ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[FRL–6564–6]

RIN 2060–AE83

National Emission Standards for Hazardous Air Pollutants for Pharmaceuticals Production

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; amendments.

SUMMARY: On September 21, 1998 (63 FR 50280), EPA promulgated national emission standards for hazardous air pollutants (NESHAP) for Pharmaceuticals Production. On November 17 and 20, 1998, petitions for reconsideration and review of the September 1998 rule were filed in the U.S. Court of Appeals for the District of Columbia Circuit. The petitioners raised over 12 technical issues and concerns with the rule. Additional issues were raised by intervenors on the side of the petitioners. In this action, EPA proposes amendments to the Pharmaceuticals Production NESHAP to address these issues and to correct any other inconsistencies that were discovered during the review process.

DATES: The EPA will accept comments regarding this proposal on or before May 10, 2000.

ADDRESSES: *Comments:* Comments should be submitted (in duplicate, if possible) to: Air and Radiation Docket and Information Center (6102), Attention Docket Number A–96–03, Room M–1500, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460. The EPA requests that a separate copy of each public comment be sent to the contact person listed below (see **FOR FURTHER INFORMATION CONTACT**). Comments may also be submitted electronically by following the instructions provided in **SUPPLEMENTARY INFORMATION.**

Docket: A docket, No. A–96–03, containing information relevant to these proposed amendments, is available for public inspection and copying between 8:30 a.m. and 5:30 p.m., Monday through Friday (except for Federal holidays) at the following address: U. S. Environmental Protection Agency, Air and Radiation Docket and Information Center (6102), 401 M Street, SW, Washington, DC 20460. The docket is located at the above address in Room M–1500, Waterside Mall (ground floor). Alternatively, a docket index, as well as individual items contained within the docket, may be obtained by calling (202) 260–7548 or (202) 260–7549. A reasonable fee may be charged for copying docket items.

FOR FURTHER INFORMATION CONTACT: Mr. Randy McDonald, Organic Chemicals Group, Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5402, electronic mail address mcdonald.randy@epa.gov.

SUPPLEMENTARY INFORMATION:

Docket

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

Comments

Comments and data may be submitted by electronic mail (e-mail) to: *a-and-r-docket@epa.gov.* Electronic comments must be submitted as an ASCII file to avoid the use of special characters and encryption problems and will also be accepted on disks in WordPerfect® version 5.1, 6.1 or Corel 8 file format. All comments and data submitted in electronic form must note the docket number: A–96–03. No confidential business information (CBI) should be submitted by e-mail. Electronic comments may be filed online at many Federal Depository Libraries.

Commenters wishing to submit proprietary information for consideration must clearly distinguish such information from other comments and clearly label it as CBI. Send submissions containing such proprietary information directly to the following address, and not to the public docket, to ensure that proprietary information is not inadvertently placed in the docket: Attention: Ms. Melva Toomer, U.S. EPA, OAQPS Document Control Officer, 411 W. Chapel Hill Street, Room 740B, Durham, NC 27701. The EPA will disclose information identified as CBI only to the extent allowed by the procedures set forth in 40 CFR part 2. If no claim of confidentiality accompanies a submission when it is received by the EPA, the information may be made available to the public without further notice to the commenter.

Worldwide Web (WWW)

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

Regulated Entities

The regulated category and entities affected by this action include:

Category	NAICS	SIC codes	Examples of regulated entities
Industry	325411 and 325412	2833 and 2834	• Producers of finished dosage forms of drugs (e.g., tablets, capsules, and solutions), active ingredients, or precursors.
	Typically 325199	Typically 2869	• Producers of material whose primary use is as an active ingredient or precursor.

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

of the promulgated rule, as well as in the proposed amendments to the applicability sections contained in this proposal. If you have questions regarding the applicability of these amendments to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

We are soliciting comment on the specific proposed amendments to the Pharmaceuticals Production NESHAP that are described below. We are not seeking comment on portions of the Pharmaceuticals Production NESHAP that we are not currently proposing to change.

I. Why Are We Proposing Changes to the Rule?

On September 21, 1998, we promulgated NESHAP for Pharmaceuticals Production as subpart GGG in 40 CFR part 63. On November 17 and 20, 1998, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed petitions for reconsideration and review of the promulgated Pharmaceuticals Production NESHAP in the U.S. Court of Appeals for the District of Columbia Circuit, *PhRMA* v. *EPA,* 98–1551 (D.C. Cir.). Issues raised by the petitioners included applicability of the rule, definition of a process, the 98 percent reduction requirement for certain process vents, the alternative standard, and recordkeeping requirements. The intervenors raised additional issues regarding the applicability of the rule to specialty chemical manufacturers and the clarity of the rule, especially with respect to the leak detection and repair (LDAR) provisions. On December 21, 1999, the parties filed a motion to lodge a settlement agreement with the court. The settlement agreement established a schedule by which EPA would propose revisions to the NESHAP and the preamble language agreed to by the parties. The settlement agreement provided that EPA would sign proposed rule amendments no later than 60 days after execution of the settlement. The settlement agreement also provided that EPA would sign final rule amendments no later than 180 days after the date on which the proposed amendments were signed. On February 22, 2000, the parties filed a motion to lodge a stipulation to modify the settlement agreement. The parties agreed to change the date by which EPA must sign the proposed rule amendments from 60 to 90 days after the execution of the settlement agreement (March 20, 2000). The date by which EPA must sign the final amendments was not changed (August 21, 2000). Today's proposed amendments address the issues raised by PhRMA and the intervenors of the promulgated Pharmaceuticals Production NESHAP and include corrections and clarifications to ensure that the rule is implemented as intended. Today's proposed amendments also provide some new compliance options, as well as new provisions that would reduce the burden associated with demonstrating compliance. For example, vapor balancing is proposed as a compliance option for storage tanks in § 63.1253(f), and the concept of a standard batch is proposed in § 63.1259(b)(5) that would allow an owner or operator to reduce the amount of recordkeeping by defining an operating scenario based on a range of process operating conditions.

II. What Changes Are We Proposing?

This section of the preamble describes the changes that we are proposing to make to subpart GGG and the rationale for the revisions.

A. Applicability of the Rule

We are proposing three minor changes to §§ 63.1250 and 63.1251 to clarify how applicability determinations are to be reported and what constitutes a new affected source. First, in § 63.1250(a), we are proposing to add a sentence specifying that applicability determinations are to be reported either as part of an operating permit application or as otherwise specified by the permitting authority. This change clarifies how to report applicability determinations. Second, § 63.1250(b) of the Pharmaceuticals Production NESHAP specifies the date after which construction of a dedicated pharmaceutical manufacturing process unit (PMPU) is to be considered a new source, but it did not address reconstructed PMPUs. To correct this oversight, we are proposing additional language in § 63.1250(b) to specify that dedicated PMPUs that are reconstructed after October 21, 1999 are new sources. This date corresponds with the completion of the settlement discussions (see section II.B of this preamble for a discussion of other changes to compliance dates). Third, in § 63.1251, we are proposing to add a sentence to the definition of the term ''construction'' to specify that adding equipment to a PMPU that is subject to existing source standards does not constitute construction, but it may constitute reconstruction. We are proposing this change to prevent any misinterpretation of the definition.

In addition to these changes, we are also proposing to clarify the intended applicability of the Pharmaceuticals Production NESHAP by revising the definition of pharmaceutical product and related definitions that are used to define the affected source. These changes would clarify when an intermediate is considered a pharmaceutical product and, therefore, subject to the rule.

1. Pharmaceutical Product Definition

We propose to revise the definition of ''pharmaceutical product.'' In the Pharmaceuticals Production NESHAP, the definition of ''pharmaceutical product,'' along with the definitions of ''primary use,'' ''active ingredient,'' and ''precursor,'' are used to identify those manufacturing operations and facilities to which the NESHAP apply. Our intent is that the NESHAP apply to the manufacture of pharmaceutical active ingredients, final dosage products, and the manufacture of precursor chemical(s) whose ultimate primary use is to be subsequently processed through additional chemical transformations and separations into final drug products and pharmaceutical active ingredients. The definition of the term ''pharmaceutical product'' specifically excludes chemicals that are used as non-reactive solvents, excipients, binders, and fillers in the pharmaceutical manufacturing process. We also did not intend to regulate the manufacture of commodity chemicals under the NESHAP. The following discussion, in conjunction with the clarification in the regulatory text, is provided to assist in properly identifying those operations subject to the NESHAP.

Most pharmaceutical products are produced in a multi-step manufacturing process. Pharmaceutical manufacturers themselves may perform all of the manufacturing steps that take comparatively basic chemicals and transform them into the typically complex molecules that are the active ingredients. The active ingredients are combined with excipients, binders, and fillers to produce finished dosage forms of the drug. Manufacturers might perform all of the steps at one site or they may perform steps at the manufacturer's different production sites. The production of active ingredients and precursors by pharmaceutical manufacturers is always subject to this standard. The sites performing these manufacturing operations are typically described by § 63.1251, paragraph (4) of the pharmaceutical product definition in 40 CFR part 63, subpart GGG, as they usually will have a primary standard industrial classification (SIC) code of 2833 or 2834.

Pharmaceutical manufacturers can also purchase commercially available pharmaceutical active ingredients and intermediates from other manufacturers or chemical brokers and rely on other manufacturers to perform some of the early or intermediate steps in the pharmaceutical manufacturing process. Many chemical manufacturers have divisions that specifically manufacture these pharmaceutical active ingredients and intermediates for sale to pharmaceutical manufacturers. Finally, pharmaceutical manufacturers often contract with another manufacturer to have a particular pharmaceutical intermediate produced. The sites performing these manufacturing operations are typically described by § 63.1251, paragraph (5) of the pharmaceutical product definition in 40 CFR part 63, subpart GGG, and their pharmaceutical manufacturing operations are subject to the Pharmaceuticals Production NESHAP, even though the site's primary operations are chemical production, not pharmaceutical production.

The Pharmaceuticals Production NESHAP are not intended to apply to the manufacture of commodity chemicals which are typically the basic building blocks of the chemicals that eventually become pharmaceutical products. Commodity chemicals are chemicals manufactured and sold in large quantities by chemical manufacturers using their own processes and formulas to meet specifications typically established by the marketplace. Commodity chemicals typically have a wide variety of applications, uses, and customers. The definition of the term ''pharmaceutical product'' has been clarified to specifically exclude chemicals that are produced in a manufacturing process subject to subparts F and G of 40 CFR part 63, commonly referred to as the Hazardous Organic NESHAP (HON). The remainder of this discussion provides guidance on how to identify chemicals that we consider to be commodity chemicals for the purposes of the Pharmaceuticals Production NESHAP.

First, we consider the chemicals identified in the ''Industrial Organic Chemical Use Trees'' (Final Report, October 1983, U.S. EPA) to be commodity chemicals (sometimes also referred to as industrial chemicals) that are not regulated by the Pharmaceuticals Production NESHAP. This list, which contains approximately 650 chemicals, is simply an illustration of some of the chemicals that are not regulated by the Pharmaceuticals Production NESHAP. Chemicals listed in subparts NNN and RRR of 40 CFR part 60, many of which are referenced in the chemical use tree report, are also to be considered commodity chemicals. There are also many inorganic chemicals, gases, other organic chemicals and mixtures with non-pharmaceutical uses that are considered commodity chemicals, not active ingredients, and are not covered by the Pharmaceuticals Production NESHAP even though some portion of their production is sold to and used by the pharmaceutical industry. It would not be possible or practical to list all such chemicals in the text of the proposed amendments or in this preamble. The list would be too long and always out of date as new chemicals and mixtures are constantly created and new uses for existing chemicals and mixtures continue to be discovered. We do not intend to bring under the Pharmaceuticals Production NESHAP the manufacture of chemicals which are not produced specifically for use as an active ingredient or as a precursor to the manufacture of an active ingredient and which are not primarily used in the manufacture of pharmaceuticals.

Second, chemicals subject to the inventory update report (IUR) requirement of the Toxic Substances Control Act (TSCA), section 8(a), and the implementing regulations found in 40 CFR part 710 are likely to be commodity chemicals or chemicals that do not have any significant pharmaceutical use and, thus, will not likely be subject to the pharmaceutical standards. Unlike the reference to the chemical tree that broadly applies to the manufacture of the listed chemicals at any site, this paragraph applies to site-specific manufacturing. The IUR requires chemical manufacturers (including importers) to provide information every 4 years about chemical substances they manufacture (including imports) in annual quantities of 10,000 pounds or more at each plant site they own or control. The information required includes company name, plant site location, plant site Dun and Bradstreet number, the identity of the chemical substance, and the production volume of the chemical substance. A material that is regulated by the Food and Drug Administration (FDA) is not a ''chemical substance'' regulated by TSCA, and as such, would not have to be on the TSCA Inventory and would not be subject to the IUR. If a chemical manufacturing facility is reporting its production of a particular chemical under the IUR, that chemical is most likely a commodity chemical and not primarily an active ingredient or a pharmaceutical precursor. Conversely, the fact that a manufacturer does not have an IUR reporting obligation for a chemical does not necessarily have any bearing on whether the material would be a ''pharmaceutical product.'' For example, under the IUR requirements, chemicals that are manufactured in annual quantities of less than 10,000 pounds do not have to be reported under the IUR, nor do certain polymers, inorganic chemicals, and naturally occurring materials which are not required to be placed on the TSCA Inventory.

We expect that manufacturers of finished drug products and active ingredients will have sufficiently complete knowledge of their products' use to enable them to make applicability determinations that fully comport with our intended implementation of the ''pharmaceutical product'' definition. Likewise, chemical manufacturing companies who market particular chemicals for use as pharmaceutical intermediates and active ingredients at the time they manufacture a chemical should be able to make accurate applicability determinations (*i.e.,* to know whether the primary use is as a pharmaceutical active ingredient or precursor). We recognize that there may be cases where the customer of the manufacturer does not inform the manufacturer of the intended use of the material due to the customer's interest in protecting its trade secrets or other competitive concerns. Chemical manufacturers who market a chemical as being used in the pharmaceutical industry or manufacture a chemical under a specific contract (toll manufacturing) with a pharmaceutical manufacturer will need to make an applicability determination at the time of manufacturing by considering information about the past and projected use of the chemical, the location to which the chemical is shipped, and other circumstances regarding the production of the chemical.

