Compliance Assistance Tool for Clean Air Act Regulations: Subpart GGG of40 CFR NESHAPS for Source Category Pharmaceutical Production

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Appendices

LIST OF ACRONYMS

ACT	Alternative Control Techniques Information Document (EPA, 1994)
APCD	Air Pollution Control Device
ASTM	American Society for Testing and Materials
BOD	Biological Oxygen Demand
BP	Boiling Point
CAA	Clean Air Act
CAS Number	Chemical Abstracts Service Number
CEF	Control Equipment Failures
CEMS	Continuous Emissions Monitoring System
CFR	Code of Federal Regulations
CH_4	Methane
CMS	Continuous Monitoring System
CO_2	Carbon Dioxide
CTG	Control Technology Guidelines (EPA, 1978)
CVS	Closed Vent System
CWA	Clean Water Act
DE	Design Evaluation
DOT	Department of Transportation
EC	Air Emissions Control
ED	Estimated Dose
EE	Emissions Estimation
EPC	Emission Potential Concentrations
EPA	U.S. Environmental Protection Agency
F_{bio}	Degradation Factor for biological treatment
Fm	Fraction measured
FDA	Food and Drug Administration
FID	Flame Ionization Detector
FR	Flowrate
gal	Gallon
GC	Gas Chromatography
GGG	subpart GGG to part 63 - NESHAP
H_2O	Water
HAPs	Hazardous Air Pollutants
HCl	Hydrogen Chloride
HDPE	High Density Polyethylene
HON	Hazardous Organic - NESHAP
IDS	Individual Drain System
I&M	Inspection and Maintenance
IWP	Improper Work Practices
Kb	Subpart of NSPS- requirements for storage tanks w/floating roofs
kg	Kilogram

lb	Pound
LDAR	Leak Detection and Repair
M^3	Cubic Meter
M21	Method 21
MACT	Maximum Achievable Control Technology
MDL	Method Detection Limit
MED	Median Effective Dose
MiBK	Methyl isobutyl Ketone
mmHg	millimeters Mercury
MW	megawatts
NAICS	North American Industrial Classification System
NESHAP	National Emission Standard for Hazardous Air Pollutants
NOC	Notification of Compliance
NOCSR	Notification of Compliance Status Report
NPDES	National Pollutant Discharge Elimination System
NSPS	New Source Performance Standards
O_2	Oxygen
O/O	Owner or Operator
P2	Pollution Prevention
Pa	Pascal
PEG	Polyethylene Glycol
PhRMA	Pharmaceutical Research and Manufacturers of America
PL	Production Levels
PMPU	Pharmaceutical Manufacturing Process Unit
POD	Point of Determination
ppm	Parts per million
ppmv	Parts per million volume
ppmw	Parts per million weight
PRV	Pressure Release Valve
PSHAP	Partially Soluble Hazardous Air Pollutants
psi	Pound per Square Inch
PT	Performance Testing
QA/QC	Quality Assistance/Quality Control
RCRA	Resource Conservation and Recovery Act
RE	Removal Efficiences
scfm	standard cubic feet per minute
SHAP	Soluble Hazardous Air Pollutants
SIC code	Standard Industrial Classification
SSM	Startup, Shutdown, or Malfunction
TOC	Total Organic Compounds
tpy	Tons per year
TSS	Total Suspended Solids
TTN	Technology Transfer Network (http://www.epa.gov/ttn/)
VHAP	Volatile Hazardous Air Pollutants
VOC	Volatile Organic Compounds

VP	Vapor Pressure
VS	Vapor Suppression
WMU	Waste Management Unit
WW	Waste Water
WWT	Wastewater Treatment

Chapter 1
Purpose

Chapter 1 at a Glance	
1.1	*Purpose of the Document*
1.2	*Document Organization*
1.3	*Disclaimer for the Use of this Guide*

1.1 Purpose of the Document

This document is intended to help owners and operators of pharmaceutical manufacturing operations understand and comply with the U.S. Environmental Protection Agency's (EPA) air pollution regulations promulgated on September 21, 1998, substantially revised on August 29, 2000 and revised again on August 2, 2001, for the pharmaceutical industry. These regulations contain new emissions standards based on the "maximum achievable control technology" or MACT. On September 21, 1998, EPA published new effluent guidelines, pretreatment standards, and new source performance standards pursuant to the Clean Water Act (CWA). These new CWA provisions are not reviewed in this document.

This document reviews the primary MACT provisions of the regulations, and in many cases, summarizes the regulations in tables or charts to facilitate a quicker review. Within most chapters, questions and answers provided in shaded boxes should help the reader with some of the more complex or confusing components. This document, does not however, attempt to provide interpretations of the rule. In some cases, owners or operators will need to review specific issues relating to their particular production facilities with the appropriate regulating agency.

1.2 Document Organization

The chapters in the document follow the organization of the Pharmaceutical MACT regulations.

Chapter 2 - *Overview of the Regulations* - provides an overview of the regulations and recreates the table of standards for the four major types of emissions sources: process vents, storage tanks, wastewater, and equipment leaks.

Chapter 3 - *Applicability and Compliance Dates* - takes the reader through the applicability provisions of the regulations and includes several questions and answers to help the reader determine applicability at his/her facility.

Chapter 4 - ***Requirements for Storage Tanks* -** describes the kinds of tanks subject to regulation and reviews provisions specific to storage tanks, including options for complying with the standards.

Chapter 5 - *Requirements for Process Vents* - describes which vents are subject to regulation, including individual vents that may be subject to a more stringent standard, and discusses the different options available for process vent standards.

Chapter 6 - *Equipment Leaks* - reviews the equipment leaks provisions, including identification of leaking equipment, and monitoring and repair requirements.

Chapter 7 - *Requirements for Wastewater* - explains the wastewater regulation, including standards for vapor suppression, air emissions control, and wastewater treatment.

Chapter 8 - *Initial Compliance Demonstrations and Testing Procedures* - reviews the compliance demonstration requirements that must be followed in demonstrating initial compliance with the regulations. This chapter covers compliance demonstrations for storage tanks, process vents, and wastewater.

Chapter 9 - *Monitoring Procedures* - reviews the monitoring requirements that owners/operators must follow to ensure on-going compliance with the regulations.

Chapter 10 - *Pollution Prevention* - goes over the pollution prevention options that are available to existing sources. The chapter includes examples that show how emissions baselines are calculated. A detailed, "real-life" pollution prevention success story is also described.

Chapter 11 - *Emissions Averaging* - describes the emissions averaging provisions that may be applied to process vents and storage tanks. The chapter provides an example for process vents and an example for tanks.

Chapter 12 - *Recordkeeping* - includes comprehensive tables that describe the recordkeeping requirements in the MACT regulations.

Chapter 13 - *Reporting* - also contains comprehensive tables, specifically for reporting requirements. Three of the tables in the chapter are organized according to the type of report - precompliance, notification of compliance status, and periodic.

1.3 Disclaimer for the Use of this Guide

The reader should note that following the information provided in this document does not shield the facility from enforcement actions taken by the EPA or authorized state agencies. This document provides an overview and "plain English" explanation of the new standards. It is not a substitute for the regulations presented in 40 CFR Part 63, Subpart GGG.

Chapter 2
Overview of the Regulations

Chapter 2 at a Glance

2.1 Purpose of the Rule

The purpose of this EPA rule, proposed on April 2, 1997, promulgated on September 21, 1998 and amended on August 29, 2000 is to reduce air emissions of hazardous air pollutants (HAP) from both existing and new facilities that manufacture pharmaceutical products. EPA estimates that implementation of the rule will reduce HAP emissions from existing sources by approximately 24,000 tons per year. In addition, the controls put in place to comply with these MACT standards also will reduce volatile organic compounds (VOC) emissions. This will be accomplished primarily by limiting emissions from storage tanks, process vents, wastewater systems, and equipment leaks. This rule will lead to increased protection of the public by reducing emissions of chemicals that are harmful to human health and the environment.

2.2 Statutory Background

This new regulation, subpart GGG to Part 63, is based on Congressional direction provided in section 112 of the Clean Air Act, which was amended in 1990. Section 112(b) contains a list of HAP to be regulated. The statutory list contains 188 substances and categories of substances designated as “hazardous air pollutants” that must be regulated. The list includes methylene chloride, methanol, toluene, and hydrogen chloride, four commonly-used chemicals in the pharmaceutical manufacturing industry.

The EPA used the set of 188 HAP, as directed under 112(c), to develop a list of source categories for which emission standards would be set. This list, published on July 16, 1992, included the pharmaceutical manufacturing industry. Therefore, EPA developed this National Emission Standard for Hazardous Air Pollutants (NESHAP) specifically for the pharmaceutical manufacturing industry.

Section 112(d) directs EPA to promulgate emissions standards that reflect use of the “maximum achievable control technology” (MACT). EPA must take into account “the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements....,” when setting the standards. The statute directs EPA to develop standards for existing sources and for new sources. New source standards cannot be “less stringent than the emission control that is achieved in practice by the best controlled similar source." The standard for existing sources should be no less stringent than the average emission control achieved by the best performing 12 percent of the existing sources. Therefore, the final rule specifies different standards for new and existing sources in some, but not all, cases.

NOTE: Whenever the terms "existing sources" or "new sources" are used in this document, this most often means "processes subject to existing source MACT" or "processes subject to new source MACT."

The pharmaceutical NESHAP rule is progressive in that it offers a pollution prevention standard for pharmaceutical manufacturers as an alternative to using add-on controls to limit emissions. Under the pollution prevention option, owners and operators can opt to reduce the overall consumption of HAPs in their processes. This option is available only for existing sources and does not apply to HAPs that are generated in the manufacturing process. The pollution prevention standard requires that owners reduce the production-indexed consumption of HAPs by 75%, using a baseline consumption factor calculated from data no earlier than 1987. The production-indexed consumption factor is expressed as kg HAP consumed/ kg product produced. A second pollution prevention alternative allows the owner or operator to reduce the production-indexed consumption factor by 50% AND use other add-on controls to achieve an overall 75% reduction. The pollution prevention option will be described in detail in a later chapter.

Sections of the Pharmaceutical MACT

63.1250 - Applicability - Defines affected sources that are subject to the rules and sources that are exempt and sets compliance deadlines.
63.1251 - Definitions - Provides definitions to terms as they are used in subpart GGG**.**
63.1252 - Standards: General - Specifies controls for closed vent systems, heat exchange systems, certain liquid streams, and certain halogenated vent streams controlled by combustion devices. Also presents pollution prevention as an alternative to achieving end-of-pipe reductions.
63.1253 - Standards: Storage Tanks - Specifies standards for storage tanks.
63.1254 - Standards: Process Vents - Specifies standards for process vents.
63.1255 - Standards: Equipment Leaks - Specifies work practices for pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems that are in HAP service (in contact with HAPs at a concentration $5% total HAP by weight) for at least 300 hours per year.
63.1256 - Wastewater Provisions - Specifies standards for wastewater tanks, surface impoundments, containers, individual drain systems, oil-water separators, treatment processes, and control devices. Provides control options for wastewater.
63.1257 - Test Methods and Compliance Procedures - Contains instructions for testing emissions from sources, and provides specific procedures for demonstrating initial compliance with standards for storage tanks, process vents, and wastewater.
63.1258 - Monitoring Requirements - Contains provisions for monitoring specified parameters to determine continued compliance. Discusses what constitutes violation of operating parameters and emission limits.
63.1259 - Recordkeeping - Provides instructions for keeping records of applicability determinations; startup, shutdown, and malfunction plans; operating parameters data, including emissions averaging data; applications for approval of construction or reconstruction; and leak detection and repair programs.
63.1260 - Reporting - Gives instructions on submittal of initial notification, applications for approval of construction or reconstruction, notification of continuous monitoring system (CMS) performance evaluation, Precompliance and Notification of Compliance Status reports, Periodic reports, notification of process changes, reports on startup, shutdown, and malfunction, leak detection and repair reports, emissions averaging calculations, and performance tests.
63.1261 - Delegation of Authority - Specifies which authorities cannot be delegated to States.

NOTE: The HAPs regulated in this rule also are subject to regulation under EPA's water program. New effluent guidelines and pretreatment standards for the pharmaceutical industry also were published on September 21, 1998. See these new regulations for further information (40 CFR Part 439).

2.3 Major Components of the Rule

The MACT regulations for the pharmaceutical industry contain eleven major sections. In addition to these standards, portions of Subpart A of Part 63 - National Emission Standards for Hazardous Air Pollutants for Source Categories- apply to the pharmaceutical manufacturing industry. The applicable Subpart A provisions are listed in Table 1 to Subpart GGG in the rule.

The complete text of the rule, including appended Tables, is available via Internet from:

http://www.epa.gov/fedrgstr/EPA-AIR/1998/September/Day-21/a23168a.htm

and

http://www.epa.gov/fedrgstr/EPA-AIR/2000/August/Day-29/a21195.htm

and

http://www.epa.gov/fedrgstr/EPA-AIR/2001/August/Day-02/a18879.htm

All three documents together comprise the complete text. Alternatively, an updated version of the Code of Federal Regulations is maintained through the Government Printing Office's website:

http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr63b_00.html

A summary of Table 1 is provided below. Refer to the full text of Table 1 in the regulations for more details.

Subpart A Provisions	Relevance to GGG
63.1 - Applicability	Confirms the general applicability of Part 63, but notes that where there are overlaps, subpart GGG takes precedence. Subpart GGG clarifies compliance dates specific to pharmaceutical operations. Confirms that, as a "major affected source," pharmaceutical manufacturing operations are subject to Title V permit requirements.
63.2 - Definitions	All definitions apply; additional ones are provided in Subpart GGG. Where there are overlaps, Subpart GGG takes precedence.
63.3 - Units and Abbreviations	All units and abbreviations apply; additional ones are provided in Subpart GGG.
63.4 - Prohibited Activities	All restrictions listed also apply to pharmaceutical manufacturing industry.

Subpart A Provisions	Relevance to GGG
63.5 - Construction and Reconstruction	Applies to pharmaceutical manufacturing operations. The terms “source” and “stationary source” are replaced with “affected source.”
63.6 - Compliance with Standards and Maintenance Requirements	Most applies to pharmaceutical manufacturing operations; Subpart GGG specifies compliance dates for new and existing sources. Opacity and visible emission standards are not applicable. Subpart GGG provides instructions for compliance extensions.
63.7 - Performance Testing Requirements	Applies to pharmaceutical manufacturing operations. Subpart GGG specifies required testing and compliance procedures, as well as test methods specific to the industry. Substitute 150 days instead of 180 days in § 63.7(a)(2). A test plan must be submitted with the notification of performance test.
63.8 - Monitoring Requirements	Generally, monitoring requirements apply to pharmaceutical manufacturing operations; specific CMS requirements are provided in Subpart GGG, however. Provisions relating to continuous opacity monitoring systems (COMS) do not apply. References to calibration procedures are in §63.1258.
63.9 - Notification Requirements	General notifications requirements apply to pharmaceutical manufacturing operations. Notification of performance test 60 days before planned test date is applicable. Requirements relating to CMS and opacity or visible emissions standards are not applicable. Initial notification and performance evaluation requirements apply.
63.10 - Recordkeeping Requirements	General recordkeeping requirements apply to pharmaceutical manufacturing operations. Subpart GGG specifies requirements with regard to information and data used in notifications and compliance reports. Requirements relating to CMS and opacity or visible emissions standards are not applicable.
63.11 - Control Device Requirements for Flares	Applies to pharmaceutical manufacturing operations using flares to comply with standards.
63.12 - State Authority and Delegations	Applies to state authorities regulating air emissions from the pharmaceutical industry.
63.13 - Addresses of State Air Agencies and EPA Regions	Applies; no changes specific to pharmaceutical industry.
63.14 - Incorporation by Reference	Applies; no changes specific to pharmaceutical industry.

Subpart A Provisions	Relevance to GGG
63.15 - Availability of Information and Confidentiality	Applies; no changes specific to pharmaceutical industry.

2.4 Standards

The new emission standards are expressed differently for the various types of sources. In some cases, such as with process vents, one of the standards options is a percentage reduction standard; this allows owners and operators flexibility in achieving the required level of control. In other cases, such as with equipment leaks, it makes more sense to specify work practice standards because it would be difficult, if not impossible, to regularly measure emissions levels from the hundreds of pieces of equipment at a production facility or to require add-on control to reduce the emissions.

The table below provides a summary of the standards in the rule. The pollution prevention option, available for existing sources, is not presented in the table. It is covered in Chapter 10.

TABLE 2-1. STANDARDS FOR NEW AND EXISTING SOURCES

Emission Point	New or Existing ?	Applicability		Standard
		Applicability Level	Cutoff	
Process Vents *	**New**	**Process producing an isolated intermediate**	**$50 ppmv HAP**	• **98% control or** • **20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit or** • **maintain actual emissions less than 900 kg/yr for sum of all vents in a process not controlled to these limits (i.e., 98% or 20 ppmv)** • **20 ppmv TOC and 20 ppmv hydrogen halide and halogen (alternative standard)[1]** • **20 ppmv TOC and controlling HCl emissions by at least 95% with a post combustion device scrubber (variation of alternative standard)**

Emission Point	New or Existing ?	Applicability		Standard
		Applicability Level	Cutoff	
	Existing	Process producing an isolated intermediate	$50 ppmv HAP	• 93% control or • 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit or • 900 kg/yr for the sum of all process vents in a process with a maximum of 1800 kg per year per facility. • [1] • 20 ppmv TOC and 20 ppmv hydrogen halide and halogen (alternative standard)[1]* • 20 ppmv TOC and controlling HCl emissions by at least 95% with a post-combustion device scrubber (variation of alternative standard)
		Large or high emitting vent[1]		• 98% for individual vents[2] (within a process) meeting cutoff based on flow and emissions

Emission Point	New or Existing ?	Applicability		Standard
		Applicability Level	Cutoff	
Storage Tanks *	**New and existing**	**$ 38 m^3 (10,000 gal) < 75 m^3 (20,000 gal)**	**13.1 kPa (1.9 psia) HAP vapor pressure of liquid stored**	**• 90% control, or • 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit, or • enclosed combustion device w/ minimum res. time of .5 sec at 760EC, or • 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit[1*], or • use vapor balancing**
		$75 m^3 (20,000 gal)	**$ 13.1 kPa (1.9 psia) HAP vapor pressure of liquid stored**	**• 95% control[3], or • 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit, or • enclosed combustion device w/ minimum res. time of .5 sec at 760EC, or • 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit[1*], or • use vapor balancing**

Emission Point	New or Existing ?	Applicability		Standard
		Applicability Level	Cutoff	
Wastewater Treatment [5, 6, 7*]	**New and existing**	**>0.25 Mg/yr total HAP load from all POD from PMPU**	**>1,300 ppmw at POD of Table 2 HAP (PSHAP) (annual average concentration)**	• 99% reduction of Table 2 HAP (PSHAP) • or to <50 ppmw PSHAP or treat in RCRA unit or • 95% reduction of total HAP using biotreatment
			>5,200 ppmw at POD of total HAP load (annual average concentration)	• 99% reduction of Table 2 HAP (PSHAP) or • to < 50 ppmw PSHAP and • 90% reduction of Table 3 HAP (SHAP) • or < 520 ppmw SHAP or • enhanced biotreatment (for SHAP only and only if PSHAP < 50 ppmw) or • 95% reduction of total HAP using biotreatment or • RCRA unit
		>1 Mg/yr total HAP load from facility	**>10,000 ppmw at POD of total HAP load (annual average concentration)**	• 99% reduction of Table 2 HAP (PSHAP) or • < 50 ppmw PSHAP and • 90% reduction of Table 3 HAP (SHAP) or • < 520 ppmw SHAP or • enhanced biotreatment (for SHAP only and only if PSHAP < 50 ppmw) or • 95% reduction of total HAP using biotreatment or • RCRA unit

Emission Point	New or Existing ?	Applicability		Standard
		Applicability Level	Cutoff	
	New	>1 Mg/yr total HAP load from all POD from PMPU	>110,000 ppmw at POD of Table 3 HAP (SHAP) (annual average concentration)	• 99% reduction of Table 3 HAP (SHAP) or • treat in RCRA unit
Equipment Leaks	New and existing	All components in HAP service where total HAP is $5% by weight	$ 300 hours/yr HAP service	LDAR program

1. Alternative Standard - Outlet limit is 50 ppmv instead of 20 ppmv if noncombustion devices are used.
2. Large Vent - at least 25 tpy uncontrolled HAP emissions from a single process and satisfying flow specifications, note equations in the rule.
3. Refer to discussion of grandfathered vents in section 5.4.1 of this document.
4. For tanks controlled at 90 percent prior to April 2, 1997, no additional control is required.
5. See Chapter 7 on wastewater for more details on vapor suppression and air pollution control device requirements for wastewater and wastewater residuals.
6. Wastewater generated from scrubbers relied upon to control PSHAPs is considered “affected” regardless of concentration.
7. Treatment options are limited if the facility chooses to “designate” wastewater streams (See Chapter 7).

* In addition to the standards listed for process vents, storage tanks, and wastewater treatment, the owner/operator may choose instead to use a flare, compliant boiler, process heater, or RCRA hazardous waste incinerator.

Note: See pages 7-3 and 7-4 for the list of Partially Soluble Hazardous Air Pollutants (PSHAPs) and page 7-4 for the list of Soluble Hazardous Air Pollutants (SHAPs).

Chapter 3
Applicability and Compliance Dates

3.1 Overview

The applicability section of the MACT regulations defines what kinds of facilities must comply with the regulations and specifies the dates by which those facilities must comply. It also contains provisions for instances in which the MACT standards overlap other regulatory programs. The applicability provisions of the MACT rule are based on a set of definitions, all of which must be reviewed to determine if the regulations apply at any particular facility. The discussion below takes the reader through a series of questions and relevant definitions.

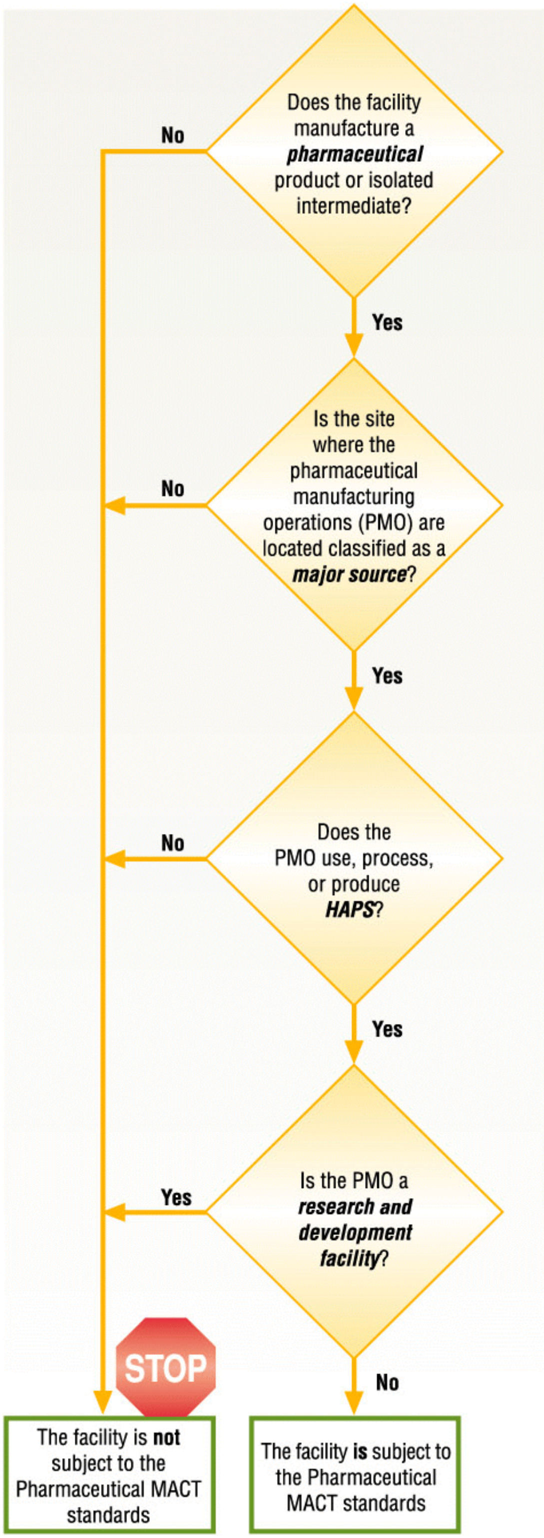
3.2 Applicability

Chapter 3 at a Glance

In general, facilities or activities covered by a National Emissions Standard for Hazardous Air Pollutants (NESHAP) are called "affected sources", which is defined in §63.2. The affected source regulated under Subpart GGG is the pharmaceutical manufacturing operations**,** which is defined in §63.1251. Furthermore, it is important to specifically identify the "affected source" and/or "pharmaceutical manufacturing process unit (PMPU)" because it is the basis for decisions regarding "construction" and "reconstruction," which in turn are the basis for determining whether a facility or manufacturing unit is subject to standards for existing or new sources. Because standards for new sources can be more stringent than those for existing sources, proper identification of the affected source is critical. The applicability regulations provide three criteria that determine whether a facility has pharmaceutical manufacturing operations that are subject to subpart GGG:

- Does the facility manufacture a pharmaceutical product?
- Is the site where the pharmaceutical manufacturing operation is located classified as a major source for HAP emissions?
- Does the pharmaceutical manufacturing operation use, process, or produce HAPs?

The following flow-chart takes the reader through the questions that must be asked to ascertain applicability of the pharmaceutical MACT standards to a specific site.



Pharmaceutical Product =

(1) Any material described by the SIC code 2833 or 2834,

(2) Any material whose manufacturing process is described by North American industrial classification system (NAICS) code 325411 or 325412,

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

(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 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.

The term does not include nonreactive solvents, binders, fillers, or excipients, but includes components such as raw starting materials or precursors that undergo chemical change or processing before they become active ingredients. It does not include material produced in a chemical manufacturing unit that is subject to the HON.

Major Source =

Any stationary source or group of stationary sources located within a contiguous area under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tpy or more of any hazardous air pollutant or 25 tpy or more of any combination of hazardous air pollutants. The Administrator may establish a lesser quantity or, in the case of radionuclides, different criteria, for a major source other than that specified in the previous sentence, on the basis of the potency of the air pollutant, persistence, potential for bioaccumulation, other characteristics of the air pollutant, or other relevant factors.

HAP =

Any Hazardous Air Pollutant listed in or pursuant to section 112(b) of the Clean Air Act.

Research and Development Facility =

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

Figure 3-1. Guidelines for Determining Subpart GGG Applicability

Intermediates

One of the first questions to be asked in making applicability determinations is whether the material being produced is a "pharmaceutical product." The full definition of pharmaceutical product is provided in the flowchart on the previous page. It is important to note that the definition of "pharmaceutical product" includes materials that are not final products, such as precursors or active ingredients. This means that pharmaceutical precursors, even if they are not manufactured at the same site as the final active ingredient, may be covered under the rule.

Exclusions

The term "pharmaceutical product" does **not include** non-reactive solvents, excipients, binders, or fillers. An excipient is a substance, other than the active drug or product, that is used in the drug delivery system to 1) aid the processing of the drug delivery system during manufacture, 2) protect, support or enhance stability, bioavailability, or patient acceptability, 3) assist in product identification, or 4) enhance any other attribute of the overall safety and effectiveness of the drug delivery system during storage or use.

In addition, substances produced in a chemical manufacturing process unit that is already subject to regulation under 40 CFR Part 63, Subparts F and G (SOCMI) are not included in the definition of pharmaceutical product.

Q and A - Example Applicability Scenarios

Q. ***If a chemical specialty company (that is a major source), not principally engaged in pharmaceutical production, receives a chemical compound from an off-site pharmaceutical manufacturer, performs a processing step on the compound, and then ships it back to the original manufacturer, is the chemical specialty company producing a "pharmaceutical product," and potentially subject to the MACT standards?***

A. *The definition of "pharmaceutical product" in the MACT regulations would include the chemical compound in this example. The definition includes active ingredients and precursors that are processed at facilities outside of the 2833 or 2834 SIC code. Such a material is considered a precursor if it has no recognized non-drug commercial use; is used on site; or sold to a pharmaceutical manufacturer, for use in the manufacture of another pharmaceutical product. A precursor is considered a "pharmaceutical product." Clearly, the intermediate in the example is considered a* *product." Clearly, the chemical compound in the example is considered a pharmaceutical product because it is sold back to the pharmaceutical manufacturer. Therefore, the chemical specialty company is subject to the MACT standards, provided it meets the other MACT applicability requirements (e.g, major source for HAPs). It is the responsibility of the chemical specialty company to determine the ultimate use of the chemical compound. For example, the material would not be subject to regulation as a pharmaceutical product if its production is subject to regulation under Subpart F and G for the Synthetic Organic Chemicals Manufacturing Industry (HON). Since it has no non-drug uses, it cannot be a commodity chemical. Chemicals listed in the "Industrial Organic Chemical Use Trees" (Final Report, October 1983, USEPA) are commodity chemicals not regulated under the pharmaceutical MACT. The chemicals listed in Table 1 of Part 63, Subpart F (HON) are not subject to the pharmaceutical MACT.*

Q. ***A facility (that is a major source but whose primary SIC code is <u>not</u> 2833 or 2834) makes a product (Product A) that is not pharmacologically active but uses HAP. The Product A is then shipped off-site and reacted with other materials to form a pharmacologically active compound. Product A is not shipped to anyone else or used for any other reactions that the company is aware of. Is the facility making Product A covered under the pharmaceutical MACT?***

A. *Yes; the process would be covered because Product A is a precursor, which is defined as material that undergoes chemical change or processing before it becomes an active ingredient. In this case because the chemical does not have any known non-drug use, its primary use must be as a precursor; therefore it is a pharmaceutical product.*

Q. ***In the making of a pharmaceutical intermediate, a reaction is done to put a blocking agent onto the molecule. Later in the synthesis of the pharmaceutical product, this blocking agent is removed from the pharmaceutical molecule and is discarded. Would the manufacture of the blocking agent be covered under this NESHAP?***

A. *No, because the blocking agent is not subsequently processed into a final drug product. It does not become an active ingredient or other pharmaceutical product covered by SIC 2833 or 2834. The blocking agent does not meet the definition of pharmaceutical intermediate.*

Q. ***If a HON unit produces HCl as a byproduct and further processes a portion of this HCl into "pharmaceutical grade" HCl (the primary use of this HCl is for pharmaceutical manufacturing), is the process subject to the rule?***

A. *No, the HCL is still considered a commodity chemical.*

Q. If a toll manufacturer (that is a major source and that uses, processes, or produces HAPs) manufactures a pharmaceutical product, what other sources at the facility (e.g., storage tanks, heat exchange systems, common solvent recovery operations) are covered by the pharmaceutical MACT standards?

A. The definition of "pharmaceutical manufacturing operations" includes the facility-wide collection of pharmaceutical manufacturing process units (PMPUs) AND any other equipment (e.g., heat exchangers, wastewater, and waste management units) that are located at a facility manufacturing pharmaceutical products. All equipment used in the manufacture of pharmaceutical products must comply with GGG. For storage tanks, this may imply issues of predominant use. For other sources, issues relating to overlapping MACT standards may be involved.

Q. Are vitamins considered pharmaceutical products?

A. Yes, vitamins are considered pharmaceutical products because they are covered by SIC code 2833. Thus their manufacture is subject to the Pharmaceutical Production MACT.

Q. Is the production of artificial sweetener covered by the standard?

A. No; the process would not be covered, because it does not meet the definition of pharmaceutical product. Specifically, it is not covered under SIC codes 2833, 2834, and the production is not covered under NAICS codes 325411 or 325412. Additionally, as a food additive that is not covered under SIC 2833 or 2834, it is also not an active ingredient. Finally, it is not a precursor.

Q. Are preparations manufactured for the treatment of animals classified as "pharmaceutical products?"

A. Yes; animal biologics (materials used in the treatment of animals) are included in the definition of active ingredients and active ingredients are pharmaceutical product.

