastewater or residual is discharged to an underground injection well for which the owner or operator has been issued a final permit under 40 CFR part 270 or 40 CFR part 144 and complies with the requirements of 40 CFR part 122. The owner or operator shall comply with all applicable requirements of this subpart prior to the point where the wastewater enters the underground portion of the injection well.

(14) *Residuals.* For each residual removed from affected wastewater, the owner or operator shall control for air emissions by complying with paragraphs (b) through (f) of this section and by complying with one of the provisions in paragraphs (g)(14)(i) through (iv) of this section.

(i) Recycle the residual to a production process or sell the residual for the purpose of recycling. Once a residual is returned to a production process, the residual is no longer subject to this section.

(ii) Return the residual to the treatment process.

(iii) Treat the residual to destroy the total combined mass flow rate of soluble and/or partially soluble HAP compounds by 99 percent or more, as determined by the procedures specified in § 63.1257(e)(2)(iii)(C) or (D).

(iv) Comply with the requirements for RCRA treatment options specified in paragraph (g)(13) of this section.

(h) *Control devices.* For each control device or combination of control devices used to comply with the provisions in paragraphs (b) through (f) and (g)(5) of this section, the owner or operator shall operate and maintain the control device or combination of control devices in accordance with the requirements of paragraphs (h) (1) through (4) of this section.

(1) Whenever organic HAP emissions are vented to a control device which is used to comply with the provisions of this subpart, such control device shall be operating.

(2) The control device shall be designed and operated in accordance with paragraph (h)(2) (i), (ii), (iii), (iv), or (v) of this section, as demonstrated by the provisions in § 63.1257(e)(3).

(i) An enclosed combustion device (including but not limited to a vapor incinerator, boiler, or process heater) shall meet the conditions in paragraph (h)(2)(i) (A), (B), or (C) of this section, alone or in combination with other control devices. If a boiler or process heater is used as the control device, then the vent stream shall be introduced into the flame zone of the boiler or process heater.

(A) Reduce the organic HAP emissions vented to the control device by 95 percent by weight or greater;

(B) Achieve an outlet TOC concentration of 20 ppmv on a dry basis corrected to 3 percent oxygen. The

owner or operator shall use either Method 18 of 40 CFR part 60, appendix A, or any other method or data that has been validated according to the applicable procedures in Method 301 of appendix A of this part; or

(C) Provide a minimum residence time of 0.5 seconds at a minimum temperature of 760°C.

(ii) A vapor recovery system (including but not limited to a carbon adsorption system or condenser), alone or in combination with other control devices, shall reduce the organic HAP emissions vented to the control device by 95 percent by weight or greater or achieve an outlet TOC concentration of 20 ppmv. The 20 ppmv performance standard is not applicable to compliance with the provisions of paragraphs (c) or (d) of this section.

(iii) A flare shall comply with the requirements of § 63.11(b).

(iv) A scrubber, alone or in combination with other control devices, shall reduce the organic HAP emissions in such a manner that 95 weight-percent is either removed, or destroyed by chemical reaction with the scrubbing liquid, or achieve an outlet TOC concentration of 20 ppmv. The 20 ppmv performance standard is not applicable to compliance with the provisions of paragraphs (c) or (d) of this section.

(v) Any other control device used shall, alone or in combination with other control devices, reduce the organic HAP emissions vented to the control device by 95 percent by weight or greater or achieve an outlet TOC concentration of 20 ppmv. The 20 ppmv performance standard is not applicable to compliance with the provisions of paragraphs (c) or (d) of this section.

(3) If the control device is a combustion device, the owner or operator shall comply with the requirements in § 63.1252(g) to control halogenated vent streams.

(4) Except as provided in paragraph (i) of this section, if gaps, cracks, tears, or holes are observed in ductwork, piping, or connections to covers and control devices during an inspection, a first effort to repair shall be made as soon as practical but no later than 5 calendar days after identification. Repair shall be completed no later than 15 calendar days after identification or discovery of the defect.

(i) *Delay of repair.* Delay of repair of equipment for which a control equipment failure or a gap, crack, tear, or hole has been identified, is allowed if the repair is technically infeasible without a shutdown, as defined in § 63.1251, or if the owner or operator determines that emissions of purged material from immediate repair would be greater than the emissions likely to result from delay of repair. Repair of this equipment shall occur by the end of the next shutdown.

(1) Delay of repair of equipment for which a control equipment failure or a gap, crack, tear, or hole has been identified, is allowed if the equipment is emptied or is no longer used to treat or manage affected wastewater or residuals removed from affected wastewater.

(2) Delay of repair of equipment for which a control equipment failure or a gap, crack, tear, or hole has been identified is also allowed if additional time is necessary due to the unavailability of parts beyond the control of the owner or operator. Repair shall be completed as soon as practical. The owner or operator who uses this provision shall comply with the requirements of § 63.1259(h) to document the reasons that the delay of repair was necessary.

§ 63.1257 Test methods and compliance procedures.

(a) *General.* Except as specified in paragraph (a)(5) of this section, the procedures specified in paragraphs (c), (d), (e), and (f) of this section are required to demonstrate initial compliance with §§ 63.1253, 63.1254, 63.1256, and 63.1252(e), respectively. The provisions in paragraphs (a) (2) through (3) apply to performance tests that are specified in paragraphs (c), (d), and (e) of this section. The provisions in paragraph (a)(5) of this section are used to demonstrate initial compliance with the alternative standards specified in §§ 63.1253(d) and 63.1254(c). The provisions in paragraph (a)(6) of this section are used to comply with the outlet concentration requirements specified in §§ 63.1253(c), 63.1254 (a)(2)(i) and (a)(3)(ii)(B), 63.1254(b)(i) and 63.1256(h)(2).

(1) *Design evaluation.* To demonstrate that a control device meets the required control efficiency, a design evaluation must address the composition and organic HAP concentration of the vent stream entering the control device. A design evaluation also must address other vent stream characteristics and control device operating parameters as specified in any one of paragraphs (a)(1)(i) through (vi) of this section, depending on the type of control device that is used. If the vent stream is not the only inlet to the control device, the efficiency demonstration also must consider all other vapors, gases, and liquids, other than fuels, received by the control device.

(i) For an enclosed combustion device used to comply with the provisions of 63.1253 (b)(2) or (c)(2), or 63.1256(h)(2)(i)(C) with a minimum residence time of 0.5 seconds and a minimum temperature of 760°C, the design evaluation must document that these conditions exist.

(ii) For a combustion control device that does not satisfy the criteria in paragraph (a)(1)(i) of this section, the design evaluation must document control efficiency and address the following characteristics, depending on the type of control device:

(A) For a thermal vapor incinerator, the design evaluation must consider the autoignition temperature of the organic HAP, must consider the vent stream flow rate, and must establish the design minimum and average temperature in the combustion zone and the combustion zone residence time.

(B) For a catalytic vapor incinerator, the design evaluation shall consider the vent stream flow rate and shall establish the design minimum and average temperatures across the catalyst bed inlet and outlet.

(C) For a boiler or process heater, the design evaluation shall consider the vent stream flow rate; shall establish the design minimum and average flame zone temperatures and combustion zone residence time; and shall describe the method and location where the vent stream is introduced into the flame zone.

(iii) For a condenser, the design evaluation shall consider the vent stream flow rate, relative humidity, and temperature and shall establish the design outlet organic HAP compound concentration level, design average temperature of the condenser exhaust vent stream, and the design average temperatures of the coolant fluid at the condenser inlet and outlet. The temperature of the gas stream exiting the condenser must be measured and used to establish the outlet organic HAP concentration.

(iv) For a carbon adsorption system that regenerates the carbon bed directly onsite in the control device such as a fixed-bed adsorber, the design evaluation shall consider the vent stream flow rate, relative humidity, and temperature and shall establish the design exhaust vent stream organic compound concentration level, adsorption cycle time, number and capacity of carbon beds, type and working capacity of activated carbon used for carbon beds, design total regeneration stream mass or volumetric flow over the period of each complete carbon bed regeneration cycle, design carbon bed temperature after regeneration, design carbon bed regeneration time, and design service

life of carbon. For vacuum desorption, the pressure drop shall be included.

(v) For a carbon adsorption system that does not regenerate the carbon bed directly onsite in the control device such as a carbon canister, the design evaluation shall consider the vent stream mass or volumetric flow rate, relative humidity, and temperature and shall establish the design exhaust vent stream organic compound concentration level, capacity of carbon bed, type and working capacity of activated carbon used for carbon bed, and design carbon replacement interval based on the total carbon working capacity of the control device and source operating schedule.

(vi) For a scrubber, the design evaluation shall consider the vent stream composition; constituent concentrations; liquid-to-vapor ratio; scrubbing liquid flow rate and concentration; temperature; and the reaction kinetics of the constituents with the scrubbing liquid. The design evaluation shall establish the design exhaust vent stream organic compound concentration level and will include the additional information in paragraphs (a)(1)(vi)(A) and (B) of this section for trays and a packed column scrubber.

(A) Type and total number of theoretical and actual trays;

(B) Type and total surface area of packing for entire column, and for individual packed sections if column contains more than one packed section.

(2) *Calculation of TOC or total organic HAP concentration.* The TOC concentration or total organic HAP concentration is the sum of the concentrations of the individual components. If compliance is being determined based on TOC, the owner or operator shall compute TOC for each run using Equation 6 of this subpart. If compliance with the wastewater provisions is being determined based on total organic HAP, the owner or operator shall compute total organic HAP using Equation 6 of this subpart, except that only the organic HAP compounds shall be summed; when determining compliance with paragraph (e)(3)(i) of this section, only the soluble and partially soluble HAP compounds shall be summed.

$$CG_T = \frac{1}{m}\sum_{j=1}^{m}\left(\sum_{i=1}^{n} CGS_{i,j}\right) \qquad \text{(Eq. 6)}$$

where:

CG_T=total concentration of TOC in vented gas stream, average of samples, dry basis, ppmv

$CGS_{i,j}$=concentration of sample components in vented gas stream for sample j, dry basis, ppmv

i=identifier for a compound

n=number of components in the sample

j=identifier for a sample

m=number of samples in the sample run

(3) *Percent oxygen correction for combustion control devices.* If the control device is a combustion device, the TOC or total organic HAP concentrations must be corrected to 3 percent oxygen. The integrated sampling and analysis procedures of Method 3B of 40 CFR part 60, appendix A shall be used to determine the actual oxygen concentration ($\%0_{2d}$). The samples shall be taken during the same time that the TOC or total organic HAP samples are taken. The concentration corrected to 3 percent oxygen (C_d) shall be computed using Equation 7 of this subpart:

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

where:

C_c = concentration of TOC or total organic HAP corrected to 3 percent oxygen, dry basis, ppmv

C_m = total concentration of TOC in vented gas stream, average of samples, dry basis, ppmv

$\%0_{2d}$ = concentration of oxygen measured in vented gas stream, dry basis, percent by volume

(4) *Exemptions from compliance demonstrations.* An owner or operator using any control device specified in paragraphs (a)(4)(i) through (iv) of this section is exempt from the initial compliance provisions in paragraphs (c), (d), and (e) of this section.

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

(ii) A boiler or process heater into which the emission stream is introduced with the primary fuel.

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

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

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

(iv) A hazardous waste incinerator for which the owner or operator has been issued a final permit under 40 CFR part 270 and complies with the requirements of 40 CFR part 264, subpart O, or has certified compliance with the interim status requirements of 40 CFR part 265, subpart O.

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

(6) *Initial compliance with the 20 ppmv outlet limit.* Initial compliance with the 20 ppmv TOC and hydrogen halide and halogen concentration is demonstrated when the outlet TOC concentration is 20 ppmv or less, and the outlet hydrogen halide and halogen concentration is 20 ppmv or less. To demonstrate initial compliance, the operator shall use test methods described in paragraph (b) of this section. The owner or operator shall comply with the monitoring provisions in § 63.1258(b)(1) through (5) of this subpart on the initial compliance date.

(b) *Test methods.* When testing is conducted to measure emissions from an affected source, the test methods specified in paragraphs (b)(1) through (10) of this section shall be used.

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

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

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

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

(5) [Reserved]

(6) Concentration measurements shall be adjusted to negate the dilution effects of introducing nonaffected gaseous streams into the vent streams prior to control or measurement. The following methods are specified for concentration measurements:

(i) Method 18 may be used to determine HAP concentration in any control device efficiency determination.

(ii) Method 25 of appendix A of part 60 may be used to determine total gaseous nonmethane organic concentration for control efficiency determinations in combustion devices.

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

(iv) Method 25A of appendix A of part 60 may be used to determine the HAP or TOC concentration for control device

efficiency determinations under the conditions specified in Method 25 of appendix A for direct measurement of an effluent with a flame ionization detector, or in demonstrating compliance with the 20 ppmv TOC outlet standard. If Method 25A is used to determine the concentration of TOC for the 20 ppmv standard, the instrument shall be calibrated on methane or the predominant HAP. If calibrating on the predominant HAP, the use of Method 25A shall comply with paragraphs (b)(6)(iv)(A) through (C) of this section.

(A) The organic HAP used as the calibration gas for Method 25A, 40 CFR part 60, appendix A, shall be the single organic HAP representing the largest percent by volume.

(B) The use of Method 25A, 40 CFR part 60, appendix A, is acceptable if the response from the high level calibration gas is at least 20 times the standard deviation of the response from the zero calibration gas when the instrument is zeroed on the most sensitive scale.

(C) The span value of the analyzer must be less than 100 ppmv.

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

(8) *Testing and compliance determination conditions for batch processes.* Testing of emissions on equipment where the flow of gaseous emissions is intermittent (batch operations) shall be conducted as specified in paragraphs (b)(8)(i) through (iii) of this section.

(i) Except as provided in paragraph (b)(9) of this section for condensers, testing shall be conducted at absolute worst-case conditions or hypothetical worst-case conditions. Gas stream volumetric flow rates shall be measured at 15-minute intervals. The HAP or TOC concentration shall be determined from samples collected in an integrated sample over the duration of the test, or from grab samples collected simultaneously with the flow rate measurements (every 15 minutes). If an integrated sample is collected for laboratory analysis, the sampling rate shall be adjusted proportionally to reflect variations in flow rate. The absolute worst-case or hypothetical worst-case conditions shall be characterized by the criteria presented in paragraphs (b)(8)(i)(A) and (B)of this section. In all cases, a site-specific plan shall be submitted to the Administrator for approval prior to testing in accordance with § 63.7(c) and § 63.1260(l). The test plan shall include the emission profile described in paragraph (b)(8)(ii) of this section.

(A) Absolute worst-case conditions are defined by the criteria presented in paragraph (b)(8)(i)(A)(*1*) or (*2*) of this section if the maximum load is the most challenging condition for the control device. Otherwise, absolute worst-case conditions are defined by the conditions in paragraph (b)(8)(i)(A)(*3*) of this section.

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

(*2*) A 1-hour period of time in which the inlet to the control device will contain the highest HAP mass loading rate, in lb/hr, capable of being vented to the control device. An emission profile as described in paragraph (b)(8)(ii)(A) of this section shall be used to identify the 1-hour period of maximum HAP loading.

(*3*) The period of time when the HAP loading or stream composition (including non-HAP) is most challenging for the control device. These conditions include, but are not limited to the following:

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

(*ii*) Periods when the streams contain HAP constituents that approach limits of solubility for scrubbing media;

(*iii*) Periods when the streams contain HAP constituents that approach limits of adsorptivity for carbon adsorption systems.

(B) Hypothetical worst-case conditions are simulated test conditions that, at a minimum, contain the highest hourly HAP load of emissions that would be predicted to be vented to the control device from the emissions profile described in paragraph (b)(8)(ii)(B) or (C) of this section.

(ii) *Emissions profile.* The owner or operator may choose to perform tests only during those periods of the worst-case conditions that the owner or operator selects to control as part of achieving the required emission reduction. The owner or operator must develop an emission profile for the vent to the control device that describes the characteristics of the vent stream at the inlet to the control device under worst case conditions. The emission profile shall be developed based on any one of the procedures described in (b)(8)(ii)(A) through (C) of this section, as required by paragraph (b)(8)(i).

(A) *Emission profile by process.* The emission profile must consider all emission episodes that could contribute to the vent stack for a period of time that is sufficient to include all processes venting to the stack and shall consider production scheduling. The profile shall describe the HAP load to the device that equals the highest sum of emissions from the episodes that can vent to the control device in any given hour. Emissions per episode shall be calculated using the procedures specified in paragraph (d)(2) of this section. Emissions per episode shall be divided by the duration of the episode only if the duration of the episode is longer than 1 hour.

(B) *Emission profile by equipment.* The emission profile must consist of emissions that meet or exceed the highest emissions, in lb/hr, that would be expected under actual processing conditions. The profile shall describe equipment configurations used to generate the emission events, volatility of materials processed in the equipment, and the rationale used to identify and characterize the emission events. The emissions may be based on using a compound more volatile than compounds actually used in the process(es), and the emissions may be generated from all equipment in the process(es) or only selected equipment.

(C) *Emission profile by capture and control device limitation.* The emission profile shall consider the capture and control system limitations and the highest emissions, in lb/hr, that can be routed to the control device, based on maximum flowrate and concentrations possible because of limitations on conveyance and control equipment (e.g., fans, LEL alarms and safety bypasses).

(iii) Three runs, at a minimum of 1 hour each and a maximum of 8 hours each, are required for performance testing. Each run must occur over the same worst-case conditions, as defined in paragraph (b)(8)(i) of this section.

(9) *Testing requirements for condensers.* For emission streams controlled using condensers, continuous direct measurement of condenser outlet gas temperature to be used in determining concentrations per the design evaluation described in § 63.1257(a)(1)(iii) is required.

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

(i) *Method 305.* Use procedures specified in Method 305 of 40 CFR part 63, appendix A and comply with requirements specified in paragraph (b)(10)(v) of this section.

(ii) *Method 624, 625, 1624, 1625, or 8270.* Use procedures specified in Method 624, 625, 1624, 1625, or 8270 of 40 CFR part 136, appendix A and comply with requirements in paragraph (b)(10)(v) of this section.

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

(A) Validate the method according to section 5.1 or 5.3 of Method 301 of 40 CFR part 63, appendix A.

(B) Follow the procedure as specified in ''Alternative Validation Procedure for EPA Waste Methods'' 40 CFR part 63, appendix D.

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

(v) *Sampling plan.* The owner or operator shall prepare a sampling plan. Wastewater samples shall be collected using sampling procedures which minimize loss of organic compounds during sample collection and analysis and maintain sample integrity. The sample plan shall include procedures for determining recovery efficiency of the relevant partially soluble and soluble HAP compounds. An example of an acceptable sampling plan would be one that incorporates similar sampling and sample handling requirements to those of Method 25D of 40 CFR part 60, appendix A. The sampling plan shall be maintained at the facility.

(c) *Initial compliance with storage tank provisions.* The owner or operator of an affected storage tank shall demonstrate initial compliance with § 63.1253(b) or (c), as applicable, by fulfilling the requirements of paragraph (c)(1),or (c)(2), or (c)(3) of this section.

(1) *Performance test.* If this option is chosen to demonstrate initial compliance with the percent reduction requirement of § 63.1253(b)(1) or (c)(1)(i), the efficiency of the control device shall be calculated using performance test data as specified in paragraphs (c)(1)(i) through (iii) of this section. Initial compliance with the outlet concentration requirement of § 63.1253(b)(2) or (c)(1)(ii) is demonstrated by fulfilling the requirements of paragraph (a)(6) of this section.