2. Definition of Precursor

We are proposing to add a definition of ''precursor'' to more clearly identify what materials are pharmaceutical intermediates. Our intent is to regulate the intermediate materials that are integral to the production of ''active ingredients.'' Typically, pharmaceutical precursors are complex chemicals that have few if any commercially recognized uses outside of the production of pharmaceuticals. We are not aware of the existence of any comprehensive list of pharmaceutical intermediates and even if such a list existed, it would be difficult to keep up-

to-date. As stated above, we do not intend to bring within the Pharmaceuticals Production NESHAP the manufacture of commodity chemicals. We intend for the precursor definition to clarify where this line between pharmaceutical intermediates and commodity chemicals can be drawn.

The term ''precursor'' means a material produced for the purpose of producing a pharmaceutical product. It does not mean any and every chemical upstream of the finished dosage form or the active ingredient because that would ultimately encompass commodity chemicals. For example, if the pharmaceutical active or intermediate is a chemical ABCD, the precursors are those chemicals specifically produced to manufacture ABCD. If the way this pharmaceutical material is produced is to manufacture the materials AB and CD and then react AB and CD, then the precursors to ABCD are AB and CD. If the raw materials for making AB and CD are chemicals A, B, C, and D, and these chemicals are commodity chemicals or chemicals that have many uses unrelated to pharmaceutical manufacturing, they are not ''precursors'' for the purposes of the Pharmaceuticals Production NESHAP. Alternatively, if chemicals A, B, C, and D are primarily produced for the purpose of producing AB and CD, then they would be considered precursors and, thus, ''pharmaceutical products'' under the Pharmaceuticals Production NESHAP.

Materials that are intended to be pharmaceutical intermediates (i.e., precursors) frequently are manufactured according to current Good Manufacturing Practices (cGMP) (21 CFR parts 210 and 211), which have been promulgated by the FDA. The requirement for cGMP is determined by the FDA and the pharmaceutical manufacturer when the drug manufacturing process is first described in a master file or drug application. Considerations the FDA uses in requiring cGMP include the commercial availability of starting materials and how close an intermediate is to the final product form. Once the FDA and the pharmaceutical manufacturer have documented the manufacturing requirements and the process in the master file and/or drug application, this process and the requirements of cGMP must be followed no matter where the manufacturing process occurs. Thus, chemicals which are required to be manufactured according to cGMP, as shown in the master file or drug application for the ultimate active ingredient or drug product, would be considered precursors. However, a chemical may be manufactured under cGMP for reasons other than because the chemical is a precursor or active ingredient. Chemicals intended for use as binders, excipients, or fillers may be manufactured under cGMP, but these materials are excluded from coverage under the Pharmaceuticals Production NESHAP. Other chemicals or materials manufactured under cGMP are not covered by the Pharmaceuticals Production NESHAP because they do not meet the definition of an ''active ingredient'' (*e.g.,* food, food additives, color additives, in-vitro diagnostic substances, x-ray file, test indicator devices, and medical devices such as implants, artificial joints, surgical bandages, and stitching materials).

3. Definition of Primary Use

We are proposing changes to the primary use criteria that apply to active ingredients and precursors to avoid the unintended regulation of chemical manufacturing processes that produce chemicals that have a minor use as a pharmaceutical active ingredient or precursor. If greater than 50 percent of the projected use of a material produced by a chemical manufacturing site will be either as an active ingredient or a precursor to an active ingredient, then the material is a ''pharmaceutical product,'' and the manufacturing operation is subject to regulation under the Pharmaceuticals Production NESHAP for the period of time it is manufacturing that material. A number of other Clean Air Act (CAA) standards have in place some type of 50 percent test to classify the manufacturing operation for regulatory applicability purposes.

A chemical manufacturer will have to consider information about past and projected uses of a chemical that is not a commodity chemical to determine whether the chemical's primary use is as a pharmaceutical product. A manufacturer should consider specific information about how its customers are using a material, if that information is available to the manufacturer. Otherwise, the chemical manufacturer will have to make assumptions about uses depending on who the customers are and based on the nature of the chemical. For example, if the manufacturer is manufacturing a chemical that is an intermediate (i.e., a chemical that will be used in a process to produce other chemicals), then the manufacturer should consider what products the customer manufactures. If the customer manufacturers pharmaceutical products (*i.e.,* has operations covered under SIC codes 2833 and 2834), the chemical manufacturer may inquire as to whether the chemical is used to manufacture an active ingredient or precursor or may assume that some or all of the chemical intermediate sent to the customer may be used as an active ingredient or precursor and produce that material subject to the Pharmaceuticals Production NESHAP. If the material sent to the same customer is not an intermediate, but rather a trade name product with a specific use or set of uses and that use or those uses would not be as an active ingredient, or as a precursor, then that quantity would not have to be considered as having a pharmaceutical use. For example, shipping a heat transfer fluid or cooling tower water treatment chemical to a pharmaceutical manufacturer does not create the presumption that the chemical is being used in the manufacture of pharmaceutical products in such a manner as to bring its manufacture under the Pharmaceuticals Production NESHAP.

The period of time to use for making the primary use determination will vary depending on the circumstances under which the chemical is manufactured. For example, if a chemical is manufactured under a specific contract with a customer or customers, then the projected use of the chemical by the customers during the period of time of the contract would be considered. Another example would be if a chemical is produced in a single campaign. The manufacturer will have to consider its customer's projected use at the start of the campaign for the material based on how the manufacturer markets the chemical and other available information to determine whether greater than 50 percent of the chemical to be produced in the upcoming campaign will be used as a pharmaceutical product, in which case the manufacturing operation would be subject to the Pharmaceuticals Production NESHAP. For the situation in which a material is manufactured on a continued basis, the primary use determination should be based on a projected annual use.

To make the primary use determination, the chemical manufacturer will use the total amount of the chemical projected to be produced over each specified period of time as the denominator, and then use as the numerator the amount of that chemical that is projected to be either used as an active ingredient and/or as a precursor for the same period of time. The chemical manufacturer will exclude from the numerator the amount of material that is used for non-

pharmaceutical uses and the amount used in the pharmaceutical industry for such uses as an excipient, binder, filler, or non-reactive solvent.

4. Definition of Active Ingredient

We are proposing to clarify the definition of ''active ingredient'' by identifying some of the materials that are not intended to come within the scope of this term. Because the definition of the term ''active ingredient'' is based on terminology used by the Federal Food Drug and Cosmetic Act, the language of what is excluded is also borrowed from that. Excluded from the definition are foods, food additives (other than vitamins and materials described in SIC codes 2833 and 2834), color additives, in-vitro diagnostic substances, x-ray film, test indicator devices, and medical devices such as implants, artificial joints, surgical bandages, and stitching materials. We never intended for the manufacture of these materials to be subject to the Pharmaceuticals Production NESHAP. The Pharmaceuticals Production NESHAP were developed to regulate the emissions from manufacturing processes that produce active ingredients and precursors.

B. Compliance Dates

1. Existing Sources

The Pharmaceuticals Production NESHAP promulgated on September 21, 1998, specifies that existing sources must be in compliance with the NESHAP no later than September 21, 2001, unless an extension is granted in accordance with § 63.1250(f)(4). We are proposing a new compliance date of October 21, 2002 because the proposed amendments are sufficiently far reaching and complex that an amended rule would effectively be a new rule warranting a new compliance date.

Section 112(a)(3) of the CAA provides that existing sources are to be in compliance with applicable emission standards ''as expeditiously as practicable, but in no event later than 3 years after the effective date of such standard.'' The September 21, 1998, Pharmaceuticals Production NESHAP specifies a compliance date 3 years from the issuance of that rule. Section 112(d)(6) provides authority for the Administrator to revise the emission standards issued under section 112 ''no less often than every 8 years.'' We believe the authority to revise the standards inherently includes the authority to set new compliance dates for revised rules. Congress provided us discretion to set a compliance date for existing sources of up to 3 years in order to provide time for retrofitting of controls where necessary. Thus, due to the extensive nature of the proposed amendments, we are proposing a new compliance date.

We believe that 13 months from the otherwise applicable compliance date will be sufficient for all sources to come into compliance with the proposed amendments. However, should any source be unable to meet that compliance date because of the need to install controls that cannot be installed by that date, each source may request an extension of up to 1 year in accordance with § 63.1250(f)(6) of the proposed amendments.

2. New Sources

The Pharmaceuticals Production NESHAP specifies that new sources must comply with the NESHAP on September 21, 1998, or upon startup, whichever is later. However, an exception to this requirement was also provided. If the Pharmaceuticals Production NESHAP were more stringent than the proposed rule, the owner or operator would have until 3 years after September 21, 1998 to comply with the NESHAP. We are proposing comparable language to address the event that the final amendments would be more stringent than either the Pharmaceuticals Production NESHAP or these proposed amendments. The compliance date for complying with the final amendments and the requirements with which the owner or operator must comply until that date vary depending on the date construction or reconstruction commenced. Separate requirements are proposed for three time periods. In each case, we believe the allotted times, based on the settlement agreement, will be sufficient for all sources to come into compliance with the proposed amendments.

The first set of requirements would apply to new sources that commenced construction or reconstruction between the proposal and promulgation dates (*i.e.,* April 2, 1997 and September 21, 1998) if final amendments were to be more stringent than the Pharmaceuticals Production NESHAP. We are proposing that these sources come into compliance by September 21, 2001, and we are proposing that they comply with the April 12, 1997 proposed rule until that date.

The second set of requirements would apply to new sources that commenced construction or reconstruction between September 21, 1998 and April 10, 2000 if final amendments were to be more stringent than the Pharmaceuticals Production NESHAP. We are proposing that these sources come into compliance by October 21, 2002. In the absence of the proposed amendments, these sources would be required to comply with the NESHAP upon startup. Therefore, we are proposing that they continue to comply with the NESHAP until October 21, 2002.

The third set of requirements would apply to new sources that commence construction or reconstruction between April 10, 2000 and the date the final amendments are published if the final amendments were to be more stringent than the proposed amendments. We are proposing that these sources come into compliance by the date 1 year after publication of the final amendments, and we are proposing that they comply with the NESHAP between startup and the date 1 year after publication of the final amendments.

C. Overlapping Regulations

1. Overlap with Subpart PPP of 40 CFR Part 63

We are proposing to add a new paragraph at § 63.1250(h)(6) that would specify alternative procedures to address overlap situations between the pharmaceuticals NESHAP and the polyether polyols NESHAP in 40 CFR part 63, subpart PPP. This paragraph would specify that an owner or operator may elect to demonstrate compliance with the process vent standards in § 63.1254 by either controlling all process vents within the process by the most stringent requirements in subpart PPP (i.e., § 63.1425(b), (c)(1), (c)(3), (d), and/or (f)), or by identifying those vents that would require control under § 63.1254 and controlling only those vents by the most stringent requirements in subpart PPP. If you own or operate an affected source and you elect to demonstrate compliance with an amended subpart GGG by controlling process vents within the process in accordance with the requirements in subpart PPP, you would still be required to comply with all other requirements in subpart GGG for the corresponding PMPU (e.g., the storage tank, wastewater, and equipment leak standards and their corresponding initial and continuous compliance requirements and recordkeeping and reporting requirements). The proposed paragraph does not simply state that compliance with the requirements of subpart PPP would constitute compliance with an amended subpart GGG because it is possible that certain process vents that require control under an amended subpart GGG would not meet the applicability requirements for

control under subpart PPP. We believe the proposed requirements are reasonable because the control achieved for process vents complying with subpart PPP would be equal to or greater than the control achieved for process vents complying with an amended subpart GGG. In addition, the monitoring, recordkeeping, and reporting requirements for process vents in the two rules are similar.

2. Overlap With Resource Conservation and Recovery Act Wastewater Provisions

We are proposing several changes to § 63.1250(h)(5) to clarify compliance requirements and options for wastewater that is subject to both subpart GGG and 40 CFR parts 260 through 272. Some of the changes are needed because it is possible that the promulgated language could be interpreted to mean that every owner or operator must determine which provisions are the most stringent. This was not our intent. However, we do believe an owner or operator must determine the most stringent requirements if the owner or operator wants to comply with only one of the rules. We believe this determination is necessary because it is not possible to categorically state which rule is the most stringent. One reason for this is that wastewater conditions and systems vary from site to site. Furthermore, subpart GGG includes requirements for individual drain systems, but 40 CFR parts 260 through 272 do not.

To clarify our intent, we are proposing to delete the last sentence in the section, state in the first sentence that the owner or operator ''may elect to determine'' which provisions are the most stringent, and add several new statements. One of the new statements specifies that compliance with provisions of 40 CFR parts 260 through 272 that are determined to be more stringent than the requirements of subpart GGG constitutes compliance with subpart GGG. As an example of more stringent requirements that constitute compliance with subpart GGG, a second statement cites the provisions of 40 CFR parts 260 through 272 for treatment units that meet the conditions specified in § 63.1256(g)(13). This example may help to reduce the burden of making a stringency determination. To address a reporting oversight in the Pharmaceuticals Production NESHAP, the third proposed statement would require the owner or operator to identify in the Notification of Compliance Status report both the more stringent provisions of 40 CFR parts 260 through 272 with which the owner or operator will comply, and the information and procedures used to make any stringency determinations. The last of the proposed new statements specifies that § 63.1250(h)(6) does not apply if the owner or operator elects not to determine which provisions are the most stringent, and that the owner or operator must comply with the provisions in both rules. Finally, we are also proposing minor editorial changes to clarify our intent.

3. Overlap with Subpart I

Section 63.1250(h)(4) specifies procedures for equipment that is subject to both subpart GGG and 40 CFR part 63, subpart I. We are proposing several editorial changes to this section to clarify that, for equipment subject to both rules, an owner or operator may elect to comply with either the provisions in § 63.1255 or with the provisions in subpart H of 40 CFR part 63.

4. Overlapping Requirements for Offsite Cleaning and Reloading Facilities

Section II.J. of this preamble describes proposed vapor balancing provisions for storage tanks. One of these provisions is that offsite reloading and cleaning facilities must control emissions from railcars and tank trucks used in vapor balancing at the affected source by either connecting them to a closed vent system with a control device that reduces emissions by 90 percent by weight, or by connecting them to a vapor balancing system during reloading. However, we are proposing to add a new paragraph at § 63.1250(h)(1)(ii) to state that an offsite reloading or cleaning facility in compliance with all of the control requirements of any other standard in 40 CFR part 63 is in compliance with the requirements of subpart GGG.