Q. Is the production of animal growth hormone covered by the standard?

A. Yes; "Hormones and derivatives" are covered by SIC code 2833 and the corresponding NAICS code 325411.

Q. Are all drug ingredients considered pharmaceutical products?

A. A substance that ***meets the definition of excipient*** *is not included in the definition of pharmaceutical product. Generally, excipients are used to enhance the drug delivery system, and include substances such as buffers, flavorings, coloring, and inert binding agents.*

Q. ***Are pilot plants subject to the MACT standards?***

A. *A pilot plant could meet the definition of "research and development facility" if its primary purpose is to conduct research and development into new processes and products, and if it is not engaged in the manufacture of products for commercial sale, except in a de minimis manner. However, if the product being made in an R + D program goes into commercial production, the commercial process becomes subject to the MACT.*

Q. ***Do the regulations apply during start-up and shutdown for batch operations?***

A. *Both batch and continuous operations are subject to SSM requirements. The regulations provide that emission limitations do not apply during periods of start-up, shutdown, and malfunction if the owner or operator follows the plan developed pursuant to §63.1259(a)(3) (or documents and reports deviations from the plan). The owner or operator is required to follow the reporting requirements for periods of start-up, shutdown, or malfunction, as specified in §63.1260(i). However, the definition of shutdown does <u>not</u> apply to the routine cessation of <u>batch</u> operations at the end of a campaign, for routine maintenance, for rinsing or washing equipment between batches, or other routine operations. Shutdown for repairing equipment (if not routine) would count as periods of shutdown. The term start-up applies only to the first time a new or reconstructed source begins production, the first time new equipment is used, or the first time a new product/process is run in equipment. Therefore, the emission limitations* ***do*** *apply to start-up and shutdown for batch operations between batches and between most product campaigns, except when non-routine maintenance or repair is necessary.*

Q. ***If a pharmaceutical manufacturing process unit (PMPU) at a facility subject to the MACT standards does not process, use, or produce HAPs or uses HAPs only in de minimis quantities, is the PMPU subject to the MACT standards?***

A. *No, the applicability provisions specify that the regulations apply only to pharmaceutical manufacturing operations that process, use, or produce HAPs. Within the regulated PMO, a process, or a PMPU, that does not process, use, or produce HAP is not subject to the emission standards. Sections 63.1260(f)(1) and (f)(2) indicate that the NOC report must include the results of any applicability determinations and supporting calculations. There is no definition in the regulations for"de minimis." The definitions of process vent, storage tank, and wastewater stream clarify EPA's intent to exclude parts of a plant that do not emit HAPs:*

- *The definition of process vent provides that if uncontrolled, undiluted emissions are less than 50 ppm HAP, the vent is not considered a regulated process vent;*
- *The definition of storage tank provides that a tank that contains HAPs only as impurities is not considered a regulated storage tank;*

- *The definition of wastewater stream includes only those wastestreams with an average concentration of partially soluble and/or soluble HAPs of at least 5 ppmw and a load of at least 0.05 kg/yr.*

3.3 Other Important Applicability Definitions

Other defined terms in the regulations need to be understood for purposes of applicability determinations. Many of these terms can be viewed as a set of nested definitions. The discussion below follows the definitions from "the top down."

Once a facility owner or operator has determined that the facility meets the basic applicability criteria as outlined in 3.2 above, it is important to determine specifically what the "affected source" is. As mentioned above, the affected source regulated under Subpart GGG is the pharmaceutical manufacturing operation.

Pharmaceutical Manufacturing Operation

A **pharmaceutical manufacturing operation** is defined as the facility-wide collection of **pharmaceutical manufacturing process units (PMPUs)** AND any other equipment such as heat exchanger systems or cooling towers, wastewater and WMU's, 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.

PMPU

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

Process

It is important to define process, because the process vent control standards are expressed in terms of "the sum of all process vents **within a process**." A process is defined according to the pharmaceutical product or isolated intermediate it yields. An "isolated intermediate" is obtained as the product of a process and stored before subsequent processing. Storage occurs when the intermediate is put in equipment used solely for storage, such as drums, totes, day tanks, and storage tanks. Storage of an isolated intermediate marks the end of a process. The concept of process is flexible, since different pieces of equipment may be used for the manufacture of different products. For example, four pieces of equipment, A, B, C, and D, may be configured differently depending on the product being manufactured that month:

- Process 1 uses units A + C + D to yield product 1, manufactured during January
- Process 2 uses units A + C + B to yield product 2, manufactured during February

The regulations do not require, for example, that unit A meet a certain standard, but instead that emissions from Process 1 and from Process 2 meet the regulatory standard.

The regulations contain a detailed definition of process, much of which is provided here. **Process** is defined in the regulations as "all equipment which collectively functions to produce a pharmaceutical product or isolated intermediate." The definition then goes on to add a number of other important provisions:

- A process may consist of one or more unit operations. A "process" includes any, all, or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment steps which are used to produce a pharmaceutical product.
- Cleaning operations conducted are considered part of the process.
- Nondedicated solvent recovery operations in a contiguous area are considered single processes that are used to recover numerous materials and/or products. For this use, "nondedicated" means a recovery operation that receives solvents from more than one PMPU (i.e., it is not dedicated to a single process). A storage tank 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. (i.e., the used solvent is not an isolated intermediate)
- Nondedicated formulation operations occurring within a contiguous area are considered a single process that is used to formulate numerous materials and/or products. Per the definition in 63.1251, "nondedicated" in this instance means the equipment is not dedicated to the manufacture of one product only.
- Quality Assurance and Quality Control laboratories are not considered part of any process.
- Ancillary activities that are not used in the processing of raw materials or in
the manufacture of a pharmaceutical product are **not** covered in the definition of "process." Ancillary activities include boilers and incinerators that are not being used to comply with the MACT standards, chillers, refrigeration systems, or other pieces of equipment that operate in a closed system such that no process fluids are introduced.

IMPORTANT NOTE: As mentioned in the beginning of section 3.2, the decisions about construction and reconstruction (which affect decisions regarding "new" vs. "existing" sources) are made at the "affected facility" and/or at the PMPU level. Process vent and wastewater emissions standards must be met at the "process" or process vent level.

The definitions reviewed above are depicted in Figure 3-2.

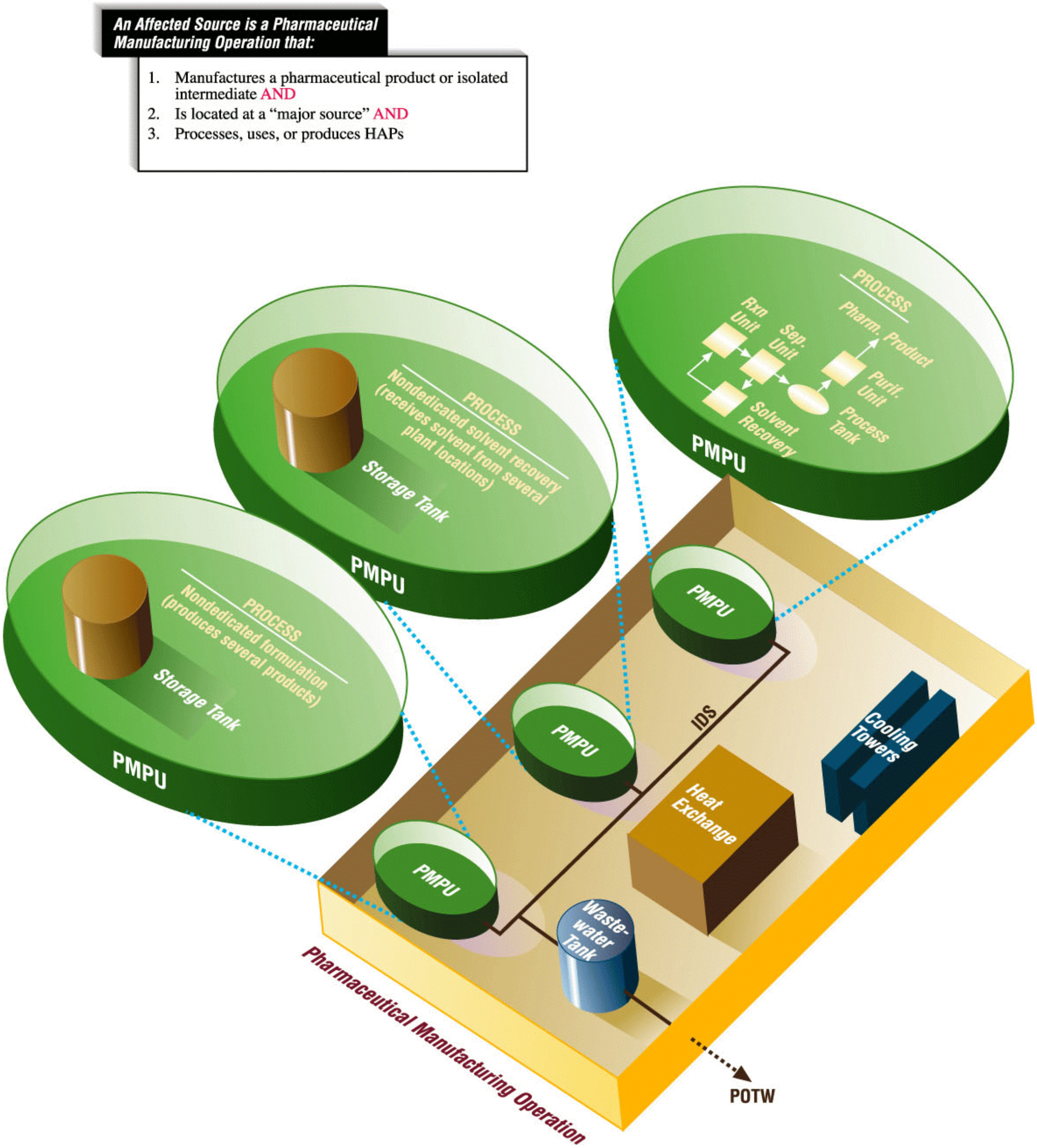


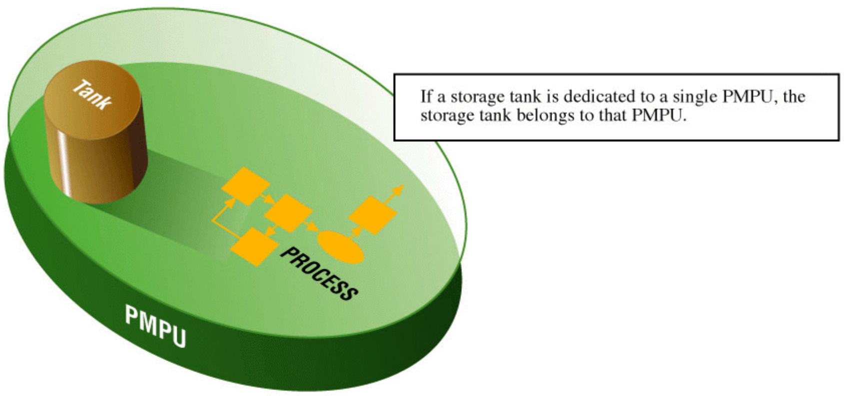
Figure 3-2. Applicability Terms

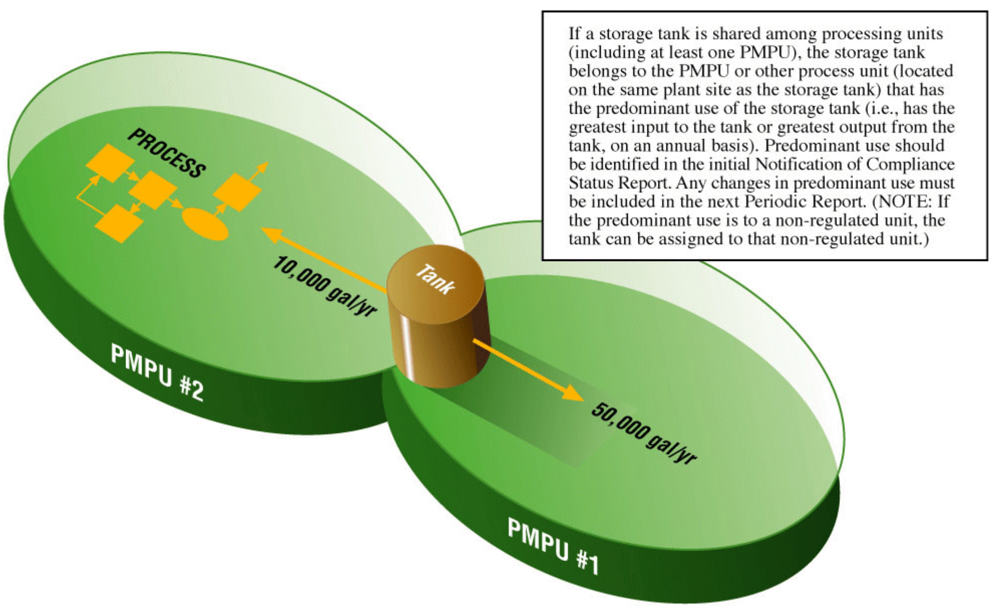
Storage Tank Ownership

Given the variability of process configurations in pharmaceutical manufacturing plants, it is possible that storage tanks are "shared" by different PMPUs. If an owner or operator produces only pharmaceutical products, then the procedures for determining ownership are only required for purposes of determining applicability and demonstrating compliance with the P2 option, or determining new source applicability for a PMPU dedicated to manufacturing a single product that has the potential to emit 10 TPY of a single HAP or 25 TPY combined HAP.

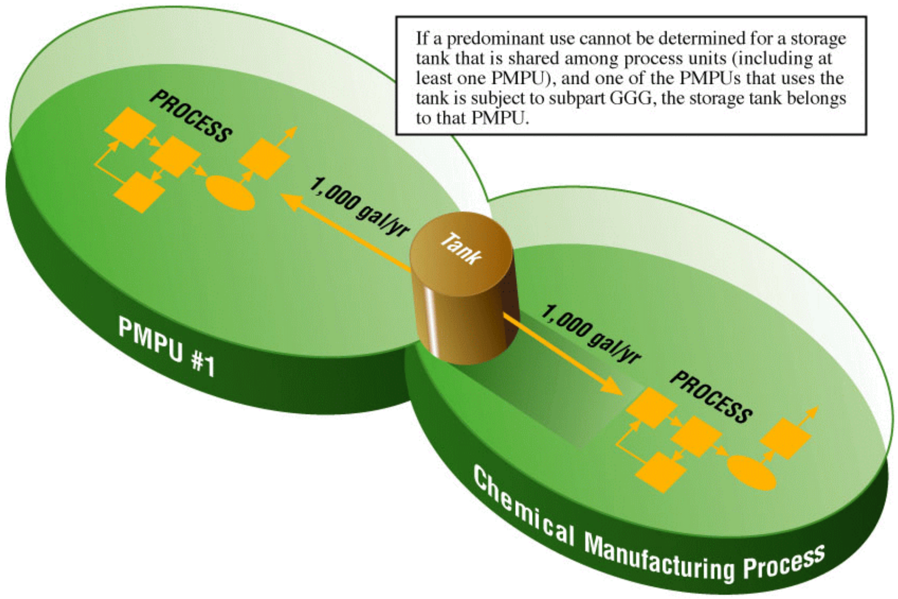
If the owner/operator is not trying to determine the applicability of new source standards, it is not necessary to assign ownership for shared storage tanks because the tanks will be subject to the same standards regardless of ownership.

The regulations at §63.1250(e) provide the following instructions for assigning ownership of tanks:





Tank "belongs" to PMPU #1.



Tank "belongs" to PMPU #1.

If the predominant use varies from year to year, then ownership is determined according to the predominant use in the year before the rule was promulgated (i.e., the year before September 21, 1998), for existing sources. For new sources, predominant use is based on the first year after initial startup. For the first operating year at a new source, the owner or operator should base ownership decisions on the anticipated use of storage tanks. Any changes in predominant use from that reported in the Notification of Compliance Status must be reported in the next Periodic Report.

New vs. Existing

Another important applicability concept relates to the distinction between **new** and **existing** sources. EPA has the statutory authority to apply stricter standards to new sources. Also, new and existing sources may have different compliance deadlines, as discussed more fully below. In the pharmaceutical MACT regulations, the process vent and certain wastewater standards are more strict for new sources than for existing. The designation of a source as new vs. existing hinges on the date of construction or reconstruction. In summary, an affected source (PMO) for which construction or reconstruction began after April 2, 1997 is considered a new source. A PMPU that is dedicated to the production of a single product AND that has the potential to emit at least 10 tons per year of any one HAP or 25 tons per year of combined HAP AND for which construction commenced after April 2, 1997, is considered a new source. When calculating the potential to emit figure, include emissions from the PMPU <u>and</u> wastewater (after controls). Additionally, a reconstructed, dedicated PMPU with the potential to emit 10 tons single HAP / 25 tons combined HAP for which the fixed capital cost of the new components exceeds 50 percent of the fixed capital costs of constructing a comparable new source, would also be considered new if the reconstruction commenced after October 21, 1999. (This date is tied to the settlement discussions after original promulgation of the rule on September 21, 1998.)

Construction and Reconstruction

The definitions of **construction** and **reconstruction** are from §63.2; they were slightly revised in the MACT rule. **Construction** means the on-site fabrication, erection, or installation of an affected source or PMPU. **Reconstruction** means the replacement of components of an affected stationary source *or pharmaceutical manufacturing process unit* to such an extent that: (1) The fixed capital cost of the new component exceeds 50 percent of the fixed capital cost that would be required to construct a comparable new source (PMPU or control device); and (2) It is technologically and economically feasible for the reconstructed source to meet the relevant standards established by the Administrator (or a State) pursuant to section 112 of the Clean Air Act.

NOTE: The addition of new equipment to an existing PMPU does not constitute construction but may constitute reconstruction if a capital expenditure occurs. The term "reconstruction" has another use besides that of defining when new sources standards are triggered. "Grandfathered" control devices (those not required to meet the 98% control standard for individual vents due to their date of installation) ARE required to meet the 98% when they are "reconstructed" or replaced.

Q and A - New vs. Existing

Q. ***If a facility with pharmaceutical operations with the potential to emit HAPs below the threshold levels for a "major source" (i.e., 10 TPY uncontrolled single HAP/25 TPY total HAP), but several new <u>non-pharmaceutical</u> processes are added at the site after April 2, 1997 such that the <u>site</u> now is above the "major source" threshold, could a pharmaceutical manufacturing operation at the site be considered new? Assume that none of the new processes have uncontrolled HAP emissions of 10 TPY single HAP/25 TPY total HAP, but that collectively they cause the site to exceed the "major source" threshold.***

A. *Upon becoming a major source, the pharmaceutical manufacturing operation is subject to the MACT standards, and must be in compliance with the standards for existing sources within three years. The PMPUs cannot be considered new because the standard was not applicable at the time of construction or reconstruction (because the PMPUs were not major sources). Even if the new processes were pharmaceutical, they still would be subject to the existing source standards, because none of the new processes individually exceed the 10 TPY/25 TPY threshold for new dedicated sources.* ***<u>However</u>****, if an existing area source adds a new, major-emitting dedicated PMPU (or a new area source later adds a new, major-emitting dedicated PMPU), that new PMPU must comply with the new source standards upon start-up. The existing portion of the source would be subject to the existing source standards and would have three years to comply.*

Q. ***If an existing facility adds a new piece of equipment, could it be considered a PMPU, and subject to the standards for new sources?***

A. *While it is unlikely that a single piece of equipment would constitute a PMPU, since the term PMPU applies to the "process and any associated tanks, equipment identified under §63.1252(f)....," it is possible for a single piece of equipment to be subject to new source standards. If the new piece of equipment will have potential emissions greater than 10 TPY single HAP /25 TPY total HAP, and it is dedicated to the manufacture of a single product, then the new source standards would apply.*

Q. ***If a facility adds a non-dedicated major-emitting PMPU to a plant site, but at a later date changes it to a dedicated PMPU, does that PMPU become subject to the new source standards?***

A. *If the unit was built before April 2, 1997, it could never be classified as "new," regardless of whether or not it is a dedicated unit. Even if the unit was built after April 2, 1997, changing to a dedicated process would not trigger the new source standards.*

Q. ***If a new area source (constructed or reconstructed after April 2, 1997) becomes a major source, does this trigger new source standards?***

A. *No; as with existing area sources that become major sources, a new area source that becomes a major source has three years to come into compliance with the* ***existing*** *source standards. New, major-emitting dedicated PMPUs would be subject to new source standards (see the* ***However*** *discussion in the answer above).*

Q. ***If a dedicated PMPU added to an existing source after April 2, 1997 is subject to the new source standards at the time of construction, but later changes to a non-dedicated operation, is the PMPU still required to meet the 98% control efficiency requirement?***

A. *The part of the PMPU that still that still produces the original product that made the PMPU "dedicated" would remain subject to the new source standards (i.e., 98% control efficiency). Non-dedicated PMPUs created from components of the original PMPU that are scavenged or reconfigured would be subject to the standards for existing sources. If the facility reverts back to the original process (whether dedicated or not) that triggered New Source MACT (NSM), NSM would again be applicable for that process.*

3.4 Compliance Dates

The dates by which sources must comply with the pharmaceutical MACT standards are shown below.

Type of Affected Source	**Compliance Date**
existing affected source (63.1250(f)(1))	**October 21, 2002***
new or reconstructed source (63.1250(f)(2)) (see below for exceptions)	**August 29, 2000,** or the date of start-up, whichever is later.
new or reconstructed source that commenced construction/reconstruction **between April 2, 1997 and September 1, 1998** (63.1250(f)(3))	**September 21, 2001**, if 1) requirements in final amendment are more stringent than those in effect before August 29, 2000 and codified in the July 1, 2000 CFR and 2) owner/operator complies with requirements published on April 2, 1997 from the later of start-up or September 21, 1998, until September 21, 2001
new or reconstructed source that commenced construction/reconstruction **between September 21, 1998 and April 10, 2000** (63.1250(f)(4))	**October 21, 2002**, if 1) requirements in final amendment are more stringent than those in effect before August 29, 2000 and 2) owner/operator complies with requirements in effect prior to August 29, 2000 from start-up until October 21, 2002
new or reconstructed source that commenced construction/reconstruction **between April 10, 2000 and August 29, 2000** (63.1250(f)(5))	**August 29, 2001,** if 1) requirements are more stringent than those published on April 10, 2000, and 2) owner/operator complies with requirements in effect prior to August 29, 2000 between start-up and August 29, 2000.

***** A 1-year extension may be granted under some circumstances. A request for an extension must be submitted no later than 120 days before the compliance date, unless the need for the compliance extension arose after that date.

3.5 Consistency with Other Regulations

There are a number of instances in which the new pharmaceutical MACT regulations may overlap other existing regulations. The regulations contain provisions relating to these areas of overlap. The following table describes what to do in these instances.

If pharmaceutical MACT regulations overlap...	Solution is to......
Another subpart of Part 63 (63.1250(h)(1)(i))	After the compliance date, choose the subpart under which you will maintain records and submit reports to the extent the subparts are consistent. Identify the chosen subpart in the Notification of Compliance Report.
Control device monitoring, recordkeeping, and reporting requirements in RCRA subparts AA, BB, or CC (parts 264 and/or 265) (63.1250(h)(2)(i))	Choose to comply with monitoring, recordkeeping, and reporting under RCRA OR subpart GGG. If choose to comply with RCRA provisions, must report all information required in 63.1260 (g) periodic reports and (i) reports of start-up, shutdown, and malfunction. Identify in the Notification of Compliance Status report which monitoring, recordkeeping, and reporting authority will be followed.
Equipment recordkeeping and reporting requirements in RCRA subpart BB (parts 264 and/or 265) (63.1250(h)(2)(ii))	Choose to comply with the recordkeeping and reporting requirements under RCRA subpart BB OR Subpart GGG, to the extent that they overlap. Identify in the Notification of Compliance Status report if the RCRA requirements will be followed.
NSPS subpart Kb requirements for storage tanks with floating roofs (63.1250(h)(3))	Floating roofs can continue to comply with Kb - this constitutes compliance with Subpart GGG. Storage tanks with fixed roof, closed vent system, and control device subject to 40 CFR 60.112 (b) must comply with monitoring, recordkeeping, and reporting under GGG. Identify tanks in Notification of Compliance Status report that are subject to Kb.
Subpart I (63.1250(h)(4))	Choose whether to comply with Subpart H OR Subpart GGG. Identify chosen subpart in Notification of Compliance Status report. NOTE: only components subject to both Subpart I **and** GGG have the option to be regulated under GGG.
Other Part 63 requirements for offsite reloading or cleaning for storage tanks using vapor balancing (63.1250(h)(1)(ii))	Choose whether to comply with emissions standards and associated initial compliance, monitoring, recordkeeping, and reporting provisions of any other subpart of Part 63 OR with 63.1253(f)(7)(ii) or (iii). Identify in the Notification of Compliance Status Report which subpart of part 63 will be followed.
Requirements in 40 CFR Parts 260-272 (RCRA) for wastewater (63.1250(h)(5)	Owner/operator may determine whether GGG of 40 CFR 260-272 is more stringent. Compliance with the more stringent components in 40 CFR 260-272 constitutes compliance with GGG. In the Notification of Compliance Status Report, identify the more stringent provisions of 40 CFR Parts 260-272 that will be followed and explain how stringency determinations were made. If owner/operator chooses not to make stringency determinations, must comply with both 40 CFR Parts 260-272 and GGG.

If pharmaceutical MACT regulations overlap...	Solution is to......
Subpart PPP requirements in the polyether polyols NESHAP (63.1250(h)(6))	Can choose to control all process vents according to PPP rules at 63.1425(b), (c)(1), (c)(3), (d), and/or (f) (the most stringent standards in PPP) OR identify the process vents subject to the percent reduction standards in 63.1254 and then controlling those according to the most stringent PPP standards as listed above. For those PMPUs, owner/operator must comply with rest of PPP rules (e.g., for storage tanks, wastewater, and equipment leaks). Identify in the Notification of Compliance Status report which PMPUs will be controlled under standards in PPP; include calculations used to identify which process vents are subject to percent reduction standards in 63.1254.

Chapter 4
Requirements for Storage Tanks

4.1 Overview

The pharmaceutical MACT standards provide several options for standards for HAP emissions from certain storage tanks (raw material tanks and certain tanks storing materials destined for recovery) that exceed a specific size and vapor pressure cut-off. The standards options are expressed as either percent reduction, TOC limit at the control device outlet, technology installation (floating roof), or vapor balancing. Alternatively, owners may elect to take advantage of a pollution prevention option that aims to reduce emissions by reducing the amount of HAP-containing materials used at the facility rather than installing end-of-pipe emissions controls. In some instances, owners can use emissions averaging to achieve emissions reductions. Existing sources must comply with the standards by October 21, 2002; in general, new sources must be in compliance immediately upon start-up, or by August 29, 2000, whichever is later. For some new sources, or reconstructed sources, the exact compliance date may depend on when construction or reconstruction commences, if there are stringency differences between the final amendments and/or the draft amendments or the final rule. Please refer to the chart on page 3-14.

The initial compliance demonstration for tanks is done through a performance test or a design evaluation of those complying with the percent reduction or TOC limit. For those complying with the floating roof option, the initial compliance demonstration is done through visual inspections of the roof. Thereafter, owners will confirm continued compliance through monitoring, recordkeeping, inspection and reporting activities.

Chapter 4 - Table of Contents

4.2 Structure of the Regulation

Major components of the regulations are illustrated in the flow diagram 4-1. Regulatory citations are provided within the flow diagram. The standards for storage tanks are given in the regulations at §63.1253. The compliance procedures for demonstrating initial compliance are at §63.1257(c). Monitoring requirements are in §63.1258. Recordkeeping and reporting requirements are found at §63.1259 and §63.1260, respectively. Readers are referred to $ **Chapter 13 - Reporting** for information on what must be included in a facility's Initial Notification, Precompliance

Report, Notification of Compliance Status Report, and Periodic Reports.

How Do I Know if My Tanks are Subject to Regulation?

4.3 Applicability

Four criteria define the storage tanks subject to substantive provisions of the MACT standards:

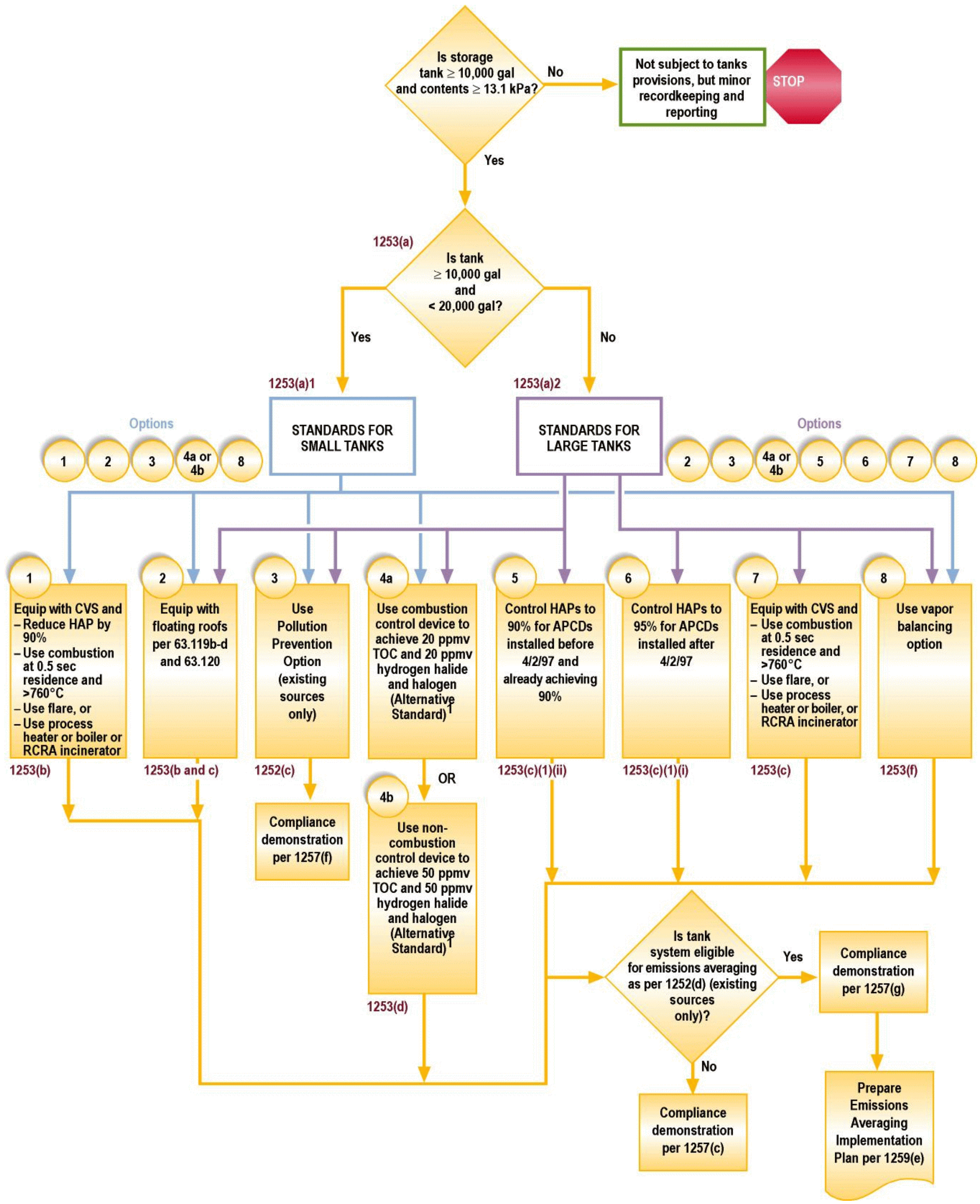
- Storage tanks or vessels that store organic HAP-containing materials (raw material feedstocks or used solvent for the purpose of solvent recovery), AND
- Have storage capacity of at least $38m^3$ (approximately 10,000 gallons), AND
- Store materials with a total HAP maximum true vapor pressure greater than or equal to 13.1 kPa (1.9 psia), AND
- The storage tank is part of a PMPU subject to the MACT. (For a discussion of assigning "ownership" to tanks, refer to pages 3-10 of this document and/or §63.1250(e).

A number of tanks and storage vessels are NOT considered storage tanks:

- Vessels permanently attached to motor vehicles such as trucks, railcars, barges, or ships
- Pressure vessels designed to operate at pressures greater than 204.9 kPa (30 psia), and without emissions to the atmosphere
- Vessels storing organic liquids that contain HAP only as impurities
- Wastewater storage tanks
- Process tanks, which are defined as tanks that are 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 a product storage tank. Surge control vessels and bottoms receivers that fit these conditions are considered process tanks. Process tanks include product tanks and isolated intermediate tanks.

IMPORTANT NOTE: Product and isolated intermediate tanks are process tanks and are part of the PMPU that produced the stored materials. Vents from these product tanks are therefore considered process vents.

IMPORTANT NOTE: Storage tanks at pharmaceutical manufacturing operations that do not meet the four criteria above are still subject to minor recordkeeping and reporting requirements. All applicability determinations must be reported in the Initial Notification of Compliance status report, per §63.1260(f)(1).



[1]As an option for the alternative standard, owner/operator may control post-combustion device HCl emissions by 95% in lieu of achieving 20 ppmv hydrogen halide and halogen emissions.

Figure 4-1. Subpart GGG Storage Tanks, Applicability and Standards

Q and A

Q. ***Is there an emissions cut-off, under which the standards for tanks do not apply?***

A. *No; the standards apply regardless of the emissions level. There is no emissions-based applicability cut-off.*

Q. ***Are so-called "day tanks," which are used to store HAP-containing liquids temporarily, considered "storage tanks," and therefore subject to the MACT regulations?***

A. *Day tanks are considered part of the PMPU with which they are associated. Day tanks meet the definition of process tank - 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 or a product storage tank. As such, emissions from day tanks that meet the definition of process tanks will be subject to process vent regulations rather than the storage tanks requirements.*

Q. ***Are tanks that are used to store recovered solvents regulated as storage tanks under the MACT standards?***

A. *It depends on the process:*

- If recovered solvent is accumulated from multiple batches, the tank is considered a storage tank.

-The tank receives recovered material from one or more unit operations in the same process or batch (e.g., a distillation overhead receiver) and sends it to one or more unit operations (e.g., a reactor within the same process or batch), the tank is a step in the process, and therefore considered a process tank rather than a storage tank.