(i) Equations 8 and 9 of this subpart shall be used to calculate the mass rate of total HAP reasonably expected maximum filling rate at the inlet and outlet of the control device for standard conditions of 20°C: where:

$$E_i = K_2\left(\sum_{j=1}^{n} C_{ij}M_{ij}\right)Q_i \qquad \text{(Eq. 8)}$$

$$E_o = K_2\left(\sum_{j=1}^{n} C_{oj}M_{oj}\right)Q_o \qquad \text{(Eq. 9)}$$

where:

C_{ij}, C_{oj} = concentration of sample component j of the gas stream at the inlet and outlet of the control device, respectively, dry basis, ppmv

E_i, E_o = mass rate of total HAP at the inlet and outlet of the control device, respectively, dry basis, kg/hr

M_{ij}, M_{oj} = molecular weight of sample component j of the gas stream at the inlet and outlet of the control device, respectively, gram/gram-mole

Q_i, Q_o = flow rate of gas stream at the inlet and outlet of the control device, respectively, dry standard cubic meter per minute

K_2 = constant, 2.494×10^{-6} (parts per million)$^{-1}$ (gram-mole per standard cubic meter) (kilogram/gram) (minute/hour), where standard temperature is 20°C

n = number of sample components in the gas stream

(ii) The percent reduction in total HAP shall be calculated using Equation 10 of this subpart:

$$R = \frac{E_i - E_o}{E_i}(100) \qquad \text{(Eq. 10)}$$

where:

R = control efficiency of control device, percent

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

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

(iii) A performance test is not required to be conducted if the control device used to comply with § 63.1253 (storage tank provisions) is also used to comply with § 63.1254 (process vent provisions), and compliance with § 63.1254 has been demonstrated in accordance with paragraph (d) of this section.

(2) *Design evaluation.* If this option is chosen to demonstrate initial compliance with the percent reduction requirement of § 63.1253(b) or (c), a design evaluation shall be prepared in accordance with the provisions in paragraph (a)(1) of this section. The design evaluation shall include documentation demonstrating that the control device being used achieves the required control efficiency during reasonably expected maximum filling rate.

(3) *Floating roof.* If the owner or operator of an affected source chooses to comply with the provisions of § 63.1253(b) or (c) by installing a floating roof, the owner or operator shall comply with the procedures described in §§ 63.119(b), (c), (d), and 63.120(a), (b), and (c), with the differences noted in paragraphs (c)(3)(i) through (v) of this section for the purposes of this subpart.

(i) When the term ''storage vessel'' is used in §§ 63.119 and 63.120, the definition of ''storage tank'' in § 63.1251 shall apply for the purposes of this subpart.

(ii) When December 31, 1992 is referred to in § 63.119, April 2, 1997 shall apply instead for the purposes of this subpart.

(iii) When April 22, 1994 is referred to in § 63.119, September 21, 1998 shall apply instead for the purposes of this subpart.

(iv) When the phrase ''the compliance date specified in § 63.100 of subpart F of this part'' is referred to in § 63.120, the phrase ''the compliance date specified in § 63.1250'' shall apply for the purposes of this subpart.

(v) When the phrase ''the maximum true vapor pressure of the total organic HAP's in the stored liquid falls below the values defining Group 1 storage vessels specified in table 5 or table 6 of this subpart'' is referred to in § 63.120(b)(1)(iv), the phrase ''the maximum true vapor pressure of the total organic HAP in the stored liquid

falls below 13.1 kPa (1.9 psia)'' shall apply for the purposes of this subpart.

(4) *Initial compliance with alternative standard.* Initial compliance with § 63.1253(d) is demonstrated by fulfilling the requirements of paragraph (a)(5) of this section.

(5) *Planned maintenance.* The owner or operator shall demonstrate compliance with the requirements of § 63.1253(e) by including the periods of planned routine maintenance specified by date and time in each Periodic Report required by § 63.1260.

(d) *Initial compliance with process vent provisions.* An owner or operator of an affected source complying with the process vent standards in § 63.1254 shall demonstrate compliance using the procedures described in paragraphs (d)(1) through (4) of this section.

(1) Except as provided in paragraph (a)(4) of this section, initial compliance with the process vent standards in § 63.1254 shall be demonstrated using the procedures specified in paragraphs (d)(1)(i) through (iv), as applicable.

(i) Initial compliance with § 63.1254(a)(1)(i) is demonstrated when the actual emissions of HAP from the sum of all process vents within a process that do not meet the criteria specified in § 63.1254(a)(3) is less than or equal to 2,000 lb/yr. Initial compliance with § 63.1254(a)(1)(ii) is demonstrated when the uncontrolled emissions of HAP from the sum of all process vents within a process is less than or equal to 100 lb/yr. Uncontrolled HAP emissions and controlled HAP emissions shall be determined using the procedures described in paragraphs (d)(2) and (3) of this section.

(ii) Initial compliance with the percent reduction requirements in §§ 63.1254(a)(2), (a)(3), and (b) is demonstrated by:

(A) Determining controlled HAP emissions using the procedures described in paragraph (d)(3) of this section and uncontrolled HAP emissions determined using the procedures described in paragraph (d)(2) of this section and demonstrating that the reductions required by §§ 63.1254(a)(2), (a)(3), and (b) are met; or

(B) Controlling the process vents using a device meeting the criteria specified in paragraph (a)(4) of this section.

(iii) Initial compliance with the outlet concentration requirements in § 63.1254(a)(2)(ii) and (3) is demonstrated when the outlet TOC concentration is 20 ppmv or less and the outlet hydrogen halide and halogen concentration is 20 ppmv or less. The owner or operator shall demonstrate compliance by fulfilling the requirements in paragraph (a)(6) of this section.

(iv) Initial compliance with § 63.1254(c) is demonstrated by fulfilling the requirements of paragraph (a)(5) of this section.

(2) *Uncontrolled emissions.* An owner or operator of an affected source complying with the emission limitation required by § 63.1254(a)(1), or emissions reductions specified in § 63.1254(a)(2), (a)(3), or (b), for each process vent within a process, shall calculate uncontrolled emissions from all equipment in the process according to the procedures described in paragraph (d)(2)(i) or (ii) of this section, as appropriate.

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

(A) *Vapor displacement.* Emissions from vapor displacement due to transfer of material shall be calculated using Equation 11 of this subpart. The individual HAP partial pressures may be calculated using Raoult's law.

$$E = \frac{(V)}{(R)(T)} \times \sum_{i=1}^{n} \left(P_i\right)\left(MW_i\right) \qquad \text{(Eq. 11)}$$

where:

E = mass of HAP emitted

V = volume of gas displaced from the vessel

R = ideal gas law constant

T = temperature of the vessel vapor space; absolute

P_i = partial pressure of the individual HAP

MW_i = molecular weight of the individual HAP

n = number of HAP compounds in the emission stream i = identifier for a HAP compound

(B) *Purging.* Emissions from purging shall be calculated using Equation 12 of this subpart. The partial pressures of individual condensable compounds may be calculated using Raoult's law, the pressure of the vessel vapor space may be set equal to 760 mmHg, and the partial pressure of HAP shall be assumed to be 25 percent of the saturated value if the purge flow rate is greater than 100 standard cubic feet per minute (scfm).

$$E = \sum_{i=1}^{n} P_i MW_i \times \frac{(V)(t)}{(R)(T)} \times \frac{P_T}{P_T - \sum_{j=1}^{m} \left(P_j\right)} \qquad \text{(Eq. 12)}$$

Where:

E = mass of HAP emitted

V = purge flow rate at the temperature and pressure of the vessel vapor space

R = ideal gas law constant

T = temperature of the vessel vapor space; absolute

P_i = partial pressure of the individual HAP

P_j = partial pressure of individual condensable VOC compounds (including HAP)

P_T = pressure of the vessel vapor space

MW_i = molecular weight of the individual HAP

t = time of purge

n = number of HAP compounds in the emission stream

i = identifier for a HAP compound

j = identifier for a condensable compound

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

(C) *Heating.* Emissions caused by the heating of a vessel to a temperature equal to or lower than 10 K below the boiling point shall be calculated using the procedures in either paragraph (d)(2)(i)(C)(*1*) or (*3*) of this section. Emissions caused by heating a vessel to a temperature that is higher than 10 K below the boiling point and less than the boiling point, must be calculated using the procedures in either paragraph (d)(2)(i)(C) (*2*) or (*3*) of this section. If the contents of a vessel are heated to the boiling point, emissions must be calculated using the procedures in paragraph (d)(2)(i)(C)(*4*) of this section.

(*1*) This paragraph describes procedures to calculate emissions if the final temperature to which the vessel contents are heated is 10 K below the boiling point of the HAP in the vessel, or lower. The owner or operator shall calculate the mass of HAP emitted per episode using either Equation 13 or 14 of this subpart. The moles of noncondensable gas displaced are calculated using Equation 15 of this subpart. The initial and final pressure of the noncondensable gas in the vessel shall be calculated using Equation 16 of this subpart. The average molecular weight of HAP in the displaced gas shall be calculated using Equation 17 of this subpart.

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

$$E = \frac{\frac{\sum_{i=1}^{n}(P_i)_{T1}}{Pa_1} + \frac{\sum_{i=1}^{n}(P_i)_{T2}}{Pa_2}}{2} \times \Delta\eta \times MW_{HAP} \qquad \text{(Eq. 14)}$$

$$\Delta\eta = \frac{V}{R}\left[\left(\frac{Pa_1}{T_1}\right) - \left(\frac{Pa_2}{T_2}\right)\right] \qquad \text{(Eq. 15)}$$

$$Pa_n = P_{atm} - \sum_{j=1}^{m}\left(P_j\right)_{Tn} \qquad \text{(Eq. 16)}$$

$$MW_{HAP} = \sum_{i=1}^{n}\frac{\left((P_i)_{T_1} + (P_i)_{T_2}\right)MW_i}{\sum_{i=1}^{n}\left((P_i)_{T_1} + (P_i)_{T_2}\right)} \qquad \text{(Eq. 17)}$$

Where:

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

x_i = mole fraction of each HAP in the liquid phase

x_j = mole fraction of each condensable VOC (including HAP) in the liquid phase

(P_i^*) = vapor pressure of each HAP in the vessel headspace at any temperature between the initial and final heatup temperatures, mmHg

(P_j^*) = vapor pressure of each condensable VOC (including HAP) in the vessel headspace at any temperature between the initial and final heatup temperatures, mmHg

760 = atmospheric pressure, mmHg

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

$\Delta\eta$ = number of moles of noncondensable gas displaced

V = volume of free space in the vessel

R = ideal gas law constant

T_1 = initial temperature of vessel contents, absolute

T_2 = final temperature of vessel contents, absolute

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

P_{atm} = atmospheric pressure (when $\Delta\eta$ is used in Equation 13 of this subpart, P_{atm} may be set equal to 760 mmHg for any vessel)

$(P_j)_{Tn}$ = partial pressure of each condensable compound (including HAP) in the vessel headspace at the initial temperature (n=1) and final (n=2) temperature

m = number of condensable compounds (including HAP) in the displaced vapor

j = identifier for a condensable compound

$(P_i)_{Tn}$ = partial pressure of each HAP in the vessel headspace at initial (T_1) and final (T_2) temperature; [for use in Equation 13, replace $(P_i)_{T1}+(P_i)_{T2}$ with P_i at the temperature used to calculate vapor pressure of HAP in Equation 13]

MW_i = molecular weight of each HAP

n = number of HAP compounds in the emission stream

i = identifier for a HAP compound

(*2*) If the vessel contents are heated to a temperature that is higher than 10 K below the boiling point and less than the boiling point, emissions must be calculated using the procedures in

paragraph (d)(2)(i)(C)(*2*)(*i*), or (*ii*), or (*iii*) of this section.

(*i*) Use Equation 13 of this subpart. In Equation 13 of this subpart, the HAP vapor pressures must be determined at the temperature 10 K below the boiling point. In the calculation of $\Delta\eta$ for Equation 13 of this subpart, T_2 must be the temperature 10 K below the boiling point, and Pa_2 must be determined at the temperature 10 K below the boiling point. In the calculation of MW_{HAP}, the HAP partial pressures must be determined at the temperature 10 K below the boiling point.

(*ii*) Use Equation 14 of this subpart. In Equation 14 of this subpart, the HAP partial pressures must be deter mined at the temperature 10 K below the boiling point. In the calculation of $\Delta\eta$ for Equation 14 of this subpart, T_2 must be the temperature 10 K below the boiling point, and Pa_2 must be determined at the temperature 10 K below the boiling point. In the calculation of MW_{HAP}, the HAP partial pressures must be determined at the temperature 10 K below the boiling point.

(*iii*) Use Equation 14 of this subpart over specific temperature increments. If the initial temperature is lower than 10 K below the boiling point, emissions must be calculated as the sum over two increments; one increment is from the initial temperature to 10 K below the boiling point, and the second is from 10 K below the boiling point to the lower of either the final temperature or the temperature 5 K below the boiling point. If the initial temperature is higher than 10 K below the boiling point, emissions are calculated over one increment from the initial temperature to the lower of either the final temperature or the temperature 5 K below the boiling point.

(*3*)(*i*) Emissions caused by heating a vessel are calculated using Equation 18 of this subpart.

$$E = MW_{HAP} \times \left(N_{avg} \times \ln\left(\frac{P_T - \sum_{i=1}^{n}\left(P_{i,1}\right)}{P_T - \sum_{i=1}^{n}\left(P_{i,2}\right)} \right) - \left(n_{i,2} - n_{i,1}\right) \right) \qquad \text{(Eq. 18)}$$

Where:

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

N_{avg} = average gas space molar volume during the heating process

P_T= total pressure in the vessel

$P_{i,1}$ = partial pressure of the individual HAP compounds at T_1

$P_{i,2}$ = partial pressure of the individual HAP compounds at T_2

MW_{HAP} = average molecular weight of the HAP compounds

$n_{i,1}$ = number of moles of condensable in the vessel headspace at T_1

$n_{i,2}$ = number of moles of condensable in the vessel headspace at T_2

n = number of HAP compounds in the emission stream

(*ii*) The average gas space molar volume during the heating process is calculated using Equation 19 of this subpart.

$$N_{avg} = \frac{VP_T}{2R}\left(\frac{1}{T_1} + \frac{1}{T_2}\right) \qquad \text{(Eq. 19)}$$

Where:

N_{avg} = average gas space molar volume during the heating process

V = volume of free space in vessel

P_T = total pressure in the vessel

R = ideal gas law constant

T_1 = initial temperature of the vessel

T_2 = final temperature of the vessel

(*iii*) The difference in the number of moles of condensable in the vessel headspace between the initial and final temperatures is calculated using Equation 20 of this subpart.

$$\left(n_{i,2} - n_{i,1}\right) = \frac{V}{(R)(T_2)}\sum_{i=1}^{n} P_{i,2} - \frac{V}{(R)(T_1)}\sum_{i=1}^{n} P_{i,1} \qquad \text{(Eq. 20)}$$

Where:

V = volume of free space in vessel

R = ideal gas law constant

T_1 = initial temperature in the vessel

T_2 = final temperature in the vessel

$P_{i,1}$ = partial pressure of the individual HAP compounds at T_1

$P_{i,2}$ = partial pressure of the individual HAP compounds at T_2

n = number of HAP compounds in the emission stream

(*4*) If the vessel contents are heated to the boiling point, emissions must be calculated using the procedure in paragraphs (d)(2)(i)(c)(4)(*i*) and (*ii*) of this section.

(*i*) Use either of the procedures in paragraph (d)(3)(i)(B)(*3*) of this section to calculate the emissions from heating to the boiling point (note that Pa_2=0 in the calculation of $\Delta\eta$); and

(*ii*) While boiling, the vessel must be operated with a properly operated process condenser. An initial demonstration that a process condenser is properly operated is required for vessels that operate process condensers without secondary condensers that are air pollution control devices. The owner or operator must either measure the condenser exhaust gas temperature and show it is less than the boiling point of the substance(s) in the vessel, or perform a material balance around the vessel and condenser to show that at least 99 percent of the material vaporized while boiling is condensed. Uncontrolled emissions are assumed to be zero under these conditions. The initial demonstration shall be conducted for all appropriate operating scenarios and documented in the Notification of Compliance report described in § 63.1260(f).

(D) *Depressurization.* Emissions from depressurization shall be calculated using the procedures in either paragraphs (d)(2)(i)(D)(*1*) through (*4*), paragraphs (d)(2)(i)(D)(*5*) through (*9*), or paragraph (d)(2)(i)(D)(*10*) of this section.

(*1*) Equations 21 and 22 of this subpart are used to calculate the initial and final volumes of noncondensable gas present in the vessel, adjusted to atmospheric pressure. The HAP partial pressures may be calculated using Raoult's law.

$$V_{nc1} = \frac{VP_{nc_1}}{760} \qquad \text{(Eq. 21)}$$

$$V_{nc2} = \frac{VP_{nc_2}}{760} \qquad \text{(Eq. 22)}$$

Where:

V_{nc1} = initial volume of noncondensable gas in the vessel

V_{nc2} = final volume of noncondensable gas in the vessel

V = free volume in the vessel being depressurized

P_{nc1} = initial partial pressure of the noncondensable gas, as calculated using Equation 23 of this subpart, mmHg

P_{nc2} = final partial pressure of the noncondensable gas, as calculated using Equation 24 of this subpart, mmHg

760 = atmospheric pressure, mmHg

(*2*) The initial and final partial pressures of the noncondensable gas in the vessel are determined using Equations 23 and 24 of this subpart:

$$P_{nc1} = P_1 - \sum_{j=1}^{m}\left(P_j*\right)\left(x_j\right) \qquad \text{(Eq. 23)}$$

$$P_{nc2} = P_2 - \sum_{j=1}^{m}\left(P_j*\right)\left(x_j\right) \qquad \text{(Eq. 24)}$$

Where:

P_{nc1} = initial partial pressure of the noncondensable gas

P_{nc2} = final partial pressure of the noncondensable gas

P_1 = initial vessel pressure

P_2 = final vessel pressure

P_j* = vapor pressure of each condensable (including HAP) in the emission stream

x_j = mole fraction of each condensable (including HAP) in the emission stream

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

j = identifier for a condensable compound

(*3*) The average ratio of moles of noncondensable to moles of HAP is calculated using Equation 25 of this subpart:

$$n_R = \frac{\left(\dfrac{P_{nc1}}{\sum_{i=1}^{n}\left(P_i*\right)\left(x_i\right)} + \dfrac{P_{nc2}}{\sum_{i=1}^{n}\left(P_i*\right)\left(x_i\right)}\right)}{2} \qquad \text{(Eq. 25)}$$

Where:

n_R = average ratio of moles of noncondensable to moles of HAP

P_{nc1} = initial partial pressure of the noncondensable gas, as calculated using Equation 23 of this subpart

P_{nc2} = final partial pressure of the noncondensable gas, as calculated using Equation 24 of this subpart

P_i* = vapor pressure of each individual HAP

x_i = mole fraction of each individual HAP in the liquid phase

n = number of HAP compounds

i = identifier for a HAP compound

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

$$E = \frac{V_{nc1} - V_{nc2}}{n_R} \times \frac{P_{atm}}{RT} \times MW_{HAP} \qquad \text{(Eq. 26)}$$

Where:

E = mass of HAP emitted

V_{nc1} = initial volume of noncondensable gas in the vessel, as calculated using Equation 21 of this subpart

V_{nc2} = final volume of noncondensable gas in the vessel, as calculated using Equation 22 of this subpart n_R = average ratio of moles of noncondensable to moles of HAP, as calculated using Equation 25 of this subpart

P_{atm} = atmospheric pressure, standard

R = ideal gas law constant

T = temperature of the vessel, absolute

MW_{HAP} = average molecular weight of the HAP, as calculated using Equation 17 of this subpart

(*5*) The moles of HAP vapor initially in the vessel are calculated using the ideal gas law using Equation 27 of this subpart:

$$n_{HAP} = \frac{\left(Y_{HAP}\right)\left(V\right)\left(P_1\right)}{R\,T} \qquad \text{(Eq. 27)}$$

Where:

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

V = free volume in the vessel being depressurized

P_1 = initial vessel pressure

R = ideal gas law constant

T = vessel temperature, absolute

(*6*) The initial and final moles of noncondensable gas present in the vessel are calculated using Equations 28 and 29 of this subpart:

$$n_1 = \frac{VP_{nc_1}}{RT} \qquad \text{(Eq. 28)}$$

$$n_2 = \frac{VP_{nc_2}}{RT} \qquad \text{(Eq. 29)}$$

Where:

n_1 = initial number of moles of noncondensable gas in the vessel

n_2 = final number of moles of noncondensable gas in the vessel

V = free volume in the vessel being depressurized
P_{nc1} = initial partial pressure of the noncondensable gas, as calculated using Equation 23 of this subpart
P_{nc2} = final partial pressure of the noncondensable gas, as calculated using Equation 24 of this subpart
R = ideal gas law constant
T = temperature, absolute

(*7*) The initial and final partial pressures of the noncondensable gas in the vessel are determined using Equations 23 and 24 of this subpart.