D. Definition of Process

We are proposing to revise the definition of the term ''process'' in order to achieve a more uniform and replicable entity for basing applicability of the rule. The Pharmaceuticals Production NESHAP uses the concept of a process as the defining entity for applicability. The NESHAP require that the owner or operator consider emissions from all sources within a process in order to determine what requirements apply. Therefore, it is important to the overall effectiveness and uniformity of the NESHAP that the definition of process is consistently applied across the industry.

In the April 2, 1997, proposed rule, the definition of process included the concept of isolated intermediates, which was intended to encompass essentially the same set of unit operations that we are proposing today. However, during the public comment period following proposal, some commenters objected to the requirement that material be removed from the process equipment in order to be considered an isolated intermediate. Other commenters believed the concept of isolated intermediates was unnecessary; they believed that all operations leading to the production of a final pharmaceutical product could be considered a single process. In addition, we realized that the definition of isolated intermediate could be problematic because it could be interpreted in many ways. To address these concerns we decided to eliminate the concept of isolated intermediates from the definition of process for the promulgated rule. We also revised the definition to consider all operations leading up to a final pharmaceutical product, except in two circumstances. One exception is where an intermediate is used to manufacture more than one product, and the second is where an intermediate is stored for more than 30 days before subsequent processing. Although we made these changes in an effort to eliminate confusion in how to define a process, the changes had other, unintended consequences.

Since promulgation, we have learned that the 30-day storage provision could lead to different interpretations of the number of operations considered within the same process boundaries. For example, the period for which a given intermediate could or would be stored prior to further processing might vary according to production scheduling depending upon availability of materials and processing equipment, demand, and other reasons. The 30-day holding time could therefore result in constantly changing, unpredictable, and unrepeatable process boundaries. We also now realize that including all intermediate steps in the definition of process may have the same effect. This could occur because not all intermediate steps are manufactured in the same process sequence or at the same facility all the time. Nonrepeatable process boundaries are problematic because they could result in inconsistencies in the way in which the NESHAP is implemented.

To address these concerns, we are proposing to eliminate the 30-day storage provision and redraw the boundaries of a process around a more repeatable unit. The unit we selected is that of the single process ''step'' that results in the production of a pharmaceutical product, which could be an isolated intermediate, active

ingredient, or final dosage form of drug. The defining characteristic of the proposed process definition is that it considers all unit operations associated with generating one or more materials that are stable, isolated, and ultimately stored (see definition of product and isolated intermediate). The concept of storage has intentionally not been defined by a period of time to prevent problems comparable to those caused by the 30-day storage period in the promulgated definition. Moreover, the intent of the storage reference in the definition of isolated intermediate is to draw the boundaries of the process around the unit operations that generate a product that is stored at any time (see discussion of isolated intermediate in section II.E of this preamble). These proposed changes provide a more clearly defined final step for a process than in the originally proposed definition. In addition, because of the proposed facilitywide cap on emissions from process vents for which the owner or operator complies with the annual mass emission limit (see section II.G. of this preamble), any incentive to create additional processes would be minimized.

As a result of this proposed change in the definition of process, we are proposing changes to other provisions to ensure that an amended rule would provide the same level of emissions reductions as the promulgated rule. For details on these other proposed changes, see discussions on definition of storage tank, annual mass emission limit standards for process vents, pollution prevention (P2) provisions, and wastewater load cutoffs in sections II.F., II.G., II.K., and II.M., respectively.

E. Definition of Isolated Intermediate

As part of the change in the definition of process, we are proposing to add the term ''isolated intermediate.'' The purpose of the term ''isolated intermediate'' is to provide a bright line guide for identifying the boundaries between processes. This definition, in conjunction with the definition of ''process,'' simply provides that a process ends when an intermediate compound is placed in equipment that is used solely within the given process for purposes of storage. For example, if a compound is produced in Reactor A and then transferred directly to Reactor B, where a subsequent reaction takes place, then Reactor A and Reactor B belong to the same process because the product of Reactor A is not placed in storage equipment prior to further processing. This would be true even if two or more batches from Reactor A must be accumulated in Reactor B prior to initiating the reaction in Reactor B. As another example, assume that the compound produced in Reactor A is sometimes put into drums for temporary storage prior to subsequent processing in Reactor B. In this case, the drum storage marks the end of a process, and Reactor B represents the beginning of the next process. This would be true even if the storage is for a short time and even if the material is drummed off infrequently. All that matters for the purposes of identifying the process boundary is that storage occurs. It may sometimes be necessary to put off-spec material into storage for the period until it can be reprocessed or disposed of. We do not intend that infrequent, unplanned events such as these should create process boundaries.

F. Definition of Storage Tank

To be consistent with the proposed changes to the definition of ''process,'' we are also proposing to revise the definition of ''storage tank.'' The promulgated definition of ''storage tank'' specifies that a storage tank contains either a feedstock or a product of a process (*i.e.,* on a process flow diagram, a storage tank is located on one side of the process—either before or after it). Process tanks are tanks within a process; the tanks receive material from the process and discharge material to the same process (*i.e.,* they would have the process on both sides). Because the promulgated process definition encompassed many processing steps, we believed that the promulgated storage tank definition would mostly capture raw material and solvent storage tanks. We believed there would be few product tanks because final products would most likely not contain solvents and would be stored in drums or other containers suitable for small quantities.

However, the proposed process definition would result in far more products of processes, such as isolated intermediates. The vessels storing these products would be considered storage tanks under the promulgated definition, but the characteristics of these tanks would more likely resemble process tanks. Isolated intermediate tanks would most likely have smaller capacities than raw material or solvent storage tanks, would be expected to operate at higher than ambient temperatures, and would be more likely to experience higher throughputs and possibly more constant levels. Emissions from these process tanks could also be linked with the other operations conducted in a process on a per-batch basis. Therefore, we decided to clarify the definition of ''storage tank'' to include only raw material coming into the process.

We are also proposing to revise the ''storage tank'' definition to include solvent storage tanks located in tank farms that receive spent solvent from one or more processes. Typically, these tanks (which are generally 20,000 gallons or higher) are considered storage tanks in previous MACT standards; therefore, the proposed change would make the rule consistent with previous rules.

G. Annual Mass Emission Limit Standards for Process Vents

As a result of the proposed change to the definition of ''process,'' we were concerned that the ''shortening'' of the process might have some unintended consequences relating to a reduction in the amount of HAP emissions reductions resulting from NESHAP. Under the promulgated rule, the owner or operator of an existing source can comply with the annual mass emission limit standard for as many as seven processes. The seven process limit was based on a review of emissions from the industry which showed only 168,000 pounds per year (lb/yr), out of 16,246,000 lb/yr nationwide, were emitted from processes with emissions less than 2,000 lb/yr. On average, there were seven processes per facility that contributed to this 168,000 lb/yr. With the proposed change in the definition of ''process,'' however, an owner or operator could conceivably exempt more emissions than the 168,000 lb/yr that were originally anticipated if they could redraw process boundaries to utilize all 2,000 lb/yr of the exemption per process. An analysis of the database also indicated that, of the approximately 12 million lb/yr reduction of HAP associated with the process vent MACT alternative, about 0.5 million lb/yr of reductions would be attributed to processes left uncontrolled or to processes controlled down to 2,000 lb/yr, and the remaining 11 million lb/yr would be attributed to achieving 93 percent reduction. For the expected 100 facilities in the source category, the amount of emissions exempted by using the 2,000 lb/yr alternative would average 5,000 lbs/yr (2.5 tons) per facility.

The average emissions per facility from processes for which an owner or operator complies with the 2,000 lb/yr limit could be much higher than 5,000 lb/yr, and nationwide emissions reductions could be much lower, under these proposed amendments than under the NESHAP. To prevent this unintended result, we are proposing several changes. One change is to replace the seven process limit with a facilitywide emission limit of 4,000 lb/

yr. This change would not only preserve the emissions reductions originally anticipated from the process definition, but would also simplify the process vent provisions. A second proposed change is to extend the 2,000 lb/yr/process emission limit to include vents in processes where at least one stream was required to meet the 98 percent reduction requirement. Under the promulgated rule, the owner or operator was required to reduce emissions from these ''leftover'' vents by 93 percent. However, this restriction is no longer necessary because the 4,000 lb/yr facility cap would preserve the intended overall emissions reductions. Similarly, we propose eliminating the 100 lb/yr process *de minimis* cutoff because the 2,000 lb/yr process limit, or the 4,000 lb/yr facility limit, would apply to these processes as well. Finally, we are proposing to express the limits only in metric units (*i.e.,* 900 kilograms per year (kg/yr) and 1,800 kg/yr, respectively).

We are also proposing to replace the 400 lb/yr (uncontrolled) cutoff for new sources with an 1,800 kg/yr (uncontrolled) facility cap. This change was needed because the new source MACT standard would have been more stringent than the existing source MACT standard had the format and emission limit not been changed.

H. 98 Percent Standard for Process Vents at Existing Sources

We are proposing to make changes to the applicability of the 98 percent individual process vent requirement. The promulgated rule requires 98 percent control of emissions from process vents that meet the total resource effectiveness (TRE) criteria. This requirement is accompanied by a ''grandfathering'' provision that exempts these process vents from the 98 percent control requirement if they were controlled to at least 93 percent prior to the proposal date.

The original basis for the grandfathering provision provided in the promulgated rule is that it was not cost effective to replace existing devices that could meet the floor level of control, 93 percent, for the incremental 5 percent control. However, upon replacement (*i.e.,* starting from scratch after the useful life of the device is over), upgrading from 93 percent to 98 percent control is cost effective. The promulgated rule language inadvertently grandfathered the process rather than the control device. As a result, the promulgated rule has an unintended adverse effect on one segment of the industry (*i.e.,* nondedicated processes). Since nondedicated, multipurpose facilities are constantly undergoing product changes, the introduction of new processes, which could not be grandfathered, would drive these facilities toward replacing existing devices with devices that could meet 98 percent almost immediately. However, for dedicated processes, the promulgated grandfathering provision exempted the existing process from the 98 percent requirement indefinitely.

To correct this unintended inequity, the proposed revisions grandfather the ''control device'' rather than the process vent. As noted above, an aspect of the original analysis was that it was cost effective to upgrade to 98 percent control when replacing the control device. In addition, further consideration was given to the useful life of a control device. The useful life typically is 10 to 20 years, depending on the type of device. Therefore, today's proposed amendments would require an owner or operator of both types of processes to meet the 98 percent control requirement upon replacement or reconstruction of the control device, or upon reaching a date either 15 years from issuance of a facility's preconstruction permit, or April 2, 2007, whichever is later. This proposed language provides a definite date by which all such devices must be replaced. Thus, in 2007, control devices installed before the Pharmaceuticals Production NESHAP proposal will be more than 10 years old and, on average, should be about at the end of their useful lives.

In addition to these changes, we are also proposing two additional exemptions from the 98 percent control requirement. The first of these proposed provisions is designed to encourage pollution prevention (P2). Specifically, the owner or operator would be exempt from the 98 percent control requirement if the TRE vent is controlled to at least the MACT floor level of control (93 percent), and the production-indexed HAP consumption factor for the process is reduced by at least 50 percent. The second of the new provisions would allow processes containing hydrogenation vents to maintain the level of control achieved on the date of these proposed amendments while requiring at least 95 percent reduction on all other vents within the process. This provision would allow an owner or operator to control processes containing hydrogenation vents at higher levels than the floor, but less than the 98 percent requirement. We are proposing to add this language to address concerns that controlling some hydrogenation vents can be unsafe.

I. The Alternative Standard

We are proposing several changes to the alternative standard. These changes include new terminology and additional language clarifying when HAP concentrations in gas streams exiting control devices must be corrected for dilution. We are also proposing additional procedures for demonstrating compliance that an owner or operator may use in lieu of the concentration corrections. The following discussion describes our rationale for developing an alternative standard, summarizes our reasons for requiring concentration corrections and how these requirements were included in the promulgated rule, and describes our proposed changes to the alternative standard.

1. Rationale for an Alternative Standard

The Pharmaceuticals Production NESHAP and today's proposed amendments contain several options that allow an owner or operator to meet a concentration cutoff at the outlet of a control device as a means of achieving compliance with the standards. The most common option is referred to as the alternative standard which requires continuous (15-minute) monitoring of control device outlet concentration. The alternative standard also enables compliance to be evaluated at a single point (the outlet of the device) regardless of how many processes or unit operations are tied into the control device inlet. In addition, only one violation per day is assigned for each device complying with the alternative standard. In contrast, compliance with other options is evaluated on a process basis even if multiple processes are tied into a common control device. If monitoring parameters for these devices are exceeded, these exceedances could result in one violation per process per day. Therefore, the alternative standard is viewed as a critical element of the NESHAP and proposed amendments for end-of-line control devices that service numerous unit operations and processes, and it is expected to be utilized widely by the industry.

2. Correcting Concentrations for Dilution

In establishing the alternative standard, we were concerned that an owner or operator could use dilution as a means of achieving compliance with the standard. Although this practice is addressed in the General Provisions (see § 63.4(b)), we recognize that there are valid circumstances where air or inert gases are introduced into manifolds for safety and design considerations, and that these practices should not be

viewed as strictly prohibited by the above-referenced passage in the General Provisions if the effect of adding these gases can somehow be considered. Therefore, we sought to address these situations in the proposed amendments in several ways.

In § 63.1257(b)(6), the NESHAP requires that concentration measurements ''be adjusted to negate the dilution effects of introducing nonaffected gaseous streams into the vent streams prior to control or measurement * * *.'' One of the intended results of this language was to require owners or operators complying with the alternative standard to adjust their measured concentrations by considering the amount of diluent gas introduced into the system prior to comparing this value against the concentration limit. (Another intended result of § 63.1257(b)(6) was to consider diluent gases in defining a process vent—process vents must contain at least 50 parts per million by volume (ppmv) HAP, on an undiluted and uncontrolled basis.)

Another requirement addressed combustion devices specifically. Because combustion devices operate such that the characteristics of the incoming stream are chemically changed, a simple correction for dilution at the inlet of the device will not directly and proportionally correct the concentration at the outlet of the device. Therefore, for combustion devices, the NESHAP also requires that an owner or operator consider dilution by correcting the outlet concentration to 3 percent oxygen (see § 63.1257(a)(3)). The NESHAP further states in § 63.1257(d)(3)(ii) that this correction should be made when the control device is a combustion device that uses supplemental combustion air.