Q. ***If a tank holds a mixture of HAP-containing materials, how is the vapor pressure calculated?***

A. *The regulations define "maximum true vapor pressure" as the equilibrium partial pressure exerted by the total organic HAP in the liquid 1) at the temperature equal to the highest calendar-month average of the storage or transfer temperature, for liquids stored or transferred* ***above or below the ambient temperature*** *or 2) at the local maximum monthly average temperature as reported by the National Weather Service, for liquids stored or transferred* ***at the ambient temperature****. The definition also refers to methods to be used in calculating vapor pressure: API publication 2517 (Evaporative Loss From External Floating-Roof Tanks - incorporated by reference at 63.14); standard reference texts; ASTM Method D2879-97 (incorporated by reference at 63.14) or; any other method approved by the Administrator.*

What are the Regulatory Standards for My Tanks?

4.4 Standards

The regulations specify standards options according to the size of the tank. Many, but not all, of the standards options are the same for "small" and "large" tanks.

In the table below, the differences in standards for small versus large tanks are shown in bolded print. Please note that there is **no distinction between new and existing tanks with regard to standards, except that new tanks cannot use P2 or emissions averaging and existing tanks may qualify for grandfathered control levels.**

Vapor Pressure ≥ 13.1 kPa (1.9 psia)	
"small tanks" **38m^3# tank < 75m^3** **(10,000 gal) (20,000 gal)**	**"large tanks"** **tank $ 75m^3** **(20,000 gal)**
STANDARDS OPTIONS: 1. Fixed roof with internal floating roof 2. External floating roof 3. External floating roof converted to internal floating roof 4. Closed vent system with device that **reduces inlet emissions of total HAP by 90%** or achieves 20 ppmv TOC and 20 ppmv halogen outlet limit 5. Closed vent system with enclosed combustion device that has minimum residence time of 0.5 seconds at 760 EC 6. Closed vent system with flare that meets the requirements of §63.11(b) 7. Closed vent system vented to a boiler, process heater, or incinerator, as described in §63.1257(a)(4) 8. Alternative Standard - Combustion control device that achieves outlet concentration of 20 ppmv or less TOC (as calibrated on methane or the predominant HAP) and 20 ppmv or less hydrogen halides and halogens.[1] (If emissions are routed to a noncombustion control device, outlet TOC concentration of 50 ppmv must be achieved, and 50 ppmv hydrogen halides/halogens.) 9. Vapor balancing, pollution prevention, and emissions averaging options - see below	STANDARDS OPTIONS: 1. Fixed roof with internal floating roof 2. External floating roof 3. External floating roof converted to internal floating roof 4. Closed vent system with device that **reduces inlet emissions of total HAP by 95% *** or achieves 20 ppmv TOC and 20 ppmv halogen outlet limit 5. Closed vent system with enclosed combustion device that has minimum residence time of 0.5 seconds at 760 EC 6. Closed vent system with flare that meets the requirements of §63.11(b) 7. Closed vent system vented to a boiler, process heater, or incinerator, as described in §63.1257(a)(4) 8. Alternative Standard - Combustion control device that achieves outlet concentration of 20 ppmv or less TOC (as calibrated on methane or the predominant HAP) and 20 ppmv or less hydrogen halides and halogens.[1] (If emissions are routed to a noncombustion control device, outlet TOC concentration of 50 ppmv must be achieved, and 50 ppmv hydrogen halides/halogens.) 9. Vapor balancing, pollution prevention, and emissions averaging options - see below

***** If a tank already is equipped before April 2, 1997, with a device that is designed to reduce emissions by 90-95%, the owner/operator is required to achieve 90% reduction (i.e., not required to achieve the additional 5% increment).
1. As an option for the alternative standard, the owner/operator may control post combustion device HCl emissions by 95% in lieu of achieving 20 ppmv hydrogen halide and halogen emissions.

The standards do not apply during periods of planned routine maintenance of the control devices. These periods of planned routine maintenance cannot exceed 240 hours per year.

It may be possible to have a facility that chooses to use several standards options concurrently. For example, an owner or operator may choose to use the 20 ppm TOC standard for a group of tanks whose emissions are routed to a central control device, but use the 90% reduction standard for other tanks not vented to the central control device. These decisions regarding control options will depend on the configuration of processes and tanks at the facility.

Vapor Balancing Option

The final rule contains a vapor balancing option for new and existing sources. The vapor balancing system must meet several criteria:

- The system must be designed and operated to route vapors from the tank to the railcar or tank truck from which the storage tank is filled.
- The tank cars and railcars must have a current DOT pressure test certification (49 CFR Part 180 for tank trucks; 49 CFR 173.31 for railcars).
- Unloading can occur only when the railcar's/tank truck's vapor collection system is connected to the tank's vapor collection system.
- Pressure relief devices on the tank truck, railcar, or storage tank should not open during loading or as a result of diurnal temperature changes (i.e., there should be no breathing losses).
- The pressure relief devices on storage tanks must be set to no less than 2.5 psig at all times to prevent breathing losses.
- During cleaning or reloading, railcars/tank trucks must either:
  (1) be connected to a closed vent system with a control device that reduces inlet emissions of HAP by 90 % weight or greater, or
  (2) have a system that routes the displaced vapors from reloading back to the tank from which the liquid being transferred originated.
  The owner/operator of the facility where the railcar/tank truck is reloaded or cleaned must submit a certification to the storage tank owner, certifying that the system will meet (1) or (2). The certifying facility may however revoke certification by sending a written statement to the tank owner, giving him/her 90 days notice that the facility will no longer accept responsibility for complying with (1) or (2).

What is the Pollution Prevention Option?

In lieu of the tank standards discussed above, an owner or operator (O/O) with existing storage tanks can choose to meet pollution prevention (P2) standards for the PMPU. The P2 requirements are either:

- reduce the production-indexed HAP consumption factor (lb HAP consumed/lb of product produced) by 75% from a specified baseline average established no earlier than 1987, or
- reduce the production-indexed HAP consumption factor by 50% from a specified baseline average established no earlier than 1987 AND reduce total PMPU HAP emissions divided by the annual production rate (lb HAP emitted per

year/lb produced per year) to a value greater than 25% of the baseline production-indexed consumption factor (i.e., achieve 50% reduction by using pollution prevention and achieve additional 25% by using add-on control devices). For more information on the pollution prevention option, see ° **Chapter 10 - Pollution Prevention Alternative.**

4.5 Emissions Averaging

The MACT rule includes provisions for **emissions averaging** for tanks. In some cases, it may be advisable for an owner to use emissions averaging when attempting to demonstrate compliance with the emission reduction standards. There are some restrictions:

- Some states may not allow emissions averaging,
- Only existing tanks may be included in an averaging group,
- Large tanks (greater than 20,000 gal capacity) that are already achieving a 90-95% reduction prior to 4/2/97 cannot be included (i.e. tanks complying with 1253(c)(1)(ii)),
- Storage tanks permanently taken out of HAP service cannot be included,
- Tanks already controlled on or before 11/15/90 cannot be included unless the level of control is increased after 11/15/90,
- Tanks already subject to control because of another State or Federal rule cannot be included, unless the level of control is increased above what is required by the other State or Federal rule, and
- No more than 20 tanks can be included in an averaging group.

Owners or operators interested in finding out more about using emissions averaging should refer to $ **Chapter 11 - Emissions Averaging for Process Vents and Storage Tanks.**

How do I Demonstrate Initial Compliance with the Regulatory Standard?

4.6 Initial Compliance Demonstration

Documentation proving initial compliance is required. The exact nature of the demonstration depends on the standard chosen by the owner or operator - percent reduction, add-on device achieving 20 ppm TOC (or 50 ppm if noncombustion device), other specific control device, floating roof, or vapor balancing. The initial compliance demonstrations are very important in that the operating parameters that are established during the compliance demonstration will be monitored later to confirm on-going compliance, if complying with the percent reduction or outlet concentration standard. The table shown on the next page describes the general compliance demonstration procedures according to the standard the owner/operator is trying to achieve.

The reader is referred to ° **Chapter 8 - Compliance Demonstrations and Testing Procedures**, for detailed instructions on conducting initial compliance demonstrations using design evaluations, performance testing, or TOC measurements (for alternative standard).

INITIAL COMPLIANCE DEMONSTRATION*	
If the regulatory standard used is....	**To demonstrate initial compliance, must...**
Floating roof	conduct compliance demonstration according to HON regulations (see section on Floating Roof Demonstration)
Percent reduction (either 90% or 95%)	either do a design evaluation or conduct performance testing of control device
Outlet concentration limit (20 ppmv TOC)	conduct performance test
Flares	meet standards of 63.11(b)
Closed vent system with combustion device (0.5 seconds residence time at 760 EC)	prepare design evaluation that documents residence time and temperature
Process heater or boiler as described in 63.1257(a)(4)	exempt from compliance demonstration
20 ppmv TOC or 50 ppmv TOC if noncombustion (alternative standard)	conduct CEM monitoring** that demonstrates outlet TOC is 20 ppmv or less, and outlet hydrogen halide and halogen concentration is 20 ppmv or less, or 50 ppmv if noncombustion device
Vapor balancing	the owner/operator of the reloading/cleaning facility must either do a design evaluation or conduct performance testing on the control device to show that it achieves 90% reduction, if an add-on control device is being used. Certification from railcar or tank truck owner that they will comply with applicable standards. Send certification to facility and Administrator. Design evaluation or performance testing is not required if the reloading/cleaning facility also does vapor balancing at their facility.

*A separate compliance demonstration for tanks is not necessary if the tanks' emissions are routed to a control device being used for process vents, and a compliance demonstration will be done in accordance with the process vent regulations.

**CEM monitoring is not always required for hydrogen halide and halogen (see 63.1258(b)(5)(i)(c) and (d).

If I Choose to Meet the Standard by Installing a Floating Roof, What Must I do to Demonstrate Compliance?

Floating Roof Demonstration

The floating roof demonstration required under the pharmaceutical MACT rule is the same as that required under the HON regulations at 63.119(b)-(d) (engineering specifications) and 63.120 (monitoring provisions).

Some practical wording changes in the referenced HON regulations are necessary:

Terminology in HON	What it means in pharm. MACT
"storage vessel"	"storage tank" as used in §63.1250
"December 31, 1992"	"April 2, 1997"
"April 22, 1994"	"September 21, 1998"
"compliance date specified in §63.100"	"compliance date specified in §63.1251"
"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 or this subpart"	"maximum true vapor pressure of the total organic HAP in the stored liquid falls below 13.1 kPa (1.9 psia)"

Owners and operators who plan to use floating roofs to comply with the emissions standards should refer to $ guidance materials developed for the HON rule: *HON Inspection Tool - EPA-305-B-97-006, September, 1997*. In particular, see Control Techniques Specific to Storage Vessels - Floating Roof Vessels (Section 6.4.2), Storage Vessel Control Requirements (Section 7.3.3), and Storage Vessel Testing, Monitoring, Recordkeeping, and Reporting (Section 7.3.4).

What On-Going Monitoring is Required (After the Initial Compliance Demonstration) to Confirm That My Tanks are Still in Compliance With the Standards?

4.7 Monitoring On-Going Compliance for Tanks Complying with the Percent Reduction Standard

Owners or operators of affected sources are required to regularly monitor the relevant control devices used to achieve the emissions control standards to confirm on-going compliance with the standards.

During the initial compliance demonstration, owners or operators establish maximum or minimum operating parameter(s). Information from any performance testing, calculations, or design evaluations is used to establish the operating parameter(s). The specific operating parameters which must be monitored regularly will depend on the control devices being used.

The reader is referred to ° **Chapter 9 - Monitoring** for a detailed discussion of establishing monitoring parameters and conducting monitoring.

IMPORTANT NOTE: Owners/operators of control devices that control **less than 1 ton/yr HAP emissions**, before control, are not required to conduct monitoring other than to verify daily that the device is working properly. If the control device is used to control batch processes as well as tank emissions, the verification may be on a per batch basis. The owner/operator must determine how the verification process is to be conducted. The steps that the owner or operator will follow in conducting these demonstrations must be described in the Precompliance Report to be submitted 6 months prior to the compliance date.

Chapter 5
Requirements for Process Vents

5.1 Overview

The pharmaceutical MACT specifies air emissions standards 1) across all process vents within a process and 2) for large, individual process vents that meet a certain flowrate threshold. The emissions standards for process vents at new sources are more stringent than those for existing sources, as allowed under the provisions of the Clean Air Act. As with the standards for wastewater and storage tanks, there are several options with regard to the type of standard and the compliance demonstrations that are used to prove initial compliance with the regulations. One option specifies a HAP mass emission limit that applies to the sum of all vents within a process. Additionally, sources can comply through a percent reduction in HAP emissions (93% for existing and 98% for new sources) or through the alternative standard, where compliance is demonstrated at the control device level through the use of a CEM. The regulations also provide a pollution prevention option that allows owners/operators of existing sources to incorporate pollution prevention initiatives instead of traditional end-of-pipe controls. After initial compliance with the standards is demonstrated, the owner/operator conducts periodic monitoring and reporting to confirm on-going compliance. Owners/operators are allowed to use emissions averaging for some processes.

Chapter 5 at a Glance

5.2 Structure of the Regulation

Process vent standards are given in §63.1254 and compliance demonstration procedures in §63.1257(d). Monitoring, recordkeeping and reporting are in §63.1258, §63.1259, and §63.1260, respectively.

5.3 Applicability

A process vent is defined in the rule as:

- A vent from a unit operation or vents from multiple unit operations within a process that are manifolded together into a common header through which a HAP-containing gas stream is, or has the potential to be released to the atmosphere.

Examples for process vents include, but are not limited to, vents on:

C condensers used for product recovery,
C bottom receivers,
C surge control vessels,
C reactors,
C filters,
C centrifuges, and
C process tanks.

The following are NOT considered regulated process vents:

C Emission streams that are **undiluted and uncontrolled** containing **less than 50 ppmv HAP**
C Vents from storage tanks regulated under §63.1253
C Vents on wastewater emission sources regulated under §63.1256
C Pieces of equipment regulated under §63.1255

To prove that process vents have less than 50 ppmv HAP, and therefore not considered regulated process vents, the owner or operator can:

C use process knowledge to assert that no HAP are present in the emission stream,
C use an engineering assessment as described in §63.1257(d)(2)(ii), or
C use test data from analysis using Method 18 of 40 CFR, Part 60, Appendix A or another test method that has been validated according to Method 301 in Part 60, Appendix A.

5.4 Standards

All process vents meeting the definition above at facilities which are major sources of HAPs, are regulated under this rule. A summary of options for standards is given in Table 5-1.

Essentially, for those vents not meeting the flowrate threshold, existing sources can choose to comply using the percent reduction standard, the 20 ppmv TOC and 20 ppmv hydrogen halide/halogen outlet standard, process heaters or boilers **Ø**, or the mass limit standard **Ù**, or the alternative standard **Ú.** Certain existing sources with individual vents which do meet the flowrate threshold must comply with the individual vent standard (98%) **Û**. Similarly, new sources may comply with the percent reduction standard **Ø**, or the mass limit standard **Ù**, or the alternative standard **Ú**. Please note there are differences between the standards for new and existing sources.

In addition, the owner/operator of some vents may choose to comply using emissions averaging (see Chapter 11) or the pollution prevention option (see Chapter 10).

NOTE: If a facility chooses Option 2 (mass limit standard), it cannot switch to Option 1 (percent reduction) until compliance with Option 2 has been demonstrated for at least 1 year. However, if a facility chooses Option 1, it can switch back to Option 2 at any time. Option 2 entails additional recordkeeping and reporting requirements, which can be reviewed in Chapters 12 and 13 of this document.

The alternative standard benefits both the Agency and the source in reduced recordkeeping and reporting and through the initial compliance demonstration. demonstration.

Isn't it repetitious that the 20 ppmv TOC standard offered as an option to the 93% or 98% reduction requirements in the §63.1254(a) is also offered again as an "alternative standard" in §63.1254(c) ?

The alternative standard was crafted such that applicability is defined around the control device rather than the processes that emit HAPs. This "alternative" standard may make it easier for owners/operators to install a centralized, add-on control device that handles emissions manifolded from several processes. (Please note that the alternative standard is not restricted to manifolds - it can be used for any vent stream.)

In addition, EPA provided the other 20 ppmv TOC standard as an equivalent demonstration of compliance with the percent reduction standard. If an O/O chooses to comply initially with this other 20 ppmv standard, §63.1257(a)(6) states that monitoring will be performed according to §63.1258(b)(1)-(4) - which allows monitoring for parameters other than TOC (e.g, combustion temperature) which are established during the performance test for the initial compliance demonstration. For the alternative standard, continuous emissions monitoring must be used to demonstrate initial and on-going compliance with the 20/50 ppmv TOC standard.

Table 5-1. PROCESS VENT STANDARDS

For Existing Sources	For New Sources
Ø Process-based Emission Reduction Standard [63.1254(a)(1)] Reduce uncontrolled emissions from *sum of all process vents w/in a process* that do not meet the flow rate criterion* **(see Û below)** by **93%**, or control to outlet concentration # 20 ppmv TOC (and # 20 ppmv hydrogen halides and halogens, if present***) , or use a flare that meets the requirements in §63.11(b), or use process heater, boiler, or incinerator as specified in §63.1257(a)(4)	**Ø Process-based Emission Reduction Standard** [63.1254(b)(1)] Reduce uncontrolled emissions from *sum of all process vents w/in a process* by **98%**, or control to outlet concentration # 20 ppmv TOC (and # 20 ppmv hydrogen halides and halogens, if present***), or use a flare that meets the requirements in §63.11(b), or use process heater, boiler, or incinerator as specified in §63.1257(a)(4)
or	**or**
Ù Process-based Annual Mass Limit Standard [63.1254(a)(2)] Limit HAP emissions from *sum of all process vents w/in a process* to 900 kg/yr (<u><</u>**2000 lbs/yr) (limited to 1,800 kg/yr per facility**) (individual vents that meet flowrate criterion* or vents complying via the alternative standard may be excluded from the 900 kg calculation)	**Ù Process-based Annual Mass Limit Standard** [63.1254(b)(2)] Limit HAP emissions from *sum of all process vents w/in a process* to 900 kg/yr (<u><</u>**2000 lbs/yr)** (vents complying via the alternative standard may be excluded from the 900 kg calculation) [63.1254(b)(2)]
or	**or**
Ú Alternative Standard**** [63.1254(c)] Install add-on combustion control device and achieve outlet concentration of # 20 ppmv TOC and # 20 ppmv hydrogen halides and halogens***. If non-combustion control device is used, must achieve 50 ppmv TOC and 50 ppmv hydrogen halides/halogens***	**Ú Alternative Standard****** [63.1254(c)] Install add-on combustion control device and achieve outlet concentration of # 20 ppmv TOC and # 20 ppmv hydrogen halides and halogens***. If non-combustion control device is used, must achieve 50 ppmv TOC and 50 ppmv hydrogen halides/halogens***
AND	

Table 5-1. PROCESS VENT STANDARDS

For Existing Sources	For New Sources
Û **Individual Vent Standard***** [63.1254(a)(3)] For each *individual vent* that meets the flowrate criterion*, **reduce uncontrolled emissions by 98%****, or control to outlet concentration less than 20 ppmv TOC (and less than 20 ppmv hydrogen halides and halogens, if present), or use a flare that meets the requirements in §63.11(b), or use process heater, boiler, or incinerator as specified in §63.1257(a)(4), or Alternative Standard Ú	

* Explanation of flowrate criterion is provided below.

** Discussion of grandfathering provisions for 98% standard is provided below.

*** Halogenated streams cannot be routed to a flare; they must be reduced to the required levels.

**** As an option for the alternative standard, the owner/operator may control post-combustion device HCl emissions by 95% in lieu of achieving 20 ppmv outlet concentrations of hydrogen halide and halogen emissions.

***** Hydrogenation vents that cannot comply with the rule because they are part of a PMPU which includes a process vent subject to the individual vent standards are subject to special standards. See 63.1254(a)(3)(ii)(c).

What is the Grandfathering Provision for an APCD Installed Prior to April 2, 1997?

5.4.1 Grandfathering Provision for the 98% Standard for Individual Vents

If an individual vent subject to the 98% reduction standard had a control device installed before April 2, 1997, and that control device achieved at least a 93% reduction (but less than 98%), the owner/operator does not need to immediately retrofit to achieve the new 98% standard. However, the device must be operated to achieve 93% reduction or the reduction percentage specified in the preconstruction permit, whichever is greater.

The owner/operator must upgrade or replace the control system such that it achieves 98% reduction:

- whenever the APCD is replaced or reconstructed, or
- by April 2, 2007 or 15 years after issuance of the preconstruction permit, whichever is later.

As an alternative, the owner/operator could choose to comply with the 20 ppmv TOC/20 ppmv hydrogen halides and halogens outlet limit OR change to a flare system, a boiler, process heater, or hazardous waste incinerator for controlling emissions.

What is the Level of Control Required in Specific Grandfathered Vents with Pollution Prevention?

In some cases, grandfathered pollution control devices are not required to be replaced or retrofitted. If all three criteria below are met, the level of control required is the level achieved on or before April 2, 1997:

- at least one vent in the process meets the flowrate criterion on or before April 2, 1997,
- the overall level of control on or before April 2, 1997 for the process containing the large vent was between 93% and 98%, and
- the production-indexed HAP consumption factor for the 12 months prior to the compliance date is less than half of the 3-year average baseline established no earlier than the 1987-1989 calendar years.

The last criterion in the list clarifies that **this provision (non-retrofit for grandfathered vents) applies to processes for which pollution prevention initiatives are being used**. In some cases, facility owners/operators may have combined vents as part of a pollution prevention program, thus yielding a large vent that meets the individual vent criterion. EPA does not want to potentially interfere with or penalize the pollution prevention program by requiring 98% control of the large vent(s). In these cases, therefore, the overall level of control required will continue to be that achieved by April 2, 1997, which must be at least 93%. Please note that if the level of control achieved by April 2, 1997 was greater than 93%, it must remain at that level. In other words, there can be no “backsliding” to 93%.

What is the Level of Control Required for Grandfathered Processes With Hydrogenation Vents?

Due to safety concerns at existing facilities, a similar provision is allowed for processes with hydrogenation vents.

Processes that contain a vent that met the flowrate criterion on or before April 2, 1997, and meeting the two conditions listed below must be operated to maintain the level of control achieved on or before April 2, 1997:

- processes that are controlled to between 93% and 98% (by weight), and
- processes with a hydrogenation vent that, considered together with the other process vents in the process that do not meet the flowrate criterion, could not meet the percent reduction standard in §63.1254(a)(1) or the mass limit standard in §63.1254(a)(2).

Any existing processes meeting just the last condition in the list above must be controlled to 95% or greater by weight, regardless of installation date of the control device.

What is the Applicability to the 98% Individual Vent Standard?

There are two questions to be answered in order in determine whether the 98% reduction standard applies to individual vents or to vents manifolded together:

- Does the vent (or manifolded vent system) have uncontrolled **emissions that exceed 25 tons per year from a single process?** If yes, go to the next question.
- Is the flow-weighted **average flowrate** (Equation 1 provided below) **less than** or equal to the **calculated flowrate index** (Equation 2)? If yes, the 98% standard applies to that vent. Where:

FR_a = actual flowrate, flow-weighted average, scfm
D_i = duration of each emission event, min
FR_i = actual flowrate of each emission event, scfm
n = number of emission events

$$FRI = [0.02 \times (HL)] - 1000 \quad \textbf{(2)}$$

Where:

FRI = Calculated flowrate index, scfm
HL = annual uncontrolled HAP emissions, lbs/yr

If $FR_a \le FRI$, HAPs in the individual vent must be reduced by 98%. Likewise, if $FR_a > FRI$, 98% reduction for the individual vent is not required.

NOTE: Several process vents from a single process that are manifolded together are considered a single process vent, and may therefore trigger the individual vent standard.

Example

An example is provided here to demonstrate how a facility owner or operator would determine whether any of the existing process vents would require control to 98%.

Figure 1 depicts a multi-batch factory (Factory A) that has several production "bays". Each bay can be used to manufacture one or more products according to Table 5-2:

Table 5-2. PRODUCTION ACTIVITIES AT FACTORY A

Bay	Process			
1	A			
2	A			
3	A	B	C	
4	A		C	
5			C	
6		B	C	D

What is the Flowrate Index (FRI) criterion based on ?

The FRI value is the gas flowrate for a given uncontrolled HAP emission rate at which EPA has determined the cost effective limit for controlling HAPs is 98% (i.e., at flows greater than FRI, it is not cost effective to control HAPs to 98%). Also, for uncontrolled rates less than 25 tpy (50,000 lbs/yr), FRI is negative and therefore, is always lower than the actual average (FR_a > FRI). **Therefore, if an existing individual vent has less than 25 tpy emissions, it will not be subject to the 98% control requirement.**

Table 5-3 presents a summary of emissions events characteristics for each process, including all information necessary to make a determination of whether the 98 percent requirement will be triggered. For purposes of this example, assume that all vents within each process A-D are manifolded.

Table 5-3. UNIT OPERATIONS AT A MULTIBATCH FACILITY AND HAP EMISSION EPISODES

Unit operations	MACT related parameters	A	B	C	D
Charging of raw materials	Flow (SCFM)	30	30	30	30
	Duration (min)	20	60	80	100
	Emission rate (lb/hr)	15	0.5	0.5	0.5
Reaction	Flow (SCFM)		20		20
	Duration (min)		440		300
	Emission rate (lb/hr)	N/A	3	N/A	5
Concent.	Flow (SCFM)	516	425	375	40
	Duration (min)	6,000	4,000	2,500	1,000
	Emission rate (lb/hr)	20.6	14	19	25
Crysta.	Flow (SCFM)	20	20	20	20
	Duration (min)	300	300	300	240
	Emission rate (lb/hr)	2.33	3	2.7	5
Filtration	Flow (SCFM)	30	40	40	40
	Duration (min)	30	150	150	120
	Emission rate (lb/hr)	2.33	3	2.7	5
Cleaning	Flow (SCFM)	30	30	30	30
	Duration (min)	500	500	500	250
	Emission rate (lb/hr)	3	3	3	3
Totals (lbs/batch)		2,102.82	1,003.33	837.58	485.00
Max. No. of batches		150	100	60	40
Max. emission potential (lb/yr)		315,422	100,333	50,255	19,400
Max. emission potential (tons/yr)		157.71	50.16	25.12	9.7
Average (SCFM)*		455	319	274	33

* Use Equation 1 from the regulations to calculate the flow-weighted average flowrate:

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

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

* Use Equation 2 from the rule to determine the calculated flowrate index:

$$FRI = [0.02 \sum (HL)] - 1,000$$

Where:

FRI = calculated flowrate index
HL = annual uncontrolled HAP emissions, lb/yr

Table 5-4 presents the results of the determination. As shown in the table, processes A and B trigger the 98 percent vent system control requirement. Therefore, the control device shown in Figure 5-1 should be demonstrated to achieve and maintain 98 percent control when products A and B are being manufactured in Factory "A".

The owner/operator may want to reconfigure the production bays such that processes "C" and "D" can vent to a control device that achieves 93% reduction. On the other hand, the owner/operator may choose to leave the current configuration as is, and use a control device that achieves 98% reduction for vent streams from all of the production bays. The regulations also allow the owner/operator to use a control device that controls the outlet concentration to 20 ppmv TOC and 20 ppmv hydrogen halides (for Alternative Standard for combustion devices or Outlet Concentration standard) or 50 ppmv TOC and 50 ppmv hydrogen halides (for Alternative Standard for non-combustion devices), or to install a flare, process heater, boiler, or incinerator as specified.

Table 5-4. APPLICATION OF THE FLOWRATE EQUATIONS AT A MULTIBATCH FACILITY

Process	A	B	C	D
FR_a	455	319	274	33
FRI	5,308	1,007	5.1	-612
Meet Flowrate Condition? (FR_a equal or less than FRI)	Yes	Yes	No	No
Required Control Efficiency	98	98	93	93

Figure 5-1 depicts a multi-batch factory (Factory A) that has several production "bays". Each bay can be used to manufacture one or more products according to Table 5-2.

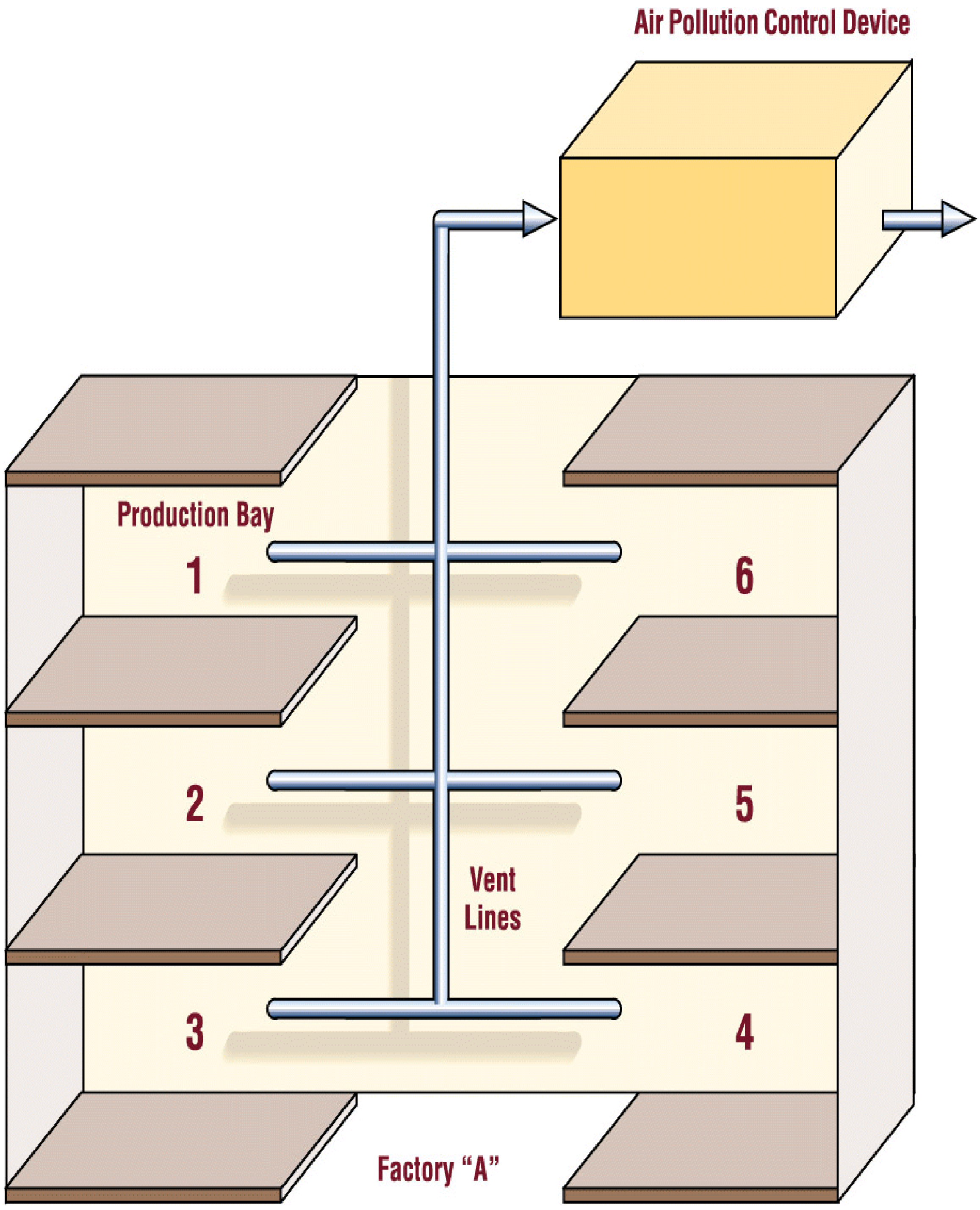


Figure 5-1. Example Multi-Batch Factory

Q and A

Q. ***If a process has one large vent that meets the flowrate criterion for the 98% standard for individual vents, does that preclude use of the 900 kg/yr standard for the remaining vents in the process?***

A. *No; the emissions from the vent controlled to 98% would be excluded from the calculation for the 900 kg/yr standard.*

Q. ***If one of the vents in a process meets the flowrate criterion for the 98% standard, are all of the vents in that process subject to the 98% standard?***

A. *No; it is possible for one vent in a process to be subject to the 98% standard, while the other vents are subject to the 93% standard, or some other standards option.*

What are the Provisions for Planned Routine Maintenance of a Centralized Combustion Control Device?

For periods of planned routine maintenance of a CCCD, up to 240 hours per year, the owner or operator can either:

- shut down the affected processes, or
- comply with the emissions standards using a different control device, or
- for a non-dedicated PMPU, follow specific provisions during the period of maintenance (NOTE: does not apply to dedicated PMPUs because it would be relatively straightforward to shut down the process in a dedicated PMPU situation.)

The special provisions for dedicated PMPUs provide that:

- If the CCCD is being used to comply with the
  - 93% reduction standard,
  - outlet concentration standard,
  - alternative standard,
  - annual mass limit standard, or
  - boiler, process heater, or hazardous waste incinerator provisions in §63.1257(a)(4), or
  - standards for large vents that exceed the flow rate criteria, then

the special provisions in §63.1252(h) can be followed during periods of planned routine maintenance on the CCCD, as shown in the table below:

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

Table 5-5. EMISSION CONTROL REQUIREMENTS DURING PLANNED ROUTINE MAINTENANCE ON A CCCD.

If organic HAP emission from the process vent are > 15 lb/day °	the organic HAP emissions must be routed through a closed-vent system to a condenser where: - outlet gas temperature must be < -50° C (-58° F), if the organic HAP has a partial pressure greater than 20 kPa (2.9 psia) - outlet gas temperature must be < -5° C (23° F), if the organic HAP has a partial pressure less than or equal to 20 kPa (2.9 psia) NOTE: the HAP partial pressures must be determined at 25° C.
If HCl emissions from the process vent are > 15 lb/day °	the HCl emissions must be routed through a caustic scrubber; the pH of the scrubber effluent must be maintained above 9.