(*8*) The moles of HAP emitted during the depressurization are calculated by taking an approximation of the average ratio of moles of HAP to moles of noncondensable and multiplying by the total moles of noncondensables released during the depressurization, using Equation 30 of this subpart:

where:

$$n_{HAP} = \frac{\left(\frac{n_{HAP,1}}{n_1} + \frac{n_{HAP,2}}{n_2}\right)}{2}\left[n_1 - n_2\right] \qquad \text{(Eq. 30)}$$

n_{HAP} = moles of HAP emitted
n_1 = initial number of moles of noncondensable gas in the vessel, as calculated using Equation 28 of this subpart
n_2 = final number of moles of noncondensable gas in the vessel, as calculated using Equation 29 of this subpart

(*9*) The mass of HAP emitted can be calculated using Equation 31 of this subpart:

$E = N_{HAP} * MW_{HAP}$ (Eq. 31)

where:
E = mass of HAP emitted
n_{HAP} = moles of HAP emitted, as calculated using Equation 30 of this subpart
MW_{HAP} = average molecular weight of the HAP as calculated using Equation 17 of this subpart

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

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

where:
V = free volume in vessel being depressurized
R = ideal gas law constant
T = temperature of the vessel, absolute
P_1 = initial pressure in the vessel
P_2 = final pressure in the vessel
P_i = partial pressure of the individual HAP compounds
MW_i = molecular weight of the individual HAP compounds
n = number of HAP compounds in the emission stream
i = identifier for a HAP compound

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

$$E = \frac{(MW_{HAP})(La)(t)}{MW_{nc}}\left(\frac{P_{system}}{P_{system} - P_i*} - 1\right) \qquad \text{(Eq. 33)}$$

where:
E = mass of HAP emitted
P_{system} = absolute pressure of receiving vessel or ejector outlet conditions, if there is no receiver
P_i* = vapor pressure of the HAP at the receiver temperature or the ejector outlet conditions
La = total air leak rate in the system, mass/time
MW_{nc} = molecular weight of noncondensable gas
t = time of vacuum operation
MW_{HAP} = average molecular weight of HAP in the emission stream, as calculated using Equation 17 of this subpart, with HAP partial pressures calculated at the temperature of the receiver or ejector outlet, as appropriate

(F) *Gas evolution.* Emissions from gas evolution shall be calculated using Equation 12 of this subpart with V calculated using Equation 34 of this subpart:

$$V = \frac{(W_g)(R)(T)}{(P_T)(MW_g)} \qquad \text{(Eq. 34)}$$

Where:
V = volumetric flow rate of gas evolution
W_g = mass flow rate of gas evolution
R = ideal gas law constant
T = temperature at the exit, absolute
P_T = vessel pressure
MW_g = molecular weight of the evolved gas

(G) *Air drying.* Emissions from air drying shall be calculated using Equation 35 of this subpart:

$$E = B \times \left(\frac{PS_1}{100 - PS_1} - \frac{PS_2}{100 - PS_2} \right) \qquad \text{(Eq. 35)}$$

Where:

E = mass of HAP emitted
B = mass of dry solids
PS_1 = HAP in material entering dryer, weight percent
PS_2 = HAP in material exiting dryer, weight percent

(H) *Empty vessel purging.* Emissions from empty vessel purging shall be calculated using Equation (36) of this subpart (Note: The term -Ft/v can be assumed to be 1):

$$E = \left(\frac{V}{RT} \times \left(\sum_{i=1}^{n} (P_i)(MW_i) \right) \left(1 - e^{-Ft/v}\right) \right) \qquad \text{(Eq. 36)}$$

Where:

V = volume of empty vessel
R = ideal gas law constant
T = temperature of the vessel vapor space; absolute
P_i = partial pressure of the individual HAP at the beginning of the purge
(MW_i) = molecular weight of the individual HAP
F = flowrate of the purge gas
t = duration of the purge
n = number of HAP compounds in the emission stream
i = identifier for a HAP compound

(ii) *Engineering assessments.* The owner or operator shall conduct an engineering assessment to calculate uncontrolled HAP emissions for each emission episode that is not due to vapor displacement, purging, heating, depressurization, vacuum operations, gas evolution, or air drying. For emission episodes caused by any of these types of activities, the owner or operator also may calculate uncontrolled HAP emissions based on an engineering assessment if the owner or operator can demonstrate to the Administrator that the methods in paragraph (d)(2)(i) of this section are not appropriate. One criterion the owner or operator could use to demonstrate that the methods in paragraph (d)(2)(i) of this section are not appropriate is if previous test data are available that show a greater than 20 percent discrepancy between the test value and the estimated value. An engineering assessment includes, but is not limited to, the following:

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

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

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

(D) Design analysis based on accepted chemical engineering principles, measurable process parameters, or physical or chemical laws or properties. Examples of analytical methods include, but are not limited to:

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

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

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

(E) All data, assumptions, and procedures used in the engineering assessment shall be documented in accordance with § 63.1260(e). Data or other information supporting a finding that the emissions estimation equations are inappropriate shall be reported in the Precompliance report.

(3) *Controlled emissions.* An owner or operator shall determine controlled emissions using the procedures in either paragraph (d)(3)(i) or (ii) of this section. For condensers, controlled emissions shall be calculated using the emission estimation equations described in paragraph (d)(3)(i)(B) of this section.

(i) *Small control devices.* Except for condensers, controlled emissions for each process vent that is controlled using a small control device shall be determined by using the design evaluation described in paragraph (d)(3)(i)(A) of this section, or conducting a performance test in accordance with paragraph (d)(3)(ii) of this section. Whenever a small control device becomes a large control device, the owner or operator must comply with the provisions in paragraph (d)(3)(ii) of this section and submit the test report in the next Periodic report.

(A) *Design evaluation.* The design evaluation shall include documentation demonstrating that the control device being used achieves the required control efficiency under worst-case conditions, as determined from the emission profile described in § 63.1257(b)(8)(ii). The control efficiency determined from this design evaluation shall be applied to uncontrolled emissions to estimate controlled emissions. The documentation must be conducted in accordance with the provisions in paragraph (a)(1) of this section. The design evaluation shall also include the value(s) and basis for the parameter(s) monitored under § 63.1258.

(B) *Emission estimation equations.* An owner or operator using a condenser as a control device shall determine controlled emissions using exhaust gas temperature measurements and calculations for each batch emission episode within each unit operation according to the engineering methodology in paragraphs (d)(3)(i)(B)(*1*) through (*8*) of this section. Individual HAP partial pressures shall be calculated as specified in paragraph (d)(2)(i) of this section.

(*1*) Emissions from vapor displacement shall be calculated using Equation 11 of this subpart with T set equal to the temperature of the receiver and the HAP partial pressures determined at the temperature of the receiver.

(*2*) Emissions from purging shall be calculated using Equation 12 of this subpart with T set equal to the temperature of the receiver and the HAP partial pressures determined at the temperature of the receiver.

(*3*) Emissions from heating shall be calculated using either Equation 13 of this subpart or Equation 37 of this subpart. In Equation 13, the HAP vapor pressures shall be determined at the temperature of the receiver. In Equations 13 and 37 of this subpart, $\Delta\eta$ is equal to the number of moles of noncondensable displaced from the vessel, as calculated using Equation 15 of this subpart. In Equations 13 and 37 of this subpart, the HAP average molecular weight shall be calculated using Equation 17 with the HAP partial pressures determined at the temperature of the receiver.

$$E = \Delta\eta \times \frac{\sum_{i=1}^{n} P_i}{P_T - \sum_{j=1}^{m} P_j} \times MW_{HAP} \quad \text{(Eq. 37)}$$

Where:

E = mass of HAP emitted

$\Delta\eta$ = moles of noncondensable gas displaced

P_T = pressure in the receiver

P_i = partial pressure of the individual HAP at the receiver temperature

P_j = partial pressure of the individual condensable (including HAP) at the receiver temperature

n = number of HAP compounds in the emission stream

i = identifier for a HAP compound

MW_{HAP} = the average molecular weight of HAP in vapor exiting the receiver, as calculated using Equation 17 of this subpart

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

(*4*)(*i*) Emissions from depressurization shall be calculated using Equation 38 of this subpart.

$$E = \left(V_{nc1} - V_{nc2}\right) \times \frac{\sum_{i=1}^{n} \left(P_i\right)}{P_T - \sum_{j=1}^{m} \left(P_j\right)} \times \frac{P_T}{RT} \times MW_{HAP} \quad \text{(Eq. 38)}$$

Where:

E = mass of HAP vapor emitted

V_{nc1} = initial volume of noncondensable in the vessel, corrected to the final pressure, as calculated using Equation 39 of this subpart

V_{nc2} = final volume of noncondensable in the vessel, as calculated using Equation 40 of this subpart

P_i = partial pressure of each individual HAP at the receiver temperature

P_j = partial pressure of each condensable (including HAP) at the receiver temperature

P_T = receiver pressure

T = temperature of the receiver

R = ideal gas law constant

MW_{HAP} = the average molecular weight of HAP calculated using Equation 17 of this subpart with partial pressures determined at the receiver temperature

i = identifier for a HAP compound

n = number of HAP compounds in the emission stream

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

j = identifier for a condensable compound

(*ii*) The initial and final volumes of noncondensable gas present in the vessel, adjusted to the pressure of the receiver, are calculated using Equations 39 and 40 of this subpart.

$$V_{nc1} = \frac{VP_{nc_1}}{P_T} \quad \text{(Eq. 39)}$$

$$V_{nc2} = \frac{VP_{nc_2}}{P_T} \quad \text{(Eq. 40)}$$

Where:

V_{nc1} = initial volume of noncondensable gas in the vessel

V_{nc2} = final volume of noncondensable gas in the vessel

V = free volume in the vessel being depressurized

P_{nc1} = initial partial pressure of the noncondensable gas, as calculated using Equation 41 of this subpart

P_{nc2} = final partial pressure of the noncondensable gas, as calculated using Equation 42 of this subpart

P_T = pressure of the receiver

(*iii*) Initial and final partial pressures of the noncondensable gas in the vessel are determined using Equations 41 and 42 of this subpart.

$$P_{nc1} = P_1 - \sum_{j=1}^{m} P_j \quad \text{(Eq. 41)}$$

$$P_{nc2} = P_2 - \sum_{j=1}^{m} P_j \quad \text{(Eq. 42)}$$

Where:

P_{nc1} = initial partial pressure of the noncondensable gas in the vessel

P_{nc2} = final partial pressure of the noncondensable gas in the vessel

P_1 = initial vessel pressure

P_2 = final vessel pressure

P_j = partial pressure of each condensable compound (including HAP) in the vessel

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

j = identifier for a condensable compound

(*5*) Emissions from vacuum systems shall be calculated using Equation 33 of this subpart.

(*6*) Emissions from gas evolution shall be calculated using Equation 12 with V calculated using Equation 34 of this subpart, T set equal to the receiver temperature, and the HAP partial pressures determined at the receiver temperature. The term for time, t, in Equation 12 of this subpart is not needed for the purposes of this calculation.

(*7*) Emissions from air drying shall be calculated using Equation 11 of this subpart with V equal to the air flow rate and P_i determined at the receiver temperature.

(*8*) Emissions from empty vessel purging shall be calculated using equation 43 of this subpart:

$$E = \frac{V}{R}\left[\left(\sum_{i=1}^{n}\frac{(P_i)_{T_1}(MW_i)}{T_1}\right)\left(-e^{-Ft/V}\right)-\left(\sum_{i=1}^{n}\frac{(P_i)_{T_2}(MW_i)}{T_2}\right)\left(\ln\left(\frac{\sum_{i=1}^{n}(P_i)_{T_2}}{\sum_{i=1}^{n}(P_i)_{T_1}}\right)+1\right)\right] \qquad \text{(Eq. 43)}$$

Where:

V = volume of empty vessel
R = ideal gas law constant
T_1 = temperature of the vessel vapor space at beginning of purge
T_2 = temperature of the receiver, absolute
$(P_i)_{T1}$ = partial pressure of the individual HAP at the beginning of the purge
$(P_i)_{T2}$ = partial pressure of the individual HAP at the receiver temperature
MW_i = molecular weight of the individual HAP
F = flowrate of the purge gas
t = duration of the purge
n = number of HAP compounds in the emission stream
i = identifier for a HAP compound

(ii) *Large control devices.* Except for condensers, controlled emissions for each process vent that is controlled using a large control device shall be determined by applying the control efficiency of the large control device to the estimated uncontrolled emissions. The control efficiency shall be determined by conducting a performance test on the control device as described in paragraphs (d)(3)(ii)(A) through (C) of this section, or by using the results of a previous performance test as described in paragraph (d)(4) of this section. If the control device is intended to control only hydrogen halides and halogens, the owner or operator may assume the control efficiency of organic HAP is zero percent. If the control device is intended to control only organic HAP, the owner or operator may assume the control efficiency for hydrogen halides and halogen is zero percent. Owners and operators are not required to conduct performance tests for devices described in paragraphs (a)(4) and (d)(4) of this section that are large control devices, as defined in § 63.1251.

(A) The performance test shall be conducted by performing emission testing on the inlet and outlet, or, if complying with the provisions of § 63.1254(c), on the outlet of the control device, following the test methods and procedures of § 63.1257(b). Concentrations shall be calculated from the data obtained through emission testing according to the procedures in paragraph (a)(2) of this section. If the control device is a combustion device that uses supplemental combustion air, the concentrations shall be corrected to 3 percent oxygen according to the procedures in paragraph (a)(3) of this section.

(B) Performance testing shall be conducted under absolute, or hypothetical worst-case conditions, as defined in paragraphs (b)(8)(i)(A) through (B) of this section.

(C) The owner or operator may elect to conduct more than one performance test on the control device for the purpose of establishing more than one operating condition at which the control device achieves the required control efficiency.

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

(i) Any control device for which a previous performance test was conducted, provided the test was conducted using the same procedures specified in § 63.1257(b) over conditions typical of the appropriate worst-case, as defined in § 63.1257(b)(8)(i). The results of the previous performance test shall be used to demonstrate compliance.

(e) *Compliance with wastewater provisions.* (1) *Determining annual average concentration and annual load.* To determine the annual average concentration and annual load of partially soluble and/or soluble HAP compounds in a wastewater stream, as required by § 63.1256(a)(1), an owner or operator shall comply with the provisions in paragraphs (e)(1)(i) through (iii) of this section. A wastewater stream is exempt from the requirements of § 63.1256(a)(2) if the owner or operator determines the annual average concentration and annual load are below all of the applicability cutoffs specified in § 63.1256(a)(1)(i)(A) through (D). For annual average concentration, only initial rinses are included. Concentration measurements based on Method 305 shall be adjusted by dividing each concentration by the compound-specific Fm factor listed in Table 8 of this subpart. Concentration measurements based on methods other than Method 305 may not be adjusted by the compound-specific Fm factor listed in Table 8 of this subpart.

(i) *Annual average concentration definition.* (A) When complying with § 63.1256(a)(1)(i)(A), the annual average concentration means the total mass of partially soluble HAP compounds occurring in the wastewater stream during the calendar year divided by the total mass of the wastewater stream discharged during the same calendar year.

(B) When complying with § 63.1256(a)(1)(i) (B) or (C), the annual average concentration means the total mass of partially soluble and/or soluble HAP compounds occurring in the wastewater stream during the calendar year divided by the total mass of the wastewater stream discharged during the same calendar year.

(C) When complying with § 63.1256(a)(1)(i)(D), the annual average concentration means the total mass of soluble HAP compounds occurring in the wastewater stream during the calendar year divided by the total mass of the wastewater stream discharged during the same calendar year.

(ii) *Determination of annual average concentration.* An owner or operator shall determine annual average concentrations of partially soluble and/or soluble HAP compounds in accordance with the provisions specified in paragraph (e)(1)(ii)(A), (B), or (C) of this section. The owner or operator may determine annual average concentrations by process simulation. Data and other information supporting the simulation shall be reported in the Precompliance Report for approval by the Administrator. The annual average concentration shall be determined either at the POD or downstream of the POD with adjustment for concentration changes made according to paragraph (e)(1)(ii)(D) of this section.

(A) *Test methods.* The concentration of partially soluble HAP, soluble HAP, or total HAP shall be measured using any of the methods described in paragraphs (b)(10)(i) through (iv) of this section.

(B) *Knowledge of the wastewater stream.* The concentration of partially soluble HAP, soluble HAP, or total HAP shall be calculated based on knowledge of the wastewater stream according to the procedures in paragraphs (e)(1)(ii)(B)(*1*) and (*2*) of this section. The owner or operator shall document concentrations in the Notification of Compliance Status report described in § 63.1260(f).

(*1*) *Mass balance.* The owner or operator shall calculate the concentrations of HAP compounds in wastewater considering the total quantity of HAP discharged to the water, the amount of water at the POD, and the amounts of water and solvent lost to other mechanisms such as reactions, air emissions, or uptake in product or other processing materials. The quantities of HAP and water shall be based on batch sheets, manufacturing tickets, or FDA bills of materials. In cases where a chemical reaction occurs that generates or consumes HAP, the amount of HAP remaining after a reaction shall be based on stoichometry assuming 100 percent theoretical consumption or yield, as applicable.

(2) *Published water solubility data.* For single components in water, owners and operators may use the water solubilities published in standard reference texts at the POD temperature to determine maximum HAP concentration.

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

(D) *Adjustment for concentrations determined downstream of the POD.* The owner or operator shall make corrections to the annual average concentration when the concentration is determined downstream of the POD at a location where: two or more wastewater streams have been mixed; one or more wastewater streams have been treated; or, losses to the atmosphere have occurred. The owner or operator shall make the adjustments either to the individual data points or to the final annual average concentration.

(iii) *Determination of annual load.* An owner or operator shall calculate the partially soluble and/or soluble HAP load in a wastewater stream based on the annual average concentration determined in paragraph (e)(1)(ii) (A), (B), or (C) of this section and the total volume of the wastewater stream, based on knowledge of the wastewater stream in accordance with paragraphs (e)(1)(ii)(B) of this section. The owner or operator shall maintain records of the total liters of wastewater discharged per year as specified in § 63.1259(b).

(2) *Compliance with treatment unit control provisions.* (i) *Performance tests and design evaluations-general.* To comply with the control options in § 63.1256(g) (10) or (13), neither a design evaluation nor a performance test is required. For any other nonbiological treatment process, the owner or operator shall conduct either a design evaluation as specified in paragraph (e)(2)(ii) of this section, or a performance test as specified in paragraph (e)(2)(iii) of this section to demonstrate that each nonbiological treatment process used to comply with § 63.1256(g) (8), (9), and/or (12) achieves the conditions specified for compliance. The owner or operator shall demonstrate by the procedures in either paragraph (e)(2) (ii) or (iii) of this section that each closed biological treatment process used to comply with § 63.1256 (g)(8)(ii), (g)(9)(ii), (g)(11), or (g)(12) achieves the conditions specified for compliance. If an open biological treatment unit is used to comply with § 63.1256 (g)(8)(ii), (g)(9)(ii), (g)(11), or (g)(12), the owner or operator shall comply with the performance test requirements in paragraph (e)(2)(iii) of this section.

(ii) *Design evaluation.* A design evaluation and supporting documentation that addresses the operating characteristics of the treatment process and that is based on operation at a wastewater stream flow rate and a concentration under which it would be most difficult to demonstrate compliance. For closed biological treatment processes, the percent reduction from removal/destruction in the treatment unit and control device shall be determined by a mass balance over the unit. The mass flow rate of soluble and/or partially soluble HAP compounds exiting the treatment process shall be the sum of the mass flow rate of soluble and/or partially soluble HAP compounds in the wastewater stream exiting the biological treatment process and the mass flow rate of the vented gas stream exiting the control device. The mass flow rate entering the treatment process minus the mass flow rate exiting the process determines the actual mass removal. Compounds that meet the requirements specified in paragraph (e)(2)(iii)(A)(*4*) of this section are not required to be included in the design evaluation; the term ''performance test'' in paragraph (e)(2)(iii)(A)(*4*) of this section shall mean ''design evaluation'' for the purposes of this paragraph.