The intent of the provisions described above was to require the correction only when nonaffected streams (*i.e.,* diluent gases or supplemental combustion air) were introduced into the vent or manifold. However, supplemental combustion air was not specifically defined, and the location of the referenced language (under the process vent compliance determination procedures, rather than the general compliance determination procedures) made the intent of this requirement somewhat unclear.

The 3 percent correction factor was first used in the new source performance standards (NSPS) for air oxidation unit processes, distillation operations, and reactor processes in the synthetic organic chemical manufacturing industry (40 CFR part 60, subparts III, NNN, and RRR), and later, the HON. The value of 3 percent originates from good engineering practices. For the oxygen deficient streams found in these industries, if the proper amount of supplemental combustion air is added, the outlet stream would contain approximately 3 percent oxygen. The concept of requiring the correction to 3 percent oxygen only when supplemental combustion air is used has a precedent in the Polymer Manufacturing NSPS (40 CFR part 60, subpart DDD). In the development of that standard, commenters suggested that requiring the 3 percent correction factor for high volume, low concentration streams would make compliance with a 20 part per million by volume (ppmv) outlet concentration standard difficult. We responded by identifying situations where additional air was added to the vent streams (*e.g.,* supplemental combustion air) prior to the control devices and required the correction only when these situations were encountered. In other words, if the vent streams originating from the processes and affected sources themselves were high volume, low concentration, then no correction was required. However, if nonaffected streams were added prior to control, then the NESHAP requires the correction.

This same concept was incorporated into the Pharmaceutical MACT. However, as mentioned previously, the promulgated rule was not clear on several aspects of the requirement, including the definition of supplemental combustion air, and when the requirement to correct to 3 percent oxygen should apply. In addition, the predominant reasons pharmaceutical facilities add excess air or other diluents to manifolds is not to provide the supplemental air necessary for combustion of emissions streams (the high volume, low concentration streams in the pharmaceuticals industry, by their very nature, should not require additional air for combustion), but rather for safety and design considerations. We also recognize that for these high oxygen streams, the correction requirement has the effect of lowering the 20 ppmv compliance level, perhaps significantly.

3. Proposed Changes in Terminology and Dilution Correction Requirements

To clarify the dilution correction requirements, we are proposing to revise terminology, to use the new terminology in the provisions describing the conditions under which outlet concentrations from combustion devices must be corrected, to explicitly state the procedures for correcting outlet concentrations from noncombustion devices, and to increase the compliance level for noncombustion devices from 20 ppmv to 50 ppmv.

In today's proposed amendments, we define a more general term called ''supplemental gases.'' This term distinguishes air added to the vent stream for combustion and gases added for design or safety purposes from the affected vent streams and air required to operate combustion device burner(s). In addition, because this is a general term, it applies in all situations; it is not limited to combustion devices. The definition also clarifies that air used to operate combustion device burner(s) is not considered supplemental gas. Failure to include this clarification could allow the interpretation that every combustion device uses supplemental gases.

Using this new terminology, we are proposing to revise the current compliance option for combustion devices to require that the correction to 3 percent oxygen be made in cases where supplemental gases are added to affected streams prior to combustion. For noncombustion devices, we are proposing to add a new § 63.1257(a)(3)(ii) requiring correction to adjust outlet concentrations by the amount of supplemental gas added. This was the intent of the language in the promulgated rule. In addition to these changes, we are proposing to increase the concentration limit for noncombustion devices from 20 ppmv to 50 ppmv to be consistent with the definition of a process vent. This change would also provide a greater allowance to meet the concentration limit for devices that are perceived to be more environmentally-friendly in terms of potential for material recovery and the minimizing of secondary air pollution.

We believe an explanation of how to determine which streams are supplemental gases is warranted at this point. We are not requiring owners and operators to measure the concentration of total organic compounds (TOC) in gas streams. The proposed definition of supplemental gases indicates that process knowledge is adequate in identifying such streams. We intend that the owner or operator can qualitatively identify these streams based on their knowledge of the process and use reasonable judgement in estimating TOC or HAP concentrations. Similarly, these proposed amendments also allow owners and operators to use process knowledge in identifying affected process vents (defined by containing 50 ppmv HAP) and affected wastewater streams (defined by containing 5 ppmw HAP and a load of at least 0.05 kg/yr).

For characterizing affected wastewater, two ''process knowledge''-based approaches, the use of a mass balance, and the use of published water solubility data are identified as adequate for determination of HAP wastewater concentrations. For defining process vents, these proposed amendments state that process knowledge that no HAP are present in an emission stream or the use of engineering assessments are both allowable approaches. Consistent with other guidance on process knowledge, the proposed amendments define engineering assessments broadly in § 63.1257(d)(2)(ii) and do not specify exact procedures or formulas for determining vent stream characteristics. In many cases, the exercise of identifying process vents will also result in identification of supplemental gases.

4. Proposed Alternative to HAP Concentration Correction for Combustion Devices

In addition to the proposed clarification of the 3 percent oxygen correction factor for combustion devices, we are also proposing to add an option that would allow owners and operators to monitor combustion devices for good operating practices in lieu of correcting to 3 percent oxygen when supplemental gases are used. The 20 ppmv concentration limit is based on concentrations achievable by properly operated incinerators—those with adequate residence times and combustion chamber temperatures. With the additional constraints of maintaining residence times and combustion chamber temperatures, owners and operators have economic incentives to minimize the amount of supplemental gases that are introduced prior to combustion devices. Nevertheless, we believe that it is reasonable to allow for monitoring of parameters in lieu of correcting to 3 percent oxygen when supplemental gas is added.

Therefore, we are proposing two sets of parameter levels as alternatives to correcting for dilution when supplemental gases are used in combustion devices. If the owner or operator complies with the alternative standard instead of a percent reduction requirement of 95 percent or less (*e.g.,* for some process vents and storage tanks), the owner or operator would be required to monitor for a minimum residence time of 0.5 seconds and a minimum combustion chamber temperature of 760°C. These values are consistent with parameters specified in subpart GGG for controlling emission streams from vents at wastewater collection and treatment systems. If the owner or operator complies with the alternative standard instead of a percent reduction requirement of 98 percent, the owner or operator would be required to monitor for a minimum residence time of 0.75 seconds and a minimum combustion chamber temperature of 816°C. Based on a considerable amount of data, we have concluded that properly designed and operated incinerators reduce emissions by 98 percent if they maintain these residence times and temperatures.

5. Proposed Alternative to HAP Concentration Correction for Noncombustion Devices

In addition to the proposed clarification of the concentration correction requirements described above, we are proposing an option to allow owners and operators of ''dense gas'' systems a simplified procedure for correction. Dense gas systems are defined as systems that are designed and operated to limit oxygen levels to less than 12 percent. We are proposing the simplified correction for dense gas systems because these systems are generally used to convey concentrated streams (above 5,000 ppmv). The proposed procedure would allow owners and operators to calculate a system flowrate setpoint. This setpoint is an indicator of stream concentration and would be monitored to demonstrate that significant dilution is not occurring. The owner or operator of a dense gas system would also be able to choose to operate at a higher flowrate than the system setpoint by making a concentration correction.

J. Vapor Balancing for Storage Tanks

We are proposing to allow vapor balancing in conjunction with the use of a pressure setting to comply with the storage tank control requirements. The vapor balancing provisions also would require that displaced vapors from the tank trucks and railcars be controlled at the reloading or cleaning facility to at least 90 percent or be vapor balanced. To demonstrate compliance with the offsite provisions, the owner or operator must obtain a certification from the cleaning and reloading facility indicating that the control requirements will be met. In general, a pressure setting of at least 2.5 pounds per square inch gage (psig) was determined to eliminate breathing losses from tanks that are typically found in this industry. As a means of demonstrating continuous compliance with the pressure setting requirement, the proposed provisions would also require the owner or operator to record the pressure vent setting during each transfer operation and to monitor the pressure relief valve on a quarterly basis to ensure no breathing losses.

K. Wastewater Standards

We are proposing several changes to the wastewater provisions. Because the proposed change in the definition of process reduces the number of steps in a process, we are proposing to reduce the wastewater load point of determination (POD) cutoffs in § 63.1256(a)(1)(i) from 1 megagram per year (Mg/yr) per process to 0.25 Mg/yr per process.

In § 63.1256(a)(5), we are proposing to clarify the offsite wastewater treatment options. Under the Pharmaceuticals Production NESHAP, offsite treatment was allowed only if the wastewater contained less than 50 ppmw of partially soluble HAP to prevent discharges that could result in significant volatilization of HAP prior to treatment. Since this objective would be met if the wastewater or residual is always managed and treated, we are proposing to add a provision to allow the wastewater to be discharged if the transferee (*i.e.,* the company or other organization accepting the discharged wastewater or residual) certifies that the wastewater or residual will be managed and treated in accordance with an amended subpart GGG. The 50 ppmw limit would still apply if this certification is not obtained, but we are also proposing to clarify the management and treatment requirements for these streams. The treatment options would be either enhanced biological treatment (§ 63.1256(g)(10)) or the 95 percent mass reduction option for biological treatment (§ 63.1256(g)(11)(i), (ii), and § 63.1256 (h)), and the management options would be either to cover the waste management units up to the activated sludge units or to demonstrate that less than 5 percent of the total soluble HAP is emitted from waste management units up to the activated sludge unit.

Another proposed change is to add specific provisions in § 63.1256(a)(3) for maintenance wastewater that differ from the provisions for process wastewater. The proposed provisions are equivalent to the provisions in the HON and other recent rules. They would require an owner or operator to prepare a description of maintenance procedures for management of maintenance wastewater as part of the startup, shutdown, and malfunction plan. Modification of the procedures would be required, as necessary.

L. Equipment Leak Provisions

We are proposing numerous clarifying changes within the LDAR provisions. One set of changes would make the difficult-to-monitor, unsafe-to-monitor, and inaccessible provisions consistent with language used in past and pending regulations (changes made to subpart H of the HON and in the proposed consolidated air rule). These changes would clarify which provisions apply to a given component and how to deal with components that cannot be accessed at any time in a safe manner. Another proposed change is to revise § 63.1255(b) to clarify which provisions in subpart H of the HON apply in these proposed amendments.

M. Pollution Prevention Provisions

We are proposing to add language to § 63.1252(e) that would allow owners and operators to merge processes for the purposes of complying with P2 provisions. This proposed change is being made because of the proposed change in the definition of a process. Our intent with regard to compliance under P2 provisions is that the owner or operator can make the P2 demonstration around the same starting and ending materials, regardless of how many ''processes'' the manufacture of these materials encompass. For example, consider the sequential manufacturing of four intermediates (A, B, C, and D) and the final product (E). Under the promulgated process definition, these five steps would be considered a single process. However, under the proposed revised definition, there are five processes. The proposed P2 language clarifies that owners and operators are allowed to consider any or all of these processes when demonstrating a reduction in the production-indexed consumption factor, as long as the activities covered under P2 provisions are limited to the same starting and ending materials for the baseline (before) and annual (after) demonstrations. In the above example, therefore, the owner or operator could make the P2 demonstration around processes A through E. Additionally, if the facility eliminated middle products C or D through a process optimization or improvement measure, the owner or operator could take credit for reducing the amount of HAP consumed by these steps. However, we stress that under P2 provisions, eliminating steps within a process by transferring operations elsewhere is not allowed. In addition, because the P2 provisions apply beyond the individual process level, other constraints are needed to make the provisions practical for documentation purposes. The baseline date for merged processes is 1992 (approximately 10 years prior to the compliance date) and merging a nondedicated formulation process or a nondedicated solvent recovery process with another process to claim a reduction from both processes is not allowed.

N. Initial Compliance Demonstration Provisions

1. Use of Equations in the 1978 Control Techniques Guideline (CTG) Document

In § 63.1257(d)(2), we are proposing to revise equations 13, 25, 26, and 33. These equations are used to estimate uncontrolled emissions from heating, depressurization, and vacuum system events. One of the proposed changes is to eliminate the requirement to use an average molecular weight in calculations for emission streams that contain more than one HAP. This change has no effect on the emissions estimates, but it makes the equations look more consistent with the equations in the 1978 CTG, which was our original intent. This change also does not apply to the optional approaches in the NESHAP to calculate emissions from heating and depressurization. We are also proposing to correct equation 33 and add new language that would provide additional flexibility in calculating emissions.

The proposed change to equation 13 (heating) is accomplished by simply removing the average molecular weight variable and adding the individual molecular weight to the summation term in the numerator. The NESHAP also includes instructions on how to modify equation 17 when it is used to calculate the average molecular weight for use in equation 13. The proposed change to equation 13 eliminates the need for these instructions, which were included with the definition of the HAP partial pressure in the variable list for equations 13 through 17. Therefore, we are proposing to delete these instructions.

The steps in the 1978 CTG to calculate emissions from depressurization are inconsistent with each other. Steps 6 through 9 describe how to calculate the ratio of air to total volatile organic compounds (VOC), but step 10 describes how to estimate the mass emissions of individual VOC assuming the previous steps were used to calculate the ratio of air to that individual VOC. We are proposing to replace the average molecular weight in equation 26 with individual compound molecular weights because this is consistent with the final step in the 1978 CTG. It appears this was the intent in the CTG (*i.e.,* procedures to calculate emissions from all other types of emission events are for single compounds), and we understand that this is how many pharmaceutical facilities calculate emissions from depressurization. To be consistent with this change in equation 26, we are also proposing to remove the summations from equation 25 so that it will calculate the average ratio of moles of noncondensables to moles of an individual HAP instead of the average ratio of moles of noncondensables to total HAP.

We are proposing two changes to equation 33, which is used to estimate emissions from vacuum systems. The first change is to replace the variable for the average molecular weight with one for an individual HAP molecular weight. This change alone would make the equation valid for emission streams with a single pollutant. To make the equation valid for multicomponent systems, the portion of the equation that represents the ratio of moles of condensable compounds to moles of noncondensable compounds must be replaced. To calculate the emissions of each HAP individually, the numerator of the revised ratio would be the partial pressure of the individual HAP, and the denominator would be the system pressure minus the sum of the partial pressures of all condensable compounds. Because we want to know the total HAP emissions, the proposed equation 33 multiplies the partial pressure of an individual HAP (in the numerator) by the molecular weight for that HAP, and sums over the number of HAPs in the emission stream.