When calculating the emissions for organic HAP and HCl in the table above, "process vent" refers to each vent from a unit operation. The emission calculation cannot be based on the aggregated emission stream from multiple unit operations that are manifolded together into a common header. During maintenance periods when these special standards are being followed, the process vents cannot be used in emissions averaging.

In instances where the process vents meet the flowrate criteria for large vents, the planned routine maintenance provisions for CCCD can be used only if the reason the planned routine maintenance is needed, and the reason it cannot be performed at a time when the large vent is not operating, have been described in the Notice of Compliance Status Report or a Periodic Report submitted before the maintenance is to occur.

What is the Pollution Prevention Option?

In lieu of the process vent standards discussed above, an owner or operator can choose to meet pollution prevention (P2) standards. The P2 requirements are either:

- reduce the production-indexed HAP consumption factor (lb HAP consumed/lb of product made) by 75% from a 3-year baseline average established using data no earlier than 1987 through 1989, or
- reduce the production-indexed HAP consumption factor by at least 50% from a specified baseline average established no earlier than 1987 AND reduce total PMPU HAP emissions divided by the annual production rate (lb HAP emitted per year/lb produced per year) to a value of at least 25% of the 3-year baseline average production-indexed consumption factor (i.e., achieve 50% reduction by using pollution prevention and achieve additional

25% by using standard control devices). For more information, see ° **Chapter 10 - Pollution Prevention Alternative.**

5.5 Initial Compliance Demonstration Procedures

Compliance demonstration procedures for process vent standards are listed in §63.1257(d) - Initial Compliance with Process Vent Provisions. This section briefly summarizes the requirements for demonstrating <u>initial</u> compliance. Further details can be found in Chapter 8. Procedures for demonstrating <u>on-going or continual</u> compliance are listed in §63.1258 (Monitoring Requirements) which are summarized in Section 5.7 and more fully discussed in Chapter 9.

Initial compliance demonstration procedures are summarized below in Table 5-5. To understand Table 5-5, it may be helpful to review the various terms for different kinds of compliance demonstrations.

Emissions estimation methods and engineering assessments are used to calculate mass rates, while design evaluations and performance tests are used to demonstrate the efficiency of control devices.

- **Emissions estimation methods** make use of equations provided in the rule to calculate emissions from eight specific activities - vapor displacement, purging, heating, depressurization, vacuum systems, gas evolution, air drying, and empty vessel purging, when a condenser is used as the control device or when estimating uncontrolled mass emission rates. Alternate methods (e.g., ACT/CTG) may be available for use.
- **Engineering assessments** make use of other equations or methods (not provided by EPA) to calculate emissions, generally from activities other than the eight specified above under emissions estimations methods. (Engineering assessments can also be used for the eight specified activities IF the owner or operator can demonstrate that the emissions estimation equations are not appropriate.)
- **Design evaluations** use the control device manufacturer's specifications, engineering principles, and/or test data to show that the device will achieve the required control.
- **Performance testing** is actually testing the equipment under specified test conditions to prove that it will achieve the required control.

Table 5-6. OPTIONS FOR DEMONSTRATING COMPLIANCE WITH PROCESS VENT PROVISIONS

Standard	Initial Compliance Demonstration Requirements	
	Uncontrolled Mass Rates	**Controlled Emission Rates**
# 900 kg HAPs/yr (mass emission limit)	C Emission Estimation Methods C Engineering Assessments	If device controls less than 10 tpy, can use: C Design Evaluations C Emission Estimation Methods[1] If device controls more than 10 tpy, must use: C Performance Tests C Previously Conducted Performance Tests C Emission Estimation Methods
93% or 98% Reduction (% reduction) or Outlet Concentration Limit (#20 ppmv TOC/ #20 ppmv hydrogen halides)	C Emission Estimation Methods C Engineering Assessments	If device controls less than 10 tpy, can use: C Design Evaluations C Emission Estimation Methods[1] If device controls more than 10 tpy, must use[2]: C Performance Tests C Previously Conducted Performance Tests C Emission Estimation Methods[1]
#20 ppmv TOC and 20 ppmv hydrogen halides and halogens (Alternative standard) (#50 ppmv and 50 ppmv hydrogen halides and halogens if non-combustion device)	N/A	Monitor & record outlet TOC (and hydrogen halides and halogens if necessary) on the initial compliance date. If a scrubber is used to achieve 95% post-combustion control device HCl emissions, a performance test or design evaluation is required.

5.6 Emissions Averaging

The MACT rule allows for emissions averaging among process vents, in both the initial compliance demonstration and in monitoring on-going compliance. There are restrictions, however, as to when emissions averaging may be used:

- Some states may not allow emissions averaging,

[1] Emissions estimations are used only if the control device used is a condenser. There is no distinction between condensers controlling < or > 10 tpy. In addition, the measurement of condenser outlet gas temperatures is required for all condensers used as APCDs, regardless of whether the standard used is # 900 kg/yr or 93%/98% reduction.

[2] If APCD is a boiler with a heat input > 44 MW, or has vent stream fed into flame zone, or is a RCRA hazardous waste boiler or RCRA hazardous waste incinerator, the unit is exempt from initial compliance demonstration.

- Only existing processes may be included in the averaging group,
- Processes already controlled on or before 11/15/90 cannot be included unless the level of control is increased after 11/15/90,
- Processes already subject to control because of another State or Federal rule cannot be included, unless the level of control is increased above what is required by the other State or Federal rule,
- No more than 20 processes can be included in an averaging group,
- Processes for which the owner/operator is using the "alternative standard" cannot be included in an averaging group,
- Processes which have been permanently shutdown cannot be included in an averaging group, and
- Individual process vents that are subject to the 98% reduction standard cannot be included in an averaging group.

Owners or operators interested in finding out more about using emissions averaging should refer to ° **Chapter 11 - Emissions Averaging for Process Vents and Storage Tanks**.

5.7 Monitoring On-Going Compliance

Owners or operators of affected sources must conduct regular monitoring to confirm on-going compliance with the emissions standards. Except when complying with the alternative standard, during the initial compliance demonstrations, maximum or minimum operating parameter levels are established that will be used in the monitoring program. Information from the performance testing, other calculations, or design evaluations are used to establish the operating parameter levels. Of course, the specific operating parameters will depend on the type of control device being used.

If the owner/operator chooses to use alternative monitoring parameters, a request for approval must be included in the Precompliance Report. The reader is referred to ° **Chapter 9 - Monitoring** for a detailed discussion of monitoring requirements, including what parameters must be monitored for each kind of control device.

IMPORTANT NOTE: Owners/operators of control devices that **control less than 1 ton/yr HAP emissions**, before control, are not required to conduct monitoring other than to verify daily that the device is working properly. If the control device is used to control batch processes alone or in combination verification may be on a per batch basis. The owner/operator must determine how the verification process will be conducted, and must describe the process in the Precompliance Report submitted six months prior to the compliance date.

Chapter 6
Equipment Leaks

6.1 Overview

The rule contains requirements for controlling leaking components such as pumps, flanges, valves, pressure relief valves, and compressors by either leak detection and repair (LDAR) using "sniffing" via Method 21 or pressure testing. These requirements are based on the requirements of subpart H of part 63 with some modifications that include reduced leak monitoring frequencies for programs that result in low leak frequencies, the allowance for subgrouping of components to demonstrate leak frequencies, and the option to not individually identify all components subject to LDAR in a master log. Identification of the subject equipment does not require physical tagging (the rule does require that leakers be tagged).

6.2 Structure of the Rule

All requirements are located in §63.1255, with many references to subpart H. Sections of §63.1255 are provided below:

(a) General Leak Requirements
(b) References (to applicable portions of subpart H of part 63)
(c) Standards for pumps
(d) Standards for open-ended valves or lines
(e) Standards for valves in gas/vapor service and light liquid service
(f) Unsafe to monitor, difficult to monitor, and inaccessible equipment
(g) Recordkeeping
(h) Reporting

Chapter 6 at a Glance

6.3 Applicability

The equipment leak provisions apply to the following components if these components are **in organic HAP service 300 hours per calendar year** within a source subject to this subpart. (See Applicability Example 2 below regarding calculation of 300 hours service.) The definition of "in organic HAP service" specifies a cut-off of at least 5% total HAP concentration by weight [expected annual average concentration - See 63.180(d)].

- Pumps
- Compressors
- Agitators
- Pressure relief devices
- Sampling connection systems
- Open-ended valves or lines
- Valves
- Connectors
- Instrumentation systems
- Closed vent systems and control

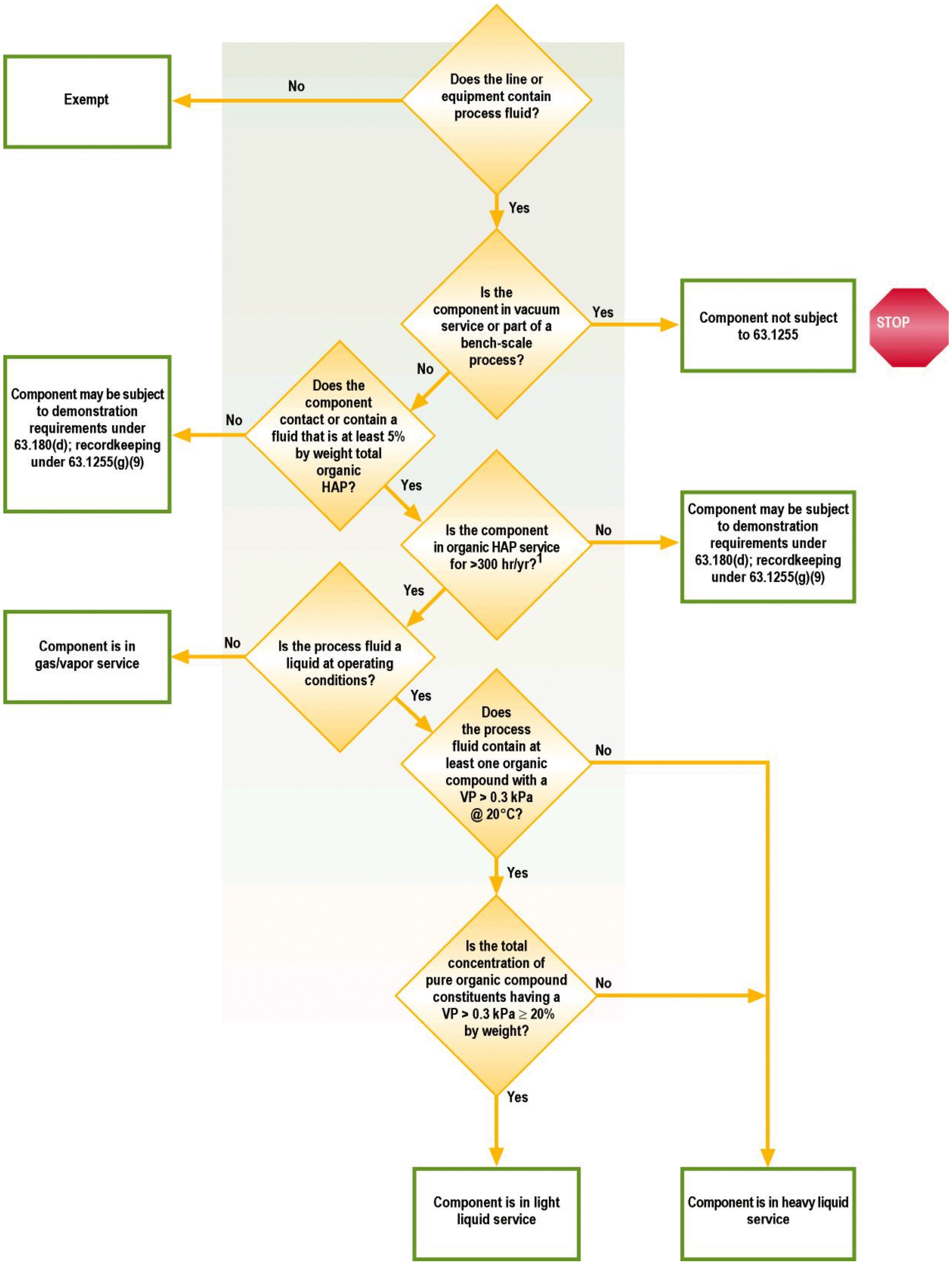
devices used to control emissions from the above components

Equipment not subject to the LDAR requirements includes:

- lines and equipment not containing process fluids. This would include utilities, and other non-process lines, such as heating and cooling systems, whose materials are not mixed with those in the process.
- bench-scale processes, even if located at the same plant site as a regulated manufacturing unit.
- equipment that is in vacuum service (equipment operating at an internal pressure which is at least 5 kPa below ambient pressure).
- equipment in organic HAP service, but that is used less than 300 hours per calendar year (these exempt units must be recorded however).

Figure 6-1 presents a logic flow diagram for applicability.

NOTE: PMPUs complying with the MACT standard through use of the Pollution Prevention option are not subject to LDAR requirements.



[1.] Only equipment that can reasonably be expected to be in organic HAP service, but is not, needs to retain records of determination. Equipment not reasonably expected to be in organic HAP service, such as non-HAP solvent supply lines, needs no records.

Figure 6-1. Logic Flow Diagram for applicability

What is the Definition of "In Organic HAP Service"?

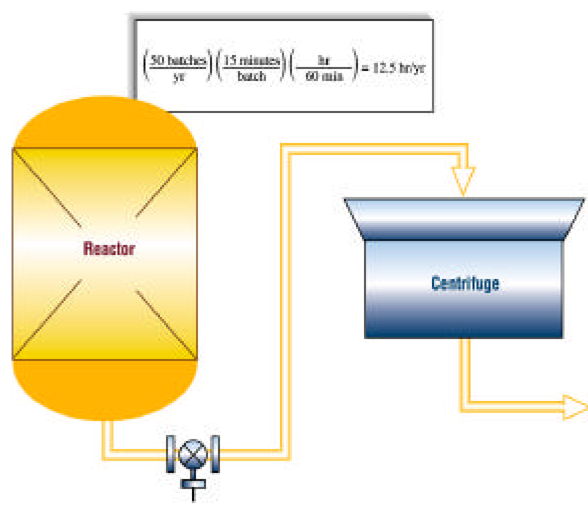
"In organic HAP service" is defined in §63.1251 and means that a piece of equipment either contains or contacts a fluid (liquid or gas) that is at least 5 percent by weight of total organic HAPs, as determined according to §63.180(d). Section 63.180(d) states that "each piece of equipment within a process unit that can reasonably be expected to contain equipment in organic HAP service is <u>presumed</u> to be in organic HAP service unless an owner or operator <u>demonstrates</u> that the piece of equipment is not in organic HAP service." For a piece of equipment to be considered not in organic HAP service, it must be determined that the percent organic HAP content can be reasonably expected not to exceed 5 percent by weight on an <u>annual average basis</u>. Section 63.180(d) allows owners or operators to use Method 18 of 40 CFR 60, appendix A (HAP concentration), or "good engineering judgment" to make the demonstration.

Applicability Example 1: Determining Whether a Component is in 5 Percent by Weight HAP Service.

An owner or operator wishes to be exempt from the provisions of §63.1255 for components in a closed vent system containing 500 ppmv methanol (a HAP) and the remainder air, as measured using Method 18. The percent by weight HAP is determined by multiplying 500 ppmv by the ratio of molecular weight of methanol (32) to the molecular weight of air (29) to yield 551 ppmw, or 0.050 percent by weight, which is well below the 5 percent by weight criteria for "organic HAP service"; therefore, the closed vent system is not subject to the provisions of §63.1255.

Applicability Example 2: Determining Whether a Component is in Service for 300 Hours Per Year.

A line from a batch reactor to a centrifuge is in contact with a process fluid during transfer of material from the reactor to the centrifuge (after each transfer, the line is purged with nitrogen to a control system to ensure that there is no fluid left in the line). The transfer operation lasts a maximum of 15 minutes each time the batch occurs, and there are a maximum of 50 batches per year anticipated. Therefore, the components in the line would be in service for a maximum of 12.5 hours per year, well below the 300 hours per year trigger for applicability. Even through the equipment is exempt, owners and operators must identify the exempted equipment per §63.1255(g)(9). If the same line is used as part of other processes as well, the portion of time it is in service for those other processes should also be added to determine the total time in service.



6.4 References to Subpart H

Since subpart GGG contains numerous references to subpart H, Table 6-1 provides a tabular cross reference of the equipment leak requirements of subpart GGG and referenced applicable sections of subpart H. The regulations in **bold print are applicable** to sources regulated under subpart GGG.

6.4.1 Consistency with Other Regulations

After the compliance date, for components subject to subpart GGG as well as 40 CFR 60 or 61, the owner or operator is required only to comply with subpart GGG (and specifically, § 63.1255 for equipment leak components).

After the compliance date, an affected source with equipment subject to subpart I of part 63 may elect to comply with either the subpart GGG leak provisions or the provisions of subpart H of the HON for <u>all</u> such equipment (i.e., the owner/operator cannot choose to comply with H for certain equipment and subpart GGG for other components). The O/O shall identify in the NOC under which subpart s/he will comply.

What are the General Standards in § 63.1255?

6.5 Standards

Identification of Equipment Subject to § 63.1255

Equipment subject to this subpart must be identified so that it can be readily located and distinguished from equipment not subjected to this standard. **Physical tagging is not required**; components can be identified on a plant site plan, in log entries, or by designation of process boundaries with weatherproof identifications. Updates for affected components must be made within 90 calendar days of the change(s), or by the next Periodic Report, following the end of the monitoring period for that component, whichever is later.

Identification of Leaking Equipment

When leaks are detected by visual, audible, or olfactory means, or by monitoring, a weatherproof and readily visible identification, marked with an equipment identification number or other number- or color-coded tag, should be attached to the component. With the exception of valves, this identification "tag" can be removed upon successful repair. For valves, the tag must be left on until they have been monitored using Method 21 at least once in three months after repair and are determined to be not leaking.

NOTE: Except for components in heavy liquid service, instrumentation systems, and pressure relief valves in liquid service, successful repair means that the component is shown to not leak using Method 21 immediately after repair. Otherwise, successful repair should be verified using the same method used to detect leaks.

Table 6-1. SUBPART GGG REFERENCES AND INTERFACE WITH HON
(Note: bolded references are applicable at pharmaceutical manufacturing operations)

Subpart H Section	**Description**	
63.160	Applicability and description of source	**63.1255(a)**
63.161	Definitions	**63.1251**
63.162	Standards: General	**63.1255(a)**
63.163	Standards: Pumps in light liquid service	**63.1255(c)**
63.164	Standards: Compressors	Direct reference to 63.164
63.165	Standards: Pressure relief devices in gas/vapor service	Direct reference to 63.165
63.166	Standards: Sampling connection systems	Direct reference to 63.166
63.167	Standards: Open-ended valves or lines	**63.1255(d)**
63.168	Standards: Valves in gas/vapor service and in light liquid service	**63.1255(e)**
63.169	Standards: Pumps, valves, connectors and agitators in heavy liquid service; instrumentation systems; and pressure relief devices in liquid service	Direct reference to 63.169
63.170	Standards: Surge control vessels and bottoms receivers	**63.1254** (these equipment are covered by the process vent standards)
63.171	Standards: Delay of repair	Reference to 63.171 with **exceptions noted in 63.1255(b)(4)(i)**
63.172	Standards: Closed vent systems and control devices	Reference to 63.172 with **exceptions noted in 63.1255(b)(4)(ii)**
63.173	Standards: Agitators in gas/vapor service and in light liquid service	**63.1255(c)**
63.174	Standards: Connectors in gas/vapor and in light liquid service.	References to 63.174, with **exception noted in 63.1255(b)(4)(iii)**
63.175	Quality improvement program for valves	No provisions in subpart GGG
	Quality improvement program for pumps	No provisions in subpart GGG

Subpart H Section	Description	
63.177	Alternative means of emission limitation: General	Direct reference to 63.177
63.178	Alternative means of emission limitation: Batch processes	Reference to 63.178, with **exceptions noted in 63.1255(b)(4)(iv)**
63.179	Alternative means of emission limitation: Enclosed-vented process units	Direct reference to 63.179
63.180	Test methods and procedures	Direct reference to 63.180, with **exceptions noted in 63.1255(b)(4)(v)**
63.181	Recordkeeping	**63.1255(g)**
	Reporting	**63.1255(h)**

Compliance Times

References to periods of time to accomplish a specific task (e.g., weekly, monthly, quarterly) refer to the standard calendar periods, unless otherwise specified in the rule.

If the initial compliance date does not coincide with the beginning of a standard calendar period, the owner/operator has some options regarding the way he/she wishes to specify time periods. The owner/operator may elect to :

- use a period beginning on the compliance date, or
- use a time period agreed upon by the owner/operator and the regulating agency,or comply before the end of the standard calendar period within which the initial compliance deadline occurs, **if there remain at least**:
  - 3 days for tasks that must be performed weekly,
  - 2 weeks for monthly tasks,
  - 1 month for quarterly tasks, and
  - 3 months for annual tasks.

In all other cases, compliance is required before the end of the first full standard calendar period after the period in which the initial compliance deadline occurs.
If the regulations require completion of a task during each of multiple successive periods, the owner/operator can conduct the task at any time during each period, as long as the intervals between completion of the tasks are reasonable. For example, for quarterly monitoring the facility may choose to monitor the first week of the first month of each quarter. It would not be reasonable to monitor the last week of March and again

the first week of April.

If a leak is detected, and the owner/operator does not try to repair the leak within the specified time period, this is a violation of the regulations. If a repair is attempted, but it does not work, this is not a violation. However, the owner/operator must take further action as required by the rule if a leak still exists.

Can Processes be Grouped Together to Facilitate Calculations of Percent Leaking Components?

The rule allows owners or operators to "group" processes together when determining percent leaking components for the purposes of selecting the appropriate monitoring frequency. For example, a processing building housing non-dedicated equipment could be designated as a "group of processes." For valves only, the rule also allows "subgrouping," in which groups of processes can be further subdivided into subgroups. The intent of the rule with respect to the subgrouping procedure is to assign components according to their propensity for leaks, allowing for reduced monitoring frequencies for some subgroups. This approach focuses the monitoring, recordkeeping, and reporting burden on those processes and types of equipment that exhibit the most significant leaks.

What are the Standards for Pumps in Light Liquid Service and Agitators in Gas/Vapor Service and in Light Liquid Service?

Figure 6-2 describes the monitoring requirements for pumps in light liquid service and agitators in gas/vapor service and in light liquid service. Once processes have been grouped, pumps and agitators must be monitored quarterly using M21 and must be visually inspected weekly for indications of liquids dripping.

Percent Leaking Pump Calculation

The calculation must be done to determine subsequent monitoring frequency unless 90 percent of the pumps in the group of processes meet the exemption criteria of § 63.1255(c)(5) and (6), which are discussed below. The percent leaking pumps ($\%P_L$) must be calculated every quarter for a 1-year rolling average. If, on the 1-year rolling average, the greater of either 10 percent of the pumps are found to leak, or at least three pumps in a group of processes (on average) per quarter leak, the monitoring frequency reverts to <u>monthly</u> and remains monthly for the group of processes, until the one year rolling average falls below 10% or 3 pumps. The owner or operator would conduct monthly monitoring for three months to yield a quarterly average. Then the new quarterly average and the three previous quarterly averages would be used to calculate the 1-year rolling average. Monthly monitoring would continue until the 1-year rolling average indicates less than 10% of the total or 3 pumps are leaking. Note that the percent leaking pump calculation also allows that pumps within <u>continuous</u> processes found to leak within 1 quarter of startup are not considered in the $\%P_L$ calculation. Also, pumps that are <u>exempt</u> from monitoring because of their design must be included in the total pump count. The equation used to calculate $\%P_L$ is presented below:

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

where:

$\%P_L$ = percent leaking pumps
P_L = number of pumps found leaking in periodic monitoring
P_T = total pumps, including those exempted
P_S = number of pumps in a continuous process leaking within 1 quarter of startup during the current monitoring period.

(See the following page for an example of calculating leaking pump percentage to determine the appropriate monitoring frequency.)

Exemptions from Monitoring

If a pump or agitator is equipped with a dual mechanical seal system that includes a barrier fluid system, the pump or agitator is exempt from periodic Method 21 monitoring if several conditions are met:

- The system must be:
  - operated with a barrier fluid at a pressure that is greater than the pump/agitator stuffing box pressure OR
  - equipped with a barrier fluid degassing reservoir that is connected by a closed-vent system to a control device OR
  - equipped with a dual mechanical seal system with a closed-loop system that purges the barrier fluid back into a process stream

  AND
- the barrier fluid is not in light liquid service, and
- each barrier fluid system has a sensor that will detect failure of the seal system, the barrier fluid system, or both, and
- each pump/agitator is checked by visual inspections each calendar week for drips from the seal.

During the weekly inspection, if there are indications of liquids dripping, the pump or agitator seal must be monitored immediately using M21 or the owner/operator must eliminate the leak before the next weekly visual inspection. Pumps/ agitators that are located at "unmanned" plant sites are exempt from weekly visual inspections. In lieu of these weekly visual inspections, these pumps/agitators must be visually inspected at least monthly.

A pump/agitator designed with no externally actuated shaft penetrating the pump/agitator housing is exempt from monitoring. In addition, pumps/agitators equipped with a closed-vent system are exempt from monitoring.

An example of the calculation of percent leaking pumps is described below:

Quarter	No. pumps (including exempted)	No. leakers	Avg. No. leakers/ quarter
1	10	1	
2	10	0	
3	10	2	
4	<u>10</u>	<u>0</u>	
TOTAL	40	3	3 leakers/ 4 quarters = 0.75

$\%P_L$ = 3/40 = 7.5 percent (less than 10 percent); also, the number of pumps leaking per quarter (on average) is 0.75 (less than 3);

ˆ Therefore the facility can continue to monitor quarterly.

NOTE: Method 21 (as described in 63.180(b)) monitoring is required quarterly unless the percent leaker calculated over a rolling 1-year period is either 10 percent or an average of at least three pumps per quarter, in which case monthly monitoring is required.

Repair Provisions

Leaks must be repaired as soon as practicable, but no later than 15 calendar days after detection, unless repair would require a process shutdown or personnel would be exposed to an immediate danger if they attempted a repair without shutting down the process. The first attempt at repair must be made within 5 calendar days and may include measures such as tightening of packing gland nuts or ensuring that the seal flush is operating at design pressure and temperature.

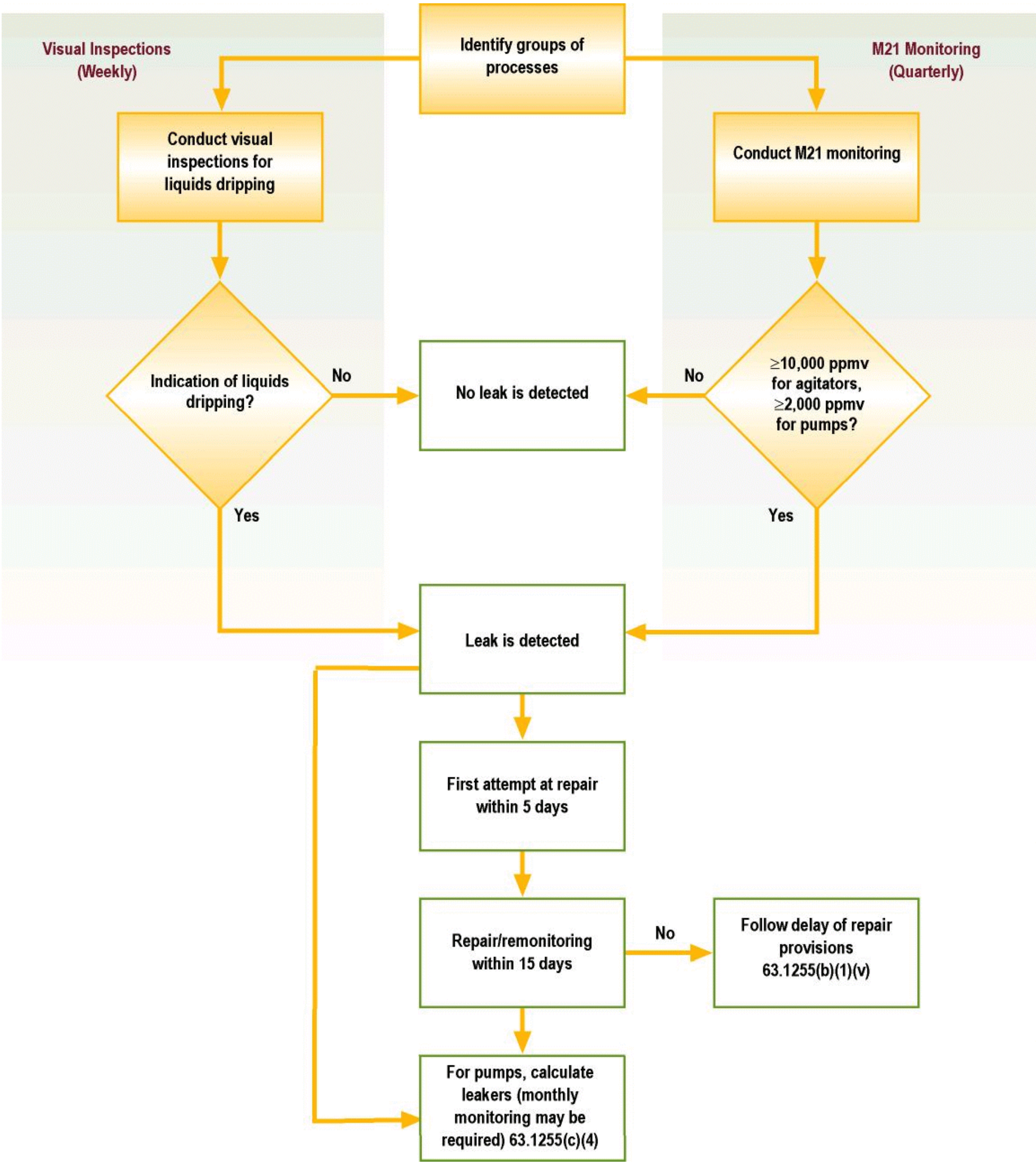


Figure 6-2. Pump/agitator monitoring in light liquid service.

What are the Standards for Open-Ended Valves or Lines?

Standards

Open-ended valves or lines must be equipped with a cap, blind flange, plug, or second valve at all times except during operations that require process fluid flow, or during maintenance or repair. Owners or operators have 1 hour after operations stop or maintenance or repair is completed, to affix caps, flanges, plugs, or double block and bleed systems. Records documenting compliance with the 1 hour standard are not required.

Other important aspects of the section:

- For open-ended valves or lines equipped with a second valve (double block and bleed), the valve on the process fluid end must be closed before the second valve is closed.
- When a double block and bleed system is used, the bleed valve or line may remain open during operations that require venting the line between the block valves only.

Exemptions

Open-ended valves or lines that meet any of the following conditions are not required to be capped, equipped with flanges, plugged, or equipped with a double block and bleed system:

- Designed to open automatically during emergency shutdown situations,
- Contain materials which would autocatalytically polymerize,
- Could cause an explosion, serious overpressure, or other safety hazard, if closed accordingly.

Example

A pipe used to convey material from a reactor to an emergency "dump pit" is not required to be capped, plugged, equipped with a flange, or equipped with a second valve because the line is designed to open automatically during an emergency shutdown situation.

What are the Standards for Valves in Gas/Vapor Service and in Light Liquid Service?

Figure 6-3 describes the monitoring requirements for valves in gas/vapor service and light liquid service for the identified groups of processes. Note that if an affected source has fewer than 250 valves, they are exempt from monthly monitoring. There are two different calculations of percent leaking valves. The first yields percent leaking valves, %VL, the value used to determine appropriate monitoring frequencies. The second calculation is for %VLO, the percent overall leaking values, which is used when the subgrouping option is chosen to determine on a semiannual basis, whether the overall percent leaking valves is less than 2 percent and the compliance strategy is still valid. Both calculations are presented below.

Percent Leaking Valves Calculation (to determine monitoring frequency)

$$\% V_L = [V_L/V_T] \times 100$$

where:

$\% V_L$ = percent leaking valves as determined through periodic monitoring

V_L = number of valves found leaking, excluding nonrepairables as provided for in 63.1255(e)(6)(iv)

V_T = total valves monitored in a monitoring period, excluding valves remonitored within 3 months after repair, per 63.1255(e)(7)(iii)

Percent Overall Leaking Valves Calculation (if subgrouping, to determine whether subgrouping is allowed)

$$\% V_{LO} = \frac{\sum_{i=1}^{n} \left(\% V_{Li} x V_i\right)}{\sum_{i=1}^{n} V_i}$$

where:

$\%V_{LO}$ = overall performance of total valves in the group of processes

$\%V_{Li}$ = percent leaking valves in subgroup i, most recent value calculated according to (e)(6)(ii) and (iii)

V_i = number of valves in subgroup i

n = number of subgroups

Option 1 - no subgrouping

Option 2 - by leakers

Option 3 - by processes

Examples of valve subgrouping

The initial round of monitoring for the group of processes in Building 1 yields the following results:

Process	Total No. Valves	No. Leaking	No. Not Leaking	$\%V_L$
A	600	10	590	1.7
B	500	2	498	0.4
C	300	0	300	0
D	200	2	198	1
Total	1600	14	1586	0.9

Option 1 - no subgrouping
Option 2 - all the 14 leaks in one group
all the non-leakers in another group
Option 3 - Process A in one subgroup
Process B, C, D in another subgroup

Option 1 - no subgrouping
Without any subgrouping, with a leak percentage of 0.9, the group of processes would require monitoring of all 1,600 valves every two quarters (twice a year).