(iii) *Performance tests.* Performance tests shall be conducted using test methods and procedures that meet the applicable requirements specified in paragraphs (e)(2)(iii)(A) through (G) of this section.

(A) *General.* This paragraph specifies the general procedures for performance tests that are conducted to demonstrate compliance of a treatment process with the control requirements specified in § 63.1256(g).

(*1*) *Representative process unit operating conditions.* Compliance shall be demonstrated for representative operating conditions. Operations during periods of malfunction and periods of nonoperation shall not constitute representative conditions. The owner or operator shall record the process information that is necessary to document operating conditions during the test.

(*2*) *Representative treatment process operating conditions.* Performance tests shall be conducted when the treatment process is operating at a representative inlet flow rate and concentration. If the treatment process will be operating at several different sets of representative operating conditions, the owner or operator shall comply with paragraphs (e)(2)(iii)(A)(*2*)(*i*) and (*ii*) of this section. The owner or operator shall record information that is necessary to document treatment process or control device operating conditions during the test.

(*i*) *Range of operating conditions.* If the treatment process will be operated at several different sets of representative operating conditions, performance testing over the entire range is not required. In such cases, the performance test results shall be supplemented with modeling and/or engineering assessments to demonstrate performance over the operating range.

(*ii*) *Consideration of residence time.* If concentration and/or flow rate to the treatment process are not relatively constant (i.e., comparison of inlet and outlet data will not be representative of performance), the owner or operator shall consider residence time, when determining concentration and flow rate.

(*3*) *Testing equipment.* All testing equipment shall be prepared and installed as specified in the applicable test methods, or as approved by the Administrator.

(*4*) *Compounds not required to be considered in performance tests.* Compounds that meet the requirements specified in (e)(2)(iii)(A)(*4*)(*i*), (*ii*), or (*iii*) of this section are not required to be included in the performance test. Concentration measurements based on

Method 305 shall be adjusted by dividing each concentration by the compound-specific Fm factor listed in Table 8 of this subpart. Concentration measurements based on methods other than Method 305 shall not be adjusted by the compound-specific Fm factor listed in Table 8 of this subpart.

(*i*) Compounds not used or produced by the PMPU; or

(*ii*) Compounds with concentrations at the POD that are below 1 ppmw; or

(*iii*) Compounds with concentrations at the POD that are below the lower detection limit where the lower detection limit is greater than 1 ppmw. The method shall be an analytical method for wastewater which has the compound of interest as a target analyte.

(*5*) *Treatment using a series of treatment processes.* In all cases where the wastewater provisions in this subpart allow or require the use of a treatment process to comply with emissions limitations, the owner or operator may use multiple treatment processes. The owner or operator complying with the requirements of § 63.1256(g)(7)(i), when wastewater is conveyed by hard-piping, shall comply with either paragraph (e)(2)(iii)(A)(*5*)(*i*) or (*ii*) of this section. The owner or operator complying with the requirements of § 63.1256(g)(7)(ii) shall comply with the requirements of paragraph (e)(2)(iii)(A)(*5*)(*ii*) of this section.

(*i*) The owner or operator shall conduct the performance test across each series of treatment processes. For each series of treatment processes, inlet concentration and flow rate shall be measured either where the wastewater enters the first treatment process in a series of treatment processes, or prior to the first treatment process as specified in paragraph (e)(2)(iii)(A)(*6*) of this section. For each series of treatment processes, outlet concentration and flow rate shall be measured where the wastewater exits the last treatment process in the series of treatment processes, except when the last treatment process is an open or a closed aerobic biological treatment process demonstrating compliance by using the procedures in paragraphs (e)(2)(iii)(E) or (F) of this section. When the last treatment process is either an open or a closed aerobic biological treatment process demonstrating compliance by using the procedures in paragraphs (e)(2)(iii)(E) or (F) of this section, inlet and outlet concentrations and flow rates shall be measured at the inlet and outlet to the series of treatment processes prior to the biological treatment process and at the inlet to the biological treatment process, except as provided in paragraph (e)(2)(iii)(A)(6)(ii) of this section. The mass flow rate destroyed in the biological treatment process for which compliance is demonstrated using paragraph (e)(2)(iii)(E) or (F) of this section shall be added to the mass flow rate removed or destroyed in the series of treatment units before the biological treatment unit. This sum shall be used to calculate the overall control efficiency.

(*ii*) The owner or operator shall conduct the performance test across each treatment process in the series of treatment processes. The mass flow rate removed or destroyed by each treatment process shall be added together and the overall control efficiency calculated to determine whether compliance has been demonstrated using paragraphs (e)(2)(iii)(C), (D), (E), (F), or (G) of this section, as applicable. If a biological treatment process is one of the treatment processes in the series of treatment processes, the inlet to the biological treatment process shall be the point at which the wastewater enters the biological treatment process, or the inlet to the equalization tank if all the criteria of paragraph (e)(2)(iii)(A)(*6*)(*ii*) of this section are met.

(*6*) The owner or operator determining the inlet for purposes of demonstrating compliance with paragraph (e)(2)(iii)(E), or (F)of this section may elect to comply with paragraph (e)(2)(iii)(A)(*6*)(*i*) or (*ii*) of this section.

(*i*) When wastewater is conveyed exclusively by hard-piping from the point of determination to a treatment process that is either the only treatment process or the first in a series of treatment processes (i.e., no treatment processes or other waste management units are used upstream of this treatment process to store, handle, or convey the wastewater), the inlet to the treatment process shall be at any location from the point of determination to where the wastewater stream enters the treatment process. When samples are taken upstream of the treatment process and before wastewater streams have converged, the owner or operator shall ensure that the mass flow rate of all affected wastewater is accounted for when using § 63.1256(g)(8)(ii), (g)(9)(ii) or (g)(12) of this subpart to comply and that the mass flow rate of all wastewater, not just affected wastewater, is accounted for when using § 63.1256(g)(11) to comply, except as provided in paragraph (e)(2)(iii)(A)(*4*) of this section.

(*ii*) The owner or operator may consider the inlet to the equalization tank as the inlet to the biological treatment process if the wastewater is conveyed by hard-piping from either the last previous treatment process or the point of determination to the equalization tank; or the wastewater is conveyed from the equalization tank exclusively by hard-piping to the biological treatment process and no treatment processes or other waste management units are used to store, handle, or convey the wastewater between the equalization tank and the biological treatment process; or the equalization tank is equipped with a fixed roof and a closed-vent system that routes emissions to a control device that meets the requirements of § 63.1256(b)(1)(i) through (iv) and § 63.1256(b)(2)(i). The outlet from the series of treatment processes prior to the biological treatment process is the point at which the wastewater exits the last treatment process in the series prior to the equalization tank, if the equalization tank and biological treatment process are part of a series of treatment processes. The owner or operator shall ensure that the mass flow rate of all affected wastewater is accounted for when using § 63.1256(g)(9)(ii) or (12) to comply and that the mass flow rate of all wastewater, not just affected wastewater is accounted for when using § 63.1256(g)(11) to comply, except as provided in paragraph (e)(2)(iii)(A)(*4*) of this section.

(B) *Noncombustion treatment process—concentration limits.* This paragraph applies to performance tests that are conducted to demonstrate compliance of a noncombustion treatment process with the ppmw wastewater stream concentration limits at the outlet of the treatment process. This compliance option is specified in § 63.1256(g)(8)(i) and (9)(i). Wastewater samples shall be collected using sampling procedures which minimize loss of organic compounds during sample collection and analysis and maintain sample integrity per paragraph (b)(10)(iii) of this section. Samples shall be collected and analyzed using the procedures specified in paragraphs (b)(10)(i), (ii), and (iii) of this section. Samples may be grab samples or composite samples. Samples shall be taken at approximately equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of three runs. Concentration measurements based on methods other than Method 305 may be adjusted by multiplying each concentration by the compound-specific Fm factor listed in Table 8 of this subpart. (For affected wastewater streams that contains both partially soluble and soluble HAP compounds, compliance is

demonstrated only if the sum of the concentrations of partially soluble HAP compounds is less than 50 ppmw, and the sum of the concentrations of soluble HAP compounds is less than 520 ppmw.)

(C) *Noncombustion, nonbiological treatment process: percent mass removal/destruction option.* This paragraph applies to performance tests that are conducted to demonstrate compliance of a noncombustion, nonbiological treatment process with the percent mass removal limits specified in § 63.1256(g)(8)(ii) and (9)(ii) for partially soluble and soluble HAP compounds, respectively. The owner or operator shall comply with the requirements specified in paragraphs (e)(2)(iii)(C)(*1*) through (*5*) of this section.

(*1*) *Concentration.* The concentration of partially soluble and/or soluble HAP compounds entering and exiting the treatment process shall be determined as provided in this paragraph. Wastewater samples shall be collected using sampling procedures which minimize loss of organic compounds during sample collection and analysis and maintain sample integrity per paragraph (b)(10)(v) of this section. The method shall be an analytical method for wastewater which has the compound of interest as a target analyte. Samples may be grab samples or composite samples. Samples shall be taken at approximately equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of three runs. Concentration measurements based on Method 305 shall be adjusted by dividing each concentration by the compound-specific Fm factor listed in Table 8 of this subpart. Concentration measurements based on methods other than Method 305 shall not be adjusted by the compound-specific Fm factor listed in Table 8 of this subpart.

(*2*) *Flow rate.* The flow rate of the entering and exiting wastewater streams shall be determined using inlet and outlet flow meters, respectively. Where the outlet flow is not greater than the inlet flow, a single flow meter may be used, and may be used at either the inlet or outlet. Flow rate measurements shall be taken at the same time as the concentration measurements.

(*3*) *Calculation of mass flow rate—for noncombustion, nonbiological treatment processes.* The mass flow rates of partially soluble and/or soluble HAP compounds entering and exiting the treatment process are calculated using Equations 44 and 45 of this subpart.

$$QMW_a = \frac{\rho}{p * 10^6}\left(\sum_{k=1}^{p}\left(Q_{a,k} * C_{T,a,k}\right)\right) \qquad \text{(Eq. 44)}$$

$$QMW_b = \frac{\rho}{p * 10^6}\left(\sum_{k=1}^{p}\left(Q_{b,k} * C_{T,b,k}\right)\right) \qquad \text{(Eq. 45)}$$

Where:

QMW_a, QMW_b = mass flow rate of partially soluble or soluble HAP compounds, average of all runs, in wastewater entering (QMW_a) or exiting (QMW_b) the treatment process, kg/hr

P = density of the wastewater, kg/m^3

$Q_{a,k}$, $Qb_{b,k}$ = volumetric flow rate of wastewater entering ($Q_{a,k}$) or exiting ($Q_{b,k}$) the treatment process during each run k, m^3/hr

$C_{T,a,k}$, $C_{T,b,k}$ = total concentration of partially soluble or soluble HAP compounds in wastewater entering ($C_{T,a,k}$) or exiting ($C_{T,b,k}$) the treatment process during each run k, ppmw

p = number of runs

k = identifier for a run

10^6 = conversion factor, mg/kg

(*4*) *Percent removal calculation for mass flow rate.* The percent mass removal across the treatment process shall be calculated as follows:

$$E = \frac{QMW_a - QMW_b}{QMW_a} \times 100 \qquad \text{(Eq. 46)}$$

Where:

E = removal or destruction efficiency of the treatment process, percent

QMW_a, QMW_b = mass flow rate of partially soluble or soluble HAP compounds in wastewater entering (QMW_a) and exiting (QMW_b) the treatment process, kg/hr (as calculated using Equations 44 and 45 of this subpart)

(*5*) *Compare mass removal efficiency to required efficiency.* Compare the mass removal efficiency (calculated in Equation 44 of this subpart) to the required efficiency as specified in § 63.1256(g)(8)(ii) or (9)(ii). If complying with § 63.1256(g)(8)(ii), compliance is demonstrated if the mass removal efficiency is 99 percent or greater. If complying with § 63.1256(g)(9)(ii), compliance is demonstrated if the mass removal efficiency is 90 percent or greater.

(D) *Combustion treatment processes: percent mass removal/destruction option.* This paragraph applies to performance tests that are conducted to demonstrate compliance of a combustion treatment process with the percent mass destruction limits specified in § 63.1256(g)(8)(ii) for partially soluble HAP compounds, and/or § 63.1256(g)(9)(ii) for soluble HAP compounds. The owner or operator shall comply with the requirements specified in paragraphs (e)(2)(iii)(D)(*1*) through (*8*) of this section.

(*1*) *Concentration in wastewater stream entering the combustion treatment process.* The concentration of partially soluble and/or soluble HAP compounds entering the treatment process shall be determined as provided in this paragraph. Wastewater samples shall be collected using sampling procedures which minimize loss of organic compounds during sample collection and analysis and maintain sample integrity per paragraph (b)(10)(v) of this section. The method shall be an analytical method for wastewater which has the compound of interest as a target analyte. Samples may be grab samples or composite samples. Samples shall be taken at approximately equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of three runs. Concentration measurements based on Method 305 of appendix A of this part shall be adjusted by dividing each concentration by the compound-specific Fm factor listed in Table 8 of this subpart. Concentration measurements based on methods other than Method 305 shall not be adjusted by the compound-specific Fm factor listed in Table 8 of this subpart.

(*2*) *Flow rate of wastewater entering the combustion treatment process.* The flow rate of the wastewater stream entering the combustion treatment process shall be determined using an inlet flow meter. Flow rate measurements shall be taken at the same time as the concentration measurements.

(*3*) *Calculation of mass flow rate in wastewater stream entering combustion treatment processes.* The mass flow rate of partially soluble and/or soluble HAP compounds entering the treatment process is calculated as follows:

$$QMW_a = \frac{\rho}{p * 10^6}\left(\sum_{k=1}^{p}\left(Q_{a,k} * C_{T,a,k}\right)\right) \qquad \text{(Eq. 47)}$$

Where:

QMW_a = mass flow rate of partially soluble or soluble HAP compounds entering the combustion unit, kg/hr

π= density of the wastewater stream, kg/m3

$Q_{a,k}$ = volumetric flow rate of wastewater entering the combustion unit during run k, m^3/hr

$C_{T,a,k}$ = total concentration of partially soluble or soluble HAP compounds in the wastewater stream entering the combustion unit during run k, ppmw

ρ = number of runs

k = identifier for a run

(*4*) *Concentration in vented gas stream exiting the combustion treatment process.* The concentration of partially soluble and/or soluble HAP compounds (or TOC) exiting the combustion treatment process in any vented gas stream shall be determined as provided in this paragraph. Samples may be grab samples or composite samples. Samples shall be taken at approximately equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of three runs. Concentration measurements shall be determined using Method 18 of 40 CFR part 60, appendix A. Alternatively, any other test method validated according to the procedures in Method 301 of appendix A of this part may be used.

(*5*) *Volumetric flow rate of vented gas stream exiting the combustion treatment process.* The volumetric flow rate of the vented gas stream exiting the combustion treatment process shall be determined using Method 2, 2A, 2C, or 2D of 40 CFR part 60, appendix A, as appropriate. Volumetric flow rate measurements shall be taken at the same time as the concentration measurements.

(*6*) *Calculation of mass flow rate of vented gas stream exiting combustion treatment processes.* The mass flow rate of partially soluble and/or soluble HAP compounds in a vented gas stream exiting the combustion treatment process shall be calculated as follows:

$$QMG_b = K_2 * \left(\sum_{i=1}^{n}\left(CG_{b,i} * MW_i\right)\right) * QG_b \qquad \text{(Eq. 48)}$$

where:

QMG_b = mass rate of TOC (minus methane and ethane) or total partially soluble and/or soluble HAP, in vented gas stream, exiting (QMG_b) the combustion device, dry basis, kg/hr

$CG_{b,i}$ = concentration of TOC (minus methane and ethane) or total partially soluble and/or soluble HAP, in vented gas stream, exiting ($CG_{b,i}$) the combustion device, dry basis, ppmv

MW_i = molecular weight of a component, kilogram/kilogram-mole

QG_b = flow rate of gas stream exiting (QG_b) the combustion device, dry standard cubic meters per hour

K_2 = constant, 41.57 x 10^{-9} (parts per million)$^{-1}$ (gram-mole per standard cubic meter) (kilogram/gram), where standard temperature (gram-mole per standard cubic meter) is 20°C

i = identifier for a compound

n = number of components in the sample

(*7*) *Destruction efficiency calculation.* The destruction efficiency of the combustion unit for partially soluble and/or soluble HAP compounds shall be calculated as follows:

$$E = \frac{QMW_a - QMG_b}{QMW_a} * 100 \qquad \text{(Eq. 49)}$$

Where:

E = destruction efficiency of partially soluble or soluble HAP compounds for the combustion unit, percent

QMW^{2a} = mass flow rate of partially soluble or soluble HAP compounds entering the combustion unit, kg/hr

QMG_b = mass flow rate of TOC (minus methane and ethane) or partially soluble and/or soluble HAP compounds in vented gas stream exiting the combustion treatment process, kg/hr

(*8*) *Compare mass destruction efficiency to required efficiency.* Compare the mass destruction efficiency (calculated in Equation 49 of this subpart) to the required efficiency as specified in § 63.1256(g)(8)(ii) or (g)(9)(ii). If complying with § 63.1256(g)(8)(ii), compliance is demonstrated if the mass destruction efficiency is 99 percent or greater. If complying with § 63.1256(g)(9)(ii), compliance is demonstrated if the mass destruction efficiency is 90 percent or greater.

(E) *Open or closed aerobic biological treatment processes: 95-percent mass destruction option.* This paragraph applies to performance tests that are conducted for open or closed aerobic biological treatment processes to demonstrate compliance with the 95-percent mass destruction provisions in § 63.1256(g)(11) for partially soluble and/or soluble HAP compounds.

(*1*) *Concentration in wastewater stream.* The concentration of partially soluble and/or soluble HAP as provided in this paragraph. Concentration measurements to determine E shall be taken as provided in paragraph (e)(2)(iii)(A)(*5*) of this section for a series of treatment processes. Wastewater samples shall be collected using sampling procedures which minimize loss of organic compounds during sample collection and analysis and maintain sample integrity per paragraph (b)(10)(v) of this section. The method shall be an analytical method for wastewater which has the compound of interest as a target analyte. Samples may

be grab samples or composite samples. Samples shall be taken at approximately equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of three runs. Concentration measurements based on Method 305 shall be adjusted by dividing each concentration by the compound-specific Fm factor listed in Table 8 of this subpart. Concentration measurements based on methods other than Method 305 shall not be adjusted by the compound-specific Fm factor listed in Table 8 of this subpart.

(*2*) *Flow rate.* Flow rate measurements to determine E shall be taken as provided in paragraph (e)(2)(iii)(A)(*5*) of this section for a series of treatment processes. Flow rate shall be determined using inlet and outlet flow measurement devices. Where the outlet flow is not greater than the inlet flow, a single flow measurement device may be used, and may be used at either the inlet or outlet. Flow rate measurements shall be taken at the same time as the concentration measurements.

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

(*i*) If the performance test is performed across the open or closed biological treatment system only, compliance is demonstrated if E is equal to F_{bio}, where E is the destruction efficiency of partially soluble and/or soluble HAP compounds and F_{bio} is the site-specific fraction of partially soluble and/or soluble HAP compounds biodegraded. F_{bio} shall be determined as specified in paragraph (e)(2)(iii)(E)(*4*) of this section and appendix C of subpart G of this part.