To provide additional flexibility in calculating emissions, we are also proposing to add a statement in § 63.1257(d)(2)(ii) that would allow an owner or operator to calculate emissions using modified versions of the equations in § 63.1257(d)(2)(i) if they meet two conditions. First, the modified equations must have been used to meet other regulatory obligations. Second, the owner or operator must demonstrate that the results obtained using the modified equations do not affect applicability assessments or compliance determinations under these proposed amendments.

2. Process Condenser Demonstration

We are proposing to revise the initial compliance demonstration procedures for process condensers. These changes exclude from the demonstration requirement any process condensers followed by either secondary condensers that would be considered air pollution control devices or air

pollution control devices complying with the alternative standard. The original compliance procedure for process condensers was promulgated to ensure that owners and operators would accurately characterize uncontrolled emissions. If a process condenser was not operating properly, then the load to a secondary condenser or an air pollution control device (APCD) would be higher than the equations contained in the NESHAP would predict.

However, if a secondary condenser operates to cool a stream down to a temperature that corresponds to the required removal, assuming HAP load is at the level estimated by the equations (even though the load is actually higher because the process condenser doesn't work as anticipated), then the secondary condenser actually removes more HAP than is estimated by the equations and, in effect, accounts for the ineffectiveness of the process condenser. A similar effect occurs for other devices whose monitoring parameters are correlated directly with compliance, such as devices meeting the outlet concentration alternative standard. For these devices, the continuous compliance demonstration (monitoring) procedures will provide an indication that the requirements of the NESHAP are met, regardless of whether the process condenser is effective. However, in cases where no control device follows a process condenser, or where the APCD monitoring is based on testing or design evaluation at worst case conditions, either the validity of monitoring correlated to worst case conditions or actual emissions to the atmosphere depend on the effectiveness of the process condenser. Therefore, these proposed amendments require a process condenser initial demonstration for these cases.

3. Clarification of Worst-Case Testing Conditions

Although we are proposing only a minor change to the language in § 63.1257(b)(8) regarding the testing conditions for batch processes, we believe additional clarification of the intent of the worst-case provisions is warranted. Worst-case conditions are the most challenging conditions that the control device will encounter when used to control emission streams subject to the NESHAP which defines two categories of worst-case conditions: Absolute and hypothetical. Absolute worst-case conditions are based on actual emission stream characteristics. If the most challenging conditions are associated with the maximum HAP load, the NESHAP provides two time periods for defining the absolute worst-case conditions: (1) The period of time when the inlet to the control device contains at least 50 percent of the HAP load in the 8-hour period that contains the maximum HAP load, or (2) The 1-hour period when the inlet to the control device contains the maximum hourly HAP load. If the most challenging conditions are associated with a characteristic(s) other than the maximum HAP load, the absolute worst-case conditions are defined as the 1-hour period when those characteristics occur. The NESHAP cites three examples of such conditions: (1) Periods of time when the emission streams contain the maximum combined VOC and HAP load, (2) periods of time when the emission streams contain HAP(s) that approach limits of solubility for scrubbing media, and (3) periods of time when the emission streams contain HAP(s) that approach limits of adsorptivity for carbon adsorption systems. To determine the absolute worst-case conditions, the owner or operator must develop an emission profile that considers the characteristics of all of the vent streams to the control device, the design and operating characteristics of the control device, and scheduling of processes that generate the emission streams.

Hypothetical worst-case conditions are simulated conditions that are at least as challenging as the absolute worst-case conditions. As with absolute worst-case conditions, the owner or operator must develop an emission profile to determine the hypothetical worst-case conditions. The NESHAP provides two options for developing these emission profiles. One option is to determine the 1-hour period of time with the most challenging actual conditions. After these conditions are defined, the owner or operator must describe the equipment configuration, type of material to be processed, and any other characteristics of the simulated conditions under which test runs will be conducted. The owner or operator must also provide rationale for why the simulated conditions are considered to be as challenging as the most challenging actual conditions. The second option is to develop an emissions profile based on characteristics of the capture and control system that limit the maximum hourly emissions that can be routed to the control device. For example, a fan may limit the flowrate, and the concentration may be limited to a certain percentage of the lower explosive limit before a bypass valve opens.

O. Recordkeeping To Demonstrate Compliance With Process Vent Standards

We are proposing several changes to the recordkeeping and reporting procedures to clarify our intent. The provisions of § 63.1259 originally required owners and operators to calculate uncontrolled and controlled emissions for all processes in the PMPU. However, because some compliance options, such as the alternative standard, do not require such calculations to demonstrate compliance, we are proposing to specify the records required to demonstrate compliance with each option. We are also proposing the concept of a ''standard'' batch to clarify when uncontrolled and controlled emissions must be recalculated as part of ongoing compliance demonstrations.

The language of § 63.1259(b)(6) in the NESHAP states that the owners or operators must keep records of uncontrolled and controlled emissions per batch for each process. In specifying this recordkeeping requirement, we intended that owners and operators keep detailed records of uncontrolled and controlled emissions for each process to be operated at the facility and the number of batches of each process operated at the facility. In order to demonstrate compliance with the percent reduction requirement, only a showing of the process uncontrolled and controlled emissions would be needed since the ongoing continuous compliance demonstration was achieved through the monitoring of process parameters. Similarly, in order to demonstrate compliance with the 2,000 lb/yr emissions limit, we required records of the number of batches run at the facility, in addition to the controlled emissions, for use in calculating a summation of yearly emissions. However, because each batch in a campaign does not necessarily operate under exactly the same conditions, the emissions may vary from batch to batch. The promulgated rule does not clearly describe how to handle these variations in the continuous compliance demonstration. It could be interpreted to mean that the owner or operator must recalculate emissions for every variation in operating conditions, but this was not our intent.

To clarify our intent, we are proposing to add the concept of a standard batch. The owner or operator would create a standard batch based on a range of operating characteristics and other processing variables that affect emissions. The standard batch would become part of an operating scenario for

the process (*i.e.,* the standard batch consists of the same operating parameters as are required in the operating scenario, but the owner or operator may specify a range instead of only a single, fixed value). The owner or operator would calculate emissions for the standard batch using the characteristics that result in the highest emissions, and these results would be used in the demonstration of initial compliance with the process vent standards. If, during the processing of a particular batch, one such process variable was operated outside of the standard batch, the owner or operator would be required to recalculate uncontrolled and controlled emissions for that batch and demonstrate compliance with an amended subpart GGG. If the batch was operated within the standard batch constraints, then only a record that the batch was operated accordingly would be required.

In establishing the standard batch, owners and operators have flexibility in determining how to identify and record nonstandard batches. For example, the owner or operator should focus on the episodes that affect emissions or control efficiency. Likewise, in some cases, tracking control device parameters would be an adequate means of detecting nonstandard batches. Moreover, insignificant episodes, under the revised standard batch concept, would not require any further monitoring for ''nonstandardness'' during the operating period. For example, a one-time demonstration would be appropriate where a given process vent handles only a small fraction of the uncontrolled emissions from the given process, or where it is not physically possible to exceed the standard batch conditions. As another example, facilities often have head tanks within their processes. These tanks are used to measure a specified quantity of raw material prior to addition to the reactor or other unit operation. Typically, the capacity of these tanks is small—often no more than 100 or 200 gallons. If operated at ambient conditions, the potential emissions from the tank are limited only by the design capacity of the tank. In this situation, it would be sufficient to make a one-time showing that emissions from filling of the tank to capacity cannot exceed emissions under standard batch conditions.

P. Minor Technical Corrections

1. Tables 1 and 5

In Table 1, we are proposing several changes to clarify how subpart A (the General Provisions) applies to these proposed amendments. Some proposed changes correct inconsistencies. For example, we are proposing to change the requirement to conduct a performance test within 180 days of the compliance date to 150 days to be consistent with the time period to conduct necessary performance tests and submit the Notification of Compliance Status report. Other changes direct the reader to appropriate sections of the NESHAP that contain language related to the specific requirements in the General Provisions. We are also proposing to specify that the preconstruction approval requirement in § 63.5(b)(3) would not apply to facilities that are covered by 40 CFR 52.2454.

In Table 5, we are proposing to delete references to fuel gas systems. We inadvertently included these references in the NESHAP. They should be deleted because we did not include requirements specific to fuel gas systems anywhere in the NESHAP. Our intent is that fuel gas systems are a form of control device, and the requirements for control devices apply. We are also proposing changes to the control requirements for in-process tanks that meet the criteria of § 63.1252(f). Table 5 of the promulgated rule required an owner or operator to maintain a fixed roof on these tanks, and if the tank meets certain criteria, to control vent streams from the tank. However, because the tank is within the process, vents from the tank are also process vents and subject to the process vent standards. To eliminate this overlap, we are proposing to replace the vent stream control requirements in Table 5 with a statement that vents on these tanks are process vents.

2. Definitions

In addition to the changes to definitions described in other sections of this preamble, we are also proposing minor changes to definitions of many other terms to correct errors, improve clarity, or to make them consistent with other regulations.

3. Wastewater Provisions

We are proposing several minor changes and corrections to the wastewater provisions. In § 63.1256(a)(3), we are proposing to add an exemption for wastewater samples of a size not greater than reasonably necessary for the method of analysis. If the owner or operator determines that it is unsafe to perform the required seal gap measurements or inspections of a wastewater tank at the specified time, the HON specifies two compliance options. Although we intended to include both of these options in the promulgated pharmaceuticals rule, one of them was inadvertently left out. Therefore, we are proposing to add § 63.1256(b)(6)(i), which would specify that an owner or operator may measure the seal gaps or inspect the tank within 30 calendar days of the determination that the floating roof is unsafe. In § 63.1256(d)(2), we are proposing to add an option to vapor balance wastewater loading operations from containers back to the process.

In § 63.1256(g)(8), (11), and (12), the promulgated rule specifies that compliance with treatment options must be determined based on a performance test; to be consistent with other rules, we are proposing to clarify that compliance with all treatment options, except open biological treatment, may also be determined using a design evaluation. Paragraphs (g)(8) and (12) in § 63.1256 of the promulgated rule cross referenced two paragraphs that describe compliance procedures for biological treatment; we are proposing editorial changes to clarify which cross referenced section applies to open biological treatment and which applies to closed biological treatment.

Finally, to be consistent with other recent rules, we are proposing to add a provision in § 63.1257(b)(10) that would allow an owner or operator to analyze wastewater using Method 8260, as well as Method 8270 in ''Test Methods for Evaluating Solid Waste, Physical/Chemical Methods'' (EPA Publication No. SW–846, Third Edition, September 1986, as amended by Update I, November 15, 1992).

4. Emissions Averaging

According to § 63.1252(d)(6) of the promulgated rule, an affected source may include, in emissions averaging groups, no more than 20 storage tanks that are subject to the 90 percent reduction requirement, and no more than 20 storage tanks that are subject to the 95 percent reduction requirement. However, this provision is inconsistent with the policy we established in the HON of limiting to 20 the number of emission points in an emissions average (59 FR 19428, April 22, 1994). Section 63.1257(g) specifies that emissions averaging for storage tanks applies to all storage tanks at an affected source (*i.e.,* all storage tanks are emission points that may be grouped for emissions averaging). Therefore, we are proposing to correct § 63.1252(d)(6) by specifying that not more than 20 storage tanks at an affected source may be included in emissions averaging.

5. Initial Compliance and Monitoring

We are proposing several minor changes and corrections to the initial compliance and monitoring provisions. In § 63.1257(b)(6)(iii), we are proposing to add that Method 26A of appendix A of 40 CFR part 60 may be used to determine hydrogen chloride concentrations, and we are proposing to specify that both Methods 26 and 26A also may be used to determine hydrogen halide and halogen concentrations. In § 63.1257(d)(2)(i)(H), we are proposing a correction to the note associated with equation 36 so that an owner or operator may elect to disregard the effect of time on the emissions and simply assume all HAP in the vapor space are emitted. In § 63.1257(e), (f), and (g), we are proposing to correct symbols used to define variables in several equations, and we are proposing to correct references to several equation numbers. To reduce the burden of demonstrating compliance with the P2 provisions, we are proposing to add a statement in § 63.1257(f) that would allow an owner or operator to calculate the annual HAP consumption factor once per month if more than 10 batches are produced in a month. We are proposing to move equation 61 from § 63.1257(h)(3) to its proper location in § 63.1257(h)(2)(i). In § 63.1258(b)(6)(iii), we are proposing a change to clarify that an exceedance for a flare occurs only upon the loss of all pilot flames. Because we are proposing to change the annual mass emission limit compliance option for process vents by adding an 1,800 kg/yr facilitywide limit, we are also proposing to add a requirement in § 63.1258(c) that owners and operators demonstrate continuous compliance with this limit by calculating daily 365-day rolling summations; this requirement parallels the requirement for demonstrating compliance with the 2,000 lb/yr limits for individual processes. We are also proposing to delete from this paragraph the sentence that describes what will be considered a violation.

6. Recordkeeping and Reporting

The promulgated rule did not include any recordkeeping and reporting requirements for storage tanks with floating roofs. To correct this oversight we are proposing to add requirements to: (1) record the results of each inspection and seal gap measurement, as specified in § 63.123(c) through (e); and (2) submit the results of inspections that detected a failure or seal gap measurements that exceed required limits, as specified in § 63.122(d) through (f). Clearly, these are the same recordkeeping and reporting requirements in the HON, and they have been applied in other rules as well.

To document compliance with the annual mass emission limit for process vents, § 63.1259(b)(4) of the NESHAP requires records of rolling annual total emission calculations, but it did not specify the recordkeeping frequency. Because the NESHAP specifies that the emission limit not be exceeded in any 365-day period, we are proposing to require daily recordkeeping. In addition, we are proposing that this requirement apply to the proposed 4,000 lb/yr facilitywide emission limit, as well as to the 2,000 lb/yr limit for individual processes.

Table 1 in the NESHAP states that § 63.10(b)(2) does not apply to the NESHAP because we have specified applicable records within the NESHAP. We did not include a requirement in the NESHAP to record all maintenance performed on the air pollution control equipment, but these are important records that we should have required. Therefore, we are proposing to add a requirement to record this information in § 63.1259(a)(3)(iii).