Option 2 - all leakers in one subgroup;
all non-leakers in another group
Under subgrouping Option 2, the owner or operator could choose to subgroup all 14 leaking valves into one subgroup, provided these leakers make up 2 percent or less of the total components. The "leaker" subgroup would require monitoring every quarter and the remaining subgroup would require monitoring every 2 years.

Option 3 - Process A in one subgroup;
Processes B, C, & D in another subgroup
If this option were chosen, the facility would be required to monitor 600 valves every quarter, and monitor the remaining 1000 valves once a year, since the leak frequency would be 0.40 (less than 0.5 percent –> yearly monitoring).

Recordkeeping and Reporting Specific to Subgrouping of Valves in Light Liquid and Gas/Vapor Service

In addition to the general requirements for all equipment leaks reporting and recordkeeping, owners and operators are also required to record and report information specific to the subgrouping option, including:

- Identification of valves assigned to each subgroup
- Monitoring results and calculations made for each subgroup and each monitoring period
- Results of semiannual $\%V_{LO}$ calculation
- Which valves are reassessed and when they were reassessed.

Finally, as shown in Figure 6-3, the owner or operator must notify the implementing agency of the decision to subgroup valves at least 30 days prior to the beginning of the next monitoring period and must identify affected groups of processes and valves assigned to each subgroup.

Repair Provisions for Valves in Light Liquid and Gas/Vapor Service

The regulations provide that the leak must be repaired as soon as practicable; the owner/operator must at least **attempt** to repair the leak within 5 calendar days of its detection. First attempts to repair include measures such as tightening the bonnet bolts, replacing the bonnet bolts, tightening the packing gland nuts, and injecting lubricant into lubricated packing. The repair must be completed within 15 days of detection, unless there is a legitimate "delay of repair" situation (discussed later in this document). After the leak is repaired and the repair is confirmed by monitoring, the valve must be monitored again at least once within the first 3 months after the repair.

NOTE: Days that the valve is not in organic HAP service do not count against the 3-month time period.

Monitoring after a Repair

The regular periodic monitoring can be done to satisfy the post-repair 3-month monitoring check IF the timing of the regular monitoring coincides with the timing required by the repair. Otherwise, the owner/operator will need to conduct some other monitoring outside the regularly-scheduled monitoring. If monitoring reveals that the leak has resumed, this valve must be counted as a leaking valve for the purposes of grouping processes IF the monitoring that detected the leak was the regular periodic monitoring. If, however, the owner/operator used some other schedule for monitoring the initial leak (after repair to see if the leak had resumed), then the valve does not have to be counted as a leaking valve IF it is repaired again, given follow-up monitoring, and shown not to be leaking by the next periodic monitoring.

What are the Standards for Equipment that is Difficult to Monitor/Inspect, Unsafe to Monitor/Inspect, or Inaccessible?

Equipment that is designated as unsafe to monitor, unsafe to inspect, difficult to monitor, difficult to inspect, or inaccessible is exempt from the monitoring and repair requirements described in Table 6-2. However, if inaccessible equipment is observed by visual, audible, olfactory or other means to be leaking, the leak is required to be repaired as soon as practicable, but no later than 15 calendar days after detection. Please note that all equipment must be assigned to a group of processes.

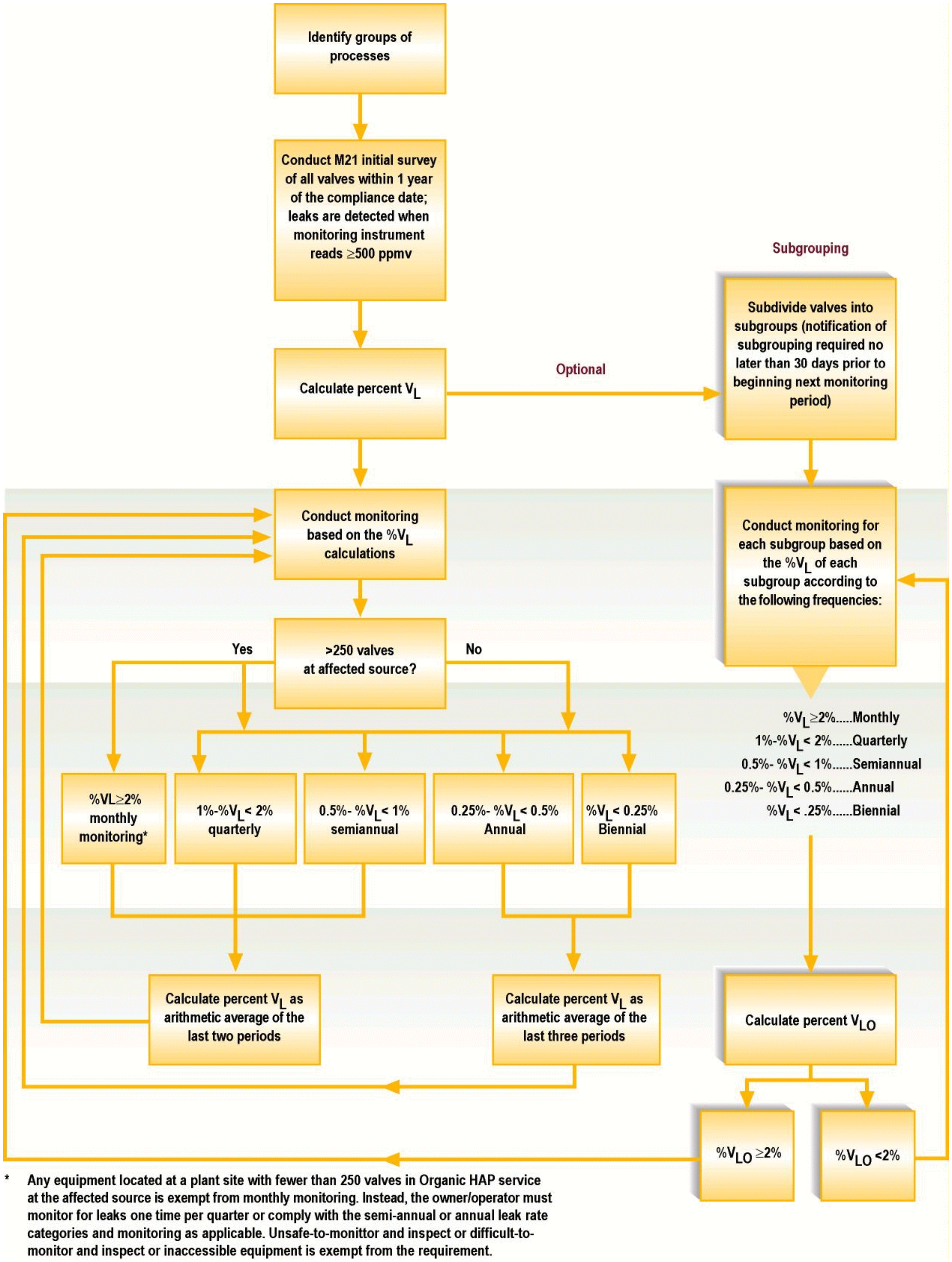


Figure 6-3. Monitoring for valves in gas/vapor service and light liquid service.

Table 6-2. EXEMPTIONS FOR DIFFICULT-TO-MONITOR/INSPECT, UNSAFE-TO-MONITOR/INSPECT, AND INACCESSIBLE EQUIPMENT

Component	Exempt requirements	Description of exemption requirements
Pumps and agitators[a]	§ 63.1255(c)(2),(c)(3),(c)(4)	Monitoring, repair, calculation of % leakers
Valves	§ 63.1255(e)(2) through (e)(7)	Monitoring, repair, calculation of % leakers
Closed-vent systems[a]	§ 63.172(f)(1) and (2) and (g); §63.1255(b)(4)(ii)(A) and (B)	Inspections and monitoring
Connectors	§ 63.174(b) through (e); §63.1255(b)(4)(iii)(A)-(F)	Monitoring and repair

[a]Pumps, valves, and closed vent systems cannot be designated as "inaccessible."

[b]Ceramic or ceramic lined connectors are subject to the same requirements as inaccessible connectors.

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 and repair requirements identified in Table 6-2 above. However, owners and operators designating components must have a written plan that requires their monitoring as frequently as practicable, but not more frequently than periodic monitoring would require.

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 identified in Table 6-2 above. However, the owner or operator must have a written plan that requires inspection of the unsafe to inspect closed vent systems as frequently as practicable during safe to inspect times, but not more frequently than periodic monitoring would require.

A valve, agitator, or pump may be designed as difficult to monitor if the owner or operator determines that the equipment cannot be monitored without elevating the monitoring personnel more than 2 meters above a support service or it is not accessible in a safe manner when it is in organic HAP service. At a new affected source, no more than 3 percent of valves can be designated as difficult to monitor. Owners and operators must have a written plan to require monitoring of each type of component designated as difficult to monitor. The monitoring must be conducted at least once per calendar year or on the periodic monitoring schedule applicable to the group of processes in which the equipment is located, whichever is less frequent.

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. The owner or operator must have a written plan that requires inspection of the closed vent system at least once every 5 years.

The “inaccessible” designation may be applied to connectors that are:

- buried
- insulated in a manner that prevents access to the connector by a monitor probe
- obstructed by equipment or piping that prevents access to the connector by a monitor probe
- 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 ground, or
- unable to be accessed at any time in a safe manner per §63.1255(f)(4)(i)(E),
- unable to be accessed without elevating monitoring personnel more than 2 meters above a permanent support surface or would require the erection of a scaffold.

Ceramic or ceramic-lined connectors are subject to the same requirements as inaccessible connectors. At a new affected source, no more than 3 percent of connectors may be designated as “inaccessible”.

If any inaccessible, ceramic, or ceramic-lined connector is observed by visual, audible, olfactory, or other means to be leaking, it must be repaired as soon as practicable, but no later than 15 calendar days after detection.

What are the Standards for Connectors in Gas/Vapor Service and in Light Liquid Service

Figure 6-4 describes the initial monitoring requirements for connectors in gas/vapor service and in light liquid service. Please note that the use of monitoring data from before April 22, 1994, is subject to some restrictions.

Percent Leaking Connector Calculation

The initial calculation of percent leaking connector ($\%C_L$), is calculated as:

$$\%C_L = \left[\frac{C_L}{(C_T + C_C)}\right] x\ 100\%$$

where:

$\%C_L$ = percent leaking connectors
C_L = number of connectors found leaking

C_T = number of connectors monitored in a period
C_C = optional credit for removed connectors = 0.67 x net

For subsequent monitoring frequencies, the following equation should be used:

$$\%C_L = [(C_L - C_{AN})/(C_t - C_C)] \text{ x } 100\%$$

where:

$\%C_L$ = percent leaking connectors
C_L = number of connectors found

leaking

C_{AN} = number of allowable nonrepairable connectors, not to exceed 2% of the total connector population

C_t = total number of monitored connectors

C_C = optional credit for removed connectors = 0.67 x net

Optional Credit for Removed Connectors

An owner or operator may choose to eliminate a connector subject to monitoring and receive credit for elimination of the connector if the following conditions are met:

1. Connector is welded after date of proposal (April 2, 1997) of Subpart GGG.
2. The integrity of the weld is demonstrated by monitoring or by testing using x-ray, acoustic monitoring, hydrotesting, or any other applicable method.
3. Welds created after April 2, 1997, but before the date of promulgation (September 21, 1998) of Subpart GGG are monitored or tested by 3 months after the compliance date.
4. Welds created after September 21, 1998 are monitored or tested within 3 months after being welded.
5. If an inadequate weld is found or the connector is not welded completely around the circumference, the connector is not considered a welded connector and is therefore not exempt from the provisions of Subpart GGG.

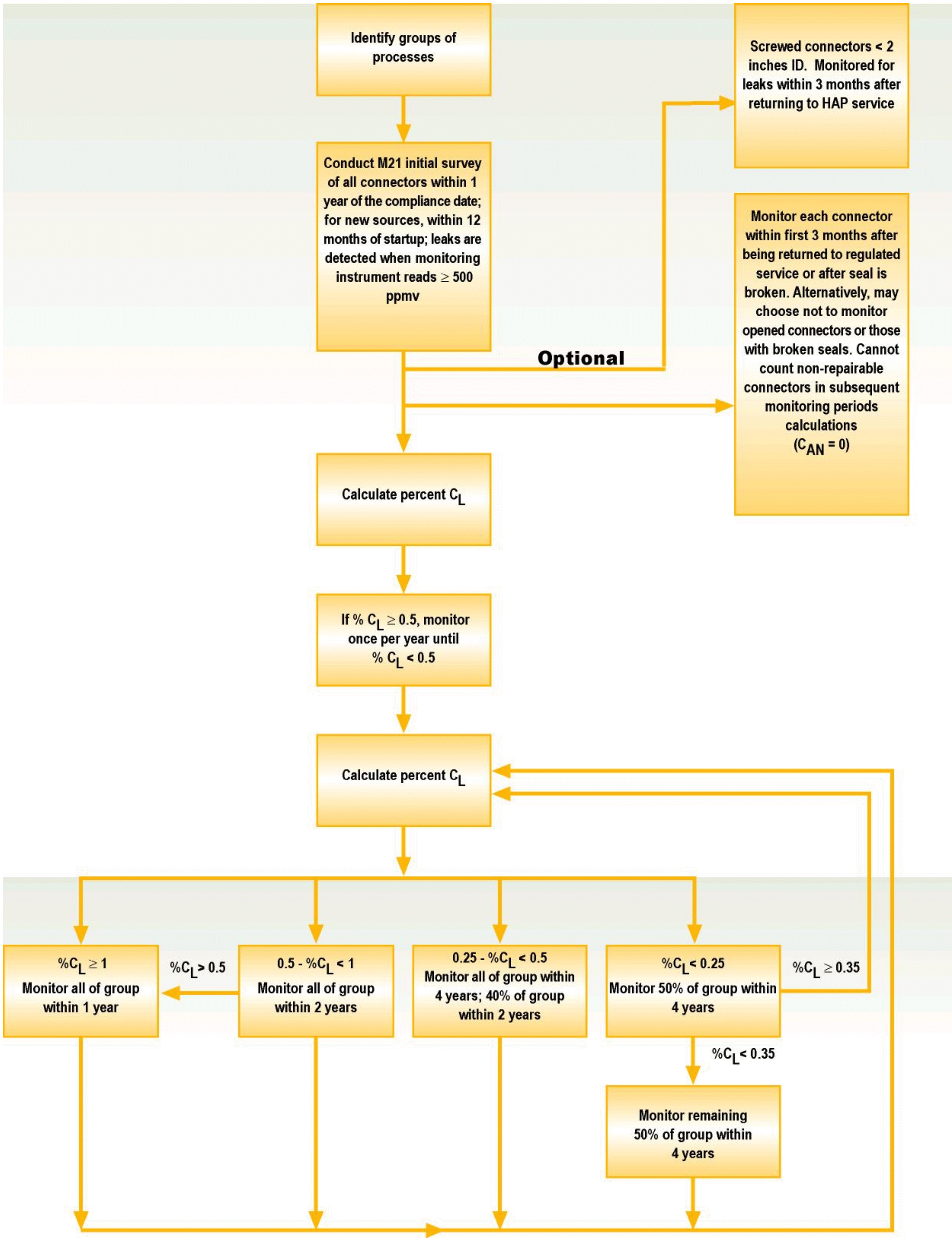


Figure 6-4. Initial Monitoring requirements for connectors in gas/vapor service and in light liquid service.

What are the Standards for Compressors?

The requirements for compressors are referenced directly to Subpart H. Compressors may comply with either an equipment design standard or a performance standard, as discussed below.

Equipment Design Standard

Compressors must be equipped with a seal system that includes a barrier fluid system that prevents leakage to the atmosphere.

Seal System with Barrier Fluid System. The regulation requires each compressor seal system to meet the following criteria:

- Each system must be:
  - Operated with the barrier fluid at a pressure that is greater than the compressor stuffing box pressure; or
  - Equipped with a degassing system that is connected by a closed-vent system to a control device; or
  - Equipped with a system that purges the barrier fluid into a process stream with zero VOC (or volatile HAP) emissions to the atmosphere.

- The barrier fluid system is to be either in heavy liquid service or not in organic service.
- Each barrier fluid system is to be equipped with a sensor that will detect failure of the seal system, the barrier fluid system, or both.
- The regulation requires the owner or operator to determine the criterion to be used to indicate failure of the seal system, the barrier fluid system or both.
- Each sensor is to be checked daily or is to be equipped with an audible alarm.
- When a leak is detected (either by visual inspection or by the sensor indicating a failure), it is to be repaired as soon as practicable, but no later than 15 days after it is detected, except as provided by the "Delay of Repair" provisions. A first attempt at repair is to take place no later than 5 days after a leak is detected.

The standards for compressors do not require weekly visual inspection for indications of a potential leak as is required for pumps in light liquid service.

Performance Standard

Owners/operators may choose to follow a performance standard for compressors instead of an equipment design standard. Compressors must be equipped with a closed-vent system designed to capture and transport leakage from the compressor driveshaft back to the process or to a control device achieving at least 95 percent control efficiency (or 20 ppmv HAP). (See following discussion on closed vent systems and combustion devices (Page 6-24)).

What are the Standards for Pressure Relief Devices in Gas/Vapor Service?

Except during pressure releases, pressure relief devices in gas/vapor service are required either to operate with no detectable emissions or to be equipped with a rupture disk or a closed-vent system and control device. Pressure relief devices complying with the no detectable emissions standard are to be returned to that condition within 5 calendar days after each pressure release, except as provided in the "Delay of Repair" provisions. The standards also require the monitoring of the pressure relief device no later than 5 calendar days after a pressure release to confirm that no detectable emissions has been achieved.

The pressure relief devices need not comply with the no detectable emissions standard if they are equipped with a rupture disk upstream of the PRV or if equipped with a closed-vent system capable of capturing and transporting leakage from the pressure relief device to a control device achieving at least 95% control efficiency or back to the process. If complying through installation of a rupture disk, the rupture disk must be installed upstream of the pressure relief device as soon as practicable, but no later than 5 days after each pressure release.

What are the Standards for Sampling Connection Systems?

Sampling connection systems are to be equipped with a closed-purge, closed loop, or a closed-vent system. Each system should do one of the following:

- Return the purged process fluid directly into the process line.
- Collect and recycle the purged process fluid.
- Capture and transport all the purged process fluid to a control device achieving at least 95% control efficiency.
- Collect, store, and transport the purged process or solid waste fluid to a waste water management unit, or to a RCRA treatment, storage or disposal facility, depending on the characteristics of the purged fluid.

Subpart H (and GGG) exempt in situ (without purge) sampling systems.

What are the Standards for Pumps, Valves, Connectors, and Agitators in Heavy Liquid Service, Instrumentation Systems, and PRV's in Liquid Service?

Pumps, agitators, and valves in heavy liquid service, pressure relief devices in light liquid or heavy liquid service, and flanges and other connectors in heavy liquid service, and instrumentation systems are to be monitored within 5 days if evidence of a potential leak is found by visual, audible, olfactory, or any other detection method. In lieu of monitoring, a potential leak can be repaired as described below. A reading of $10,000 ppmv for agitators, 2,000 ppmv for pumps, or 500 ppmv for valves, connectors, instrumentation systems, and PRV's, indicates a leak.

Repair Provisions

If a leak is detected, a first attempt at repair must be made within 5 days after the leak is detected and the leak must be fixed within 15 calendar days. For the leak to be considered repaired, visual, audible, or olfactory indications of leaking should be eliminated; owners and operators can do leak checks using soap solutions or pressure tests. The use of M21 is not required to certify that the repair is complete if the leak was determined to exist without M21. If M21 is used to determine the presence of a leak (for heavy liquid) then the repair must be certified by M21.

What if My Repair is Unsuccessful?

If action is taken to repair a leak within the specified time, but the repair is not successful, this is not considered a violation. However, the owner or operator is required to take further action to repair the leak.

What are the Standards for Delay of Repair?

The following circumstances under which repairs may be delayed are provided in the rule:

- Delay of repair of leaking equipment is allowed if the repair is technically infeasible without a process unit shutdown. An example of such a situation would be a leaking valve that could not be isolated from the process stream and that would require complete replacement or replacement of internal parts. When a valve cannot be physically isolated from the process stream, the process unit must be shut down to repair the valve.

- Delay of repair of leaking components is allowed if the owner or operator determines that repair personnel would be exposed to an immediate danger if attempting to repair without a process shutdown.

- Delay of repair is allowed for equipment that is isolated from the process and does not remain in organic HAP service. This typically applies to spare equipment that is out of service.

- Delay of repair for valves, connectors, and agitators is allowed if the emissions of purged material resulting from repair are greater than the fugitive emissions likely to result from the delay, and if, during repair, the purged material is collected and destroyed or recovered in a control device achieving > 95% control efficiency.

- Delay of repair for pumps is allowed if repairs require replacing the existing seal design with a new system, or a dual mechanical seal system that includes a barrier fluid system, or a pump that meets the requirements in §63.163(f), or a closed vent system and control device that meets the requirements of §63.163(g). The repair must be completed as soon as practicable, but not later than 6 months after the leak is detected.

- Delay of repair beyond a process unit shutdown is allowed for valves if the following conditions are met:
  - Valve assembly replacement is necessary during the

process unit shutdown.
- Valve assembly supplies have been depleted.
- Valve assembly supplies had been stocked sufficiently before the supplies were depleted.
- Delay of repair beyond the next process unit shutdown is not allowed unless the next process unit shutdown occurs sooner than 6 months after the first process unit shutdown.

Specific recordkeeping requirements relating to delay of repair are discussed later in this chapter under Requirements for Recordkeeping.

What are the Standards for Closed-Vent Systems Used to Control Equipment Regulated Under 63.1255?

The regulations require proper operation and maintenance of a control device and vent system to control leaks. The closed-vent system provisions include inspection and monitoring requirements and requirements for specific control devices which are at 95 percent efficiency, or achieving outlet concentrations 20 ppmv HAP. Monitoring requirements of specific control devices are covered under other sections of this document (Chapter 9).

Vent System Requirements

- Initial inspection using M21; annual visual, audible, olfactory inspection if <u>hardpiped</u>; annual M21 inspection if <u>duct work</u>.

- Leak definition of 500 ppmv or visual (audible and olfactory) indication.

- First attempt to repair leak should be made within 5 calendar days of detection.

- Repair must be completed within 15 calendar days unless there is a legitimate delay of repair (i.e., requires process shutdown or emissions from immediate repair would be greater than fugitive emissions resulting from delay).

Bypass provisions

For any bypass line that <u>could</u> divert a vent stream away from the control device and to the atmosphere, either a flow indicator located at the inlet of the bypass line that takes a reading every 15 minutes or a lock-and-key (car seal) type configuration is required to be installed. For a lock-and-key or car seal configuration,
a visual inspection of the seal or closure mechanism is required monthly to ensure that the valves are maintained in a nondiverting position.   Records are generated for the flow indicator or the inspection, as applicable, as discussed in Chapter 12 on Recordkeeping.

Exemptions from Bypass Provisions

Low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, and PRV's needed for safety purposes are not required to have either flow indicators or car seals.

Exemptions from Closed Vent System Provisions

Any closed-vent system operating at a pressure below atmospheric pressure is exempt from the monitoring and inspection provisions. The vent system must be equipped with a 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 it is operating.

Any parts of the closed-vent system that are designated as unsafe to inspect are exempt from inspection requirements if personnel inspecting would be exposed to an imminent or potential danger and the o/o has a written plan to inspect these pieces of equipment during safe-to-inspect times, not more than annually.

What are the Standards for Batch Processes/Alternative Means of Emission Limitation?

As an alternative to complying with the standards for all components (pumps, agitators, connectors, valves, pressure relief devices, sampling connection systems, open-ended valves or lines, and instrumentation systems), owners or operators may elect to comply with equipment leak standards for batch processes in two ways: through batch pressure testing, or through less frequent monitoring, depending on the percent of time that the processes are operating, as compared to continuous. Per Table 6-1, the provisions of subpart H are directly referenced, with the exception that continuous processes are also allowed to undergo batch pressure testing. Pressure testing also can be applied to supply lines between storage areas and processing areas.

The source may switch among the alternatives (pressure testing or monitoring for leaks) provided the change is documented.

Pressure Testing

The process train or supply line is required to be pressure tested each time equipment is <u>reconfigured</u> for production of a different product or intermediate prior to introducing the HAP into the equipment or at least once per calendar year for each process carried out in that equipment. If a leak is detected, the repair must be completed and the equipment retested before startup of the process. Pressure testing is only required for that equipment which is reconfigured (new or disturbed) and pressure testing is not required for routine seal breaks which are not part of the reconfiguration.

If a leak is detected during pressure testing, it must be repaired and retested before process start-up. If the batch process fails the retest or the second of two consecutive pressure tests and is started up, it must be repaired as soon as practicable, but no later than 30 calendar days after the second pressure test, unless there is a legitimate “delay of repair” situation: equipment supplies are depleted and supplies had been sufficiently stocked before the supplies were depleted. The repair must be made no later than 10 days after delivery of the replacement equipment.

NOTE: An exception to this requirement is if the delay of repair provisions of § 63.178(d) apply. Delay of repair applies if the reason the leak cannot be fixed is because replacement equipment is needed to fix the leak, and this equipment is not available; provided the equipment had been in stock before supplies were depleted and provided the repair is made no later than 10 calendar days after delivery of replacement equipment. If these conditions apply, the batch process train can be put into service, provided it is fixed within 30 calendar days after the batch test failure. Therefore, owners and operators have a maximum of 30 days of operation in which the batch process equipment train can operate without having passed a pressure test.

Batch Test Methodology

1. <u>Using Gas Pressure for Pressure or Vacuum Loss</u>

The process equipment should be pressurized with a gas to a pressure above the operating pressure of the equipment and less than the set pressure of any safety relief device, or placed under vacuum. Once the pressure or vacuum has been established, the pressure or source vacuum should be shut off. A pressure measurement device capable of measuring ± 2.5 mmHg in the range of the test pressure or at least ±10 percent of the test pressure should be used to detect any change in pressure, in psig/hr, that can occur over the course of at least 15 minutes; if the amount of time for the pressure test is 15 minutes exactly, the corresponding change in pressure to equal a 1 psig/hr change would be 12.9 mmHg. Therefore, a leak would be detected if the pressure device indicates an increase or decrease of 12.9 mmHg. The rate of change in pressure is calculated according to the following equation:

$$\Delta \frac{P}{t} = \frac{(|P_f - P_i|)}{(t_f - t_i)}$$

where:

delta P/t = change in pressure, psig/hr
P_f = final pressure, psig
P_i = initial pressure, psig
t_f-ti = elapsed time, hours

A leak is also detected if there is evidence of a leak by visible, audible, or olfactory evidence of fluid loss.

2. <u>Using Liquid for Indications of Liquids Dripping</u>

A batch pressure test can also be conducted using a liquid, in which the equipment is filled with the liquid until normal operating pressure is achieved. Once this occurs, the liquid source is also shut off. This test occurs for at least 60 minutes, unless it is obvious that the test is a failure prior to 60 minutes. Once the operating pressure is achieved, each seal in the equipment being tested should be inspected for indications of liquids dripping or other indications of fluid loss. Any of these indications constitutes a leak.

Table 6-3. BATCH PROCESSES MONITORING FREQUENCIES FOR EQUIPMENT OTHER THAN CONNECTORS AND PUMPS

Operating time, % of year	Equivalent continuous process monitoring frequency time in use		
	Monthly	Quarterly	Semiannually
0 to <25	Quarterly	Annually	Annually
25 to <50	Quarterly	Semiannually	Annually
50 to <75	Bimonthly	Three times	Semiannually
75 to 100	Monthly	Quarterly	Semiannually

Batch Method 21 Monitoring

Owners and operators may also choose to monitor for leaks using Method 21. The provisions of subpart H (and subpart GGG, by reference) allow for reduced monitoring frequencies for all components, except connectors and pumps, based on the proportion of the year that the process subject to the provisions is operating, monitoring must occur at any time the equipment is operating in organic HAP service, in use with an acceptable surrogate VOC which is not a HAP or is in use with any other detected gas or vapor. For example, if a batch process and equipment are operated for one 6-week campaign per year, the percent operating time is:

$$\left(\frac{6\,\text{weeks}}{\text{campaign}}\right)\left(\frac{\text{yr}}{52\,\text{weeks}}\right)\text{x}100 = 11\%\ \text{operating time}$$

Table 6-3 presents the adjusted monitoring frequencies for batch processes; however, for pumps, the frequency is always quarterly. Monitoring is allowed any time during the specified monitoring period (e.g., monthly, quarterly, yearly) provided sufficient time between scheduled monitoring occurs. For example, it would not be acceptable to monitor Dec. 31st of one year and Jan. 1st of the subsequent year. In addition, if the equipment is not operating during the scheduled monitoring period, the monitoring can be done during the next period when the process is operating.

In addition to the scheduled monitoring that must be conducted according to the frequencies established for various components, § 63.178(c) also requires that M21 monitoring be conducted within 30 days of reconfiguration. However, this monitoring effort is separate from the scheduled monitoring. Leaks detected during this effort are not included in determining percent leaking equipment in the groups of processes.

If a leak is detected using Method 21, any leaks detected must be repaired within 15 days of detection, unless there is a legitimate “delay of repair” situation, as described in the preceding paragraph.

What are the Requirements for Enclosed-Vented Process Units?

Process units that are totally enclosed such that all emissions from equipment leaks are vented through a closed vent system to a control device are exempt from the monitoring requirements. Negative pressure must be maintained during process operation to ensure that all emissions are routed to the control device.

What are the Requirements for Recordkeeping?

NOTE: For ease of referencing, the following list uses the same numbering found in the regulations at §63.1255(g)(1)-(10).

- An owner or operator with more than one group of processes subject to the leak detection rules can keep all of the records in one recordkeeping system if it identifies the program being done (e.g. quarterly monitoring) for each type of equipment. The following information is required to be maintained in a manner that can be readily accessed at the plant site, either from records kept at the plant site or accessed from a central location by computer at the plant site.

2. General Records

   List of Equipment ID Numbers
   - List of identification numbers of all equipment, except for connectors that have been designated as inaccessible. If equipment is not individually identified, it should be identified as a group, and the number of subject items of equipment within a designated area associated with the group recorded. The list must be completed no later than the initial survey required for the component type and changes noted within 90 days or in the Periodic Report that covers the period in which the changes were made, whichever is later.
   - List of identification numbers of equipment complying by being sent to a closed-vent system and control device.
   - List of identification numbers of compressors designated as no detectable emissions.
   - List of identification numbers for pressure relief devices subject to monitoring and those equipped with rupture disks.
   - List of instrumentation systems subject to provisions (individual components need not be identified).
   - List of equipment designated as difficult-to-monitor, unsafe-to-monitor, and inaccessible and a copy of the written plan for monitoring or inspecting this equipment.
   - If credit for removed connectors is used, list of connectors removed from and added to process groupings

and documentation of the integrity of the weld.

- List of equipment added to batch processes since the last monitoring period that is monitored using Method 21 according to the alternative means of emission limitation for batch processes; this list must be completed within 90 days of the completion of each monitoring period, or by the next Periodic Report, following the end of the monitoring period, whichever is later. Also, if the owner or operator elects to adjust monitoring frequency by the time in use provisions in 63.175(c)(3)(iii), record the proportion of the year equipment subject to the standards was in use (63.1255(g)(2)(viii).

Schedule of Monitoring

- Schedule for monitoring of connectors and valves in gas/vapor service and light liquid service.

Design Information

- Design information on pumps with dual mechanical seal systems.
- Design information on closed-vent system and control device, if used to control emissions from LDAR components.

3. Records of Visual Inspections

- Records of dates of visual inspection for pumps, agitators and closed-vent systems.

4. Monitoring Records (leaker logs)

When a leak is detected (either by M21 or visual, audible, or olfactory means), the following information is required to be recorded and kept for a total of 5 years (2 years onsite and an additional 3 years onsite or offsite):

- Instrument and equipment identification number and operator name, initials, or I.D. number.
- Date leak was detected and date of first attempt to repair.
- Date of successful repair.
- The maximum instrument reading measured by M21 after a leak is successfully repaired or determined to be nonrepairable.
- “Repair delayed” and reason for delay of repair, if applicable.
- If delay of repair involved, dates of process unit shutdowns that occurred while equipment was not repaired.
- If applicable, the written procedure that identifies the conditions that justify delay of repair.
- The procedures can be included as part of the startup/shutdown/malfunction plan OR can be in a separate

document that is kept at the site.
- If the delay was caused by a depletion of parts, documentation that the spare parts had been sufficiently stocked before depletion and the reason for depletion.

Also, even if leaks are not detected, the following information is required to be recorded and kept for 2 years onsite and 3 years offsite:

- Dates and results of startup or reconfiguration monitoring required by monitoring requirements for batch processes (§ 63.178(c)(3)) for equipment added to the processes since the last monitoring period and, if no leaks found, a record that the inspection was performed.
- If connectors whose seals have been broken are being monitored, identification by list, location (area or grouping), or tagging of connectors disturbed since the last monitoring period.
- Copies of periodic reports.