(*ii*) If compliance is being demonstrated in accordance with paragraphs (e)(2)(iii)(A)(*5*)(*i*) or (*ii*) of this section, the removal efficiency shall be calculated using Equation 49 of this subpart. When complying with paragraph (e)(2)(iii)(A)(*5*)(*i*) of this section, the series of nonbiological treatment processes comprise one treatment process segment. When complying with paragraph (e)(2)(iii)(A)(*5*)(*ii*) of this section, each nonbiological treatment process is a treatment process segment.

$$E = \frac{\text{Nonbiotreatment HAP load removal} + \text{Biotreatment HAP load removal}}{\text{Total influent HAP load}} = \frac{\left(\sum_{i=1}^{n}\left(QMW_{a,i} - QMW_{b,i}\right)\right) + QMW_{bio} * F_{bio}}{QMW_{all}} \quad \text{(Eq. 50)}$$

Where:

$QMW_{a,i}$ = the soluble and/or partially soluble HAP load entering a treatment process segment

$QMW_{b,i}$ = the soluble and/or partially soluble HAP load exiting a treatment process segment

n = the number of treatment process segments

i = identifier for a treatment process element

QMW_{bio} = the inlet load of soluble and/or partially soluble HAP to the biological treatment process. The inlet is defined in accordance with paragraph (e)(2)(iii)(A)(*6*) of this section. If complying with paragraph (e)(2)(iii)(A)(*6*)(*ii*) of this section, QMW_{bio} is equal to $QMW_{b,n}$

F_{bio} = site-specific fraction of soluble and/or partially soluble HAP compounds biodegraded. F_{bio} shall be determined as specified in paragraph (e)(2)(iii)(E)(*4*) of this section and Appendix C of subpart G of this part.

QMW_{all} = the total soluble and/or partially soluble HAP load to be treated.

(*4*) *Site-specific fraction biodegraded (F_{bio}).* The procedures used to determine the compound-specific kinetic parameters for use in calculating F_{bio} differ for the compounds listed in Tables 2 and 3 of this subpart. An owner or operator shall calculate F_{bio} as specified in either paragraph (e)(2)(iii)(E)(*4*)(*i*) or (*ii*) of this section.

(*i*) For biological treatment processes that do not meet the definition for enhanced biological treatment in § 63.1251, the owner or operator shall determine the F_{bio} for the compounds in Tables 2 and 3 of this subpart using any of the procedures in appendix C to part 63, except procedure 3 (inlet and outlet concentration measurements). (The symbol ''F_{bio}'' represents the site-specific fraction of an individual partially soluble or soluble HAP compound that is biodegraded.)

(*ii*) If the biological treatment process meets the definition of ''enhanced biological treatment process'' in § 63.1251, the owner or operator shall determine F_{bio} for the compounds in Table 2 of this subpart using any of the procedures specified in appendix C to part 63. The owner or operator shall calculate F_{bio} for the compounds in Table 3 of this subpart using the defaults for first order biodegradation rate constants (K_1) in Table 9 of this subpart and follow the procedure explained in Form III of appendix C, 40 CFR part 63, or any of the procedures specified in appendix C of 40 CFR part 63.

(F) *Open or closed aerobic biological treatment processes: percent removal for partially soluble or soluble HAP compounds.* This paragraph applies to the use of performance tests that are conducted for open or closed aerobic biological treatment processes to demonstrate compliance with the percent removal provisions for either partially soluble HAP compounds in § 63.1256(g)(8)(ii) or soluble HAP compounds in § 63.1256(g)(9)(ii) or (g)(12). The owner or operator shall comply with the provisions in paragraph (e)(2)(iii)(E) of this section, except that compliance with § 63.1256(g)(8)(ii) shall be demonstrated when E is equal to or greater than 99 percent, compliance with § 63.1256(g)(9)(ii) shall be demonstrated when E is equal to or greater than 90 percent, and compliance with § 63.1256(g)(12) shall be demonstrated when E is equal to or greater than 99 percent.

(G) *Closed biological treatment processes: percent mass removal option.* This paragraph applies to the use of performance tests that are conducted for closed biological treatment processes to demonstrate compliance with the percent removal provisions in §§ 63.1256(g)(8)(ii), (g)(9)(ii), (g)(11), or (g)(12). The owner or operator shall comply with the requirements specified in paragraphs (e)(2)(iii)(G) (*1*) through (*4*) of this section.

(*1*) Comply with the procedures specified in paragraphs (e)(2)(iii)(C) (*1*) through (*3*) of this section to determine characteristics of the wastewater entering the biological treatment unit, except that the term ''partially soluble and/or soluble HAP'' shall mean ''soluble HAP'' for the purposes of this section if the owner or operator is complying with § 63.1256(g)(9)(ii) or (g)(12), and it shall mean ''partially

soluble HAP'' if the owner or operator is complying with § 63.1256(g)(8)(ii).

(*2*) Comply with the procedures specified in paragraphs (e)(2)(iii)(D) (*4*) through (*6*) of this section to determine the characteristics of gas vent streams exiting a control device, with the differences noted in paragraphs (e)(2)(iii)(G)(*3*) (*i*) and (*ii*) of this section.

(*i*) The term ''partially soluble and/or soluble HAP'' shall mean ''soluble HAP'' for the purposes of this section if the owner or operator is complying with § 63.1256(g)(9)(ii) or (g)(12), and it shall mean ''partially soluble HAP'' if the owner or operator is complying with § 63.1256(g)(8)(ii).

(*ii*) The term ''combustion treatment process'' shall mean ''control device'' for the purposes of this section.

(*3*) *Percent removal/destruction calculation.* The percent removal and destruction across the treatment unit and any control device(s) shall be calculated using Equation 51 of this subpart:

$$E = \frac{\left(QMW_a - \left(QMW_b + QMG_b\right)\right)}{QMW_a} \qquad \text{(Eq. 51)}$$

Where:

E = removal and destruction efficiency of the treatment unit and control device(s), percent

QMW_a, QMW_b = mass flow rate of partially soluble or soluble HAP compounds in wastewater entering (QMW_a) and exiting (QMW_b) the treatment process, kilograms per hour (as calculated using Equations WW1 and WW2)

QMG_b = mass flow rate of partially soluble or soluble HAP compounds in vented gas stream exiting the combustion treatment process, kg/hr

(*4*) *Compare mass removal/destruction efficiency to required efficiency.* Compare the mass removal/destruction efficiency (calculated using Equation 51 of this subpart) to the required efficiency as specified in § 63.1256(g)(8)(ii), (g)(9)(ii), (g)(11), or (g)(12). If complying with § 63.1256(g)(8)(ii), compliance is demonstrated if the mass removal/destruction is 99 percent or greater. If complying with § 63.1256(g)(9)(ii), compliance is demonstrated if the mass removal/destruction efficiency is 90 percent or greater. If complying with § 63.1256(g)(11), compliance is demonstrated if the mass removal/destruction efficiency is 95 percent or greater. If complying with § 63.1256(g)(12), compliance is demonstrated if the mass removal/destruction efficiency is 99 percent or greater.

(3) *Compliance with control device provisions.* Except as provided in paragraph (e)(3)(iv) of this section, an owner or operator shall demonstrate that each control device or combination of control devices achieves the appropriate conditions specified in § 63.1256(h)(2) by using one or more of the methods specified in paragraphs (e)(3)(i), (ii), or (iii) of this section.

(i) *Performance test for control devices other than flares.* This paragraph applies to performance tests that are conducted to demonstrate compliance of a control device with the efficiency limits specified in § 63.1256(h)(2). If complying with the 95-percent reduction efficiency requirement, comply with the requirements specified in paragraphs (e)(3)(i) (A) through (J) of this section. If complying with the 20 ppm by volume requirement, comply with the requirements specified in paragraphs (e)(3)(i) (A) through (G) and (e)(3)(i)(J) of this section.

(A) *General.* The owner or operator shall comply with the general performance test provisions in paragraphs (e)(2)(iii)(A) (*1*) through (*4*) of this section, except that the term ''treatment unit'' shall mean ''control device'' for the purposes of this section.

(B) *Sampling sites.* Sampling sites shall be selected using Method 1 or 1A of 40 CFR part 60, appendix A, as appropriate. For determination of compliance with the 95 percent reduction requirement, sampling sites shall be located at the inlet and the outlet of the control device. For determination of compliance with the 20 ppmv limit, the sampling site shall be located at the outlet of the control device.

(C) *Concentration in gas stream entering or exiting the control device.* The concentration of total organic HAP or TOC in a gas stream shall be determined as provided in this paragraph. Samples may be grab samples or composite samples (i.e., integrated samples). Samples shall be taken at approximately equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of three runs. Concentration measurements shall be determined using Method 18 of 40 CFR part 60, appendix A. Alternatively, any other test method validated according to the procedures in Method 301 of appendix A of this part may be used.

(D) *Volumetric flow rate of gas stream entering or exiting the control device.* The volumetric flow rate of the gas stream shall be determined using Method 2, 2A, 2C, or 2D of 40 CFR part 60, appendix A, as appropriate. Volumetric flow rate measurements shall be taken at the same time as the concentration measurements.

(E) *Calculation of TOC concentration.* The owner or operator shall compute TOC in accordance with the procedures in paragraph (a)(2) of this section.

(F) *Calculation of total organic HAP concentration.* The owner or operator determining compliance based on total organic HAP concentration shall compute the total organic HAP concentration in accordance with the provisions in paragraph (a)(2) of this section.

(G) *Requirements for combustion control devices.* If the control device is a combustion device, the owner or operator shall correct TOC and organic HAP concentrations to 3 percent oxygen in accordance with the provisions in paragraph (a)(3) of this section, and demonstrate initial compliance with the requirements for halogenated streams in accordance with paragraph (a)(6) of this section.

(H) *Mass rate calculation.* The mass rate of either TOC (minus methane and ethane) or total organic HAP for each sample run shall be calculated using the following equations. Where the mass rate of TOC is being calculated, all organic compounds (minus methane and ethane) measured by methods specified in paragraph (e)(3)(i)(C) of this section are summed using Equations 52 and 53 of this subpart. Where the mass rate of total organic HAP is being calculated, only soluble and partially soluble HAP compounds shall be summed using Equations 52 and 53.

$$QMG_a = K_2 * \left(\sum_{i=1}^{n} \left(CG_{a,i} \right) * \left(MW_i \right) \right) * QG_a \qquad \text{(Eq. 52)}$$

$$QMG_b = K_2 * \left(\sum_{i=1}^{n} \left(CG_{b,i} \right) * \left(MW_i \right) \right) * QG_b \qquad \text{(Eq. 53)}$$

Where:

$CG_{a,i}$, $CG_{b,i}$ = concentration of TOC or total organic HAP, in vented gas stream, entering ($CG_{a,i}$) and exiting ($CG_{b,i}$) the control device, dry basis, ppmv

QMG_a, QMG_b = mass rate of TOC or total organic HAP, in vented gas stream, entering (QMG_a) and exiting (QMG_b) the control device, dry basis, kg/hr

M_{wi} = molecular weight of a component, kilogram/kilogram-mole

QG_a,QG_b = flow rate of gas stream entering (QG_a) and exiting (QG_b) the control device, dry standard cubic meters per hour

K_2 = constant, 41.57×10^{-9} (parts per million)$^{-1}$ (gram-mole per standard cubic meter) (kilogram/gram), where standard temperature (gram-mole per standard cubic meter) is 20°C

i = identifier for a compound

n = number of components in the sample

(I) *Percent reduction calculation.* The percent reduction in TOC or total organic HAP for each sample run shall be calculated using Equation 54 of this subpart:

$$E = \frac{QMG_a - QMG_b}{QMG_a} (100\%) \qquad \text{(Eq. 54)}$$

where:

E = destruction efficiency of control device, percent

QMG_a,QMG_b = mass rate of TOC or total organic HAP, in vented gas stream entering and exiting (QMG_b) the control device, dry basis, kilograms per hour

(J) *Compare mass destruction efficiency to required efficiency.* If complying with the 95-percent reduction efficiency requirement, compliance is demonstrated if the mass destruction efficiency (calculated in Equation 51 of this subpart) is 95 percent or greater. If complying with the 20 ppmv limit, compliance is demonstrated if the outlet TOC concentration is 20 ppmv, or less.

(ii) *Design evaluation.* A design evaluation conducted in accordance with the provisions in paragraph (a)(1) of this section. Compounds that meet the requirements specified in paragraph (e)(2)(iii)(A)(4) of this section are not required to be included in the design evaluation.

(iii) *Compliance demonstration for flares.* When a flare is used to comply with § 63.1256(h), the owner or operator shall comply with the flare provisions in § 63.11(b). An owner or operator is not required to conduct a performance test to determine percent emission reduction or outlet organic HAP or TOC concentration when a flare is used.

(iv) *Exemptions from compliance demonstrations.* An owner or operator using any control device specified in paragraph (a)(4) of this section is exempt from the requirements in paragraphs (e)(3)(i) through (e)(3)(iii) of this section and from the requirements in § 63.6(f).

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

(1) Compliance is demonstrated when the annual kg/kg factor, calculated according to the procedure in paragraphs (f)(1)(i) and (iii) of this section, is reduced by at least 75 percent as calculated according to the procedure in paragraph (f)(1)(i) and (ii) of this section.

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

(ii) The baseline factor is calculated from yearly production and consumption data for the first 3-year period in which the PMPU was operational, beginning no earlier than the 1987 calendar year, or for a minimum period of 12 months from startup of the process until the present in which the PMPU was operational and data are available, beginning no earlier than the 1987 calendar year.

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

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

(B) For batch processes, the annual factor shall be calculated every 10 batches for the 12-month period preceding the 10th batch (10-batch rolling average). The annual factor shall be calculated every 5 batches if the number of batches is less than 10 for the 12-month period preceding the 10th batch and shall be calculated every year if the number of batches is less than 5 for the 12-month period preceding the 5th batch.

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

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

(ii) The yearly reductions associated with add-on controls that meet the criteria of §§ 63.1252(h)(3)(ii)(A) through (D) must be equal to or greater than the amounts calculated in paragraphs (f)(2)(ii)(A) and (B) of this section:

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

$$[\text{kg reduced}]_a = [\text{kg/kg}]_b(0.75 - P_R)[\text{kg produced}]_a \quad \text{(Eq. 55)}$$

Where:

$[\text{kg/kg}]_b$ = the baseline production-indexed HAP consumption factor, in kg/kg

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

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

P_R = the fractional reduction in the annual kg/kg factor achieved using pollution prevention where P_R is ≥0.5

(B) The mass of VOC calculated using Equation 56 of this subpart:

$$VOC_{reduced} = (VF_{base} - VF_P - VF_{annual}) \times M_{prod} \quad \text{(Eq. 56)}$$

Where:

$VOC_{reduced}$ = required VOC emission reduction from add-on controls, kg/yr

VF_{base} = baseline VOC factor, kg VOC emitted/kg production

VF_p = reduction in VOC factor achieved by pollution prevention, kg VOC emitted/kg production

VF_{annual} = target annual VOC factor, kg VOC emitted/kg production

M_{prod} = production rate, kg/yr

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

(iv) The annual reduction achieved by the add-on control shall be quantified using the methods described in § 63.1257(d).

(3) Each owner or operator of a PMPU complying with the P2 standard shall prepare a P2 demonstration summary that shall contain, at a minimum, the following information:

(i) Descriptions of the methodologies and forms used to measure and record daily consumption of HAP compounds reduced as part of the P2 standard.

(ii) Descriptions of the methodologies and forms used to measure and record daily production of products which are included in the P2 standard.

(iii) Supporting documentation for the descriptions provided in paragraphs (f)(3)(i) and (ii) including, but not limited to, operator log sheets and copies of daily, monthly, and annual inventories of materials and products.

(g) *Compliance with storage tank provisions by using emissions averaging.* An owner or operator with two or more affected storage tanks may demonstrate compliance with § 63.1253, as applicable, by fulfilling the requirements of paragraphs (g)(1) through (4) of this section.

(1) The owner or operator shall develop and submit for approval an Implementation Plan containing all the information required in § 63.1259(e) 6 months prior to the compliance date of the standard. The Administrator shall have 90 days to approve or disapprove the emissions averaging plan after which time the plan shall be considered approved.

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

(3) Equations 57 and 58 of this subpart shall be used to calculate total HAP emissions for those tanks subject to § 63.1253(b) or (c):

$$E_{Ti} = \sum_{j=1}^{n} E_{ij} \quad \text{(Eq. 57)}$$

$$E_{To} = \sum_{j=1}^{n} E_{oj} \quad \text{(Eq. 58)}$$

Where:

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

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

ET_i = total yearly uncontrolled HAP emissions

E_{To} = total yearly actual HAP emissions

$_n$ = number of tanks included in the emissions average

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

$$R = \frac{E_{Ti} - D\,E_{To}}{E_{Ti}} 100\% \quad \text{(Eq. 59)}$$

where:

R = overall percent reduction efficiency

D = discount factor = 1.1 for all controlled storage tanks

(h) *Compliance with process vent provisions by using emissions averaging.* An owner or operator with two or more affected processes complying with § 63.1254 by using emissions averaging shall demonstrate compliance with paragraphs (h)(1), (2) and (3) of this section.

(1) The owner or operator shall develop and submit for approval an Implementation Plan at least 6 months prior to the compliance date of the standard containing all the information required in § 63.1259(e). The Administrator shall have 90 days to approve or disapprove the emissions averaging plan. The plan shall be considered approved if the Administrator either approves the plan in writing, or fails to disapprove the plan in writing. The 90-day period shall begin when the Administrator receives the request. If the request is denied, the owner or operator must still be in compliance with the standard by the compliance date.

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

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

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

where:

E_{Ui} = yearly uncontrolled emissions from process I

E_{Ci} = yearly actual emissions for process I

E_{TU} = total yearly uncontrolled emissions

E_{TC} = total yearly actual emissions

n = number of processes included in the emissions average

(3) The overall percent reduction efficiency shall be calculated using Equation 62 of this subpart:

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

$$R = \frac{E_{TU} - D\,E_{TC}}{E_{TU}}\,(100\%) \qquad \text{(Eq. 62)}$$

where:
R = overall percent reduction efficiency
D = discount factor = 1.1 for all controlled emission points

§ 63.1258 Monitoring Requirements.

(a) The owner or operator of any existing, new, or reconstructed affected source shall provide evidence of continued compliance with the standard as specified in this section. During the initial compliance demonstration, maximum or minimum operating parameter levels, as appropriate, shall be established for emission sources that will indicate the source is in compliance. Test data, calculations, or information from the evaluation of the control device design shall be used to establish the operating parameter level.

(b) *Monitoring for control devices.* (1) *Parameters to monitor.* Except as specified in paragraph (b)(1)(i) of this section, for each control device, the owner or operator shall install and operate monitoring devices and operate within the established parameter levels to ensure continued compliance with the standard. Monitoring parameters are specified for control scenarios in Table 4 of this subpart and in paragraphs (b)(1)(ii) through (xi) of this section.

(i) *Periodic verification.* For control devices that control vent streams totaling less than 1 ton/yr HAP emissions, before control, monitoring shall consist of a daily verification that the device is operating properly. If the control device is used to control batch process vents alone or in combination with other streams, the verification may be on a per batch basis. This verification shall include, but not be limited to, a daily or per batch demonstration that the unit is working as designed and may include the daily measurements of the parameters described in (b)(1)(ii) through (x) of this section. This demonstration shall be included in the Precompliance report, to be submitted 6 months prior to the compliance date of the standard.

(ii) *Scrubbers.* For affected sources using liquid scrubbers, the owner or operator shall establish a minimum scrubber liquid flow rate or pressure drop as a site-specific operating parameter which must be measured and recorded every 15 minutes during the period in which the scrubber is functioning in achieving the HAP removal required by this subpart. If the scrubber uses a caustic solution to remove acid emissions, the owner or operator shall establish a minimum pH of the effluent scrubber liquid as a site-specific operating parameter which must be monitored at least once a day. The minimum scrubber flowrate or pressure drop shall be based on the conditions anticipated under worst-case conditions, as defined in § 63.1257(b)(8)(i).

(A) The monitoring device used to determine the pressure drop shall be certified by the manufacturer to be accurate to within a gage pressure of ±10 percent of the maximum pressure drop measured.

(B) The monitoring device used for measurement of scrubber liquid flowrate shall be certified by the manufacturer to be accurate within ±10 percent of the design scrubber liquid flowrate.

(C) The monitoring device shall be calibrated annually.

(iii) *Condensers.* For each condenser, the owner or operator shall establish the maximum condenser outlet gas temperature as a site-specific operating parameter which must be measured and recorded at least every 15 minutes during the period in which the condenser is functioning in achieving the HAP removal required by this subpart.

(A) The temperature monitoring device must be accurate to within ±2 percent of the temperature measured in degrees Celsius or ±2.5°C, whichever is greater.

(B) The temperature monitoring device must be calibrated annually.