We are proposing several statements to clarify our intent. In § 63.1260(e), we are proposing to add paragraphs (6) and (7) to reiterate requirements already stated in § 63.1257(e)(1)(ii) that data used in determining the annual average concentration of wastewater streams must be included in the precompliance report. We are proposing to edit § 63.1260(g)(1)(ii) to clarify when quarterly reporting is required. We are proposing to move a statement from the definition of the term ''operating scenario'' to § 63.1260(g)(2)(vii) because it deals with information the owner or operator must provide to verify that requirements for new operating scenarios have been met. In § 63.1260(h)(1), we are proposing to add a statement to clarify that process changes for which the owner or operator must submit a notification of process change means the startup of a new process.

7. Units

The NESHAP specifies most emission limits and other numerical requirements in two sets of units. This can create confusion when a parameter meets the value in one set of units but not the other. One approach to resolve this problem would be to specify the values using an unreasonable number of significant figures. However, we are proposing to simply specify all terms using only one set of units.

III. What are the administrative requirements of the rule?

A. Executive Order 12866, Regulatory Planning and Review

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

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

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

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

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

Pursuant to the terms of Executive Order 12866, it has been determined that these proposed amendments do not constitute a ''significant regulatory action'' because they do not add any new control requirements. Consequently, this action was not submitted to OMB for review under Executive Order 12866.

B. Executive Order 13132, Federalism

Executive Order 13132 (64 FR 43255, August 10, 1999) requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local

governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. The EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

If EPA complies by consulting, Executive Order 13132 requires EPA to provide to OMB, in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns and EPA's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the Agency's Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner.

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

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

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

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

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

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

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

E. Unfunded Mandates Reform Act of 1995

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

The EPA has determined that the proposed amendments do not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, or tribal governments, in the aggregate, or the private sector in any 1 year. The maximum total annual cost of the Pharmaceuticals Production NESHAP for any year has been estimated to be approximately $64 million (63 FR 50287, September 21, 1998), and today's proposed amendments do not add new requirements that would increase this cost. Thus, today's proposed amendments are not subject to the requirements of sections 202 and 205 of the UMRA. In addition, EPA has determined that these proposed amendments contain no regulatory requirements that might significantly or uniquely affect small governments because they contain no requirements that apply to such governments or impose obligations upon them. Therefore, today's proposed amendments are not subject to the requirements of section 203 of the UMRA.

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

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's proposed amendments on small entities, a small entity is defined as: (1) A small business in SIC code 2833 or 2834 that has as many as 750 employees; (2) a small business in SIC code 2869 that has as many as 1,000 employees; (3) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (4) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed amendments on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The EPA has determined that none of the small entities will experience a significant impact because the proposed amendments impose no additional regulatory requirements on owners or operators of affected sources.

Although these proposed amendments will not have a significant economic impact, EPA nonetheless has tried to reduce the impact of the proposed amendments on small entities. Many of the proposed amendments define optional means of compliance. For example, vapor balancing was added as an optional means of compliance for storage tanks, a facilitywide limit on the mass of process vent emissions replaces the limit on the number of processes that may comply with the process-based emission limit, additional compliance alternatives are included for process vents that meet the criteria for 98 percent control, and optional parameter monitoring is included as an alternative to correcting to 3 percent O_2 when supplemental gas is introduced to a dense gas system or a system controlled with a combustion device and the owner or operator complies with the alternative standard. The proposed amendments also include simplified recordkeeping requirements when the owner or operator documents conditions that define a standard batch, and the process is operated within that range of conditions. We continue to be interested in the potential impacts of the proposed amendments on small entities and welcome comments on issues related to such impacts.

G. Paperwork Reduction Act

The OMB has approved the information collection requirements contained in the 1998 NESHAP under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control No. 2060–0358. An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 1781.01), and a copy may be obtained from Sandy Farmer by mail at U.S. Environmental Protection Agency, Office of Environmental Information, Collection Strategies Division (2822), 1200 Pennsylvania Avenue, NW, Washington DC 20460, by email at *farmer.sandy@epa.gov,* or by calling (202) 260–2740.

Today's proposed amendments to the NESHAP will have no net impact on the information collection burden estimates made previously. An oversight has been corrected by adding recordkeeping and reporting requirements for storage tanks equipped with floating roofs. The promulgated rule only included recordkeeping and reporting requirements for add-on control devices for storage tanks even though add-on control devices and floating roofs were considered in the cost impacts and burden estimates. Also, the proposed amendments clarify the intent of several provisions in the 1998 NESHAP and correct inadvertent omissions and minor drafting errors in the 1998 NESHAP. Consequently, the ICR has not been revised.

H. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), Pub. L. 104–113 (March 7, 1996), directs all Federal agencies to use voluntary consensus standards instead of government-unique standards in their regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., material specifications, test methods, sampling and analytical procedures, and business practices) that are developed or adopted by one or more voluntary consensus bodies. Examples of organizations generally regarded as voluntary consensus standards bodies include the American Society for Testing and Materials (ASTM), the National Fire Protection Association (NFPA), and the Society of Automotive Engineers (SAE). The NTTAA requires Federal agencies like EPA to provide Congress, through OMB, with explanations when an agency does not use available and applicable voluntary consensus standards.

The proposed amendments to subpart GGG do not involve the proposal of any new technical standards or incorporate by reference existing technical standards. The EPA welcomes comments on this aspect of these proposed amendments and, specifically, invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

List of Subjects in 40 CFR Part 63

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

Dated: March 20, 2000.

Carol M. Browner,

Administrator.

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

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

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

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

Subpart GGG—National Emission Standards for Pharmaceuticals Production

2. Section 63.1250 is amended by:
a. Revising paragraph (a),
b. Revising paragraph (b),
c. Revising paragraph (c),
d. Revising paragraph (f);
e. Revising paragraph (h)(1);
f. Revising paragraphs (h)(4) and (5); and
g. Adding paragraph (h)(6).

The revisions and additions read as follows:

§ 63.1250 Applicability.

(a) *Definition of affected source.* (1) The affected source subject to this subpart consists of the pharmaceutical

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

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

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

(iii) Process, use, or produce HAP.

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

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

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

* * * * *

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

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

(2) An owner or operator of a new or reconstructed affected source must comply with the provisions of this subpart on [date of publication of the final amendments] or upon startup, whichever is later.

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

(i) The requirements of this subpart are more stringent than requirements of this subpart in effect before [effective date of the final rule] and contained in the 40 CFR, part (63.1200-end), edition revised as of July 1, 2000; and

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

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

(i) The requirements of this subpart are more stringent than the requirements of this subpart in effect before [effective date of the final rule]; and

(ii) The owner or operator complies with the requirements of this subpart in effect before [effective date of the final rule] during the period between startup and October 21, 2002.

(5) Notwithstanding the requirements of paragraph (f)(2) of this section, a new source which commences construction or reconstruction after April 10, 2000 and before [date of publication of final amendments] shall not be required to comply with this subpart until [date 1 year after publication of final amendments] if:

(i) The requirements of this subpart are more stringent than the requirements published on April 2, 1997 (62 FR 15754); and

(ii) The owner or operator complies with the requirements of this subpart in effect before [effective date of the final rule] during the period between startup and [date 1 year after publication of final amendments].

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

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

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

* * * * *

(h) * * *

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

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

* * * * *

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

(5) *Compliance with other regulations for wastewater.* After the compliance dates specified in this section, the owner or operator of an affected wastewater stream that is also subject to provisions in 40 CFR parts 260 through 272 may elect to determine whether this subpart or 40 CFR parts 260 through 272 contain the more stringent control requirements (*e.g.,* design, operation, and inspection requirements for waste management units; numerical treatment standards; etc.) and the more stringent testing, monitoring, recordkeeping and reporting. Compliance with provisions of 40 CFR parts 260 through 272 that are determined to be more stringent than the requirements of this subpart

constitutes compliance with this subpart. For example, provisions of 40 CFR parts 260 through 272 for treatment units that meet the conditions specified in § 63.1256(g)(13) constitute compliance with this subpart. In the Notification of Compliance Status report required by § 63.1260(f), the owner or operator shall identify the more stringent provisions of 40 CFR parts 260 through 272 with which the owner or operator will comply. The owner or operator shall also identify in the Notification of Compliance Status report required by § 63.1260(f) the information and procedures used to make any stringency determinations. If the owner or operator does not elect to determine the more stringent requirements, the owner or operator must comply with both the provisions of 40 CFR parts 260 through 272 and the provisions of this subpart.

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

* * * * *

3. Section 63.1251 is amended by:

a. Revising the definitions for ''Active ingredient,'' Annual average concentration,'' ''Construction,'' ''Consumption,'' ''Excipient,'' ''Large control device,'' ''Pharmaceutical manufacturing operations,'' ''Pharmaceutical product,'' ''Primary use,'' ''Process,'' ''Process tank,'' ''Repaired,'' ''Shutdown,'' ''Small control device,'' ''Startup,'' ''Storage tank,'' and ''Vapor-mounted seal'';

b. Removing the definition of ''Component'';

c. Removing the last sentence from the definition of ''Wastewater stream'';

d. Revising paragraphs (3) and (8) in the definition for ''Operating scenario'';

e. Adding definitions in alphabetical order for ''Combustion device burner,'' ''Dense gas system,'' ''Isolated intermediate,'' ''Maintenance wastewater,'' ''Precursor,'' ''Reconstruction,'' ''Standard batch,'' ''Supplemental gases,'' and ''System flowrate.''

The revisions and additions read as follows:

§ 63.1251 Definitions.

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

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

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

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

Maintenance wastewater means wastewater generated by the draining of process fluid from components in the pharmaceutical manufacturing process unit into an individual drain system in preparation for or during maintenance activities. Maintenance wastewater can be generated during planned and unplanned shutdowns and during periods not associated with a shutdown. Examples of activities that can generate maintenance wastewater include

descaling of heat exchanger tubing bundles, cleaning of distillation column traps, draining of pumps into an individual drain system, and draining of portions of the pharmaceutical manufacturing process unit for repair. Wastewater from cleaning operations is not considered maintenance wastewater.

* * * * *

Operating scenario, * * *

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

* * * * *

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

* * * * *

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

* * * * *

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

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

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

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

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

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

* * * * *

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

* * * * *

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

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

* * * * *

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

* * * * *

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

* * * * *

Repaired means that equipment:

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

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

* * * * *

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

* * * * *

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

* * * * *

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

Startup means the setting in operation of a continuous process unit for any purpose; the first time a new or reconstructed batch process unit begins production; for new equipment added, including equipment used to comply with this subpart, the first time the equipment is put into operation; or, for the introduction of a new product/process, the first time the product or process is run in equipment. For batch process units, startup does not apply to the first time the equipment is put into operation at the start of a campaign to

produce a product that has been produced in the past, after a shutdown for maintenance, or when the equipment is put into operation as part of a batch within a campaign. As used in § 63.1255, startup means the setting in operation of a piece of equipment or a control device that is subject to this subpart.

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

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

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

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

(4) Wastewater storage tanks; and

(5) Process tanks (including product tanks and isolated intermediate tanks).

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

* * * * *

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

* * * * *

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

* * * * *

4. Section 63.1252 is amended by:

a. Revising the introductory paragraph;

b. Revising paragraph (d)(2);

c. Revising the first sentence in paragraph (d)(5);

d. Revising paragraph (d)(6);

e. Revising paragraph (e) introductory text;

f. Revising the second sentence in paragraph (e)(1); and

g. Adding paragraph (e)(4).

The revisions and additions read as follows:

§ 63.1252 Standards: General.

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

* * * * *

(d) * * *

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

* * * * *

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

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

* * * * *

(e) *Pollution prevention alternative.* Except as provided in paragraph (e)(1) of this section, an owner or operator may choose to meet the pollution prevention alternative requirement specified in either paragraph (e)(2) or (3) of this section for any PMPU or for any situation described in paragraph (e)(4) of this section, in lieu of the requirements specified in §§ 63.1253, 63.1254, 63.1255, and 63.1256. Compliance with paragraphs (e)(2) and (3) of this section shall be demonstrated through the procedures in § 63.1257(f). Any PMPU for which the owner or operator seeks to comply by using the pollution prevention alternative shall begin with the same starting material(s) and end with the same product(s). The owner or operator may not comply with the pollution prevention alternative by eliminating any steps of a process by transferring the step offsite (to another manufacturing location).

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

* * * * *

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

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

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

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

5. Section 63.1253 is amended by:

a. Revising paragraph (a);

b. Revising paragraph (d); and

c. Adding paragraph (f).

The revisions and additions read as follows:

§ 63.1253 Standards: Storage tanks.

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

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

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

* * * * *

(d) As an alternative standard, the owner or operator of an existing or new affected source may comply with the storage tank standards by routing storage tank vents to a combustion control device achieving an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 20 ppmv or

less, and an outlet concentration of hydrogen halides and halogens of 20 ppmv or less. If the owner or operator is routing emissions to a noncombustion control device, it must achieve an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 50 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 50 ppmv or less. Compliance with the outlet concentrations shall be determined by the initial compliance procedures of § 63.1257(c)(4) and the continuous emission monitoring requirements of § 63.1258(b)(5).

* * * * *

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

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

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

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

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

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

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

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

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

(6) Railcars or tank trucks that deliver HAPs to an affected storage tank must be reloaded or cleaned at a facility that utilizes one of the following control techniques:

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

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

(7) The owner or operator of the facility where the railcar or tank truck is reloaded or cleaned must comply with the following requirements:

(i) Submit to the owner or operator of the affected storage tank and to the Administrator a written certification that the reloading or cleaning facility will meet the requirements of this section. The certifying entity may revoke the written certification by sending a written statement to the owner or operator of the affected storage tank giving at least 90 days notice that the certifying entity is rescinding acceptance of responsibility for compliance with the requirements of this paragraph.

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

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

(A) The equipment to be used and the procedures to be followed when reloading the railcar or tank truck and displacing vapors to the storage tank from which the liquid originates, and (B) Each time the vapor balancing system is used to comply with paragraph (f)(6)(ii) of this section.

6. Section 63.1254 is revised to read as follows:

§ 63.1254 Standards: Process vents.

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

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

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

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

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

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

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

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

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

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

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

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

(3) *Individual vent emission reduction requirements.*

(i) Except as provided in paragraph (a)(3)(ii) of this section, uncontrolled HAP emissions from a process vent must be reduced by 98 percent or in accordance with any of the procedures

in paragraphs (a)(1)(ii)(A) through (D) of this section if the uncontrolled HAP emissions from the vent exceed 25 tons per year, and the flow-weighted average flowrate (FR_a) calculated using Equation 1 of this subpart is less than or equal to the flowrate index (FRI) calculated using Equation 2 of this subpart.