5. Records of Pressure Tests

Instead of the records in 2., 3., and 4. above, owners/operators using pressure testing must keep the following records:

- Identification of each product produced during the year.
- Dates of pressure tests, test pressures, and pressure drops observed during the test.
- Records of any visible, audible, or olfactory evidence of fluid loss.
- Identification of equipment subject to pressure testing. Physical tagging is not required. Equipment may be identified on a plant site plan in log entries or other appropriate methods.
- When a process equipment train does not pass two consecutive pressure tests and is put into HAP service prior to being repaired and passing a test, the following information is required and must be retained for 2 years:
  - date of each pressure test and date of each leak repair attempt.
  - repair methods applied in each attempt
  - reason for delay of repair
  - expected date for delivery of replacement equipment and actual date of delivery
  - date of successful repair.

6. Records of Compressor and Pressure Relief Device Compliance

Tests and Relief Device Compliance Tests

- Dates and result of each compliance test required for compressors designated as "no detectable emissions," including:
  - background level

  - measured during each compliance test
  - maximum instrument reading measured at the compressor seal
- Dates and results of the monitoring following each PRV release, including:
  - background level measured during each compliance test
  - maximum instrument reading measured at the PRV

7. Records for Closed Vent Systems (CVS)

For closed vent systems to which fugitive emissions are ducted, design specifications and performance demonstrations of the control device and piping and instrumentation diagrams should be maintained for the life of the equipment.

These include:

- detailed schematics, design specs of the control device, and piping and instrumentation diagrams
- dates and descriptions of any changes in the design specs
- the flare design (whether it is steam assisted, air assisted, or nonassisted) and the results of the compliance demonstration
- a description of the parameter(s) monitored and an explanation of why the parameter(s) were chosen.

Also, for at least 2 years, records should be maintained of:

- Dates and duration of non-operation of the systems
- Dates and duration when monitored parameters are outside ranges established in initial compliance determination.
- Dates and durations of startup/shutdown/malfunction occurrences.
- Records of inspection of CVS and results (documenting no leaks or information in (4.) above).
- Records of operations of CVS and control device.

8. Records for Components in Heavy-Liquid Service

Information used to demonstrate that a component is in heavy liquid service should be recorded.

The demonstration should show that the process fluids do not meet the criteria of "in light liquid or gas service." Information could include records of chemicals purchased for the process, analyses of process stream composition, engineering calculations, or process knowledge, or other information offered by the owner/operator.

9. Records of Exempt Components

Information used to identify and identification of equipment in organic HAP service less than 300 hours per year should be recorded. Identification may be either by list or location.

10. Records of Alternative Means of Compliance Demonstration: Enclosed-Vented Unit

Owners and operators complying by enclosing emissions through a closed vent system operating under negative pressure should maintain the following information:

- Identification of processes and the organic HAP they handle
- Schematics of the process, the enclosure, and closed-vent system
- Description of the system used to create a negative pressure in the enclosure to ensure that all emissions are routed to the control device.

What are the Reporting Requirements?

Subpart GGG requires that the following reports be submitted for equipment subject to § 63.1255:

- Notification of Compliance Status Report (NOC) (submitted within 150 days of compliance date) containing:
  - process group identification
  - numbers of each equipment type (except equipment in vacuum service)
  - method of compliance with the standard
  - products or product codes subject to processes complying by pressure testing, if available
  - planned schedule for pressure testing
  - identification of processes complying with § 63.179 (enclosure to negative pressure manifold) and a description of the system used to create negative pressure

- Periodic Reports (submitted semiannually 240 days after NOCSR). The first Periodic Report covers the 6 months beginning on the due date of the NOCSR (See section 63.1255(g)(3)(i). Owners/operators of all equipment except for that complying through pressure testing must provide the following:
  - the number of valves for which leaks were detected, the percent leakers and total number of valves monitored
  - the number of valves for which leaks were not repaired and the number of valves that are nonrepairable
  - the number of pumps for which leaks were detected, the percent leakers for pumps, and the total number of pumps monitored
  - the number of pumps and agitators for which leaks were not repaired
  - the number of compressors for which leaks were detected
  - the number of compressors for which leaks were not repaired

- the number of connectors for which leaks were detected, the percent of connectors leaking, and the total number of connectors monitored
- the number of connectors for which leaks were not repaired and the number of those determined to be nonrepairable
- the facts that explain any delay of repairs and when appropriate, why a process shutdown was technically infeasible
- the results of all monitoring of compressors designated as no detectable emissions, PRV's, and closed vent systems
- if applicable, the initiation of monthly monitoring for valves or pumps
- if applicable, a change in connector monitoring alternatives as described in § 63.174(c)(1)
- **for processes complying by pressure testing**,
  - the product process equipment train identification
  - the number of pressure tests conducted
  - the number of pressure tests where equipment train failed either the retest or two consecutive pressure tests
  - the facts that explain any delay of repairs, and
  - the results of all monitoring to determine compliance with § 63.172(f) of Subpart H.
- any revisions to items reported in the NOC, if the method of compliance has changed.

Chapter 7
Requirements for Wastewater

7.1 Overview - Suppression and Control

Chapter 7 at a Glance

The wastewater provisions of the MACT differ from the provisions for tanks and process vents in that they are concerned with both suppressing air emissions within the wastewater treatment chain (i.e. individual drain systems, treatment tanks, etc) as well as reducing HAP in the wastewater itself through performance standards. Additionally, any air emissions vented during the treatment process must be controlled via traditional air pollution control devices and equipment leak provisions apply to vapor collection systems, closed vent systems, roofs, covers or other enclosures used to comply with the rule. Residuals created from treatment processes must either be recycled, returned to the treatment process or destroyed. Although not considered wastewater, this chapter also describes requirements for heat exchangers and equipment in open systems. The suppression and control requirements are summarized below:

TYPE OF STANDARD	MEDIA	PURPOSE
Vapor Suppression (VS)	air	Use equipment specs and operating practices to minimize HAP losses to the air from tanks, surface impoundments, containers, and individual drain systems (i.e., cover equipment to limit emissions)
Performance Standards (PS) **1. Wastewater Treatment** (WWT)	water	! Use wastewater treatment processes to reduce the HAP content in the wastewater (i.e. removal, destruction, treatment in bio units, etc)
2. Air Emissions Control (EC)	air	! Use control device specs or performance standards for air pollution control devices (APCDs) to reduce HAP emissions (i.e., use APCDs) vented from treatment processes

These two types of standards - VS and PS (with EC and WWT subsets) - will appear throughout this chapter, since they establish the structure of the regulations for wastewater.

The rule contains many of the same requirements found in the wastewater section of Subpart G of the HON (§63.131-.149). This includes vapor suppression requirements, air pollution control device (APCD) requirements, compliance demonstration procedures, inspection and monitoring requirements, and requirements for certain liquid streams in open systems. Please be aware that the HON regulations are not exactly the same as the pharmaceutical MACT regulations, and the HON regulations should not be used to interpret specific requirements of the pharmaceutical MACT.

7.2 Structure of the Regulation

The pharmaceutical MACT addresses wastewater requirements in several sections. General applicability provisions are contained in §63.1250 and definitions are provided in §63.1251. More specifically, §63.1256 covers wastewater standards and §63.1257(e) covers initial compliance demonstration procedures for wastewater. Wastewater also is addressed in §63.1252 (Standards: General) and §63.1258-1260 (Monitoring, Record Keeping and Reporting). The primary components of the wastewater provisions are shown in Figure 7-1.

What Wastewaters are Subject to the Pharmaceutical MACT ?

7.3 Applicability

A wastewater stream is subject to this regulation if it meets the definition of a wastewater stream, per §63.1251.

Wastewater Stream Definition

The definition of a wastewater stream is:

1. Water that is discarded from a PMPU through a single ***Point of Determination (POD),***
2. Has a concentration of Partially Soluble HAP (PSHAP) and /or Soluble HAP (SHAP) compounds of at least 5 parts per million by weight (ppmw), and
3. Has a Total HAP load of at least 0.05 kg/yr.

> ***Point of Determination -*** *Point where a wastewater stream exits the process, storage tank, or last recovery device. If the soluble or partially soluble HAPs are not recovered for re-use before discharge, then the discharge point from the process equipment or storage tank is the POD. There can be more than one POD per process or PMPU.*

The regulated wastewater compounds identified above as Partially Soluble HAP (PSHAP) and Soluble HAP (SHAP) are listed in Tables 2 and 3 of the regulation. The sum of PSHAP and SHAP compounds is referred to as Total HAP.

Exemptions

The following are not considered regulated wastewaters per the definition of wastewater stream:

- Stormwater from segregated sewers,
- Water from firefighting & deluge systems (including testing of such systems),
- Spills,
- Water from safety showers,
- Samples of a reasonable size for analysis,
- Equipment leaks,
- Wastewater drips from procedures such as disconnecting hoses after clearing lines, and
- Noncontact cooling water.

Scrubber Effluent

If a scrubber is being used to control vent streams containing partially soluble HAP (PSHAP), in order to meet the process vent standards in §63.1254, the effluent from the scrubber is considered an affected wastewater stream and is therefore subject to the wastewater provisions in the MACT.

Multiphase Wastewater Streams

The regulations at §63.1256(a)(3) provide that a separate phase that can be isolated through gravity separation cannot be discharged to a waste management or treatment unit, unless it is discharged to a RCRA unit.

Table 2 to Subpart GGG. Partially Soluble HAP

1,1,1-Trichloroethane (methyl chloroform)
1,1,2,2-Tetrachloroethane
1,1,2-Trichloroethane
1,1-Dichloroethylene (vinylidene chloride)
1,2-Dibromoethane
1,2-Dichloroethane (ethylene dichloride)
1,2-Dichloropropane
1,3-Dichloropropene
2,4,5-Trichlorophenol
2-Butanone (mek)
1,4-Dichlorobenzene
2-Nitropropane
4-Methyl-2-pentanone (mibk)
Acetaldehyde
Acrolein
Acrylonitrile
Allyl chloride
Benzene
Benzyl chloride
Biphenyl
Bromoform (tribromomethane)
Bromomethane
Butadiene
Carbon disulfide
Chlorobenzene
Chloroethane (ethyl chloride)
Chloroform
Chloromethane
Chloroprene
Cumene
Dichloroethyl ether
Dinitrophenol
Epichlorohydrin
Ethyl acrylate
Ethylbenzene
Ethylene oxide
Hexachlorobenzene
Hexachlorobutadiene
Hexachloroethane
Methyl methacrylate
Methyl-t-butyl ether
Methylene chloride

Table 2 to Subpart GGG. Partially Soluble HAP (cont.)
N,N-dimethylaniline
Propionaldehyde
Propylene oxide
Styrene
Tetrachloroethene (perchloroethylene)
Tetrachloromethane (carbon tetrachloride
Toluene
Trichlorobenzene (1,2,4-)
Trichloroethylene
Trimethylpentane
Vinyl acetate
Vinyl chloride
Xylene (m)
Xylene (o)
Xylene (p)
N-hexane

Table 3 to Subpart GGG. Soluble HAP
1,1-Dimethylhydrazine
1,4-Dioxane
Acetonitrile
Acetophenone
Diethyl sulfate
Dimethyl sulfate
Dinitrotoluene
Ethylene glycol dimethyl ether
Ethylene glycol monobutyl ether acetate
Ethylene glycol monomethyl ether acetate
Isophorone
Methanol (methyl alcohol)
Nitrobenzene
Toluidene

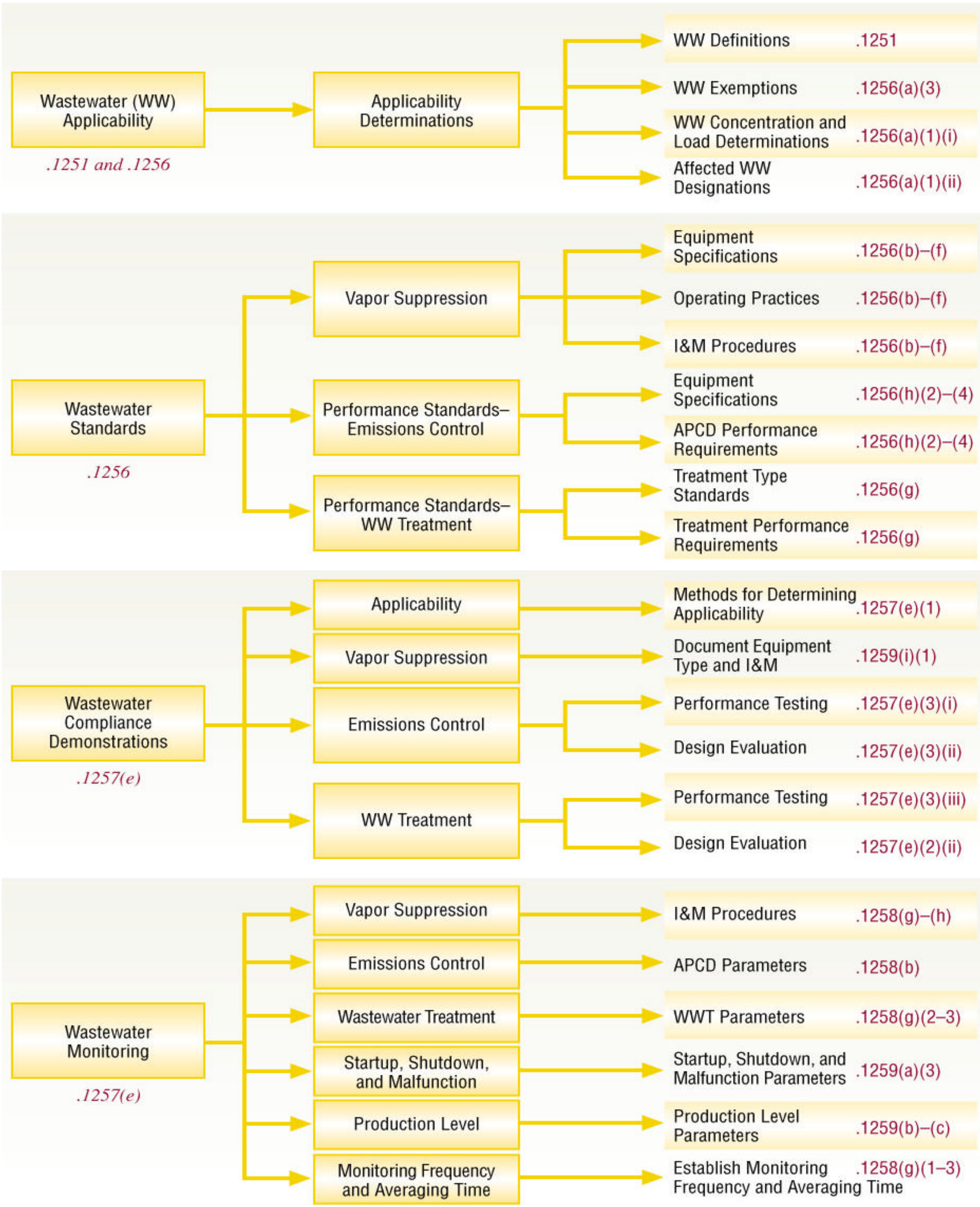


Figure 7-1. Primary Components of Wastewater Provisions (not including Recordkeeping or Reporting)

Maintenance Wastewater

Wastewater generated during maintenance activities is not subject to the full extent of the MACT standards. There are, however, substantive requirements for **maintenance wastewater**. Primarily, the regulations require that the owner/operator follow a written plan to control emissions to the atmosphere.

> ***Maintenance Wastewater*** *- Wastewater generated by the draining of process fluid from components in the pharmaceutical manufacturing process unit into an individual drain system prior to 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 wastewaters 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.*

Owners/operators with maintenance wastewater containing HAPs must comply with the following four requirements:

1. Prepare a description of management for wastewater generated from the emptying and purging of equipment during temporary shutdowns for inspections, maintenance, and repair AND during periods that are not shutdowns (i.e. routine maintenance). In the description:
    - Identify process equipment or maintenance tasks that are anticipated to create wastewater during maintenance activities,
    - Describe the procedures that will be followed to manage the wastewater and control HAP emissions to the air, and
    - Describe the procedures that will be followed when clearing materials from process equipment.
2. Modify the information provided in 1. as needed after each maintenance procedure, based on actual procedures followed and wastewater generated.
3. Follow these plans as part of the startup, shutdown and malfunction (SSM) plan required under §63.6(e)(3).
4. Maintain a record of the information needed to prepare the description under 1.) and the adjustments under 2.). The recorded information must be maintained.

Heat Exchange Systems

Heat exchange systems that cool process equipment or materials used in a pharmaceutical manufacturing operation must be checked for releases of HAPs if the process equipment contains materials that are greater than 5% HAPs. The specific requirements are provided at §63.104 and 63.1252(c)(2). For equipment that meets current good manufacturing practice (CGMP) requirements in 21 CFR Part 211, the owner/operator may elect to use the physical integrity of the reactor as the surrogate indicator of heat exchanger system leaks around the reactor. If a leak is detected, the system must be repaired no later than 45 days.

If CGMP is not used to identify leaks in heat exchange systems, then one of the following methods from §63.104 must be used. Cooling water in heat exchanger systems may be monitored quarterly using HAP, TOC, or an alternative constituent that will identify the presence of leaks. If the cooling water in a heat exchange system is subject to NPDES permit limits on HAP, TOC, or a related compound, and such limits are 1 ppmw or less, then the NPDES permit compliance monitoring can be used to detect cooling system leaks.

If the heat exchange system is operated with a minimum pressure on the cooling water side at least 35 kPa greater than the maximum pressure on the process side, cooling water monitoring is not required.

If a leak is detected by any of the above methods, the system must be repaired no later than 45 days following detection.

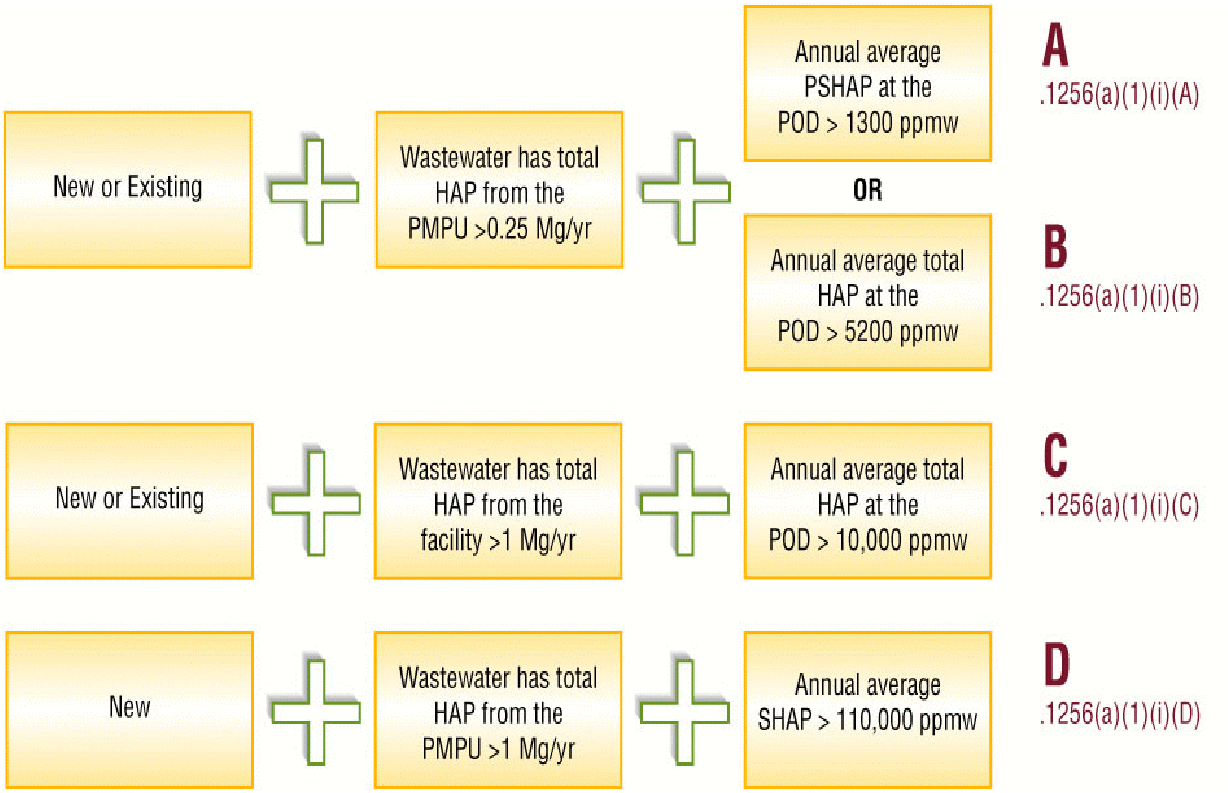
Equipment in Open Systems - Drains, Manholes, Lift Stations, Trenches, Pipes, Oil/Water Separators, Tanks

Section 63.1252(f) of the MACT regulations requires that steps be taken to prevent releases in systems upstream of the point of determination (POD). Drains or drain hubs, manholes, lift stations, trenches, pipes, oil/water separators, and tanks that handle affected liquid streams are subject to these requirements. The specific requirements are listed in Table 5 of the regulations. They essentially require tightly-fitting solid covers; emissions can be vented to process or to a control device that meets the wastewater control device standards at §63.1256(h)(2). The intent of this section is to require the closure of systems such as in-process recycle/recovery systems. It is not intended to be applied to process and storage tanks with vents that are in compliance with the process vent standards.

7.3.1 Affected Wastewater Criteria

If a wastewater meets the definition of a "wastewater stream" and the HAP concentration and load threshold levels described below, it must meet the requirements of this regulation. This document describes the 4 affected wastewater categories as shown below in Figure 7-2.

> ***NOTE*** *- PMOs opting to comply with the wastewater standards by using the 95% mass reduction option for biological treatment processes are subject to more stringent suppression standards. In this circumstance any wastewater stream (i.e. any stream containing at least 5 ppmw PSHAP or SHAP) is subject to the vapor suppression standards and all wastewater streams must be included in the percent reduction demonstration. Under the other compliance options only "affected" wastewater streams are subject to the vapor suppression standards.*



*Note - Regardless of annual loading or concentration, wastewater from a scrubber used to control PSHAP containing vent streams in order to comply with the process vent standards is considered to be an affected wastewater stream.

Figure 7-2. Four Affected Wastewater Categories A-D

Note on Wastewater HAP Concentrations: Wastewater HAP concentration is used in two ways throughout this rule. One is what can be called the wastewater HAP emission potential concentration and the other is just the wastewater HAP concentration. The emission potential concentration is the portion of a wastewater HAP compound that theoretically volatilizes into air. Emission potential values are determined by dividing true HAP wastewater concentration by the compound specific fraction measured (Fm) factors listed in Table 8 of the regulation. The rule does not specifically use the term "emission potential concentration," but whenever Method 305* is mentioned, this means emission potentials. (i.e., Method 305 is used to determine wastewater HAP emission potential concentration).

If method 305 is used to determine PSHAP and SHAP concentrations in wastewater, the measured concentrations must be adjusted by
the F_m value to determine if a wastewater is affected. If any of the other analytical methods listed in 63.1257(a)(10) are used for the determination, the measured PSHAP and SHAP concentrations are not adjusted.

*Method 305 = Measurement of Emissions Potential of Individual Volatile Organic Compounds in Waste

Where is a Wastewater Stream Characterized for Determining Applicability ?

7.3.2 Characterizing or Designating Wastewater as Affected

For determining whether a wastewater is affected, an owner/operator (O/O) can either:

1) **Characterize** a wastewater stream at each Point of Determination (POD), OR
2) **Designate** a wastewater stream as affected.

If the owner/ operator....	Then....
Characterizes the wastestream	Owner/operator must determine annual average concentration and load (see 4 categories A-D on previous page)
Designates the wastestream	Owner/operator not required to determine annual average concentration and load. Must meet same standards as those applicable to characterized streams. The wastewater handling equipment upstream of point of determination must meet vapor suppression and emissions control standards (discussed in section 7.1). Downstream of the point of determination, wastewater must meet treatment standards as well as vapor suppression and control requirements. Wastewater treatment options for designated streams do not include treating streams to 50 ppmw PSHAP, 520 ppmw SHAP or using enhanced biological treatment.

The O/O may use a combination of characterization or designation for different affected wastewaters generated at the source. The designation procedure allows an O/O to choose a location further downstream of multiple potential affected wastewater streams without having to determine applicability for each one. There are no restrictions on where a wastewater stream is designated, other than that it must be at or downstream from the point of determination (POD).

> ***Recovery device*** *- an individual unit of equipment used for recovering chemicals for fuel value, use, reuse, or for sale for fuel value, use, or reuse. Examples include decanters, strippers, and thin-film evaporation units.*

7.3.3 POD

If a wastewater stream is to be **characterized** for determining applicability, the **characterization must be at a POD**. A POD means the point where the stream exits the process, storage tank, or last ***recovery device***. If HAPs are not recovered for reuse from the water before discharge, the discharge point at the process equipmjent or storage tank is the POD, as shown in the example below for Site #2. If streams are routed to a recovery device, the discharge from the recovery device is the POD, as shown below for Site #1.

There can be more than 1 POD per process or PMPU.

Figure 7-3 presents sample process wastewater flow layouts showing example PODs and PMPUs.

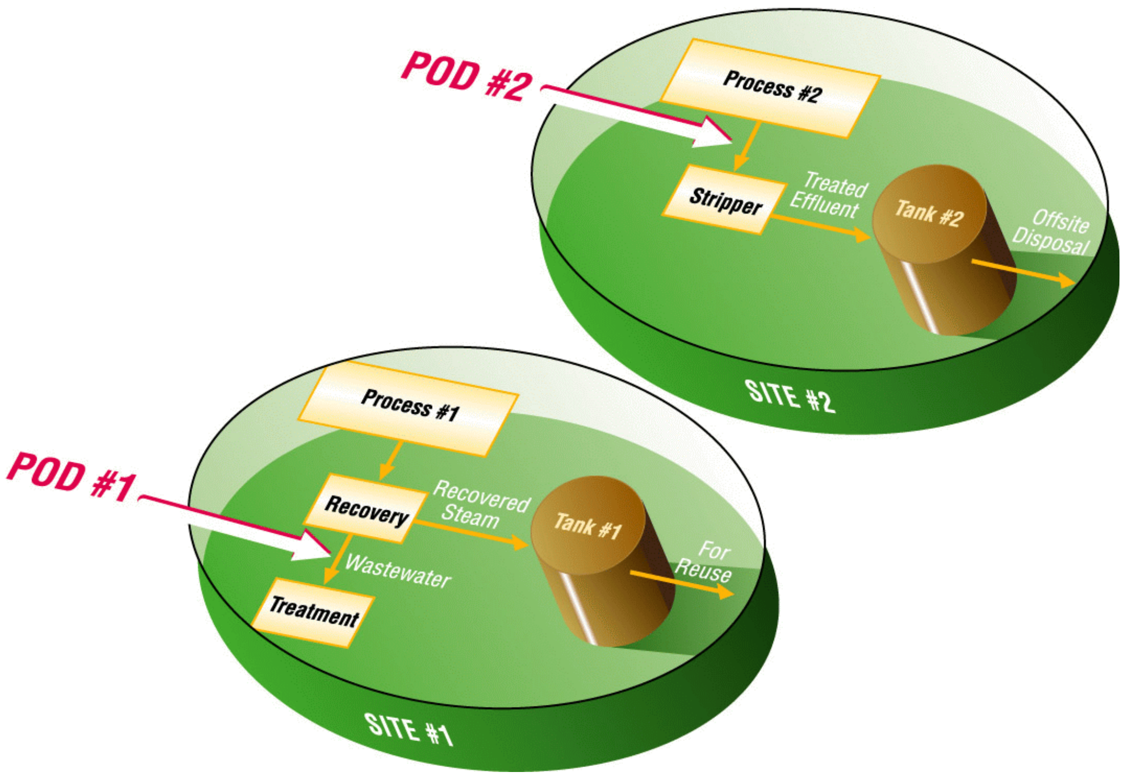


Figure 7-3. Example Wastewater Flow Scheme Showing POD Locations.

7.4 Standards

If a wastewater stream (including scrubber blowdown from units that treat PSHAPs) falls into one of the four criteria categories (referred to as A-D in Figure 7-2) and is not excluded as listed above, the facility is subject to Subpart GGG wastewater standards. The requirements can be separated into:

- vapor suppression standards (cover and operate equipment to avoid losses to the air),
- performance standards
- wastewater treatment standards (treat wastewater to remove HAPs) and
- air emissions control standard (use APCDs to control emissions of PSHAPs and SHAPs vented during wastewater treatment)

7.4.1 Vapor Suppression Standards Summary

Vapor Suppression (VS) requirements are provided for five kinds of waste management units:

- wastewater tanks
- surface impoundments
- containers
- individual drain systems
- oil water separators

Vapor suppression standards, summarized in Table 7-1 below, include:

- equipment specifications
- operating practices, and
- equipment inspection and monitoring (I and M) procedures.

Table 7-1. SUMMARY OF WASTEWATER VAPOR SUPPRESSION STANDARDS

Standard	Specification
Equipment Specifications	specified equipment types designed to minimize loss of airborne HAPs to the atmosphere (e.g., tank roofs, surface impoundment covers, container vent systems, sewer drain water seals)
Operating Practices	specified procedures to follow to minimize loss of HAP vapors (e.g. wastewater container filling guidelines)
Inspection and Monitoring Procedures	periodic inspections conducted to minimize HAP losses from worn equipment or improper operating practices (e.g., visually inspect for cracks, gaps, or holes in wastewater junction box covers)

In characterizing a wastestream to determine applicability of MACT wastewater provisions, is the owner or operator required to determine the annual average concentration of Partially Soluble HAPs and Soluble HAPs ? The O/O may choose to designate a wastewater stream as affected. If this is done, then the annual average PSHAP and SHAP wastewater concentrations need not be determined. However, if the O/O chooses to determine concentrations for assessing (i.e., **characterize**), then it must be done in such a way that concentration values represent the annual average. The annual average is defined as the total mass of HAP (PSHAP or SHAP) occurring in the wastewater during a calendar year divided by the total mass of the wastewater. Determinations can be made using either **test methods, knowledge of the wastewater stream, or bench-scale or pilot scale test data.** If the determination is made:

1) downstream of the POD where two or more streams have joined,
2) after the stream has been treated, or
3) after losses to the atmosphere have occurred,

then adjustments must be made to the data so that it represents conditions at the POD. Values derived from testing or from applying knowledge of the wastewater must be reported in the Notification of Compliance Status report. Values derived from bench-scale or pilot scale test data must be documented in the Precompliance report. Additionally, if a site conducts wastewater sampling to characterize the wastewater, then the site must develop and maintain, on-site, a Sampling Plan to document measures taken to ensure that volatization losses are minimized during sampling.

VS: Wastewater Storage Tanks

The first of the vapor suppression standards is for ***wastewater tanks***, which are provided in §63.1256(b). These requirements are summarized in Table 7-2.

> ***Wastewater Tank*** **-** *a stationary waste management unit that is designed to contain an accumulation of wastewater or residuals and is constructed primarily of nonearthen materials (e.g., wood, concrete, steel, plastic) which provide structural support. Flow equalization tanks are included in the definition.*

If the tank meets certain size and maximum true vapor pressure criteria, the O/O must comply with Tank Roof requirements (Fixed, Floating, etc) and associated Closed Vent System and APCD requirements (if applicable). The definition of ***maximum true vapor pressure*** provides guidance on how to calculate it.

Note on using open or closed biological treatment processes: Waste management units specifically used for biological treatment are **not subject to wastewater storage tank or surface impoundment vapor suppression requirements**. The processes must be designed to meet the definition of either an open biological treatment process or a closed biological treatment process in order for the exemption to apply.

> ***Maximum True Vapor Pressure*** **-** *the equilibrium partial pressure exerted by the total organic HAP in the stored or transferred liquid at the temperature equal to the highest calendar-month average of the liquid storage or transfer temperature for liquids stored or transferred above or below the ambient temperature or at the local maximum monthly average temperature as reported by the National Weather Service for liquids stored or transferred at the ambient temperature, as determined:*
>
> - *In accordance with methods described in Chapter 19.2 of the American Petroleum Institute's Manual of Petroleum Measurement Standards, Evaporative Loss From Floating-Roof Tanks (incorporated by reference as specified in §63.14); or*
> - *As obtained from standard reference texts; or*
> - *As determined by the American Society for Testing and Materials Method D2879-97, Test Method for Vapor Pressure-Temperature Relationship and Initial Decomposition Temperature of Liquids by Isoteniscope (incorporated by reference as specified in §63.14); or*
> - *Any other method approved by the Administrator.*

Table 7-2. WASTEWATER STORAGE TANK VAPOR SUPPRESSION STANDARDS

Criteria		**Vapor Suppression Standards**	
Tank Capacity, T (m^3)	**Maximum True Vapor Pressure (kPa)**	**Required Standard**	**Description & Section No. {63.1256___)}**
T < 75		63.1256(b) (1)	**- (b)(1)** = Control w/ Fixed Roof (If tank is used for heating, exothermic treatment, or sparging, resulting in an increase in HAP emissions of 5% over that which would occur if no heating, exothermic treatment, or sparging activities occurred, then standard is (b)(2)) **- (b)(2)** = Comply w/ Inspection & Maintenance procedures {(b)(3-9)}[1] and control emissions using one of the following: C Fixed Roof/Closed Vent System to APCD, C Fixed Roof/Internal Floating Roof C External Floating Roof C Equivalent means of control
75 # T < 151	< 13.1	63.1256(b) (1)	
	$ 13.1	63.1256(b) (2)	
T $151	< 5.2	63.1256(b) (1)	
	$ 5.2	63.1256(b) (2)	

[1] A complete list of I & M procedures is given in the Monitoring chapter.