(iv) *Regenerative carbon adsorbers.* For each regenerative carbon adsorber, the owner or operator shall comply with the provisions in paragraphs (b)(1)(iv)(A) through (F) of this section.

(A) Establish the regeneration cycle characteristics specified in paragraphs (b)(1)(iv)(A)(*1*) through (*4*) of this section under worst-case conditions, as defined in § 63.1257(b)(8)(i).

(*1*) Minimum regeneration frequency (i.e., operating time since last regeneration);

(*2*) Minimum temperature to which the bed is heated during regeneration;

(*3*) Maximum temperature to which the bed is cooled, measured within 15 minutes of completing the cooling phase; and

(*4*) Minimum regeneration stream flow.

(B) Monitor and record the regeneration cycle characteristics specified in paragraphs (b)(1)(iv)(B)(*1*) through (*4*) of this section for each regeneration cycle.

(*1*) Regeneration frequency (operating time since end of last regeneration);

(*2*) Temperature to which the bed is heated during regeneration;

(*3*) Temperature to which the bed is cooled, measured within 15 minutes of the completion of the cooling phase; and

(*4*) Regeneration stream flow.

(C) Use a temperature monitoring device that is accurate to within ±2 percent of the temperature measured in degrees Celsius or ± 2.5 °C, whichever is greater.

(D) Use a regeneration stream flow monitoring device capable of recording the total regeneration stream flow to within ± 10 percent of the established value (i.e., accurate to within ± 10 percent of the reading).

(E) Calibrate the temperature and flow monitoring devices annually.

(F) Conduct an annual check for bed poisoning in accordance with manufacturer's specifications.

(v) *Nonregenerative carbon adsorbers.* For each nonregenerative carbon adsorber, the owner or operator shall establish and monitor the maximum time interval between replacement based on the conditions anticipated under worst-case, as defined in § 63.1257(b)(8)(i).

(vi) *Flares.* For each flare, the presence of the pilot flame shall be monitored every 15 minutes during the period in which the flare is functioning in achieving the HAP removal required by this subpart.

(vii) *Thermal incinerators.* For each thermal incinerator, the owner or operator shall establish the minimum temperature of the gases exiting the combustion chamber as the site-specific operating parameter which must be measured and recorded at least once every 15 minutes during the period in which the combustion device is functioning in achieving the HAP removal required by this subpart.

(A) The temperature monitoring device must be accurate to within ± 0.75 percent of the temperature measured in degrees Celsius or ± 2.5 °C, whichever is greater.

(B) The monitoring device must be calibrated annually.

(viii) *Catalytic incinerators.* For each catalytic incinerator, the owner or operator shall monitor the temperature of the gas stream immediately before and after the catalyst bed. The owner or operator shall establish the minimum temperature of the gas stream immediately before the catalyst bed and the minimum temperature difference across the catalyst bed as the site-specific operating parameter which must be monitored and recorded at least

once every 15 minutes during the period in which the catalytic incinerator is functioning in achieving the HAP removal required by this subpart.

(A) The temperature monitoring devices must be accurate to within ± 0.75 percent of the temperature measured in degrees Celsius or ± 2.5 °C, whichever is greater.

(B) The temperature monitoring devices must be calibrated annually.

(ix) *Process heaters and boilers.* (A) Except as specified in paragraph (b)(1)(ix)(B) of this section, for each boiler or process heater, the owner or operator shall establish the minimum temperature of the gases exiting the combustion chamber as the site-specific operating parameter which must be monitored and recorded at least once every 15 minutes during the period in which the boiler or process heater is functioning in achieving the HAP removal required by this subpart.

(*1*) The temperature monitoring device must be accurate to within ±0.75 percent of the temperature measured in degrees Celsius or ±2.5°C, whichever is greater.

(*2*) The temperature monitoring device must be calibrated annually.

(B) The owner or operator is exempt from the monitoring requirements specified in paragraph (b)(1)(ix)(A) of this section if either:

(*1*) All vent streams are introduced with primary fuel; or

(*2*) The design heat input capacity of the boiler or process heater is 44 megawatts or greater.

(x) *Continuous emission monitor.* As an alternative to the parameters specified in paragraphs (b)(1)(ii) through (ix) of this section, an owner or operator may monitor and record the outlet HAP concentration or both the outlet TOC concentration and outlet hydrogen halide and halogen concentration every 15 minutes during the period in which the control device is functioning in achieving the HAP removal required by this subpart. The owner or operator need not monitor the hydrogen halide and halogen concentration if, based on process knowledge, the owner or operator determines that the emission stream does not contain hydrogen halides or halogens. The HAP or TOC monitor must meet the requirements of Performance Specification 8 or 9 of appendix B of part 60 and must be installed, calibrated, and maintained, according to § 63.8. As part of the QA/QC Plan, calibration of the device must include, at a minimum, quarterly cylinder gas audits.

(xi) *CVS visual inspections.* The owner or operator shall perform monthly visual inspections of each closed vent system as specified in § 63.1252(b).

(2) *Averaging periods.* Averaging periods for parametric monitoring levels shall be established according to paragraphs (b)(2)(i) through (iii) of this section.

(i) Except as provided in paragraph (b)(2)(iii) of this section, a daily (24-hour) or block average shall be calculated as the average of all values for a monitored parameter level set according to the procedures in (b)(3)(iii) of this section recorded during the operating day or block.

(ii) The operating day or block shall be defined in the Notification of Compliance Status report. The daily average may be from midnight to midnight or another continuous 24-hour period. The block average is limited to a period of time that is, at a maximum, equal to the time from the beginning to end of a batch process.

(iii) Monitoring values taken during periods in which the control devices are not functioning in controlling emissions, as indicated by periods of no flow, shall not be considered in the averages. Where flow to the device could be intermittent, the owner or operator shall install, calibrate and operate a flow indicator at the inlet or outlet of the control device to identify periods of no flow.

(3) *Procedures for setting parameter levels for control devices used to control emissions from process vents.* (i) *Small control devices.* Except as provided in paragraph (b)(1)(i) of this section, for devices controlling less than 10 tons per year of HAP for which a performance test is not required, the parametric levels shall be set based on the design evaluation required in § 63.1257(d)(3)(i). If a performance test is conducted, the monitoring parameter level shall be established according to the procedures in (b)(3)(ii) of this section.

(ii) *Large control devices.* For devices controlling greater than 10 tons per year of HAP for which a performance test is required, the parameter level must be established as follows:

(A) If the operating parameter level to be established is a maximum, it must be based on the average of the values from each of the three test runs.

(B) If the operating parameter level to be established is a minimum, it must be based on the average of the values from each of the three test runs.

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

(iii) *Parameters for control devices controlling batch process vents.* For devices controlling batch process vents alone or in combination with other streams, the parameter level(s) shall be established in accordance with paragraph (b)(3)(iii)(A) or (B) of this section.

(A) If more than one batch emission episode has been selected to be controlled, a single level for the batch process(es) shall be determined from the initial compliance demonstration.

(B) Instead of establishing a single level for the batch process(es), as described in paragraph (b)(3)(iii)(A) of this section, an owner or operator may establish separate levels for each batch emission episode, selected to be controlled. If separate monitoring levels are established, the owner or operator must provide a record indicating at what point in the daily schedule or log of processes required to be recorded per the requirements of § 63.1259(b)(9) the parameter being monitored changes levels and must record at least one reading of the new parameter level, even if the duration of monitoring for the new parameter is less than 15-minutes.

(4) *Request approval to monitor alternative parameters.* An owner or operator may request approval to monitor parameters other than those required by paragraphs (b)(1)(ii) through (ix) of this section. The request shall be submitted according to the procedures specified in § 63.8(f) or included in the Precompliance report.

(5) *Monitoring for the alternative standards.* For control devices that are used to comply with the provisions of § 63.1253(d) or 63.1254(c), the owner or operator shall monitor and record the outlet TOC concentration and the outlet hydrogen halide and halogen concentration every 15 minutes during the period in which the device is functioning in achieving the HAP removal required by this subpart. A TOC monitor meeting the requirements of Performance Specification 8 or 9 of appendix B of part 60 shall be installed, calibrated, and maintained, according to § 63.8. The owner or operator need not

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

(6) *Exceedances of operating parameters.* An exceedance of an operating parameter is defined as one of the following:

(i) If the parameter, averaged over the operating day or block, is below a minimum value established during the initial compliance demonstration.

(ii) If the parameter, averaged over the operating day or block, is above the maximum value established during the initial compliance demonstration.

(iii) Each loss of pilot flame for flares.

(7) *Excursions.* Excursions are defined by either of the two cases listed in paragraphs (b)(7)(i) or (ii) of this section.

(i) When the period of control device operation is 4 hours or greater in an operating day and monitoring data are insufficient to constitute a valid hour of data, as defined in paragraph (b)(7)(iii) of this section, for at least 75 percent of the operating hours.

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

(iii) Monitoring data are insufficient to constitute a valid hour of data, as used in paragraphs (b)(7)(i) and (ii) of this section, if measured values are unavailable for any of the required 15-minute periods within the hour.

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

(i) Except as provided in paragraph (b)(8)(iv) of this section, for episodes occurring more than once per day, exceedances of established parameter limits or excursions will result in no more than one violation per operating day for each monitored item of equipment utilized in the process.

(ii) Except as provided in paragraph (b)(8)(iv) of this section, for control devices used for more than one process in the course of an operating day, exceedances or excursions will result in no more than one violation per operating day, per control device, for each process for which the control device is in service.

(iii) Except as provided in paragraph (b)(8)(iv) of this section, exceedances of the 20 ppmv TOC outlet emission limit, averaged over the operating day, will result in no more than one violation per day per control device. Except as provided in paragraph (b)(8)(iv) of this section, exceedances of the 20 ppmv hydrogen halide or halogen outlet emission limit, averaged over the operating day, will result in no more than one violation per day per control device.

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

(c) *Monitoring for emission limits.* The owner or operator of any affected source complying with the provisions of § 63.1254(a)(1) shall demonstrate continuous compliance with the 2,000 lb/yr emission limits by calculating daily a 365-day rolling summation of emissions. For owners and operators opting to switch compliance strategy from the 93 percent control requirement to the 2,000 lb/yr compliance method, as decribed in § 63.1254(a), the rolling average must include emissions from the past 365 days. Each day that the total emissions per process exceeds 2,000 lb/yr will be considered a violation of the emission limit.

(d) *Monitoring for equipment leaks.* The owner or operator of any affected source complying with the requirements of § 63.1255 of this subpart shall meet the monitoring requirements described § 63.1255 of this subpart.

(e) *Pollution prevention.* The owner or operator of any affected source that chooses to comply with the requirements of §§ 63.1252(e)(2) and (3) shall calculate a yearly rolling average of kg HAP consumption per kg production and kg VOC consumption per kg production every month or every 10 batches. Each rolling average kg/kg factor that exceeds the value established in § 63.1257(f)(1)(ii) will be considered a violation of the emission limit.

(f) *Emissions averaging.* The owner or operator of any affected source that chooses to comply with the requirements of § 63.1252(d) shall meet all monitoring requirements specified in paragraphs (b)(1) and (3) of this section, as applicable, for all processes and storage tanks included in the emissions average.

(g) *Inspection and monitoring of waste management units and treatment processes.* (1) For each wastewater tank, surface impoundment, container, individual drain system, and oil-water separator that receives, manages, or treats wastewater, a residual removed from wastewater, a recycled wastewater, or a recycled residual removed from wastewater, the owner or operator shall comply with the inspection requirements specified in Table 7 of this subpart.

(2) For each biological treatment unit used to comply with § 63.1256(g), the owner or operator shall monitor TSS, BOD, and the biomass concentration at a frequency approved by the permitting authority and using methods approved by the permitting authority. The owner or operator may request approval to monitor other parameters. The request shall be submitted in the Precompliance report according to the procedures specified in § 63.1260(e), and shall include a description of planned reporting and recordkeeping procedures. The owner or operator shall include as part of the submittal the basis for the selected monitoring frequencies and the methods that will be used. The Administrator will specify appropriate reporting and recordkeeping requirements as part of the review of the permit application or by other appropriate means.

(3) For nonbiological treatment units, the owner or operator shall request approval to monitor appropriate parameters that demonstrate proper operation of the selected treatment process. The request shall be submitted in the Precompliance report according to the procedures specified in § 63.1260(e), and shall include a description of planned reporting and recordkeeping procedures. The Administrator will specify appropriate reporting and recordkeeping requirements as part of the review of the permit application or by other appropriate means.

(h) *Leak inspection provisions for vapor suppression equipment.* (1) Except as provided in paragraph (h)(9) of this section, for each vapor collection system, closed-vent system, fixed roof, cover, or enclosure required to comply

with this section, the owner or operator shall comply with the requirements of paragraphs (h)(2) through (8) of this section.

(2) Except as provided in paragraphs (h)(6) and (7) of this section, each vapor collection system and closed-vent system shall be inspected according to the procedures and schedule specified in paragraphs (h)(2)(i) and (ii) of this section and each fixed roof, cover, and enclosure shall be inspected according to the procedures and schedule specified in paragraph (h)(2)(iii) of this section.

(i) If the vapor collection system or closed-vent system is constructed of hard-piping, the owner or operator shall:

(A) Conduct an initial inspection according to the procedures in paragraph (h)(3) of this section, and

(B) Conduct annual visual inspections for visible, audible, or olfactory indications of leaks.

(ii) If the vapor collection system or closed-vent system is constructed of ductwork, the owner or operator shall:

(A) Conduct an initial inspection according to the procedures in paragraph (h)(3) of this section, and

(B) Conduct annual inspections according to the procedures in paragraph (h)(3) of this section.

(C) Conduct annual visual inspections for visible, audible, or olfactory indications of leaks.

(iii) For each fixed roof, cover, and enclosure, the owner or operator shall:

(A) Conduct an initial inspection according to the procedures in paragraph (h)(3) of this section, and

(B) Conduct semiannual visual inspections for visible, audible, or olfactory indications of leaks.

(3) Each vapor collection system, closed-vent system, fixed roof, cover, and enclosure shall be inspected according to the procedures specified in paragraphs (h)(3)(i) through (v) of this section.

(i) Inspections shall be conducted in accordance with Method 21 of 40 CFR part 60, appendix A.

(ii) *Detection instrument performance criteria.* (A) Except as provided in paragraph (h)(3)(ii)(B) of this section, the detection instrument shall meet the performance criteria of Method 21 of 40 CFR part 60, appendix A, except the instrument response factor criteria in section 3.1.2(a) of Method 21 shall be for the average composition of the process fluid not each individual VOC in the stream. For process streams that contain nitrogen, air, or other inerts which are not organic HAP or VOC, the average stream response factor shall be calculated on an inert-free basis.

(B) If no instrument is available at the plant site that will meet the performance criteria specified in paragraph (h)(3)(ii)(A) of this section, the instrument readings may be adjusted by multiplying by the average response factor of the process fluid, calculated on an inert-free basis as described in paragraph (h)(3)(ii)(A) of this section.

(iii) The detection instrument shall be calibrated before use on each day of its use by the procedures specified in Method 21 of 40 CFR part 60, appendix A.

(iv) Calibration gases shall be as follows:

(A) Zero air (less than 10 parts per million hydrocarbon in air); and

(B) Mixtures of methane in air at a concentration less than 10,000 parts per million. A calibration gas other than methane in air may be used if the instrument does not respond to methane or if the instrument does not meet the performance criteria specified in paragraph (h)(2)(ii)(A) of this section. In such cases, the calibration gas may be a mixture of one or more of the compounds to be measured in air.

(v) An owner or operator may elect to adjust or not adjust instrument readings for background. If an owner or operator elects to not adjust readings for background, all such instrument readings shall be compared directly to the applicable leak definition to determine whether there is a leak. If an owner or operator elects to adjust instrument readings for background, the owner or operator shall measure background concentration using the procedures in § 63.180(b) and (c). The owner or operator shall subtract background reading from the maximum concentration indicated by the instrument.

(vi) The background level shall be determined according to the procedures in Method 21 of 40 CFR part 60 appendix A.

(vii) The arithmetic difference between the maximum concentration indicated by the instrument and the background level shall be compared with 500 parts per million for determining compliance.

(4) Leaks, as indicated by an instrument reading greater than 500 parts per million above background or by visual inspections, shall be repaired as soon as practicable, except as provided in paragraph (h)(5) of this section.

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

(ii) Repair shall be completed no later than 15 calendar days after the leak is detected, except as provided in paragraph (h)(4)(iii) of this section.

(iii) For leaks found in vapor collection systems used for transfer operations, repairs shall be completed no later than 15 calendar days after the leak is detected or at the beginning of the next transfer loading operation, whichever is later.

(5) Delay of repair of a vapor collection system, closed-vent system, fixed roof, cover, or enclosure for which leaks have been detected is allowed if the repair is technically infeasible without a shutdown, as defined in § 63.1251, or if the owner or operator determines that emissions resulting from immediate repair would be greater than the fugitive emissions likely to result from delay of repair. Repair of such equipment shall be complete by the end of the next shutdown.

(6) Any parts of the vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated, as described in paragraph (h)(8)(i) of this section, as unsafe to inspect are exempt from the inspection requirements of paragraphs (h)(2)(i), (ii), and (iii) of this section if:

(i) The owner or operator determines that the equipment is unsafe to inspect because inspecting personnel would be exposed to an imminent or potential danger as a consequence of complying with paragraphs (h)(2)(i), (ii), or (iii) of this section; and

(ii) The owner or operator has a written plan that requires inspection of the equipment as frequently as practicable during safe-to-inspect times.

(7) Any parts of the vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated, as described in paragraph (h)(8)(ii) of this section, as difficult to inspect are exempt from the inspection requirements of paragraphs (h)(2)(i), (ii), and (iii)(A) of this section if:

(i) The owner or operator determines that the equipment cannot be inspected without elevating the inspecting personnel more than 2 meters above a support surface; and

(ii) The owner or operator has a written plan that requires inspection of the equipment at least once every 5 years.

(8) Records shall be maintained as specified in § 63.1259(i) (4) through (9).

(9) If a closed-vent system subject to this section is also subject to the equipment leak provisions of § 63.1255, the owner or operator shall comply with the provisions of § 63.1255 and is exempt from the requirements of this section.

§ 63.1259 Recordkeeping requirements.

(a) *Requirements of subpart A of this part.* The owner or operator of an affected source shall comply with the recordkeeping requirements in subpart A of this part as specified in Table 1 of this subpart and in paragraphs (a)(1) through (5) of this section.

(1) *Data retention.* Each owner or operator of an affected source shall keep copies of all records and reports required by this subpart for at least 5 years, as specified in § 63.10(b)(1).

(2) *Records of applicability determinations.* The owner or operator of a stationary source that is not subject to this subpart shall keep a record of the applicability determination, as specified in § 63.10(b)(3).

(3) *Startup, shutdown, and malfunction plan.* The owner or operator of an affected source shall develop and implement a written startup, shutdown, and malfunction plan as specified in § 63.6(e)(3). This plan shall describe, in detail, procedures for operating and maintaining the affected source during periods of startup, shutdown, and malfunction and a program for corrective action for malfunctioning process, air pollution control, and monitoring equipment used to comply with this subpart. The owner or operator of an affected source shall keep the current and superseded versions of this plan onsite, as specified in § 63.6(e)(3)(v). The owner or operator shall keep the startup, shutdown, and malfunction records specified in paragraphs (b)(3)(i) through (iii) of this section. Reports related to the plan shall be submitted as specified in § 63.1260(i).

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

(ii) The owner or operator shall record the occurrence and duration of each malfunction of continuous monitoring systems used to comply with this subpart.

(iii) For each startup, shutdown, or malfunction, the owner or operator shall record all information necessary to demonstrate that the procedures specified in the affected source's startup, shutdown, and malfunction plan were followed, as specified in § 63.6(e)(3)(iii); alternatively, the owner or operator shall record any actions taken that are not consistent with the plan, as specified in § 63.6(e)(3)(iv).

(4) *Recordkeeping requirements for sources with continuous monitoring systems.* The owner or operator of an affected source who elects to install a continuous monitoring system shall maintain records specified in § 63.10(c)(1) through (14).

(5) *Application for approval of construction or reconstruction.* For new affected sources, each owner or operator shall comply with the provisions in § 63.5 regarding construction and reconstruction, excluding the provisions specified in § 63.5(d)(1)(ii)(H), (d)(2), and (d)(3)(ii).