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

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

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
FRI=flowrate index, scfm
HL=annual uncontrolled HAP emissions, lb/yr, as defined in § 63.1251

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

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

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

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

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

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

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

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

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

(*3*) The production-indexed HAP consumption factor for the 12-month period in which the process was operated prior to the compliance date is less than one-half of the 3-year average baseline value established no earlier than the 1987 through 1989 calendar years.

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

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

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

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

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

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

(c) *Alternative standard.* As an alternative standard, the owner or operator of an existing or new affected source may comply with the process vent standards by routing vents from a process to a combustion control device achieving an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 20 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 20 ppmv or less. If the owner or operator is routing emissions to a noncombustion control device, it must achieve an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 50 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 50 ppmv or less. Any process vents within a process that are not routed to this control device must be controlled in accordance with the provisions of paragraph (a) or (b) of this section, as applicable. Initial compliance with the outlet concentrations is demonstrated in accordance with the initial compliance procedures described in § 63.1257(d)(1)(iv), and continuous compliance is demonstrated in accordance with the emission monitoring requirements described in § 63.1258(b)(5).

7. Section 63.1255 is amended by:

a. Revising paragraph (a)(1);

b. Revising paragraph (a)(7);

c. Revising paragraphs (a)(10)(ii) and (iii);

d. Adding paragraphs (a)(11) and (12);

e. Revising paragraph (b);

f. Revising paragraph (c)(2)(i);

g. Revising ''paragraph (b)(1)(v)'' to read ''paragraph (b)(4)(i)'' in paragraph (c)(3)(i);

h. Revising the definitions of the terms ''P_L'' and ''P_T'' following Equation 3 in paragraph (c)(4)(iv);

i. Removing the definition of the term ''P_S'' following Equation 3 in paragraph (c)(4)(iv) and adding the definition of the term ''P_S'' following Equation 3 in paragraph (c)(4)(iv);

j. Revising ''paragraph (b)(1)(vi)'' to read ''paragraph (b)(4)(ii)'' in paragraph (c)(5)(i)(B);

k. Revising paragraphs (c)(5)(vi)(B) and (C);
l. Revising paragraphs (c)(6) and (7);
m. Revising paragraph (c)(9);
n. Revising paragraphs (d)(1)(i) and (ii);
o. Revising paragraph (e)(2);
p. Revising paragraph (e)(3) introductory text;
q. Revising paragraph (e)(3)(i);
r. Revising the definition of the term ''$\%V_L$'' following Equation 5 in paragraph (e)(6)(ii);
s. Revising ''paragraph (b)(1)(v)'' to read ''paragraph (b)(4)(i)'' in paragraph (e)(7)(i);
t. Adding paragraphs (e)(7)(iii)(A) through (C);
u. Revising the second sentence in paragraph (e)(9);
v. Revising paragraph (f);
w. Revising paragraph (g)(2) introductory text;
x. Revising paragraph (g)(2)(i)(A);
y. Removing paragraph (g)(2)(v), redesignating paragraphs (g)(2)(vi) through (ix) as paragraphs (g)(2)(v) through (viii), and revising redesignated paragraphs (g)(2)(vi) and (viii);
z. Revising the first sentence in paragraph (g)(3);
aa. Revising paragraph (g)(4) introductory text;
bb. Revising paragraph (g)(4)(iv);
cc. Revising paragraph (g)(4)(v)(A);
dd. Revising ''§ 63.174(c)'' to read ''§ 63.174(c)(1)(i) and (c)(2)(ii)'' in the first sentence in paragraph (g)(4)(vii)(B);
ee. Revising ''§§ 63.178(c)(3)(ii) and (c)(3)(iii)'' to read ''§ 63.178(c)(3)(ii) and (iii)'' in the first sentence in paragraph (g)(4)(viii);
ff. Revising the first sentence in paragraph (g)(5) introductory text;
gg. Removing paragraph (g)(5)(ii), redesignating paragraphs (g)(5)(iii) through (vi) as paragraphs (g)(5)(ii) through (v), and revising ''appendix'' to read ''section'' in the second sentence of redesignated paragraph (g)(5)(ii);
hh. Revising paragraph (g)(6) heading;
ii. Revising the first sentence in paragraph (g)(7) introductory text;
jj. Revising ''paragraph (b)(1)(vi)'' to read ''paragraph (b)(4)(ii)'' in paragraph (g)(7)(i)(D);
kk. Revising paragraph (h)(2) heading;
ll. Revising paragraph (h)(2)(i)(B);
mm. Revising ''paragraph (b)(1)(ix)'' to read ''paragraph (b)(4)(iv)'' in paragraph (h)(2)(ii);
nn. Revising ''paragraph (b)(1)(vi)'' to read ''paragraph (b)(4)(ii)'' in paragraph (h)(2)(iii)(B);
oo. Revising paragraph (h)(2)(iv);
pp. Revising ''§ 63.1250(e)'' to read ''§ 63.1250(f)'' in the second sentence in paragraph (h)(3)(i);
qq. Revising paragraph (h)(3)(ii) introductory text;
rr. Revising paragraphs (h)(3)(ii)(C) and (D); and
ss. Revising paragraph (h)(3)(iv);

The revisions and additions read as follows:

§ 63.1255 Standards: Equipment leaks.

(a) * * *

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

* * * * *

(7) Equipment to which this section applies shall be identified such that it can be distinguished readily from equipment that is not subject to this section. Identification of the equipment does not require physical tagging of the equipment. For example, the equipment may be identified on a plant site plan, in log entries, or by designation of process boundaries by some form of weatherproof identification. If changes are made to the affected source subject to the leak detection requirements, equipment identification for each type of component shall be updated, if needed, within 90 calendar days, or by the next Periodic Report, following the end of the monitoring period for that component, whichever is later.

* * * * *

(10) * * *

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

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

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

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

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

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

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

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

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

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

(b) *References.* (1) The owner or operator of a source subject to this section shall comply with the provisions of subpart H of this part, as specified in paragraphs (b)(2) through (4) of this section. The term ''process unit'' as used in subpart H of this part

shall be considered to be defined the same as ''group of processes'' for sources subject to this subpart GGG. The term ''fuel gas system,'' as used in subpart H of this part, shall not apply for the purposes of this subpart GGG.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iii) Section 63.174, shall apply except:

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

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

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

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

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

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

(iv) Section 63.178, shall apply except:

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

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

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

million for all other equipment, except as provided in § 63.180(b)(4)(iii).

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

(c) * * *

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

(4) * * *

(iv) * * *

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

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

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

(5) * * *

(vi) * * *

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

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

* * * * *

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

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

* * * * *

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

(d) * * *

(1)(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. The owner or operator is not required to keep a record documenting compliance with the 1-hour requirement.

* * * * *

(e) * * *

(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)(4)(i) of this section, § 63.178(b) and § 63.179.

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

* * * * *

(6) * * *

(ii) * * *

$\%V_L$ = percent leaking valves as determined through periodic monitoring required in paragraphs (e)(2) through (4) of this section.

* * *

* * * * *

(7) * * *

(iii) * * *

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

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

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

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

(*2*) If the owner or operator elects to use other monitoring prior to the periodic monitoring required by paragraphs (e)(2) through (4) of this section to satisfy the requirements of paragraph (e)(7)(iii) of this section, then the valve shall be counted as a leaking valve unless it is repaired and shown by periodic monitoring not to be leaking.

* * * * *

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

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

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

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

(iii) For connectors, § 63.174(b) through (e) and paragraphs (b)(3)(iii)(B) through (F) of this section do not apply.

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

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

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

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

(iv) For any parts of a closed-vent system designated as unsafe to inspect, the owner or operator must have a written plan that requires inspection of the closed-vent systems as frequently as practicable during safe to inspect times, but not more frequently than annually.

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

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

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

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

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

(A) Buried;

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

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

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

(E) Not able to be accessed at any time in a safe manner to perform monitoring. Unsafe access includes, but is not limited to, the use of a wheeled scissor-lift on unstable or uneven terrain, the use of a motorized man-lift basket in areas where an ignition potential exists, or access would require near proximity to hazards such as electrical lines, or would risk damage to equipment.

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

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

(iv) If any inaccessible, ceramic, or ceramic-lined connector is observed by visual, audible, olfactory, or other means to be leaking, the leak shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in paragraph (b)(3)(i) of this section.

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

(g) * * *

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

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

* * * * *

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

* * * * *

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

(3) *Records of visual inspections.* For visual inspections of equipment subject to the provisions of paragraphs (c)(2)(iii)

and (c)(5)(iv) of this section, the owner or operator shall document that the inspection was conducted and the date of the inspection. * * *

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

* * * * *

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

(v) * * *

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

* * * * *

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

* * *

* * * * *

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

* * * * *

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

* * *

* * * * *

(h) * * *

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

(i) * * *

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

* * * * *

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

(3) * * *

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

* * * * *

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

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

* * * * *

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

8. Section 63.1256 is amended by:

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

b. Revising paragraph (a)(3);

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

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

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

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

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

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

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

j. Revising paragraph (g)(12).

The revisions and additions read as follows:

§ 63.1256 Standards: Wastewater.

(a) * * *

(1) * * *

(i) * * *

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

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

* * * * *

(3) *Exemptions from wastewater requirements.* (i) The following wastewaters are not subject to the wastewater provisions of this subpart:

(A) Stormwater from segregated sewers;

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

(C) Spills;

(D) Water from safety showers; and

(E) Samples of a size not greater than reasonably necessary for the method of analysis that is used.

(ii) *Maintenance wastewater.* Each owner or operator of a source subject to this subpart shall comply with the requirements of paragraphs (a)(3)(ii)(A) through (D) of this section for maintenance wastewater containing partially soluble or soluble HAPs listed in Tables 2 and 3 of this subpart.

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

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

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

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

(B) The owner or operator shall modify and update the information required by paragraph (a)(3)(ii)(A) of this section as needed following each maintenance procedure based on the actions taken and the wastewater generated in the preceding maintenance procedure.

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

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

* * * * *

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

residual, or to an offsite treatment operation.

* * * * *

(ii) * * *

(C) Section 63.6(g); or

(D) If the affected wastewater streams or residuals removed from affected wastewater streams received by the transferee contain less than 50 ppmw of partially soluble HAP, then the transferee must, at a minimum, manage and treat the affected wastewater streams and residuals in accordance with one of the following:

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

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

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

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

* * * * *

(b) * * *

(6) * * *

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

* * * * *

(d) * * *

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

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

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

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

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

* * * * *

(g) * * *

(8) * * *

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

* * * * *

(11) * * *

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

* * * * *

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

* * * * *

9. Section 63.1257 is amended by:

a. Revising paragraph (a)(3);

b. Revising paragraph (a)(5);

c. Revising paragraph (b)(6) introductory text;

d. Revising paragraph (b)(6)(iii);

e. Adding a new sentence at the end of paragraph (b)(8)(i)(A) introductory text;

f. Revising paragraph (b)(8)(i)(A)(*3*)(*i*);

g. Revising paragraph (b)(10) introductory text;

h. Revising paragraphs (b)(10)(i) and (ii);

i. Redesignating paragraphs (b)(10)(iii) through (v) as paragraphs (b)(10)(iv) through (vi) and revising redesignated paragraphs (b)(10)(iv) introductory text and (b)(10)(v);

j. Adding paragraph (b)(10)(iii);

k. Revising the second sentence in paragraph (c)(1) introductory text;

l. Revising paragraph (c)(3)(v);

m. Revising paragraphs (d)(1)(i) through (iii);

n. Revising equation 13 and the definitions of the terms ''$(P_i)_{Tn}$'' and ''MW_i'' for Equations 13 through 17 in paragraph (d)(2)(i)(C)(*1*);

o. Removing the definitions of the terms ''(P_i^*)'' and ''(P_j^*)'' for Equations 13 through 17 in paragraph (d)(2)(i)(C)(*1*) and adding definitions for the terms ''P_i^*'' and ''P_j^*'' for Equations 13 through 17 in paragraph (d)(2)(i)(C)(*1*);

p. Removing the last sentence in paragraph (d)(2)(i)(C)(2)(i);

q. Revising paragraph (d)(2)(i)(C)(*4*) introductory text;

r. Revising paragraph (d)(2)(i)(C)(*4*)(*ii*);

s. Revising the definition of the term ''x_j'' after Equation 24 in paragraph (d)(2)(i)(D)(2);

t. Revising paragraphs (d)(2)(i)(D)(*3*) and (*4*);

u. Revising paragraph (d)(2)(i)(E);

v. Revising paragraph (d)(2)(i)(H);

w. Adding a new sentence between the third and fourth sentences in paragraph (d)(2)(ii);

x. Revising paragraph (d)(3) introductory text;

y. Revising paragraph (d)(3)(ii)(A);

z. Adding paragraph (d)(3)(iii);

aa. Removing the definition of the term ''P'' following Equation 45 in paragraph (e)(2)(iii)(C)(*3*) and adding in its place the definition of the term ''ρ'' in paragraph (e)(2)(iii)(C)(*3*);

bb. Revising ''Equation 44'' to read ''Equation 46'' in the first sentence in paragraph (e)(2)(iii)(C)(*5*);

cc. Removing the definition of the term ''π'' for Equation 47 in paragraph (e)(2)(iii)(D)(*3*) and revising the definition of the term ''ρ'' for Equation 47 in paragraph (e)(2)(iii)(D)(*3*);

dd. Adding the definition of the term ''ρ'' for Equation 47 in paragraph (e)(2)(iii)(D)(*3*);

ee. Revising paragraph (e)(2)(iii)(E)(*3*) introductory text;

ff. Revising ''Equation 49'' to read ''Equation 50'' in the first sentence in paragraph (e)(2)(iii)(E)(*3*)(*ii*);

gg. Revising the definitions of the terms ''QMW_a, QMW_b'' and ''QMG_b'' for Equation 51 in paragraph (e)(2)(iii)(G)(*3*);

hh. Revising the first sentence in paragraph (f)(1)(iii)(B);

ii. Revising paragraph (f)(2)(ii)(A); and

jj. Redesignating paragraphs (h)(2)(i) and (h)(3) as paragraphs (h)(3) and (4), revising redesignated paragraph (h)(3), and removing Equation 61 from redesignated paragraph (h)(4).

The revisions and additions read as follows:

§ 63.1257 Test methods and compliance procedures.