VS: Wastewater Surface Impoundments

Wastewater Surface Impoundments standards are listed in §63.1256(c) and summarized in Table 7-3. The regulation addresses any surface impoundment that receives, manages or treats affected wastewater. Vapors from surface impoundments are suppressed using either (1) a Cover (i.e, rigid) and Closed Vent System routed to a control device or (2) a Floating Membrane system.

Table 7-3. WASTEWATER SURFACE IMPOUNDMENT VAPOR SUPPRESSION STANDARDS {§63.1256(c)}

Vapor Suppression Method (Choice)	Standard
Cover/Closed Vent System to a Control Device, <u>or</u>	**A**. Unless system is maintained under vacuum, a Cover/Closed Vent System must be maintained according to 63.1258(h) {Leak inspection provisions for Vapor Suppression Equipment}, **B**. Openings maintained in closed position, and **C**. Cover used at all times
Floating Membranes	**A**. Designed to float and form continuous barrier **B**. Constructed from synthetic that is either **1**. HDPE >100 mils **2**. A material or composite of materials having the equivalent organic permeability and physical and chemical properties of 100 mils HDPE and that maintains material integrity for service life of material. **C**. No visible cracks, holes, gaps or open spaces between cover section seams or between the interface of the cover edge and its foundation mountings **D**. Each opening equipped w/ closure device that when closed shows no visible cracks, holes, gaps, or other open spaces in the closure device or between the perimeter of the cover opening and the closure device. **E**. Equipped w/ one or more emergency storm water drains (optional) **F**. Closure devices shall be made of suitable material **G**. When wastewater is present, openings shall be closed and cover on except during inspection, maintenance, etc. Shall be maintained (inspected) according to 63.1258(h).

VS: Wastewater Containers

Wastewater Containers standards contained in §63.1256(d) are summarized in Table 7-4. The regulation addresses any <u>container</u> with a capacity greater than or equal to 0.1 m^3 (25 gallons) that receives, manages or treats affected wastewater. For containers with capacity greater than 0.42 m^3 (110 gal), the standards call for using a cover and openings to be maintained according to §63.1258(h), Leak Inspection Provisions for Vapor Suppression Equipment. For those less than 0.42 m^3 (but greater than 0.1 m^3), the O/O can choose between meeting existing DOT regulations (49 CFR part 178) or maintaining w/o leaks according to 63.1258(h).

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

Table 7-4. WASTEWATER CONTAINERS VAPOR SUPPRESSION STANDARDS {§63.1256(d)}

Size	Standard Description (with Section Numbers)
> 0.42 m^3 (110 gal)	**1.** Maintain cover as follows; - Maintain cover and openings according to §63.1258(h), - Keep cover and openings closed unless for filling, removal, inspection, sampling, pressure relief or safety related reasons. **2.** When filling; - Either use submerged pipe when filling, with end of fill pipe no more than 15 cm or 2 pipe diameters from the bottom of the container, OR locate container within enclosure that has closed vent system that routes organic HAP vapors vented from the container to a control device, OR use a closed vent system to vent displaced vapors from the container either to a control device or back to the equipment from which the wastewater is transferred. - Keep cover and openings closed unless needed for filling **3.** When it is necessary for container to be open, locate it w/in an enclosure w/ Closed Vent System that routes vapors to APCD and: - Maintain enclosure according to §63.1258(h) - see Monitoring chapter for I and M requirements, - Maintain APCD according to §63.1256(h), - Inspect Closed Vent System according to §63.1258(h), - If under vacuum, not required to maintain according to §63.1258(h).
# 0.42 m^3 (110 gal)	**1.** Maintain cover as follows; - Comply with either: **A.** Meet DOT 49 CFR 178, or **B.** Maintain without leaks according to §63.1258(h). See Monitoring chapter for I and M requirements. - Keep cover and openings closed unless for filling, removal, inspection, sampling, pressure relief or safety related reasons. **2.** When it is necessary for container to be open, locate it w/in an enclosure w/ Closed Vent System that routes vapors to APCD and: - Maintain enclosure according to §63.1258(h). See Monitoring chapter for I and M requirements. - Maintain APCD according to §63.1256(h), - Inspect Closed Vent System according to §63.1258(h), - If under vacuum, not required to maintain according to §63.1258(h).

VS: Individual Drain System

Wastewater Individual Drain Systems standards contained in §63.1256(e) are summarized in Table 7-5. The standard addresses any individual drain system that receives or manages affected wastewater or residual removed from affected wastewater.

The standards present 2 options for suppressing emissions from individual drain systems (IDS). The first option is using a closed IDS with a Closed Vent System that is vented to an APCD. The second option is to minimize emissions using water seals and/or tightly fitting caps or plugs on all entrances to the drain systems and for junction boxes.

Junction boxes may be vented to the atmosphere if they have minimal water depth fluctuations, have vapor blocks at either their entrance(s) or exit(s), and have a vent pipe that meets specified design criteria. Building sewers may be vented through roof vents and outside sewers may be vented at locations other than at junction boxes, provided that the vent pipe height (at least 90 cm) and diameter (no greater than 10.2 cm in inside diameter) are the same as those for junction box vents AND the sewer has a water seal at the first downstream junction box.

Table 7-5. WASTEWATER INDIVIDUAL DRAIN SYSTEM VAPOR SUPPRESSION REQUIREMENTS {§63.1256(e)}

Standard (choice of either)	Description
1256(e) (1-3), **OR**	**1**. Maintain cover on each opening. If vented route through Closed Vent System to APCD and: - For cover and openings: **A.** Maintain according to 63.1258(h) **-** see Monitoring chapter for I and M requirements **B.** Keep in closed position when wastewater is in drain except for sampling, removal, inspection, maintenance or repair. - APCD designed/operated/inspected according to 63.1256(h) - Closed Vent System inspected according to 63.1258(h), - If under vacuum, not required to maintain by 63.1258(h), and - Design individual drain system to segregate vapors from drain systems that do not manage affected wastewaters and prevent releases to atmosphere. **2 & 3.** Inspection and Maintenance procedures **-** in Monitoring chapter
1256(e)(4-6)	**4**. Comply w/ following - Equip drain system openings w/ water seal, tightly fitting caps or plugs and - For water seal, maintain system to verify flow of water in trap, and **-** If water seal on drain receiving wastewater, discharge pipe must be submerged or flexible shield installed (except on water seals used on hubs receiving wastewater not subject to this provision) - Each junction box must have tightly fitting solid cover. If vented, comply w/ either **A.** Vent to process or to Closed Vent System vented to APCD. Closed Vent System maintained according to 63.1258(h) and APCD according to 63.1256(h), or **B.** If box uses gravity flow or there is only slight variation in liquid level then **1.** Vent pipe $\geq$ 90 cm length and $\leq$ 10.2 cm inside diameter, and **2.** Water seals installed to restrict ventilation on either the box influent or effluent. - Each sewer line carrying affected wastewater must not be vented to atmosphere unless the sewer line entrance to the first downstream junction box is water sealed and the sewer line vent pipe is $\geq$ 90 cm long and $\leq$ 10.2 cm inside diameter. **5 & 6.** Inspection and Maintenance procedures **-** in Monitoring chapter

VS: Oil-Water Separators

Wastewater Oil-Water separators standards contained in §63.1256(f) are summarized in Table 7-6. The regulation addresses any oil-water separator that receives, manages, or treats affected wastewater or residuals removed from wastewater. Vapors are to be suppressed using either a Fixed Roof (with a closed vent system and control device), Floating Roof, or Equivalent Means. An Equivalent Means of vapor suppression must be demonstrated by performance testing or engineering evaluation.

Table 7-6. WASTEWATER OIL WATER SEPARATORS VAPOR SUPPRESSION STANDARDS {§63.1256(f)}

Equip with...	Description (with Section Numbers)
Fixed Roof with CVS and Control Device, **OR**	**1.** Maintain Roof and openings according to §63.1258(h) (see Monitoring chapter for I and M requirements), and **2.** Keep in closed position when wastewater is in oil/water separator except for sampling, removal, inspection, maintenance or repair, and **3.** Design, operate, inspect APCD according to §63.1256(h) (See Table 7-2), and **4.** Inspect Closed Vent System according to §63.1258(h) **5.** Negative pressure not required to comply with §63.1258(h)
Floating Roof	**1.** Design floating roof per §60.693-2(a)(1)(i) and (ii), (a)(2), (a)(3), and (a)(4). - Primary seal - liquid-mounted or mechanical shoe - Secondary seal above the primary seal; cover the annular space between the floating roof and the wall of the separator - Equip each opening in the roof with gasketed cover, seal, or lid. Keep closed except during inspection and maintenance. - Roof must float on liquid (i.e., off the roof supports) except during abnormal conditions. - Roof may be equipped with emergency roof drains for removal of stormwater; use slotted membrane fabric cover that covers at least 90% of the drain opening area or a flexible fabric sleeve seal. **2.** Perform <u>seal gap measurements</u> according to 40 CFR 60 Subpart QQQ 60.696(d)(1) and scheduled as follows: - Primary seals: w/in 60 days after installation/wastewater introduction and once every 5 yrs thereafter, and - Secondary Seals: w/in 60 days after installation/wastewater introduction and annually thereafter.

Q and A

Q. ***What are CEFs and IWPs ?***

A. *Listed with each vapor suppression standard are inspection procedures for Control Equipment Failures (CEF) and/or Improper Work Practices (IWP) for each equipment type. For example, one of the CEFs listed for wastewater tanks is when a "gasket, joint, lid or cover has a crack, gap or is broken." An example of an IWP for fixed roof tanks is leaving open any access doors or any other opening when such door or opening is not in use.*

What are the Performance Standards for Wastewater Treatment?

7.4.2 Wastewater Treatment Standards

The wastewater treatment standards are found in §63.1256(g). Basically, there are six treatment standards in (g)(8 -13). A summary of how they apply to the four affected wastewater categories, A - D (Figure 7-2), is discussed below and shown in Table 7-7.

Wastewater from New and Existing Sources

For new or existing sources, the owner must:

- Treat an affected PSHAP wastewater stream (**category A**)
  - to remove 99% PSHAP, or
  - to less than 50 ppmw PSHAP,* or
  - remove 95% total HAP (from all wastewaters whether affected or unaffected) in a biological treatment unit, or
  - use a RCRA-permitted (or interim status) treatment device, such as an incinerator, boiler, or underground injection.
- Treat an affected Total HAP wastewater (**categories B & C)**
  - to remove 99% PSHAP <u>and</u> 90% SHAP, or
  - to less than 50 ppmw PSHAP and less than 520 ppmw SHAP,* or
  - use enhanced biotreatment (allowed only if PSHAP is less than 50 ppmw or if the wastewater has been treated upstream in compliance with (g)(8) (50 ppmw PSHAP or 99% reduction of PSHAP) and the wastewater is not designated), or
  - remove 99% PSHAP and treat to 520 ppmw SHAP, or
  - treat to 50 ppmw PSHAP and remove 90% SHAP, or
  - to remove 95% Total HAP (from all wastewaters whether affected or unaffected) in a biological treatment unit, or
  - use a RCRA-permitted (or interim status) treatment device, such as an incinerator, boiler, or underground injection.

NOTE(*): Concentration standards cannot be used (1) when biological treatment is used or (2) when the wastewater streams are designated.

For an existing source that has been **designated** as affected (per §63.1256(a)(1)(ii)), the wastewater treatment requirements are:

- PSHAP reduced by 99% and SHAP reduced by 90%, or
- Total HAP reduced by 95% in a biotreatment unit, or
- Treatment in a RCRA-permitted treatment device.

Wastewater from New Sources

For new sources, the owner/operator must:

- Treat an affected SHAP wastewater stream with greater than 110,000 ppmw SHAP (**category D)**

- to remove 99% SHAP, or
- use a RCRA-permitted (or interim status) treatment device, such as an incinerator, boiler, or underground injection.

Management of Residuals from Wastewater Treatment

Wastewater residuals are defined as HAP-containing liquids or solid materials removed from a wastewater stream by a waste management unit or treatment process that does not destroy organics. Examples of residuals include:

- the organic layer and bottom residue removed by a decanter or organic-water separator, and
- overheads from a steam stripper or air stripper.

Materials not classified as residuals include:

- silt, mud, or leaves,
- bottoms from a steam stripper or air stripper, and
- sludges, ash, or other materials from destructive treatment devices such as biological treatment units and incinerators.

There are several options for managing residuals taken from the treatment of affected wastewater:

- recycle the residual back into the production process or sell it to another firm for recycling. Once the residual is returned to a production process, it is no longer subject to regulation. OR
- return the residual to the treatment process. OR
- treat the residual to reduce the total combined mass flow rate of SHAP and/or PSHAP by 99 percent or more. (Use the performance tests in 63.1257(e)(2)(iii)(C) - noncombustion, nonbiological treatment process - or (D) - combustion treatment process - to demonstrate compliance.) OR
- treat the residual in a RCRA-regulated unit (hazardous waste incinerator or underground injection well.

In addition, tanks, surface impoundments, containers, individual drain systems, and oil/water separators used for the storage or management of residuals must meet the same design and operating requirements that apply to these units when used for treatment of affected wastewater (63.1256(b) - (f)).

What are the Standards for Air Emissions Control?

7.4.3 Emissions Control Standards

Standards for control of air emissions vented during the treatment process and from other waste management units with covers and closed vent systems are specified for air pollution control devices (APCD) as either:

1) equipment specifications - for combustion devices in terms of residence time and temperature specifications.

or

2) APCD performance levels - in the form of

Removal Efficiencies (RE) or APCD outlet HAP concentrations.

A summary of the standards is shown in Figure 7-4. Basically, there is a choice of 5 control standards as follows:

C Combustion device achieving 95% RE HAP, 20 ppmv outlet TOC @3% O_2, or provide 0.5 sec residence time at 760 deg C,

C Vapor recovery system achieving 95% RE HAP or 20 ppmv outlet TOC,

C Flare meeting requirements of §63.11(b),

C Scrubber or other APCD achieving 95% RE HAP or 20 ppmv TOC.

NOTE: The APCD outlet standard of 20 ppmv TOC is not available for APCDs controlling vent streams from wastewater surface impoundments or containers.

With regard to repairs to air pollution control devices, if gaps, cracks, tears, or holes are observed in the ductwork, piping, or connection to covers and control devices during an inspection, the owner/operator must make an attempt within 5 calendar days to fix the problem. Repair can be delayed only if:

- the repair cannot be done without a shutdown or if the emissions resulting from immediate repair would be greater than those anticipated to result from delaying the repair. The equipment must be repaired by the end of the next shutdown, OR
- the equipment is emptied or is no longer being used to treat affected wastewater or residuals, OR
- if additional time is necessary due to the unavailability of parts, due to circumstances beyond the control of the owner/operator. Repair must be done as soon as practical, In this case, the reasons for delaying the repair must be documented.

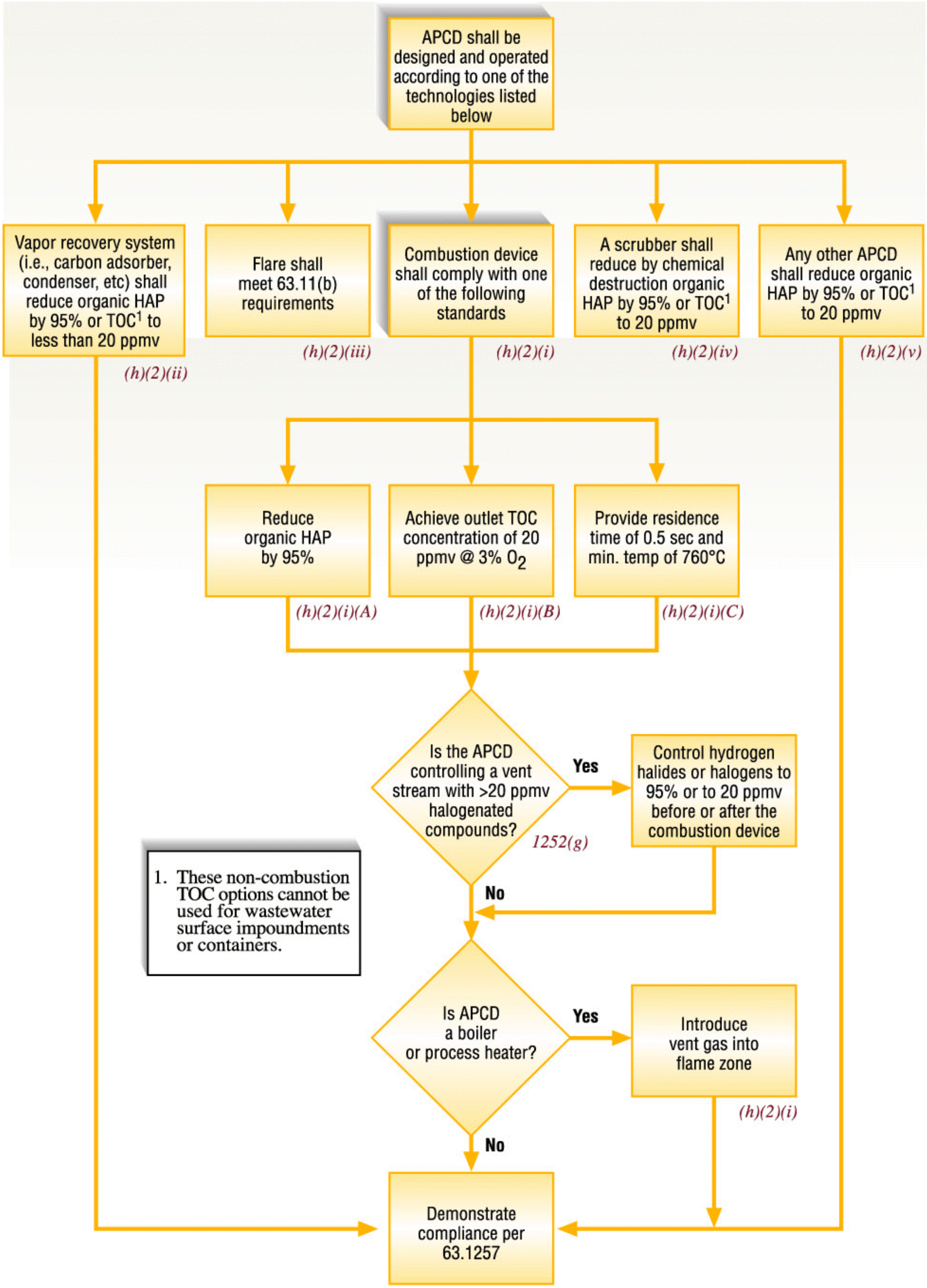


Figure 7-4. Wastewater APCD Requirements in §63.1256(h)

Table 7-7. WASTEWATER TREATMENT STANDARDS

Treatment Options	Used To Treat	Source Type	Limitations	Citations
treat to < 50 ppmw	PSHAP	new and existing (categories A, B, and C)	- no biotreatment or dilution - not available for designated streams	.1256(g)(8)(i) .1256(a)(1)(ii)
99% total mass removal/ destruction of HAP	PSHAP	new and existing (categories A, B, and C)		.1256(g)(8)(ii)
	SHAP	new (category D)	- only required when SHAP concentration is 110,000 ppmw and the total PSHAP and SHAP load in wastewater from the PMPU is > 1Mg/yr	.1256(g)(12)
treat to <520 ppmw	SHAP	new and existing (categories B and C)	- no biotreatment or dilution - not available for designated streams	.1256(g)(9)(i) .1256(a)(1)(ii)
90% total mass removal/ destruction of HAP	SHAP	new and existing (categories B and C)		.1256(g)(9)(ii)
enhanced biological treatment	SHAP	new and existing (categories A, B, and C)	- system must meet the definition of enhanced biological treatment - may only be used for affected wastewater with < 50 ppmw PSHAP, or wastewater that has been treated to less than 50 ppmw PSHAP or to 99% reduction of PSHAP - not available for designated streams	.1256(g)(10) .1256(a)(1)(ii)
95% mass removal/ destruction of total HAP with biological treatment unit	Total PSHAP and SHAP	new and existing (categories A, B, and C)	- biological treatment is required - all wastewater streams (as defined in 63.1252) entering the system must achieve 95% HAP removal, except wastewater already treated in compliance with another treatment option - all wastewater streams (as defined in 63.1252) entering the system must be managed in wastewater management units (sewers, etc.) in compliance with the MACT	.1256(g)(11)

Treatment Options	Used To Treat	Source Type	Limitations	Citations
RCRA permitted or interim status treatment device	PSHAP and/or SHAP	new and existing (categories A, B, C, and D)	- systems include heaters, incinerators, boilers, industrial furnaces, and underground injection	.1256(g)(13)

Offsite Treatment or Onsite Treatment by Someone Other Than Owner/Operator

The owner/operator may elect to transfer affected wastewater (or a residual removed from such wastewater) to an offsite treatment operation or to an on-site treatment operation being run by someone else.

Owner/ Operator:	Responsibilities include...
of the Affected Source	C ensuring that all waste management units on-site handling affected streams are in compliance with wastewater management requirements (e.g., all drain systems and tanks containing affected streams must comply with §63.1256(b)-(f)). C submitting a notice with each shipment stating that the wastewater or residual from the wastewater contains PSHAP and/or SHAP that must be treated in compliance with the regulations. If the transfer is continuous or ongoing, submit the notice with the first shipment and whenever there is a change in the treatment required. Keep a record of the notice in accordance with §63.1259(g).

Owner/ Operator:	Responsibilities include...
of a Treatment System Receiving the Wastewater	C Submitting to EPA, prior to receiving any affected wastewater, a written certification stating that any affected wastewater or affected wastewater residual will be treated in compliance with: S §63.1256(b)-(i) (requirements for tanks, surface impoundments, containers, individual drain systems, oil water separators, plus other performance standards for treatment), or S Subpart D (if alternative emissions limitations have been approved), or S §63.6(g) (use of an alternative nonopacity emission standard), or S If the affected wastewater streams or residuals contain less than 50 ppmw partially soluble HAP, then the person receiving them for treatment can: i. comply with (g)(10) (enhanced biotreatment for SHAP) and cover the waste management units up to the activated sludge unit, or ii. comply with (g)(11)(i) and (ii) (95 percent reduction in a biological treatment unit), and (h) (emissions control device standards) and cover the waste management units up to the activated sludge unit, or iii. comply with (g)(10) (enhanced biotreatment for SHAP) provided that the affected source owner/operator demonstrates that less than 5 percent of the total SHAP is emitted from waste management units up to the activated sludge unit, or iv. comply with (g)(11)(i) and (ii), (95 percent reduction in a biological treatment unit), and (h) (emissions control device standards), provided that the affected source owner/operator demonstrates that less than 5 percent of the total SHAP is emitted from waste management units up to the activated sludge unit. C Securing the signature of the responsible official on the certification, and providing the name and address of the certifying entity to the EPA Regional office. **NOTE ON REVOKING CERTIFICATION:** A written statement must be sent to both EPA and the owner/operator of the affected wastewater stating that the transferee is no longer accepting responsibility for treatment of the affected wastewater. The transferee must give at least 90 days notice. When the 90-day period is up, the owner/operator may not transfer affected wastewater or residuals to the treatment operation.

Q and A

Q. ***What are the standards for wastewater treatment using multiple treatment processes in series ?***

A. *The mass removal/destruction efficiency requirements are the same. However, efficiency calculation techniques differ for different treatment configurations. If wastewater is conveyed by hard piping then mass removal / destruction efficiency is determined across the combination of treatment processes. If wastewater is not conveyed by hard piping then efficiency is determined across each treatment process with total efficiency equal to the sum of efficiencies from each component process.*

What is the Pollution Prevention Option?

In lieu of the wastewater standards discussed above, an owner or operator (O/O) can choose to meet pollution prevention (P2) standards. The P2 requirements are either:

- reduce the production-indexed HAP consumption factor (kg HAP consumed/kg product produced) by 75% from a specified baseline average established no earlier than 1987, or
- reduce the production-indexed HAP consumption factor by at least 50% from a specified baseline average established no earlier than 1987 AND reduce total PMPU HAP emissions divided by the annual production rate (kg HAP emitted per year/kg produced per year) to a value greater than 25% of the average production-indexed consumption factor (i.e., achieve 50% reduction by using pollution prevention and achieve additional 25% by using standard control devices). For more information on the pollution prevention option, see ° **Chapter 10- Pollution Prevention Alternative.**

7.5 Compliance Demonstration

Compliance demonstration procedures for wastewater standards are listed in §63.1257(e) - Test Methods and Compliance Procedures - Compliance with Wastewater Provisions. This section lists requirements for demonstrating initial compliance. Procedures for demonstrating on-going or continual compliance are listed in §63.1258 (Monitoring Requirements). A complete description of the required monitoring procedures can be found in ° **Chapter 9 - Monitoring**. The following paragraph presents a brief introduction to the initial compliance demonstration requirements for wastewater. A more complete description of the requirements can be found in ° **Chapter 8 - Compliance Demonstration and Testing Procedures.**

Q and A

Q. ***How do I demonstrate compliance for:***
1) wastewater with multiple phases
2) treatment residuals ?

A*.* *Wastestreams with free phase HAP cannot be sent to individual drain systems, stored in wastewater tanks or surface impoundments, or sent to treatment units. The free phase HAP can only be discharged to a RCRA treatment unit, per 63.1256(a)(3). For wastewater treatment residuals, the O/O must either:*

1. *recycle the residual back to the production process, or sell the material for the purpose of recycling*
2. *return the residual back to the treatment process,*
3. *destroy combined PSHAP/SHAP by at least 99%, or*
4. *treat the residual in a RCRA unit per §63.1256(g)(13).*

To demonstrate compliance with option 1 or 2, the O/O must document process configuration. To demonstrate compliance with option 3, the O/O should use compliance demonstration technique C or D as discussed in Appendix WWT.

The initial compliance demonstration procedures as listed in §63.1257(e) are basically separated into 3 parts:

- Determination of wastewater HAP concentration and load as it pertains to wastewater **applicability** criteria (i.e. annual concentration and annual load),
- Design Evaluation and Performance Test procedures for demonstrating compliance with **air emissions control (i.e., APCD**) requirements, and
- Design Evaluation and Performance Test procedures for demonstrating compliance with **wastewater treatment** standards.

Compliance with the **vapor suppression standards** is done primarily through the reporting provisions of the rule, which require that the owner or operator document the results of Inspection and Monitoring procedures that are followed for wastewater management units.

The reader is referred to Chapters 8 and 9 for more complete details on compliance demonstrations and monitoring requirements.

Table 7-4. WASTEWATER CONTAINERS VAPOR SUPPRESSION STANDARDS {§63.1256(d)}

Size	Standard Description (with Section Numbers)
> 0.42 m³ (110 gal)	**1.** Maintain cover as follows; - Maintain cover and openings according to §63.1258(h), - Keep cover and openings closed unless for filling, removal, inspection, sampling, pressure relief or safety related reasons. **2.** When filling; - Either use submerged pipe when filling, with end of fill pipe no more than 15 cm or 2 pipe diameters from the bottom of the container, OR locate container within enclosure that has closed vent system that routes organic HAP vapors vented from the container to a control device, OR use a closed vent system to vent displaced vapors from the container either to a control device or back to the equipment from which the wastewater is transferred. - Keep cover and openings closed unless needed for filling **3.** When it is necessary for container to be open, locate it w/in an enclosure w/ Closed Vent System that routes vapors to APCD and: - Maintain enclosure according to §63.1258(h) - see Monitoring chapter for I and M requirements, - Maintain APCD according to §63.1256(h), - Inspect Closed Vent System according to §63.1258(h), - If under vacuum, not required to maintain according to §63.1258(h).
# 0.42 m³ (110 gal)	**1.** Maintain cover as follows; - Comply with either: **A.** Meet DOT 49 CFR 178, or **B.** Maintain without leaks according to §63.1258(h). See Monitoring chapter for I and M requirements. - Keep cover and openings closed unless for filling, removal, inspection, sampling, pressure relief or safety related reasons. **2.** When it is necessary for container to be open, locate it w/in an enclosure w/ Closed Vent System that routes vapors to APCD and: - Maintain enclosure according to §63.1258(h). See Monitoring chapter for I and M requirements. - Maintain APCD according to §63.1256(h), - Inspect Closed Vent System according to §63.1258(h), - If under vacuum, not required to maintain according to §63.1258(h).

VS: Individual Drain System

Wastewater Individual Drain Systems standards contained in §63.1256(e) are summarized in Table 7-5. The standard addresses any individual drain system that receives or manages affected wastewater or residual removed from affected wastewater.

The standards present 2 options for suppressing emissions from individual drain systems (IDS). The first option is using a closed IDS with a Closed Vent System that is vented to an APCD. The second option is to minimize emissions using water seals and/or tightly fitting caps or plugs on all entrances to the drain systems and for junction boxes.

Junction boxes may be vented to the atmosphere if they have minimal water depth fluctuations, have vapor blocks at either their entrance(s) or exit(s), and have a vent pipe that meets specified design criteria. Building sewers may be vented through roof vents and outside sewers may be vented at locations other than at junction boxes, provided that the vent pipe height (at least 90 cm) and diameter (no greater than 10.2 cm in inside diameter) are the same as those for junction box vents AND the sewer has a water seal at the first downstream junction box.

Table 7-5. WASTEWATER INDIVIDUAL DRAIN SYSTEM VAPOR SUPPRESSION REQUIREMENTS {§63.1256(e)}

Standard (choice of either)	Description
1256(e) (1-3), **OR**	**1**. Maintain cover on each opening. If vented route through Closed Vent System to APCD and: - For cover and openings: **A.** Maintain according to 63.1258(h) **-** see Monitoring chapter for I and M requirements **B.** Keep in closed position when wastewater is in drain except for sampling, removal, inspection, maintenance or repair. - APCD designed/operated/inspected according to 63.1256(h) - Closed Vent System inspected according to 63.1258(h), - If under vacuum, not required to maintain by 63.1258(h), and - Design individual drain system to segregate vapors from drain systems that do not manage affected wastewaters and prevent releases to atmosphere. **2 & 3.** Inspection and Maintenance procedures **-** in Monitoring chapter
1256(e)(4-6)	**4**. Comply w/ following - Equip drain system openings w/ water seal, tightly fitting caps or plugs and - For water seal, maintain system to verify flow of water in trap, and **-** If water seal on drain receiving wastewater, discharge pipe must be submerged or flexible shield installed (except on water seals used on hubs receiving wastewater not subject to this provision) - Each junction box must have tightly fitting solid cover. If vented, comply w/ either **A.** Vent to process or to Closed Vent System vented to APCD. Closed Vent System maintained according to 63.1258(h) and APCD according to 63.1256(h), or **B.** If box uses gravity flow or there is only slight variation in liquid level then **1.** Vent pipe $\geq$ 90 cm length and $\leq$ 10.2 cm inside diameter, and **2.** Water seals installed to restrict ventilation on either the box influent or effluent. - Each sewer line carrying affected wastewater must not be vented to atmosphere unless the sewer line entrance to the first downstream junction box is water sealed and the sewer line vent pipe is $\geq$ 90 cm long and $\leq$ 10.2 cm inside diameter. **5 & 6.** Inspection and Maintenance procedures **-** in Monitoring chapter

VS: Oil-Water Separators

Wastewater Oil-Water separators standards contained in §63.1256(f) are summarized in Table 7-6. The regulation addresses any oil-water separator that receives, manages, or treats affected wastewater or residuals removed from wastewater. Vapors are to be suppressed using either a Fixed Roof (with a closed vent system and control device), Floating Roof, or Equivalent Means. An Equivalent Means of vapor suppression must be demonstrated by performance testing or engineering evaluation.

Table 7-6. WASTEWATER OIL WATER SEPARATORS VAPOR SUPPRESSION STANDARDS {§63.1256(f)}

Equip with...	Description (with Section Numbers)
Fixed Roof with CVS and Control Device, **OR**	**1.** Maintain Roof and openings according to §63.1258(h) (see Monitoring chapter for I and M requirements), and **2.** Keep in closed position when wastewater is in oil/water separator except for sampling, removal, inspection, maintenance or repair, and **3.** Design, operate, inspect APCD according to §63.1256(h) (See Table 7-2), and **4.** Inspect Closed Vent System according to §63.1258(h) **5.** Negative pressure not required to comply with §63.1258(h)
Floating Roof	**1.** Design floating roof per §60.693-2(a)(1)(i) and (ii), (a)(2), (a)(3), and (a)(4). - Primary seal - liquid-mounted or mechanical shoe - Secondary seal above the primary seal; cover the annular space between the floating roof and the wall of the separator - Equip each opening in the roof with gasketed cover, seal, or lid. Keep closed except during inspection and maintenance. - Roof must float on liquid (i.e., off the roof supports) except during abnormal conditions. - Roof may be equipped with emergency roof drains for removal of stormwater; use slotted membrane fabric cover that covers at least 90% of the drain opening area or a flexible fabric sleeve seal. **2.** Perform <u>seal gap measurements</u> according to 40 CFR 60 Subpart QQQ 60.696(d)(1) and scheduled as follows: - Primary seals: w/in 60 days after installation/wastewater introduction and once every 5 yrs thereafter, and - Secondary Seals: w/in 60 days after installation/wastewater introduction and annually thereafter.