(b) *Records of equipment operation.* The owner or operator must keep the following records up-to-date and readily accessible:

(1) Each measurement of a control device operating parameter monitored in accordance with § 63.1258 and each measurement of a treatment process parameter monitored in accordance with § 63.1258(g)(2) and (3).

(2) For processes subject to § 63.1252(e), records of consumption, production, and the rolling average values of the production-indexed HAP and VOC consumption factors.

(3) For each continuous monitoring system used to comply with this subpart, records documenting the completion of calibration checks and maintenance of continuous monitoring systems.

(4) For processes in compliance with the 2,000 lb/yr emission limit of § 63.1254(a)(1), records of the rolling annual total emissions.

(5) Records of the following, as appropriate:

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

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

(6) Uncontrolled and controlled emissions per batch for each process.

(7) Wastewater concentration per POD or process.

(8) Number of storage tank turnovers per year, if used in an emissions average.

(9) Daily schedule or log of each operating scenario prior to its operation.

(10) Description of worst-case operating conditions as determined using the procedures described in § 63.1257(b)(8) for control devices.

(11) Periods of planned routine maintenance as described in § 63.1257 (c)(5).

(c) *Records of operating scenarios.* The owner or operator of an affected source shall keep records of each operating scenario which demonstrates compliance with this subpart.

(d) *Records of equipment leak detection and repair programs.* The owner or operator of any affected source implementing the leak detection and repair (LDAR) program specified in § 63.1255 of this subpart, shall implement the recordkeeping requirements in § 63.1255 of this subpart.

(e) *Records of emissions averaging.* The owner or operator of any affected source that chooses to comply with the requirements of § 63.1252(d) shall maintain up-to-date records of the following information:

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

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

(ii) The uncontrolled and controlled emissions of HAP and the overall percent reduction efficiency as determined in §§ 63.1257(g)(1) through (4) or 63.1257(h)(1) through (3) as applicable.

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

(iv) The estimated values for all parameters required to be monitored under § 63.1258(f) for each process and storage tank included in an average.

(v) A statement that the compliance demonstration, monitoring, inspection, recordkeeping and reporting provisions in §§ 63.1257(g) and (h), 63.1258(f), and 63.1260(k) that are applicable to each emission point in the emissions average will be implemented beginning on the date of compliance.

(2) The Implementation Plan must demonstrate that the emissions from the processes and storage tanks proposed to be included in the average will not result in greater hazard or, at the option of the operating permit authority, greater risk to human health or the environment than if the storage tanks and process vents were controlled according to the provisions in §§ 63.1253 and 63.1254, respectively.

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

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

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

(ii) An emissions averaging plan that does not demonstrate hazard or risk equivalency to the satisfaction of the Administrator shall not be approved.

The Administrator may require such adjustments to the emissions averaging plan as are necessary in order to ensure that the average will not result in greater hazard or risk to human health or the environment than would result if the emission points were controlled according to §§ 63.1253 and 63.1254.

(iii) A hazard or risk equivalency demonstration must:

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

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

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

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

(4) A rolling quarterly calculation of the annual percent reduction efficiency as specified in § 63.1257(g) and (h).

(f) *Records of delay of repair.* Documentation of a decision to use a delay of repair due to unavailability of parts, as specified in § 63.1256(i), shall include a description of the failure, the reason additional time was necessary (including a statement of why replacement parts were not kept onsite and when delivery from the manufacturer is scheduled), and the date when the repair was completed.

(g) *Record of wastewater stream or residual transfer.* The owner or operator transferring an affected wastewater stream or residual removed from an affected wastewater stream in accordance with § 63.1256(a)(5) shall keep a record of the notice sent to the treatment operator stating that the wastewater stream or residual contains organic HAP which are required to be managed and treated in accordance with the provisions of this subpart.

(h) *Records of extensions.* The owner or operator shall keep documentation of a decision to use an extension, as specified in § 63.1256(b)(6)(ii) or (b)(9), in a readily accessible location. The documentation shall include a description of the failure, documentation that alternate storage capacity is unavailable, and specification of a schedule of actions that will ensure that the control equipment will be repaired and the tank will be emptied as soon as practical.

(i) *Records of inspections.* The owner or operator shall keep records specified in paragraphs (i)(1) through (9) of this section.

(1) A record that each waste management unit inspection required by § 63.1256(b) through (f) was performed.

(2) A record that each inspection for control devices required by § 63.1256(h) was performed.

(3) A record of the results of each seal gap measurement required by § 63.1256(b)(5) and (f)(3). The records shall include the date of measurement, the raw data obtained in the measurement, and the calculations described in § 63.120(b)(2) through (4).

(4) Records identifying all parts of the vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated as unsafe to inspect in accordance with § 63.1258(h)(6), an explanation of why the equipment is unsafe to inspect, and the plan for inspecting the equipment.

(5) Records identifying all parts of the vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated as difficult to inspect in accordance with § 63.1258(h)(7), an explanation of why the equipment is difficult to inspect, and the plan for inspecting the equipment.

(6) For each vapor collection system or closed-vent system that contains bypass lines that could divert a vent stream away from the control device and to the atmosphere, the owner or operator shall keep a record of the information specified in either paragraph (i)(6)(i) or (ii) of this section.

(i) Hourly records of whether the flow indicator specified under § 63.1252(b)(1) was operating and whether a diversion was detected at any time during the hour, as well as records of the times and durations of all periods when the vent stream is diverted from the control device or the flow indicator is not operating.

(ii) Where a seal mechanism is used to comply with § 63.1252(b)(2), hourly records of flow are not required. In such cases, the owner or operator shall record that the monthly visual inspection of the seals or closure mechanisms has been done, and shall record the occurrence of all periods when the seal mechanism is broken, the bypass line valve position has changed, or the key for a lock-and-key type lock has been checked out, and records of any car-seal that has broken.

(7) For each inspection conducted in accordance with § 63.1258(h)(2) and (3) during which a leak is detected, a record of the information specified in paragraphs (i)(7)(i) through (viii) of this section.

(i) The instrument identification numbers; operator name or initials; and identification of the equipment.

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

(iii) Maximum instrument reading measured by the method specified in § 63.1258(h)(4) after the leak is successfully repaired or determined to be nonrepairable.

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

(v) The name, initials, or other form of identification of the owner or operator (or designee) whose decision it was that repair could not be effected without a shutdown.

(vi) The expected date of successful repair of the leak if a leak is not repaired within 15 calendar days.

(vii) Dates of shutdowns that occur while the equipment is unrepaired.

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

(8) For each inspection conducted in accordance with § 63.1258(h)(3) during which no leaks are detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected.

(9) For each visual inspection conducted in accordance with § 63.1258(h)(2)(i)(B) or (h)(2)(iii)(B) of this section during which no leaks are detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected.

§ 63.1260 Reporting requirements.

(a) The owner or operator of an affected source shall comply with the reporting requirements of paragraphs (b) through (l) of this section. Applicable reporting requirements of §§ 63.9 and 63.10 are also summarized in Table 1 of this subpart.

(b) *Initial notification.* The owner or operator shall submit the applicable initial notification in accordance with § 63.9(b) or (d).

(c) *Application for approval of construction or reconstruction.* An owner or operator who is subject to § 63.5(b)(3) shall submit to the Administrator an application for approval of the construction of a new major affected source, the reconstruction of a major affected source, or the reconstruction of a major source such that the source becomes a major affected source subject to the standards. The application shall be prepared in accordance with § 63.5(d).

(d) *Notification of CMS performance evaluation.* An owner or operator who is required by the Administrator to conduct a performance evaluation for a continuous monitoring system shall notify the Administrator of the date of the performance evaluation as specified in § 63.8(e)(2).

(e) *Precompliance report.* The Precompliance report shall be submitted at least 6 months prior to the

compliance date of the standard. For new sources, the Precompliance report shall be submitted to the Administrator with the application for approval of construction or reconstruction. The Administrator shall have 90 days to approve or disapprove the plan. The plan shall be considered approved if the Administrator either approves the plan in writing, or fails to disapprove the plan in writing. The 90 day period shall begin when the Administrator receives the request. If the request is denied, the owner or operator must still be in compliance with the standard by the compliance date. To change any of the information submitted in the report, the owner or operator shall notify the Administrator 90 days before the planned change is to be implemented; the change shall be considered approved if the Administrator either approves the change in writing, or fails to disapprove the change in writing. The Precompliance report shall include:

(1) Requests for approval to use alternative monitoring parameters or requests to set monitoring parameters according to § 63.1258(b)(4).

(2) Descriptions of the daily or per batch demonstrations to verify that control devices subject to § 63.1258(b)(1)(i) are operating as designed.

(3) A description of test conditions, and the corresponding monitoring parameter values for parameters that are set according to § 63.1258(b)(3)(ii)(C).

(4) For owners and operators complying with the requirements of § 63.1252(e), the P2 demonstration summary required in § 63.1257(f).

(5) Data and rationale used to support an engineering assessment to calculate uncontrolled emissions from process vents as required in § 63.1257(d)(2)(ii).

(f) *Notification of Compliance Status report.* The Notification of Compliance Status report required under § 63.9 shall be submitted no later than 150 days after the compliance date and shall include:

(1) The results of any applicability determinations, emission calculations, or analyses used to identify and quantify HAP emissions from the affected source.

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

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

(4) Listing of all operating scenarios.

(5) Descriptions of worst-case operating and/or testing conditions for control devices.

(6) Identification of emission points subject to overlapping requirements described in § 63.1250(h) and the authority under which the owner or operator will comply.

(g) *Periodic reports.* An owner or operator shall prepare Periodic reports in accordance with paragraphs (g)(1) and (2) of this section and submit them to the Administrator.

(1) *Submittal schedule.* Except as provided in (g)(1) (i), (ii) and (iii) of this section, an owner or operator shall submit Periodic reports semiannually, beginning 60 operating days after the end of the applicable reporting period. The first report shall be submitted no later than 240 days after the date the Notification of Compliance Status is due and shall cover the 6-month period beginning on the date the Notification of Compliance Status is due.

(i) When the Administrator determines on a case-by-case basis that more frequent reporting is necessary to accurately assess the compliance status of the affected source; or

(ii) When the monitoring data are used directly for compliance determination and the source experience excess emissions, in which case quarterly reports shall be submitted. Once an affected source reports excess emissions, the affected source shall follow a quarterly reporting format until a request to reduce reporting frequency is approved. If an owner or operator submits a request to reduce the frequency of reporting, the provisions in § 63.10(e)(3)(ii) and (iii) shall apply, except that the term ''excess emissions and continuous monitoring system performance report and/or summary report'' shall mean ''Periodic report'' for the purposes of this section.

(iii) When a new operating scenario has been operated since the last report, in which case quarterly reports shall be submitted.

(2) *Content of Periodic report.* The owner or operator shall include the information in paragraphs (g)(2)(i) through (vii) of this section, as applicable.

(i) Each Periodic report must include the information in § 63.10(e)(3)(vi)(A) through (I) and (K) through (M). For each continuous monitoring system, the Periodic report must also include the information in § 63.10(e)(3)(vi)(J).

(ii) If the total duration of excess emissions, parameter exceedances, or excursions for the reporting period is 1 percent or greater of the total operating time for the reporting period, or the total continuous monitoring system downtime for the reporting period is 5 percent or greater of the total operating time for the reporting period, the Periodic report must include the information in paragraphs (g)(2)(ii)(A) through (D) of this section.

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

(B) Duration of excursions, as defined in § 63.1258(b)(7).

(C) Operating logs and operating scenarios for all operating scenarios for all operating days when the values are outside the levels established in the Notification of Compliance Status report or operating permit.

(D) When a continuous monitoring system is used, the information required in § 63.10(c)(5) through (13).

(iii) For each inspection conducted in accordance with § 63.1258(h)(2) or (3) during which a leak is detected, the records specified in § 63.1259(i)(7) must be included in the next Periodic report.

(iv) For each vapor collection system or closed vent system with a bypass line subject to § 63.1252(b)(1), records required under § 63.1259(i)(6)(i) of all periods when the vent stream is diverted from the control device through a bypass line. For each vapor collection system or closed vent system with a bypass line subject to § 63.1252(b)(2), records required under § 63.1259(i)(6)(ii) of all periods in which the seal mechanism is broken, the bypass valve position has changed, or the key to unlock the bypass line valve was checked out.

(v) The information in paragraphs (g)(2)(iv)(A) through (D) of this section shall be stated in the Periodic report, when applicable.

(A) No excess emissions.

(B) No exceedances of a parameter.

(C) No excursions.

(D) No continuous monitoring system has been inoperative, out of control, repaired, or adjusted.

(vi) For each tank subject to control requirements, periods of planned routine maintenance during which the control device does not meet the specifications of § 63.1253(b) through (d).

(vii) Each new operating scenario which has been operated since the time period covered by the last Periodic report. For the initial Periodic report,

each operating scenario for each process operated since the compliance date shall be submitted.

(h) *Notification of process change.*

(1) Except as specified in paragraph (h)(2) of this section, whenever a process change is made, or a change in any of the information submitted in the Notification of Compliance Status Report, the owner or operator shall submit a report quarterly. The report may be submitted as part of the next Periodic report required under paragraph (g) of this section. The report shall include:

(i) A brief description of the process change.

(ii) A description of any modifications to standard procedures or quality assurance procedures.

(iii) Revisions to any of the information reported in the original Notification of Compliance Status Report under paragraph (f) of this section.

(iv) Information required by the Notification of Compliance Status Report under paragraph (f) of this section for changes involving the addition of processes or equipment.

(2) An owner or operator must submit a report 60 days before the scheduled implementation date of either of the following:

(i) Any change in the activity covered by the Precompliance report.

(ii) A change in the status of a control device from small to large.

(i) *Reports of startup, shutdown, and malfunction.* For the purposes of this subpart, the startup, shutdown, and malfunction reports shall be submitted on the same schedule as the periodic reports required under paragraph (g) of this section instead of the schedule specified in § 63.10(d)(5)(i). These reports shall include the information specified in § 63.1259(a)(3)(i) through (iii) and shall contain the name, title, and signature of the owner or operator or other responsible official who is certifying its accuracy. Reports are only required if a startup, shutdown, or malfunction occurred during the reporting period. Any time an owner or operator takes an action that is not consistent with the procedures specified in the affected source's startup, shutdown, and malfunction plan, the owner or operator shall submit an immediate startup, shutdown, and malfunction report as specified in § 63.10(d)(4)(ii).

(j) *Reports of LDAR programs.* The owner or operator of any affected source implementing the LDAR program specified in § 63.1255 of this subpart shall implement the reporting requirements in § 63.1255 of this subpart. Copies of all reports shall be retained as records for a period of 5 years, in accordance with the requirements of § 63.10(b)(1).

(k) *Reports of emissions averaging.* The owner or operator of any affected source that chooses to comply with the requirements of § 63.1252(d) shall submit the implementation plan described in § 63.1259(e) 6 months prior to the compliance date of the standard and the following information in the periodic reports:

(1) The records specified in § 63.1259(e) for each process or storage tank included in the emissions average;

(2) All information as specified in paragraph (g) of this section for each process or storage tank included in the emissions average;

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

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

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

(6) Every second semiannual or fourth quarterly report, as appropriate, shall include the results according to § 63.1259(e)(4) to demonstrate the emissions averaging provisions of §§ 63.1252(d), 63.1257(g) and (h), 63.1258(f), and 63.1259(f) are satisfied.

(l) *Notification of performance test and test plan.* The owner or operator of an affected source shall notify the Administrator of the planned date of a performance test at least 60 days before the test in accordance with § 63.7(b). The owner or operator also must submit the test plan required by § 63.7(c) and the emission profile required by 63.1257(b)(8)(ii) with the notification of the performance test.

(m) *Request for extension of compliance.* An owner or operator may submit to the Administrator a request for an extension of compliance in accordance with § 63.1250(f)(4).

§ 63.1261 Delegation of authority.

(a) In delegating implementation and enforcement authority to a State under § 112(d) of the Clean Air Act, the authorities contained in paragraph (b) of this section shall be retained by the Administrator and not transferred to a State.

(b) The authority conferred in § 63.177; the authority to approve applications for determination of equivalent means of emission limitation; and the authority to approve alternative test methods shall not be delegated to any State.

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

General provisions reference	Summary of requirements	Applies to subpart GGG	Comments
63.1(a)(1)	General applicability of the General Provisions	Yes	Additional terms defined in § 63.1251; when overlap between subparts A and GGG of this part, subpart GGG takes precedence.
63.1(a)(2–7)		Yes	
63.1(a)(8)		No	Discusses state programs.
63.1(a)(9–14)		Yes	
63.1(b)(1)	Initial applicability determination	Yes	Subpart GGG clarifies the applicability in § 63.1250.
63.1(b)(2)	Title V operating permit—see part 70	Yes	All major affected sources are required to obtain a title V permit.
63.1(b)(3)	Record of the applicability determination	Yes	All affected sources are subject to subpart GGG according to the applicability definition of subpart GGG.
63.1(c)(1)	Applicability after standards are set	Yes	Subpart GGG clarifies the applicability of each paragraph of subpart A to sources subject to subpart GGG.
63.1(c)(2)	Title V permit requirement	No	All major affected sources are required to obtain a title V permit. Area sources are not subject to subpart GGG.