(a) * * *

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

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

Where:

C_c = concentration of TOC or total organic HAP or hydrogen halide and halogen corrected to 3 percent oxygen, dry basis, ppmv

C_m = total concentration of TOC or total organic HAP or hydrogen halide and halogen in vented gas stream, average of samples, dry basis, ppmv

$\%O_{2d}$ = concentration of oxygen measured in vented gas stream, dry basis, percent by volume

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

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

Where:

C_a = corrected outlet TOC, organic HAP, and hydrogen halides and halogens concentration, dry basis, ppmv

C_m = actual TOC, organic HAP, and hydrogen halides and halogens concentration measured at control device outlet, dry basis, ppmv

V_a = total volumetric flow rate of all gas streams vented to the control device, except supplemental gases

V_s = total volumetric flow rate of supplemental gases

* * * * *

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

* * * * *

(b) * * *

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

* * * * *

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

* * * * *

(8) * * *

(i) * * *

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

* * * * *

(*3*) * * *

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

* * * * *

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

(i) *Method 305.* Use procedures specified in Method 305 of 40 CFR part 63, appendix A, and comply with requirements specified in paragraph (b)(10)(vi) of this section.

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

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

(A) Documentation of site-specific procedures to minimize the loss of compounds due to volatilization, biodegradation, reaction, or sorption during the sample collection, storage, and preparation steps.

(B) Documentation of specific quality assurance procedures followed during sampling, sample preparation, sample introduction, and analysis.

(C) Measurement of the average accuracy and precision of the specific procedures, including field duplicates and field spiking of the material source before or during sampling with compounds having similar chemical characteristics to the target analytes.

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

* * * * *

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

* * * * *

(c) * * *

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

* * * * *

(3) * * *

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

* * * * *

(d) * * *

(1) * * *

(i) Initial compliance with § 63.1254(a)(2)(i) is demonstrated when the actual emissions of HAP from the sum of all process vents within a process is less than or equal to 900 kg/yr. Initial compliance with § 63.1254(a)(2)(ii) is demonstrated when the actual emissions of HAP from the sum of all process vents in compliance with § 63.1254(a)(2)(i) is less than or equal to 1,800 kg/yr. Uncontrolled HAP emissions and controlled HAP emissions shall be determined using the procedures described in paragraphs (d)(2) and (3) of this section.

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

(A) Determining controlled HAP emissions using the procedures described in paragraph (d)(3) of this section, and uncontrolled HAP emissions determined using the procedures described in paragraph (d)(2) of this section, and demonstrating that the reductions required by § 63.1254(a)(1)(i), § 63.1254(a)(3), and § 63.1254(b) are met; or

(B) Controlling the process vents using a device meeting the criteria specified in paragraph (a)(4) of this section.

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

* * * * *

(2) * * *

(i) * * *

(C) * * *

(*1*) * * *

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

* * * * *

P_i^* = vapor pressure of each HAP in the vessel headspace at any temperature between the initial and final heatup temperatures, mmHg

P_j^* = vapor pressure of each condensable VOC (including HAP) in the vessel headspace at any temperature between the initial and final heatup temperatures, mmHg

* * *

$(P_i)_{Tn}$ = partial pressure of each HAP in the vessel headspace at initial (T1) and final (T2) temperature

MW_i = molecular weight of the individual HAP * * *

* * * * *

(*4*) If the vessel contents are heated to the boiling point, emissions must be calculated using the procedure in paragraphs (d)(2)(i)(C)(*4*)(*i*) and (*ii*) of this section.

* * * * *

(*ii*) While boiling, the vessel must be operated with a properly operated process condenser. An initial demonstration that a process condenser is properly operated is required for some process condensers, as described in paragraph (d)(2)(iii) of this section.

(D) * * *

(*2*) * * *

x_j = mole fraction of each condensable (including HAP) in the liquid phase

* * * * *

(*3*) The average ratio of moles of noncondensable to moles of an individual HAP in the emission stream is calculated using Equation 25 of this subpart; this calculation must be repeated for each HAP in the emission stream:

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

Where:

n_{Ri} = average ratio of moles of noncondensable to moles of individual HAP

P_{nc1} = initial partial pressure of the noncondensable gas, as calculated using Equation 23 of this subpart

P_{nc2} = final partial pressure of the noncondensable gas, as calculated using Equation 24 of this subpart

P_i^* = vapor pressure of each individual HAP

x_i = mole fraction of each individual HAP in the liquid phase

n = number of HAP compounds

i = identifier for a HAP compound

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

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

Where:

E = mass of HAP emitted

V_{nc1} = initial volume of noncondensable gas in the vessel, as calculated using Equation 21 of this subpart

V_{nc2} = final volume of noncondensable gas in the vessel, as calculated using Equation 22 of this subpart

n_{Ri} = average ratio of moles of noncondensable to moles of individual HAP, as calculated using Equation 25 of this subpart

P_{atm} = atmospheric pressure, standard

R = ideal gas law constant

T = temperature of the vessel, absolute

MW_i = molecular weight of each HAP

* * * * *

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

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

Where:

E = mass of HAP emitted

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

P_i = partial pressure of the HAP at the receiver temperature or the ejector outlet conditions
P_j = partial pressure of condensable (including HAP) at the receiver temperature or the ejector outlet conditions
La = total air leak rate in the system, mass/time
MW_{nc} = molecular weight of noncondensable gas
t = time of vacuum operation
MWi = molecular weight of the individual HAP in the emission stream, with HAP partial pressures calculated at the temperature of the receiver or ejector outlet, as appropriate

* * * * *

(H) *Empty vessel purging.* Emissions from empty vessel purging shall be calculated using Equation 36 of this subpart (Note: The term $e^{-Ft/v}$ can be assumed to be 0):

* * * * *

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

* * *

* * * * *

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

* * * * *

(ii) * * *

(A) The performance test shall be conducted by performing emission testing on the inlet and outlet of the control device following the test methods and procedures of § 63.1257(b). Concentrations shall be calculated from the data obtained through emission testing according to the procedures in paragraph (a)(2) of this section.

* * * * *

(iii) *Initial compliance demonstration for condensers.*

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

(B) *Process condensers.* During periods when the condenser is operating as a process condenser, the owner or operator is required to demonstrate that the process condenser is properly operated if the process condenser meets either of the criteria described in paragraphs (d)(2)(iii)(B)(*1*) and (*2*) of this section. The owner or operator must either measure the condenser exhaust gas temperature and show it is less than the boiling or bubble point of the substance(s) in the vessel, or perform a material balance around the vessel and condenser to show that at least 99 percent of the material vaporized while boiling is condensed. The initial demonstration shall be conducted for all appropriate operating scenarios and documented in the Notification of Compliance report described in § 63.1260(f).

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

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

* * * * *

(e) * * *

(2) * * *

(iii) * * *

(C) * * *

(*3*) * * *

ρ= density of the wastewater, kg/m^3

* * * * *

(D) * * *

(*3*) * * *

ρ= density of the wastewater stream, kg/m^3

* * * * *

p = number of runs

* * * * *

(E) * * *

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

* * * * *

(G) * * *

(*3*) * * *

QMW_a, QMW_b = mass flow rate of partially soluble and/or soluble HAP compounds in wastewater entering (QMW_a) and exiting (QMW_b) the treatment process, kilograms per hour (as calculated using Equations 44 and 45)
QMG_b = mass flow rate of partially soluble and/or soluble HAP compounds in vented gas stream exiting the control device, kg/hr

* * * * *

(f) * * *

(1) * * *

(iii) * * *

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

(2) * * *

(ii) * * *

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

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

Where:

$[kg/kg]_b$ = the baseline production-indexed HAP consumption factor, in kg/kg
M_{prod} = the annual production rate, in kg/yr
M = the annual reduction required by add-on controls, in kg/yr
P_R = the fractional reduction in the annual kg/kg factor achieved using pollution prevention where P_R is ≥0.5

* * * * *

(h) * * *

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

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

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

Where:

E_{Ui} = yearly uncontrolled emissions from process i
E_{Ci} = yearly actual emissions for process i
E_{TU} = total yearly uncontrolled emissions
E_{TC} = total yearly actual emissions
n = number of processes included in the emissions average

* * * * *

10. Section 63.1258 is amended by:

a. Revising paragraph (b)(5);

b. Revising paragraph (b)(6)(iii);

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

d. Revising paragraph (c).

The revisions read as follows:

§ 63.1258 Monitoring requirements.

* * * * *

(b) * * *

(5) *Monitoring for the alternative standards.* (i) For control devices that are used to comply with the provisions of § 63.1253(d) or 63.1254(c), the owner or operator shall monitor and record the outlet TOC concentration and the outlet hydrogen halide and halogen concentration every 15 minutes during the period in which the device is

functioning in achieving the HAP removal required by this subpart. 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.

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

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

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

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

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

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

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

Where:

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

(*2*) Annual emissions used in Equation 63 of this subpart must be based on the actual mass of organic compounds entering the control device, as calculated from the most representative emissions inventory data submitted within the 5 years before the Notification of Compliance Status report is due. The owner or operator must recalculate the system flowrate setpoint once every 5 years using the annual emissions from the most representative emissions inventory data submitted during the 5-year period after the previous calculation. Results of the initial calculation must be included in the Notification of Compliance Status report, and recalculated values must be included in the next Periodic report after each recalculation. For all calculations after the initial calculation, to use emissions inventory data calculated using procedures other than those specified in § 63.1257(d), the owner or operator must submit the emissions inventory data calculations and rationale for their use in the Notification of Process Change report or an application for a part 70 permit renewal or revision.

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

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

Where:

C_a = adjusted outlet concentration limit, dry basis, ppmv
50 = outlet concentration limit associated with the flowrate setpoint, dry basis, ppmv
F_s = system flowrate setpoint, scfm
F_a = actual system flowrate limit, scfm

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

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

(6) * * *

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

* * * * *

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

* * *

* * * * *

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

* * * * *

11. Section 63.1259 is amended by:

a. Revising paragraph (a)(3)(i);

b. Revising paragraph (a)(3)(iii);

c. Revising paragraph (b)(4);

d. Revising paragraphs (b)(5)(i) and (b)(5)(ii);

e. Removing paragraph (b)(6), redesignating paragraphs (b)(7) through (b)(11) as paragraphs (b)(6) through (b)(10), and revising the redesignated paragraphs (b)(6) and (b)(9); and

f. Adding paragraphs (b)(11) and (12).

The revisions and additions read as follows:

§ 63.1259 Recordkeeping requirements.

(a) * * *

(3) * * *

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

* * * * *

(iii) For each startup, shutdown, or malfunction, the owner or operator shall record all information necessary to demonstrate that the procedures specified in the affected source's startup, shutdown, and malfunction plan were followed, as specified in § 63.6(e)(3)(iii), and shall record all maintenance performed on the air pollution control equipment, as specified in § 63.10(b)(2)(iii); alternatively, the owner or operator shall record any actions taken that are not consistent with the plan, as specified in § 63.6(e)(3)(iv).

* * * * *

(b) * * *

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

(5) * * *

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

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

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

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

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

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

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

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

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

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

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

* * * * *

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

* * * * *

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

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

* * * * *

12. Section 63.1260 is amended by:

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

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

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

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

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

f. Revising the reference ''§ 63.10(d)(4)(ii)'' to read ''§''63.10(d)(5)(ii)'' in the last sentence in paragraph (i).

The revisions and additions read as follows:

§ 63.1260 Reporting requirements.

* * * * *

(e) * * *

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

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

* * * * *

(g) * * *

(1) * * *

(ii) Quarterly reports shall be submitted when the source experiences an exceedance of a temperature limit monitored according to the provisions of § 63.1258(b)(1)(iii) or an exceedance of the outlet concentration monitored according to the provisions of § 63.1258(b)(1)(x) or § 63.1258(b)(5). Once an affected source reports quarterly, the affected source shall follow a quarterly reporting format until a request to reduce reporting frequency is approved. If an owner or operator submits a request to reduce the frequency of reporting, the provisions in § 63.10(e)(3)(ii) and (iii) shall apply, except that the phrase ''excess emissions and continuous monitoring system performance report and/or summary report'' shall mean ''Periodic report'' for the purposes of this section.

* * * * *

(2) * * *

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

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

(h) * * *

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

* * * * *

13. Section 63.1261 is revised to read as follows:

§ 63.1261 Delegation of Authority.

(a) This subpart can be administered by EPA, or a delegated authority such as a State, local, or tribal agency. If the Administrator has delegated authority to a State, local, or tribal agency, then that agency has the authority to administer and enforce this subpart. To find out if this subpart is delegated to a State, local, or tribal agency, the appropriate EPA Regional Office should be contacted.

(b) In delegating implementation and enforcement authority of this subpart to a State, local, or tribal agency under 40 CFR part 63, subpart E, the authorities contained in paragraph (c) of this section are retained by the Administrator and are not transferred to the State, local, or tribal agency.

(c) The authorities that will not be delegated to State, local, or tribal agencies are as follows:

(1) Approval of alternatives to the emission standards in §§ 63.1252 through 63.1256 under § 63.6(g).

(2) Approval of major alternatives to test methods under § 63.1257 as defined in § 63.90.

(3) Approval of major alternatives to monitoring under § 63.1258 as defined in § 63.90.

(4) Approval of major alternatives to recordkeeping and reporting under §§ 63.1259 and 63.1260 as defined in § 63.90.

14. Table 1 to subpart GGG is amended by:

a. Revising the column heading ''Comments'' to read ''Explanation'';

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

c. Removing the entry ''63.7(a)(2)(i–ix)'' and adding in its place the entry ''63.7(a)(2)(i)–(ix);''

d. Removing the entry ''63.8(b)(3)–(c)(3)'' and adding in its place the entry ''63.8(b)(3)–(c)(4);''

e. Removing the entry ''63.8(c)(4–5)'' and adding in its place the entry ''63.8(c)(5);''

f. Removing the entry ''63.8(c)6)–(8)'' and adding in its place the entry ''63.8(c)(6)–(8).''

The revisions and additions read as follows:

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

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

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

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

Item of equipment	Control requirement[a]
Drain or drain hub	(a) Tightly fitting solid cover (TFSC); or (b) TFSC with a vent to either a process or to a control device meeting the requirements of § 63.1256(h)(2); or

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

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

[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.
[b] Manhole includes sumps and other points of access to a conveyance system.
[c] A fixed roof may have openings necessary for proper venting of the tank, such as pressure/vacuum vent, j-pipe vent.

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