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

General provisions reference	Summary of requirements	Applies to subpart GGG	Comments
63.1(c)(3)	Reserved		
63.1(c)(4)	Requirements for existing source that obtains an extension of compliance.	Yes	
63.1(c)(5)	No	Notification requirements for an area source that increases HAP emissions to major source levels.	Yes
63.1(d)	[Reserved]	NA	
63.1(e)	Applicability of permit program before a relevant standard has been set.	Yes	
63.2	Definitions.	Yes	Additional terms defined in § 63.1251; when overlap between subparts A and GGG of this part occurs, subpart GGG takes precedence.
63.3	Units and abbreviations.	Yes	Other units used in subpart GGG are defined in that subpart.
63.4	Prohibited activities.	Yes	
63.5(a)	Construction and reconstruction—applicability	Yes	Except replace the terms ''source'' and ''stationary source'' with ''affected source''.
63.5(b)(1)	Upon construction, relevant standards for new sources.	Yes	
63.5(b)(2)	[Reserved]	NA	
63.5(b)(3)	New construction/reconstruction	Yes	
63.5(b)(4)	Construction/reconstruction notification	Yes	
63.5(b)(5)	Construction/reconstruction compliance	Yes	
63.5(b)(6)	Equipment addition or process change	Yes	
63.5(c)	[Reserved]	NA	
63.5(d)	Application for approval of construction/reconstruction	Yes	Except for certain provisions identified in 63.1259(a)(5)
63.5(e)		Construction/reconstruction approval..	Yes
63.5(f)	Construction/reconstruction approval based on prior State review..	Yes	Except replace ''source'' with ''affected source''.
63.6(a)(1)	Compliance with standards and maintenance requirements.	Yes	
63.6(a)(2)	Requirements for area source that increases emissions to become major.	Yes	
63.6(b)(1–2)	Compliance dates for new and reconstructed sources	No	Subpart GGG specifies compliance dates.
63.6(b)(3–6)	Compliance dates for area sources that become major sources.	Yes	
63.6 (b)(7)	Compliance dates for new sources resulting from new unaffected area sources becoming subject to standards.	No	Subpart GGG specifies NS applicability and compliance dates
63.6(c)	Compliance dates for existing sources	Yes	Except replace ''source'' with ''affected source''. Subpart GGG specifies compliance dates.
63.6(e)	Operation and maintenance requirements	Yes	Startup, Shutdown, Malfunction Plan requirements specifically include malfunction process, control and monitoring equipment.
63.6(f)–(g)	Compliance with nonopacity and alternative nonopacity emission standards.	Yes	Except that subpart GGG specifies performance test conditions.
63.6(h)	Opacity and visible emission standards	No	Subpart GGG does not contain any opacity or visible emission standards.
63.6(i)	Extension of compliance with emission standards	No	§ 63.1250(f)(4) specifies provisions for compliance extensions.
63.6(j)	Exemption from compliance with emission standards	Yes	
63.7(a)(1)	Performance testing requirements.	Yes	Subpart GGG specifies required testing and compliance procedures.
63.7(a)(2)(I-ix)		Yes	
63.7(a)(3)		Yes	
63.7(b)(1)	Notification of performance test	Yes	
63.7(b)(2)	Notification of delay in conducting a scheduled performance test.	Yes	

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

General provisions reference	Summary of requirements	Applies to subpart GGG	Comments
63.7(c)	Quality assurance program	Yes	Except that the test plan must be submitted with the notification of the performance test.
63.7(d)	Performance testing facilities.	Yes	Except replace ''source'' with ''affected source''.
63.7(e)	Conduct of performance tests.	Yes	Subpart GGG also contains test methods and procedures specific to pharmaceutical sources.
63.7(f)	Use of alternative test method	Yes	
63.7(g)	Data analysis, recordkeeping, and reporting	Yes	
63.7(h)	Waiver of performance tests	Yes	
63.8(a)	Monitoring requirements	Yes	See § 63.1258.
63.8(b)(1)	Conduct of monitoring	Yes	
63.8(b)(2)	CMS and combined effluents	No	§ 63.1258 of subpart GGG provides specific CMS requirements.
63.8(b)(3)–(c)(3)	CMS requirements	Yes	
63.8(c)(4–5)	CMS operation requirements	Yes	
63.8 (c)6–8)	CMS calibration and malfunction provisions	Yes	
63.8(d)	CMS quality control program	Yes	
63.8(e)(1)	Performance evaluations of CMS	Yes	
63.8(e)(2)	Notification of performance evaluation	Yes	
63.8(e)(3–4)	CMS requirements/alternatives	Yes	
63.8(e)(5)(i)	Reporting performance evaluation results	Yes	See § 63.1260 (a)..
63.8(e)(5)(ii)	Results of COMS performance evaluation	No	Subpart GGG does not contain any opacity or visible emission standards.
63.8(f)–(g)	Alternative monitoring method/reduction of monitoring data.	Yes	
63.9(a)–(d)	Notification requirements—Applicability and general information.	Yes	
63.9(e)	Notification of performance test	Yes	
63.9(f)	Notification of opacity and visible emissions observations.	No	Subpart GGG does not contain any opacity or visible emission standards.
63.9(g)(1)	Additional notification requirements for sources with CMS.	Yes	
63.9(g)(2)	Notification of compliance with opacity emission standard.	No	Subpart GGG does not contain any opacity or visible emission standards.
63.9(g)(3)	Notification that criterion to continue use of alternative to relative accuracy testing has been exceeded.	Yes	
63.9(h)	Notification of compliance status.	Yes	Due 150 days after compliance date.
63.9(i)	Adjustment to time periods or postmark deadlines for submittal and review of required communications.	Yes	
63.9(j)	Change in information provided	Yes	
63.10(a)	Recordkeeping requirements	Yes	See § 63.1259..
63.10(b)(1)	Records retention	Yes	
63.10(b)(2)	Information and documentation to support notifications.	No	Subpart GGG specifies recordkeeping requirements.
63.10(b)(3)	Records retention for sources not subject to relevant standard.	Yes	Applicability requirements are given in § 63.1250.
63.10(c)-(d)(2)	Other recordkeeping and reporting provisions	Yes.	
63.10(d)(3)	Reporting results of opacity or visible emissions observations.	No	Subpart GGG does not include any opacity or visible emission standards.
63.10(d)(4-5)	Other recordkeeping and reporting provisions	Yes.	
63.10(e)	Additional CMS reporting requirements	Yes.	
63.10(f)	Waiver of recordkeeping or reporting requirements. ..	Yes.	
63.11	Control device requirements for flares	Yes.	
63.12	State authority and delegations	Yes	See § 63.1261.
63.13	Addresses of State air pollution control agencies	Yes.	
63.14	Incorporations by reference	Yes.	
63.15	Availability of information and confidentiality	Yes.	

TABLE 2 TO SUBPART GGG.—PARTIALLY SOLUBLE HAP

1,1,1-Trichloroethane (methyl chloroform)
1,1,2,2-Tetrachloroethane
1,1,2-Trichloroethane
1,1-Dichloroethylene (vinylidene chloride)
1,2-Dibromoethane
1,2-Dichloroethane (ethylene dichloride)

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

1,2-Dichloropropane
1,3-Dichloropropene
2,4,5-Trichlorophenol
2-Butanone (mek)
1,4-Dichlorobenzene
2-Nitropropane
4-Methyl-2-pentanone (mibk)

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

Acetaldehyde
Acrolein
Acrylonitrile
Allyl chloride
Benzene
Benzyl chloride
Biphenyl

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

Bromoform (tribromomethane)
Bromomethane
Butadiene
Carbon disulfide
Chlorobenzene
Chloroethane (ethyl chloride)
Chloroform
Chloromethane
Chloroprene
Cumene
Dichloroethyl ether
Dinitrophenol
Epichlorohydrin

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

Ethyl acrylate
Ethylbenzene
Ethylene oxide
Hexachlorobenzene
Hexachlorobutadiene
Hexachloroethane
Methyl methacrylate
Methyl-t-butyl ether
Methylene chloride
N,N-dimethylaniline
Propionaldehyde.
Propylene oxide
Styrene

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

Tetrachloroethene (perchloroethylene)
Tetrachloromethane (carbon tetrachloride
Toluene
Trichlorobenzene (1,2,4-)
Trichloroethylene
Triethylamine
Trimethylpentane
Vinyl acetate
Vinyl chloride
Xylene (m)
Xylene (o)
Xylene (p)
N-hexane

TABLE 3 TO SUBPART GGG.—SOLUBLE HAP

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

TABLE 4 TO SUBPART GGG.—MONITORING REQUIREMENTS FOR CONTROL DEVICES [a]

Control device	Monitoring equipment required	Parameters to be monitored	Frequency
All control devices	1. Flow indicator installed at all bypass lines to the atmosphere and equipped with continuous recorder *or*.	1. Presence of flow diverted from the control device to the atmosphere *or*.	Hourly records of whether the flow indicator was operating and whether a diversion was detected at any time during each hour.
	2. Valves sealed closed with car-seal or lock-and-key configuration.	2. Monthly inspections of sealed valves.	Monthly.
Scrubber	Liquid flow rate or pressure drop mounting device. Also a pH monitor if the scrubber is used to control acid emissions.	1. Liquid flow rate into or out of the scrubber or the pressure drop across the scrubber.	1. Every 15 minutes.
		2. pH of effluent scrubber liquid	2. Once a day.
Thermal incinerator	Temperature monitoring device installed in firebox or in ductwork immediately downstream of firebox [b].	Firebox temperature	Every 15 minutes.
Catalytic incinerator	Temperature monitoring device installed in gas stream immediately before and after catalyst bed.	Temperature difference across catalyst bed.	Every 15 minutes.
Flare	Heat sensing device installed at the pilot light.	Presence of a flame at the pilot light.	Every 15 minutes.
Boiler or process heater <44 mega watts and vent stream is not mixed with the primary fuel.	Temperature monitoring device installed in firebox [b].	Combustion temperature	Every 15 minutes.
Condenser	Temperature monitoring device installed at condenser exit.	Condenser exit (product side) temperature.	Every 15 minutes.
Carbon adsorber (nonregenerative).	None	Operating time since last replacement.	N/A.
Carbon adsorber (regenerative)	Stream flow monitoring device, *and*.	1. Total regeneration stream mass or volumetric flow during carbon bed regeneration cycle(s).	1. For each regeneration cycle, record the total regeneration stream mass or volumetric flow.

TABLE 4 TO SUBPART GGG.—MONITORING REQUIREMENTS FOR CONTROL DEVICES [a]—Continued

Control device	Monitoring equipment required	Parameters to be monitored	Frequency
	Carbon bed temperature monitoring device.	2. Temperature of carbon bed after regeneration.	2. For each regeneration cycle, record the maximum carbon bed-temperature.
		3. Temperature of carbon bed within 15 minutes of completing any cooling cycle(s).	3. Within 15 minutes of completing any cooling cycle, record the carbon bed temperature.
		4. Operating time since end of last regeneration.	4. Operating time to be based on worst-case conditions.
		5. Check for bed poisoning	5. Yearly.

[a] As an alternative to the monitoring requirements specified in this table, the owner or operator may use a CEM meeting the requirements of Performance Specifications 8 or 9 of appendix B of part 60 to monitor TOC every 15 minutes.

[b] Monitor may be installed in the firebox or in the ductwork immediately downstream of the firebox before any substantial heat exchange is encountered.

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

Item of equipment	Control requirement [a]
Drain or drain hub	(a) Tightly fitting solid cover (TFSC); or (b) TFSC with a vent to either a process, or to a fuel gas system, or to a control device meeting the requirements of § 63.1256(h)(2); or (c) Water seal with submerged discharge or barrier to protect discharge from wind.
Manhole [b]	(a) TFSC; or (b) TFSC with a vent to either a process, or to a fuel gas system, or to a control device meeting the requirements of § 63.1256(h)(2); or (c) If the item is vented to the atmosphere, use a TFSC with a properly operating water seal at the entrance or exit to the item to restrict ventilation in the collection system. The vent pipe shall be at least 90 cm in length and not exceeding 10.2 cm in nominal inside diameter.
Lift station	(a) TFSC; or (b) TFSC with a vent to either a process, or to a fuel gas system, or to a control device meeting the requirements of § 63.1256(h)(2); or (c) If the lift station is vented to the atmosphere, use a TFSC with a properly operating water seal at the entrance or exit to the item to restrict ventilation in the collection system. The vent pipe shall be at least 90 cm in length and not exceeding 10.2 cm in nominal inside diameter. The lift station shall be level controlled to minimize changes in the liquid level.
Trench	(a) TFSC; or (b) TFSC with a vent to either a process, or to a fuel gas system, or to a control device meeting the requirements of § 63.1256(h)(2); or (c) If the item is vented to the atmosphere, use a TFSC with a properly operating water seal at the entrance or exit to the item to restrict ventilation in the collection system. The vent pipe shall be at least 90 cm in length and not exceeding 10.2 cm in nominal inside diameter.
Pipe	Each pipe shall have no visible gaps in joints, seals, or other emission interfaces
Oil/Water separator	(a) Equip with a fixed roof and route vapors to a process or to a fuel gas system, or equip with a closed-vent system that routes vapors to a control device meeting the requirements of § 63.1256(h)(2); or (b) Equip with a floating roof that meets the equipment specifications of § 60.693 (a)(1)(i), (a)(1)(ii), (a)(2), (a)(3), and (a)(4).
Tank	Maintain a fixed roof.[c] If the tank is sparged[d] or used for heating or treating by means of an exothermic reaction, a fixed roof and a system shall be maintained that routes the organic hazardous air pollutants vapors to other process equipment or a fuel gas system, or a closed-vent system that routes vapors to a control device that meets the requirements of 40 CFR § 63.119 (e)(1) or (e)(2).

AAA[a] Where a tightly fitting solid cover is required, it shall be maintained with no visible gaps or openings, except during periods of sampling, inspection, or maintenance.

AAA[b] Manhole includes sumps and other points of access to a conveyance system.

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

AAA[d] The liquid in the tank is agitated by injecting compressed air or gas.

TABLE 6 TO SUBPART GGG.—WASTEWATER—COMPLIANCE OPTIONS FOR WASTEWASTER TANKS

Capacity, m^3	Maximum true vapor pressure, kPa	Control requirements
<75	.....	§ 63.1256(b)(1).
≥75 and <151	<13.1	§ 63.1256(b)(1).
	≥13.1	§ 63.1256(b)(2).
≥151	<5.2	§ 63.1256(b)(1).
	≥5.2	§ 63.1256(b)(2).

TABLE 7 TO SUBPART GGG.—WASTEWATER—INSPECTION AND MONITORING REQUIREMENTS FOR WASTE MANAGEMENT UNITS

To comply with	Inspection or monitoring requirement	Frequency of inspection or monitoring	Method
TANKS:			
63.1256(b)(3)(i)	Inspect fixed roof and all openings for leaks.	Initially Semiannually	Visual.
63.1256(b)(4)	Inspect floating roof in accordance with §§ 63.120(a)(2) and (a)(3).	See §§ 63.120(a)(2) and (a)(3)	Visual.
63.1256(b)(5)	Measure floating roof seal gaps in accordance with §§ 63.120(b)(2)(i) through (b)(4).		See § 63.120(b)(2)(i) through (b)(4).
	—Primary seal gaps	Initially Once every 5 years (annually if no secondary seal).	
	—Secondary seal gaps	Initially Semiannually	
63.1256(b)(7)	Inspect wastewater tank for control equipment failures and improper work practices.	Initially Semiannually	Visual.
63.1256(b)(8)			
SURFACE IMPOUNDMENTS:			
63.1256(c)(1)(i)	Inspect cover and all openings for leaks.	Initially Semiannually	Visual.
63.1256(c)(2)	Inspect surface impoundment for control equipment failures and improper work practices.	Initially Semiannually	Visual.
CONTAINERS:			
63.1256(d)(1)(i)	Inspect cover and all openings for leaks.	Initially Semiannually	Visual.
63.1256(d)(1)(ii)			
63.1256(d)(3)(i)	Inspect enclosure and all openings for leaks.	Initially Semiannually	Visual.
63.1256(d)(4)	Inspect container for control equipment failures and improper work practices.	Initially Semiannually	Visual.
INDIVIDUAL DRAIN SYSTEMS [a]:			
63.1256(e)(1)(i)	Inspect cover and all openings to ensure there are no gaps, cracks, or holes.	Initially Semiannually	Visual.
63.1256(e)(2)	Inspect individual drain system for control equipment failures and improper work practices.	Initially Semiannually	Visual.
63.1256(e)(4)(i)	Verify that sufficient water is present to properly maintain integrity of water seals.	Initially Semiannually	Visual.
63.1256(e)(4)(ii)	Inspect all drains using tightly-fitted caps or plugs to ensure caps and plugs are in place and properly installed.	Initially Semiannually	Visual.
63.1256(e)(5)(i)			
63.1256(e)(5)(ii)	Inspect all junction boxes to ensure covers are in place and have no visible gaps, cracks, or holes.	Initially Semiannually	Visual or smoke test or other means as specified.
63.1256(e)(5)(iii)	Inspect unburied portion of all sewer lines for cracks and gaps.	Initially Semiannually	Visual.
OIL-WATER SEPARATORS:			
63.1256(f)(2)(i)	Inspect fixed roof and all openings for leaks.	Initially Semiannually	Visual.
63.1256(f)(3)	Measure floating roof seal gaps in accordance with 40 CFR 60.696(d)(1).	Initially [b]	See 40 CFR 60.696(d)(1).
	—Primary seal gaps	Once every 5 years.	
63.1256(f)(3)	—Secondary seal gaps	Initially [b] Annually.	
63.1256(f)(4)	Inspect oil-water separator for control equipment failures and improper work practices.	Initially Semiannually	Visual.

[a] As specified in § 63.1256(e), the owner or operator shall comply with either the requirements of § 63.1256(e)(1) and (2) or § 63.1256(e)(4) and (5).

[b] Within 60 days of installation as specified in § 63.1256(f)(3).

TABLE 8 TO SUBPART GGG.—FRACTION MEASURED (F_m) for HAP Compounds in Wastewater Streams

Chemical name	CAS No. [a]	F_m
Acetaldehyde	75070	1.00
Acetonitrile	75058	0.99
Acetophenone	98862	0.31
Acrolein	107028	1.00
Acrylonitrile	107131	1.00
Allyl chloride	107051	1.00
Benzene	71432	1.00
Benzyl chloride	100447	1.00
Biphenyl	92524	0.86
Bromoform	75252	1.00
Butadiene (1,3-)	106990	1.00
Carbon disulfide	75150	1.00
Carbon tetrachloride	56235	1.00
Chlorobenzene	108907	0.96
Chloroform	67663	1.00
Chloroprene (2-Chloro-1,3-butadiene)	126998	1.00
Cumene	98828	1.00
Dichlorobenzene (p-1,4-)	106467	1.00
Dichloroethane (1,2-) (Ethylene dichloride)	107062	1.00
Dichloroethylether (Bis(2-Chloroethyl ether))	111444	0.76
Dichloropropene (1,3-)	542756	1.00
Diethyl sulfate	64675	0.0025
Dimethyl sulfate	77781	0.086
Dimethylaniline (N,N-)	121697	0.00080
Dimethylhydrazine (1,1-)	57147	0.38
Dinitrophenol (2,4-)	51285	0.0077
Dinitrotoluene (2,4-)	121142	0.085
Dioxane (1,4-) (1,4-Diethyleneoxide)	123911	0.87
Epichlorohydrin(1-Chloro-2,3-epoxypropane)	106898	0.94
Ethyl acrylate	140885	1.00
Ethylbenzene	100414	1.00
Ethyl chloride (Chloroethane)	75003	1.00
Ethylene dibromide (Dibromomethane)	106934	1.00
Ethylene glycol dimethyl ether	110714	0.86
Ethylene glycol monobutyl ether acetate	112072	0.043
Ethylene glycol monomethyl ether acetate	110496	0.093
Ethylene oxide	75218	1.00
Ethylidene dichloride (1,1-Dichloroethane)	75343	1.00
Hexachlorobenzene	118741	0.97
Hexachlorobutadiene	87683	0.88
Hexachloroethane	67721	0.50
Hexane	110543	1.00
Isophorone	78591	0.47
Methanol	67561	0.85
Methyl bromide (Bromomethane)	74839	1.00
Methyl chloride (Chloromethane)	74873	1.00
Methyl ethyl ketone (2-Butanone)	78933	0.99
Methyl isobutyl ketone (Hexone)	108101	0.98
Methyl methacrylate	80626	1.00
Methyl tert-butyl ether	1634044	1.00
Methylene chloride (Dichloromethane)	75092	1.00
Naphthalene	91203	0.99
Nitrobenzene	98953	0.39
Nitropropane (2-)	79469	0.99
Phosgene	75445	1.00
Propionaldehyde	123386	1.00
Propylene dichloride (1,2-Dichloropropane)	78875	1.00
Propylene oxide	75569	1.00
Styrene	100425	1.00
Tetrachloroethane (1,1,2,2-)	79345	1.00
Tetrachloroethylene (Perchloroethylene)	127184	1.00
Toluene	108883	1.00
Toluidine (o-)	95534	0.15
Trichlorobenzene (1,2,4-)	120821	1.00
Trichloroethane (1,1,1-) (Methyl chloroform)	71556	1.00
Trichloroethane (1,1,2-) (Vinyl Trichloride)	79005	0.98
Trichloroethylene	79016	1.00
Trichlorophenol (2,4,5-)	95954	1.00
Triethylamine	121448	1.00
Trimethylpentane (2,2,4-)	540841	1.00
Vinyl acetate	108054	1.00
Vinyl chloride (Chloroethylene)	75014	1.00

TABLE 8 TO SUBPART GGG.—FRACTION MEASURED (F_m) for HAP Compounds in Wastewater Streams—Continued

Chemical name	CAS No. [a]	F_m
Vinylidene chloride (1,1-Dichloroethylene)	75354	1.00
Xylene (m-)	108383	1.00
Xylene (o-)	95476	1.00
Xylene (p-)	106423	1.00

[a] CAS numbers refer to the Chemical Abstracts Service registry number assigned to specific compounds, isomers, or mixtures of compounds.

TABLE 9 TO SUBPART GGG.—DEFAULT BIORATES FOR LIST 1 COMPOUNDS

Compound name	Biorate (K1), L/g MLVSS-hr
Acetonitrile	0.100
Acetophenone	0.538
Diethyl sulfate	0.105
Dimethyl hydrazine(1,1)	0.227
Dimethyl sulfate	0.178
Dinitrotoluene(2,4)	0.784
Dioxane(1,4)	0.393
Ethylene glycol dimethyl ether	0.364
Ethylene glycol monomethyl ether acetate	0.159
Ethylene glycol monobutyl ether acetate	0.496
Isophorone	0.598
Methanol	([a])
Nitrobenzene	2.300
Toluidine (-0)	0.859

[a] For direct dischargers, the default biorate for methanol is 3.5 L/g MLVSS-hr; for indirect dischargers, the default biorate for methanol is 0.2 L/g MLVSS-hr.

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