Q and A

Q. ***What are CEFs and IWPs ?***

A. *Listed with each vapor suppression standard are inspection procedures for Control Equipment Failures (CEF) and/or Improper Work Practices (IWP) for each equipment type. For example, one of the CEFs listed for wastewater tanks is when a "gasket, joint, lid or cover has a crack, gap or is broken." An example of an IWP for fixed roof tanks is leaving open any access doors or any other opening when such door or opening is not in use.*

What are the Performance Standards for Wastewater Treatment?

7.4.2 Wastewater Treatment Standards

The wastewater treatment standards are found in §63.1256(g). Basically, there are six treatment standards in (g)(8 -13). A summary of how they apply to the four affected wastewater categories, A - D (Figure 7-2), is discussed below and shown in Table 7-7.

Wastewater from New and Existing Sources

For new or existing sources, the owner must:

- Treat an affected PSHAP wastewater stream (**category A**)
  - to remove 99% PSHAP, or
  - to less than 50 ppmw PSHAP,* or
  - remove 95% total HAP (from all wastewaters whether affected or unaffected) in a biological treatment unit, or
  - use a RCRA-permitted (or interim status) treatment device, such as an incinerator, boiler, or underground injection.
- Treat an affected Total HAP wastewater (**categories B & C)**
  - to remove 99% PSHAP <u>and</u> 90% SHAP, or
  - to less than 50 ppmw PSHAP and less than 520 ppmw SHAP,* or
  - use enhanced biotreatment (allowed only if PSHAP is less than 50 ppmw or if the wastewater has been treated upstream in compliance with (g)(8) (50 ppmw PSHAP or 99% reduction of PSHAP) and the wastewater is not designated), or
  - remove 99% PSHAP and treat to 520 ppmw SHAP, or
  - treat to 50 ppmw PSHAP and remove 90% SHAP, or
  - to remove 95% Total HAP (from all wastewaters whether affected or unaffected) in a biological treatment unit, or
  - use a RCRA-permitted (or interim status) treatment device, such as an incinerator, boiler, or underground injection.

NOTE(*): Concentration standards cannot be used (1) when biological treatment is used or (2) when the wastewater streams are designated.

For an existing source that has been **designated** as affected (per §63.1256(a)(1)(ii)), the wastewater treatment requirements are:

- PSHAP reduced by 99% and SHAP reduced by 90%, or
- Total HAP reduced by 95% in a biotreatment unit, or
- Treatment in a RCRA-permitted treatment device.

Wastewater from New Sources

For new sources, the owner/operator must:

- Treat an affected SHAP wastewater stream with greater than 110,000 ppmw SHAP (**category D)**

- to remove 99% SHAP, or
- use a RCRA-permitted (or interim status) treatment device, such as an incinerator, boiler, or underground injection.

Management of Residuals from Wastewater Treatment

Wastewater residuals are defined as HAP-containing liquids or solid materials removed from a wastewater stream by a waste management unit or treatment process that does not destroy organics. Examples of residuals include:

- the organic layer and bottom residue removed by a decanter or organic-water separator, and
- overheads from a steam stripper or air stripper.

Materials not classified as residuals include:

- silt, mud, or leaves,
- bottoms from a steam stripper or air stripper, and
- sludges, ash, or other materials from destructive treatment devices such as biological treatment units and incinerators.

There are several options for managing residuals taken from the treatment of affected wastewater:

- recycle the residual back into the production process or sell it to another firm for recycling. Once the residual is returned to a production process, it is no longer subject to regulation. OR
- return the residual to the treatment process. OR
- treat the residual to reduce the total combined mass flow rate of SHAP and/or PSHAP by 99 percent or more. (Use the performance tests in 63.1257(e)(2)(iii)(C) - noncombustion, nonbiological treatment process - or (D) - combustion treatment process - to demonstrate compliance.) OR
- treat the residual in a RCRA-regulated unit (hazardous waste incinerator or underground injection well.

In addition, tanks, surface impoundments, containers, individual drain systems, and oil/water separators used for the storage or management of residuals must meet the same design and operating requirements that apply to these units when used for treatment of affected wastewater (63.1256(b) - (f)).

What are the Standards for Air Emissions Control?

7.4.3 Emissions Control Standards

Standards for control of air emissions vented during the treatment process and from other waste management units with covers and closed vent systems are specified for air pollution control devices (APCD) as either:

1) equipment specifications - for combustion devices in terms of residence time and temperature specifications.

or

2) APCD performance levels - in the form of

Removal Efficiencies (RE) or APCD outlet HAP concentrations.

A summary of the standards is shown in Figure 7-4. Basically, there is a choice of 5 control standards as follows:

C Combustion device achieving 95% RE HAP, 20 ppmv outlet TOC @3% O_2, or provide 0.5 sec residence time at 760 deg C,

C Vapor recovery system achieving 95% RE HAP or 20 ppmv outlet TOC,

C Flare meeting requirements of §63.11(b),

C Scrubber or other APCD achieving 95% RE HAP or 20 ppmv TOC.

NOTE: The APCD outlet standard of 20 ppmv TOC is not available for APCDs controlling vent streams from wastewater surface impoundments or containers.

With regard to repairs to air pollution control devices, if gaps, cracks, tears, or holes are observed in the ductwork, piping, or connection to covers and control devices during an inspection, the owner/operator must make an attempt within 5 calendar days to fix the problem. Repair can be delayed only if:

- the repair cannot be done without a shutdown or if the emissions resulting from immediate repair would be greater than those anticipated to result from delaying the repair. The equipment must be repaired by the end of the next shutdown, OR
- the equipment is emptied or is no longer being used to treat affected wastewater or residuals, OR
- if additional time is necessary due to the unavailability of parts, due to circumstances beyond the control of the owner/operator. Repair must be done as soon as practical, In this case, the reasons for delaying the repair must be documented.

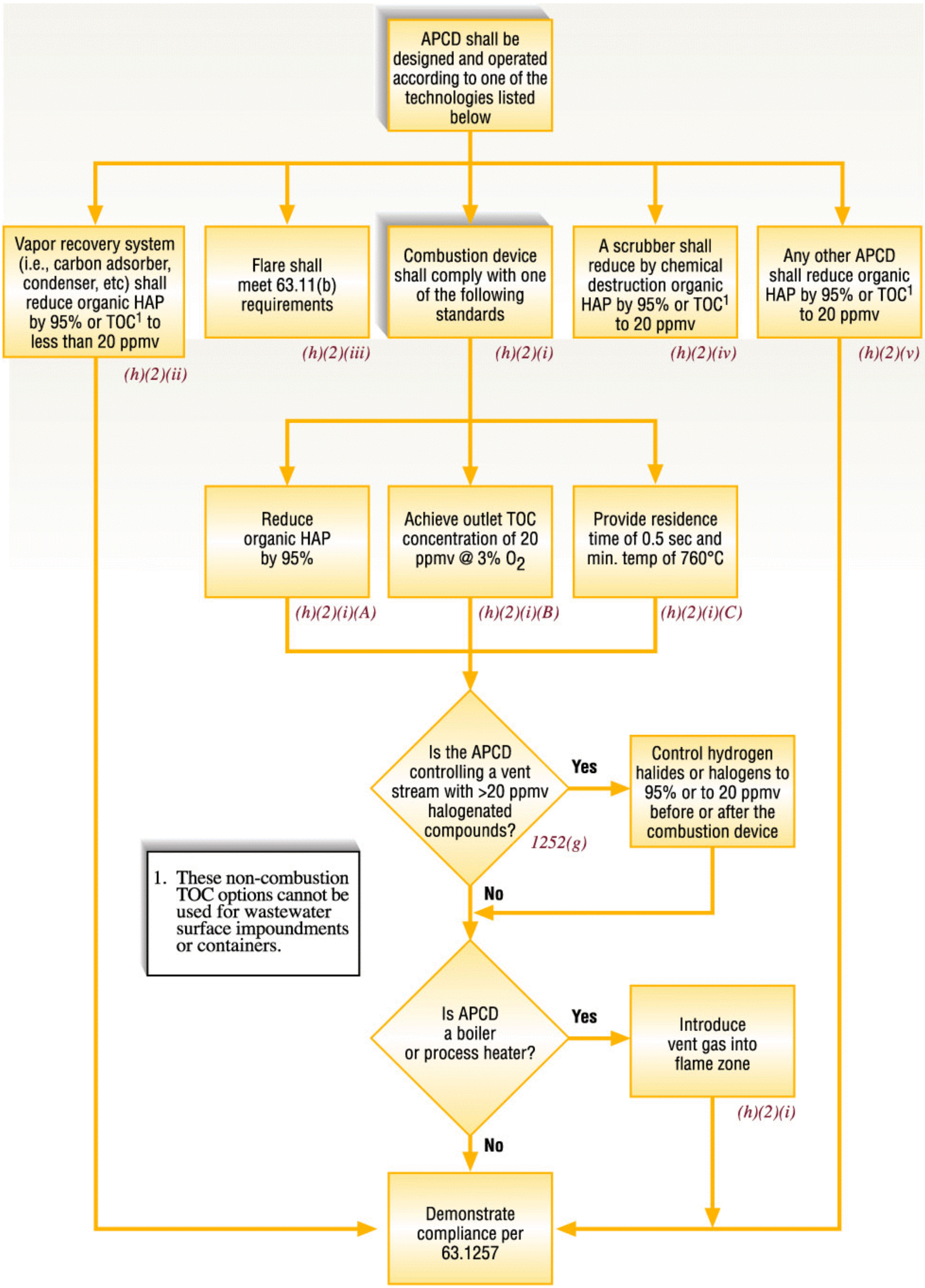


Figure 7-4. Wastewater APCD Requirements in §63.1256(h)

Table 7-7. WASTEWATER TREATMENT STANDARDS

Treatment Options	Used To Treat	Source Type	Limitations	Citations
treat to < 50 ppmw	PSHAP	new and existing (categories A, B, and C)	- no biotreatment or dilution - not available for designated streams	.1256(g)(8)(i) .1256(a)(1)(ii)
99% total mass removal/ destruction of HAP	PSHAP	new and existing (categories A, B, and C)		.1256(g)(8)(ii)
	SHAP	new (category D)	- only required when SHAP concentration is 110,000 ppmw and the total PSHAP and SHAP load in wastewater from the PMPU is > 1Mg/yr	.1256(g)(12)
treat to <520 ppmw	SHAP	new and existing (categories B and C)	- no biotreatment or dilution - not available for designated streams	.1256(g)(9)(i) .1256(a)(1)(ii)
90% total mass removal/ destruction of HAP	SHAP	new and existing (categories B and C)		.1256(g)(9)(ii)
enhanced biological treatment	SHAP	new and existing (categories A, B, and C)	- system must meet the definition of enhanced biological treatment - may only be used for affected wastewater with < 50 ppmw PSHAP, or wastewater that has been treated to less than 50 ppmw PSHAP or to 99% reduction of PSHAP - not available for designated streams	.1256(g)(10) .1256(a)(1)(ii)
95% mass removal/ destruction of total HAP with biological treatment unit	Total PSHAP and SHAP	new and existing (categories A, B, and C)	- biological treatment is required - all wastewater streams (as defined in 63.1252) entering the system must achieve 95% HAP removal, except wastewater already treated in compliance with another treatment option - all wastewater streams (as defined in 63.1252) entering the system must be managed in wastewater management units (sewers, etc.) in compliance with the MACT	.1256(g)(11)

Treatment Options	Used To Treat	Source Type	Limitations	Citations
RCRA permitted or interim status treatment device	PSHAP and/or SHAP	new and existing (categories A, B, C, and D)	- systems include heaters, incinerators, boilers, industrial furnaces, and underground injection	.1256(g)(13)

Offsite Treatment or Onsite Treatment by Someone Other Than Owner/Operator

The owner/operator may elect to transfer affected wastewater (or a residual removed from such wastewater) to an offsite treatment operation or to an on-site treatment operation being run by someone else.

Owner/ Operator:	Responsibilities include...
of the Affected Source	C ensuring that all waste management units on-site handling affected streams are in compliance with wastewater management requirements (e.g., all drain systems and tanks containing affected streams must comply with §63.1256(b)-(f)). C submitting a notice with each shipment stating that the wastewater or residual from the wastewater contains PSHAP and/or SHAP that must be treated in compliance with the regulations. If the transfer is continuous or ongoing, submit the notice with the first shipment and whenever there is a change in the treatment required. Keep a record of the notice in accordance with §63.1259(g).

Owner/ Operator:	Responsibilities include...
of a Treatment System Receiving the Wastewater	C Submitting to EPA, prior to receiving any affected wastewater, a written certification stating that any affected wastewater or affected wastewater residual will be treated in compliance with: S §63.1256(b)-(i) (requirements for tanks, surface impoundments, containers, individual drain systems, oil water separators, plus other performance standards for treatment), or S Subpart D (if alternative emissions limitations have been approved), or S §63.6(g) (use of an alternative nonopacity emission standard), or S If the affected wastewater streams or residuals contain less than 50 ppmw partially soluble HAP, then the person receiving them for treatment can: i. comply with (g)(10) (enhanced biotreatment for SHAP) and cover the waste management units up to the activated sludge unit, or ii. comply with (g)(11)(i) and (ii) (95 percent reduction in a biological treatment unit), and (h) (emissions control device standards) and cover the waste management units up to the activated sludge unit, or iii. comply with (g)(10) (enhanced biotreatment for SHAP) provided that the affected source owner/operator demonstrates that less than 5 percent of the total SHAP is emitted from waste management units up to the activated sludge unit, or iv. comply with (g)(11)(i) and (ii), (95 percent reduction in a biological treatment unit), and (h) (emissions control device standards), provided that the affected source owner/operator demonstrates that less than 5 percent of the total SHAP is emitted from waste management units up to the activated sludge unit. C Securing the signature of the responsible official on the certification, and providing the name and address of the certifying entity to the EPA Regional office. **NOTE ON REVOKING CERTIFICATION:** A written statement must be sent to both EPA and the owner/operator of the affected wastewater stating that the transferee is no longer accepting responsibility for treatment of the affected wastewater. The transferee must give at least 90 days notice. When the 90-day period is up, the owner/operator may not transfer affected wastewater or residuals to the treatment operation.

Q and A

Q. What are the standards for wastewater treatment using multiple treatment processes in series ?

A. The mass removal/destruction efficiency requirements are the same. However, efficiency calculation techniques differ for different treatment configurations. If wastewater is conveyed by hard piping then mass removal / destruction efficiency is determined across the combination of treatment processes. If wastewater is not conveyed by hard piping then efficiency is determined across each treatment process with total efficiency equal to the sum of efficiencies from each component process.

What is the Pollution Prevention Option?

In lieu of the wastewater standards discussed above, an owner or operator (O/O) can choose to meet pollution prevention (P2) standards. The P2 requirements are either:

- C reduce the production-indexed HAP consumption factor (kg HAP consumed/kg product produced) by 75% from a specified baseline average established no earlier than 1987, or
- C reduce the production-indexed HAP consumption factor by at least 50% from a specified baseline average established no earlier than 1987 AND reduce total PMPU HAP emissions divided by the annual production rate (kg HAP emitted per year/kg produced per year) to a value greater than 25% of the average production-indexed consumption factor (i.e., achieve 50% reduction by using pollution prevention and achieve additional 25% by using standard control devices). For more information on the pollution prevention option, see ° **Chapter 10- Pollution Prevention Alternative.**

7.5 Compliance Demonstration

Compliance demonstration procedures for wastewater standards are listed in §63.1257(e) - Test Methods and Compliance Procedures - Compliance with Wastewater Provisions. This section lists requirements for demonstrating initial compliance. Procedures for demonstrating on-going or continual compliance are listed in §63.1258 (Monitoring Requirements). A complete description of the required monitoring procedures can be found in ° **Chapter 9 - Monitoring**. The following paragraph presents a brief introduction to the initial compliance demonstration requirements for wastewater. A more complete description of the requirements can be found in ° **Chapter 8 - Compliance Demonstration and Testing Procedures.**

Q and A

Q. ***How do I demonstrate compliance for:***
1) wastewater with multiple phases
2) treatment residuals ?

A. *Wastestreams with free phase HAP cannot be sent to individual drain systems, stored in wastewater tanks or surface impoundments, or sent to treatment units. The free phase HAP can only be discharged to a RCRA treatment unit, per 63.1256(a)(3). For wastewater treatment residuals, the O/O must either:*

1. *recycle the residual back to the production process, or sell the material for the purpose of recycling*
2. *return the residual back to the treatment process,*
3. *destroy combined PSHAP/SHAP by at least 99%, or*
4. *treat the residual in a RCRA unit per §63.1256(g)(13).*

To demonstrate compliance with option 1 or 2, the O/O must document process configuration. To demonstrate compliance with option 3, the O/O should use compliance demonstration technique C or D as discussed in Appendix WWT.

The initial compliance demonstration procedures as listed in §63.1257(e) are basically separated into 3 parts:

- Determination of wastewater HAP concentration and load as it pertains to wastewater **applicability** criteria (i.e. annual concentration and annual load),
- Design Evaluation and Performance Test procedures for demonstrating compliance with **air emissions control (i.e., APCD**) requirements, and
- Design Evaluation and Performance Test procedures for demonstrating compliance with **wastewater treatment** standards.

Compliance with the **vapor suppression standards** is done primarily through the reporting provisions of the rule, which require that the owner or operator document the results of Inspection and Monitoring procedures that are followed for wastewater management units.

The reader is referred to Chapters 8 and 9 for more complete details on compliance demonstrations and monitoring requirements.

Chapter 8
Initial Compliance Demonstrations and Testing Procedures

8.1 Overview

The MACT regulations require that affected sources provide proof that the facility is in initial compliance with the standards. The exact format of the initial compliance demonstration depends on the nature of the source and the regulatory standard option chosen by the owner or operator. In some cases, performance testing of the control devices will be necessary; in others, engineering calculations can be used to demonstrate that the emissions will be controlled to the required level.

Because the owner or operator has flexibilities or options, with regard to the regulatory standard chosen, he/she must develop a strategy that best suits the facility. It is important to remember that the pharmaceutical MACT is process-based. This means that the standards apply to a process (a group of steps that result in the production of a product or isolated intermediate), rather than a particular piece of equipment.

Other than the Alternative Standard, the initial compliance demonstration will also be used to establish monitoring parameter levels, as necessary. For example, during the initial compliance performance test, the O/O will establish control device and/or process monitoring parameter levels to be used to demonstrate on-going compliance. Details of this procedure will be discussed in Chapter 9.

Chapter 8 at a Glance

What are the Elements of a Compliance Strategy?

For the pharmaceutical manufacturing operations, the owner or operator should develop a compliance strategy, considering at least the following elements:

- Identification of PMPUs,
- Emission sources within each PMPU,
- The associated standards for those

PMPUs,
- Control options for emissions standards
- The associated compliance demonstration procedures for the standards, and
- The associated monitoring requirements.

The owner or operator may need to ask some questions relating to the overall facility, such as:

How often do the processes change and how will this affect the choice of standards and compliance demonstrations?

Which emission episodes will be controlled by which control device and to what level?

Will it make sense to vent numerous process streams to one centralized control device?

Would additional costs incurred in reconfiguring to a centralized control device be offset by a reduction in compliance demonstration and monitoring costs?

Are there pollution prevention technologies that could be applied instead of using traditional end-of-pipe controls ?

8.2 Structure of the Regulation

Compliance demonstration requirements are listed in §63.1257 for the following categories:

§63.1257(a)	General Requirements
§63.1257(b)	Methods
§63.1257(c)	Storage Tanks
§63.1257(d)	Process Vents
§63.1257(e)	Wastewater Sources
§63.1257(f)	Pollution Prevention *
§63.1257(g)	Compliance w/ Storage Tank Provisions by Using Emissions Averaging**
§63.1257(h)	Compliance with Process Vent Provisions by Using Emissions Averaging**

* Compliance information for this section is covered in Chapter 10.
** Compliance information for these sections is covered in Chapter 11.

8.3 Exemptions from Compliance Demonstrations

No initial compliance demonstration is required if the following devices are used to control emissions:

- a boiler or process heater with a design heat input capacity of 44 megawatts or greater,
- a boiler or process heater in which the emission stream is introduced with the primary fuel,
- a boiler or process heater that burns hazardous waste and which is either permitted under RCRA and in compliance with Part 266, Subpart H (Hazardous Waste Burned in Boilers and Industrial Furnaces) or has certified compliance with the interim status requirements of Part 266, Subpart H,
- a hazardous waste incinerator that is either permitted under RCRA and in compliance with Part 264, Subpart O (Incinerators) or has certified compliance with the interim status requirements of Part 265, Subpart O.

A compliance demonstration, per se, is not required when the alternative standard is being used. The owner/operator must be in compliance with the applicable monitoring requirements (63.1258 (b)(5)) on the initial compliance date.

8.4 Compliance Demonstration Procedures - Summary

Table 8-1 details which kinds of compliance demonstrations are required for each type of emission source - process vents, storage tanks,
and wastewater, assuming that the owner or operator is not using one of the control devices listed above that are exempt from compliance demonstrations.

NOTE: Separate compliance demonstrations are not required for storage tanks if their emissions are routed to control devices which have met the process vent compliance demonstration.

Before the comprehensive table of compliance demonstration requirements by source type is reviewed (Table 8-1), it may be helpful to gain an understanding of some of the terms used in the regulations for types of demonstrations:

Type of Demonstration	Plain English Definition
Emissions Estimation Methods	Using a **set of equations provided by EPA (or other validated equations)** in the rule to calculate emissions for process vents from **eight specific activities -** vapor displacement, purging, heating, depressurization, vacuum systems, gas evolution, air drying, and empty vessel purging.
Engineering Assessments	Using **other methods** (e.g., data from previous emissions tests) to calculate emissions primarily from **activities other than the eight listed above**. Engineering assessments <u>can</u> be used to calculate emissions from those eight activities <u>if</u> the emissions estimations equations aren't accurate or appropriate for the specific process. (NOTE: Must be approved by EPA)
Design Evaluation	Using control device **manufacturer's specifications** and other relevant site-specific data to show that the device will achieve the required efficiency.
Performance Testing	Designing and conducting **test runs of the process** to demonstrate that required emission reductions are achieved. Conditions under which testing was conducted must be carefully documented. Owners/operators must use EPA-specified test methods unless the source has petitioned and gained approval to use an alternative test method.

Condensers

Finally, before the table is reviewed, it should be understood that **if a condenser is used as the control device**, the owner/operator **must use the emissions estimations procedures** to demonstrate compliance at a measured temperature.

If the condenser is used as a process condenser, the owner/operator must initially demonstrate that the condenser is properly operated if:

- - the process condenser is not followed by an APCD, or
- - the APCD following the process condenser is not a condenser or is not meeting the 20 ppmv TOC

alternative standard (50 ppmv, if non-combustion device).

The owner or operator must either:

1. Show that the condenser exhaust gas temperature is less than the boiling or bubble point of the vessel contents, or
2. Perform a material balance around the vessel and condenser to show that at least 99 percent of the material that vaporizes is condensed.

This initial demonstration must be done for all appropriate operating scenarios and documented in the Notification of Compliance report.

Each kind of compliance demonstration is indicated with a bold number in Table 8-1 below.

Table 8-1. INITIAL COMPLIANCE DEMONSTRATION TECHNIQUES

Source	Regulatory Standard or Criteria	Type of Compliance Demonstration
Storage Tanks	Percent reduction	**Ú** Design evaluation or **Ü** Performance testing (note: testing not required if device also controls emissions from process vents and compliance has been demonstrated under process vent provisions.
	Alternative standard **-** 20 ppmv TOC if combustion, 50 ppmv if noncombustion	**Þ** TOC Monitoring at outlet of control device. Monitor must meet Performance Specification 8 (QA and calibration for CEMs) or 9 (QA and calibration for GC analysis) of Part 60, Appendix B. Use Method 18 to determine predominant HAP, if monitor is calibrated on predominant HAP.
	floating roof	**HON demonstration -** Refer to HON Inspection Tool **-** EPA 305-B-97-006, September, 1997 for guidance on engineering specifications in §63.119 (b)–(d) and monitoring in §63.120.
	vapor balancing	Information from reloading/cleaning facility (see page 8-25)
Wastewater Effluent	applicability criteria (PSHAP and SHAP conc. and loading) (alternatively, may designate as affected)	**ß** calculation of **annual average concentrations** and **annual load,** using EPA-approved methods, previous knowledge of wastewater, or bench-scale/pilot-scale test data
	wastewater treatment unit standards **-** percent removal or specific concentration of PSHAP or SHAP in ppmw	**RCRA units (with RCRA permit or interim status)** or **enhanced biological treatment meeting definition in §63.1251 - no demonstration required under this subpart**. **Non-biological or closed biological**: **à** Wastewater treatment performance testing, or **á** Wastewater design evaluation **Open biological**: **à** Wastewater treatment performance testing

Source	Regulatory Standard or Criteria	Type of Compliance Demonstration
Wastewater Air Emissions	air pollution control device standards - percent reduction	Ü Performance testing, or á Wastewater design evaluation
	Outlet TOC standard - 20 ppm TOC	Ú Design evaluation or testing using Method 25A
Process Vents	Mass emission limit	**Determine uncontrolled HAP**: Use either: Ø Emission estimation methods, (for vapor displacement, purging, heating, depressurization, vacuum systems, gas evolution, air drying, and empty vessel purging) or Ù Engineering assessments (for operations other than those listed above). AND **Determine controlled emissions**: For <u>small devices</u> controlling less than 10 TPY HAP, use: Ú Design evaluation (except for condensers), or Û Emission estimation methods (condensers only), or Ü Performance testing. For <u>large devices</u> controlling 10 TPY or more, use: Û Emission estimation methods (condensers only), or Ü Performance testing, or Ý Previous performance test performed under conditions required by §63.12.
	Percent reduction	Ü Performance testing, or **Determine uncontrolled HAP**: Use either: Ø Emission estimation methods (for vapor displacement, purging, heating, depressurization, vacuum systems, gas evolution, air drying, and empty vessel purging), or Ù Engineering assessments (for operations other than those listed above or where the owner/operator has demonstrated that the equations are not appropriate), AND **Determine controlled emissions**: For <u>small devices</u> controlling less than 10 TPY HAP, use: Ú Design evaluation (except for condensers), or Û Emission estimation methods (condensers only), or Ü Performance testing. For <u>large devices</u> controlling 10 TPY or more, use: Û Emission estimation methods (condensers only), or Ü Performance testing, or Ý Previous performance test performed under conditions required by §63.12.

Source	Regulatory Standard or Criteria	Type of Compliance Demonstration
	Outlet TOC standard - 20 ppm TOC	Ú Design evaluation or testing using Method 25A
	Alternative TOC Standard (20 ppmv if combustion, 50 ppmv if non-combustion)	Þ TOC Monitoring at outlet of control device. Monitor must meet Performance Specification 8 (QA and calibration for CEMs) or 9 (QA and calibration for GC analysis) of Part 60, Appendix B. Use Method 18 to determine predominant HAP, if monitor is calibrated on predominant HAP.

A general discussion of compliance demonstration procedures for each source type is presented in Sections 8.5 - 8.7. Each type of compliance demonstration procedure will be discussed by referencing the numbering system used in the above table.

8.5 Compliance Demonstration Procedures for Process Vents

Compliance demonstration procedures for process vents are listed in §63.1257(d). Procedures are given to demonstrate compliance with the following types of standards:

- Mass emissions limit
- Percent reduction or outlet TOC concentration
- Alternative standard

To determine mass emission rates and percent reductions, the rule provides compliance demonstration procedures for calculating uncontrolled emissions and controlled emissions. A further breakdown of these techniques is given in Figure 8-1a (uncontrolled emissions) and Figure 8-1b (controlled emissions). Uncontrolled emission rates from vents are calculated using ***emission estimations*** (equations provided for eight specified operations that produce emissions) or ***engineering assessment*** procedures (for emissions events other than the eight specified or for emission events not accurately represented by the emission estimation equations). Controlled emission rates are determined by ***design evaluations***, ***emission estimation*** or ***performance testing***.

NOTE: For control devices, except for condensers, controlling sources with HAP emissions at least 10 tpy (large device), performance testing must be used to determine controlled emissions (except for sources using the alternative standard option). Compliance with TOC standards is demonstrated using parametric monitoring when monitoring TOC as a surrogate for percent reduction and TOC CEM monitoring when monitoring TOC for the alternative standard. Þ

What are the Emission Estimation Procedures for Calculating Uncontrolled Emissions for Process Vents?

Equations are provided to calculate uncontrolled emissions from process vents for the following emission episodes types:

C Vapor Displacement

- Purging
- Heating
- Depressurization
- Vacuum Systems
- Gas Evolution
- Air Drying
- Empty Vessel Purging

These equations are listed in §63.1257(d)(2)(I) A through H, respectively. Basic chemical engineering principles are used to calculate mass rates of HAPs. Appendix EE to this tool provides a listing of the equations and equation inputs.

Equations from the 1978 document "Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products," EPA - 450/2-78-029 (CTG) and equations from the 1994 ACT are included in the rule.

Other equations, as approved by EPA, may be used for emissions estimations.

Figure 8-1a provides a flow diagram illustrating the determination of uncontrolled emissions from process vents. Figure 8-1b shows the determination of controlled emissions.

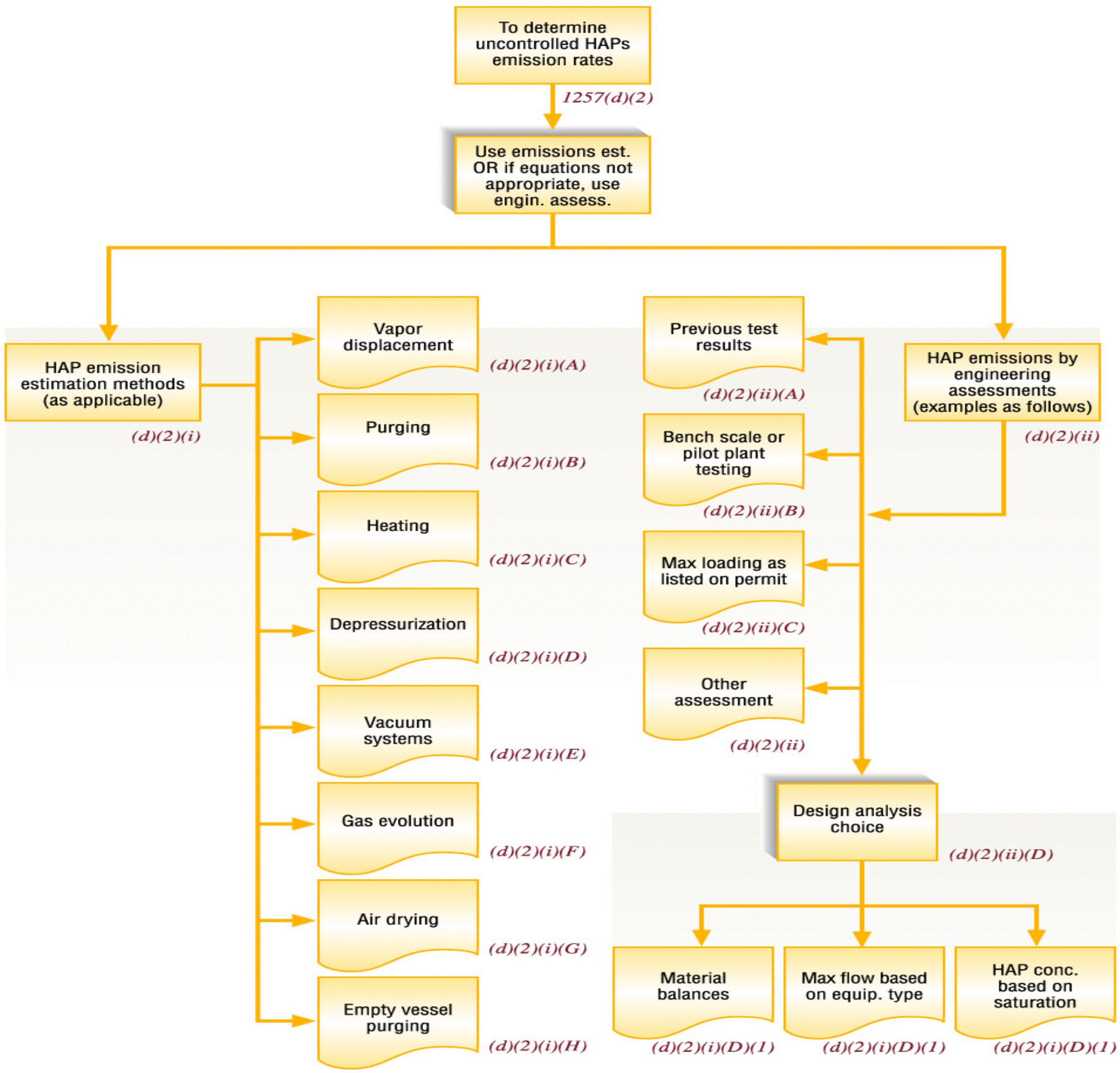


Figure 8.1a. Determining Uncontrolled Emissions from Process Vents

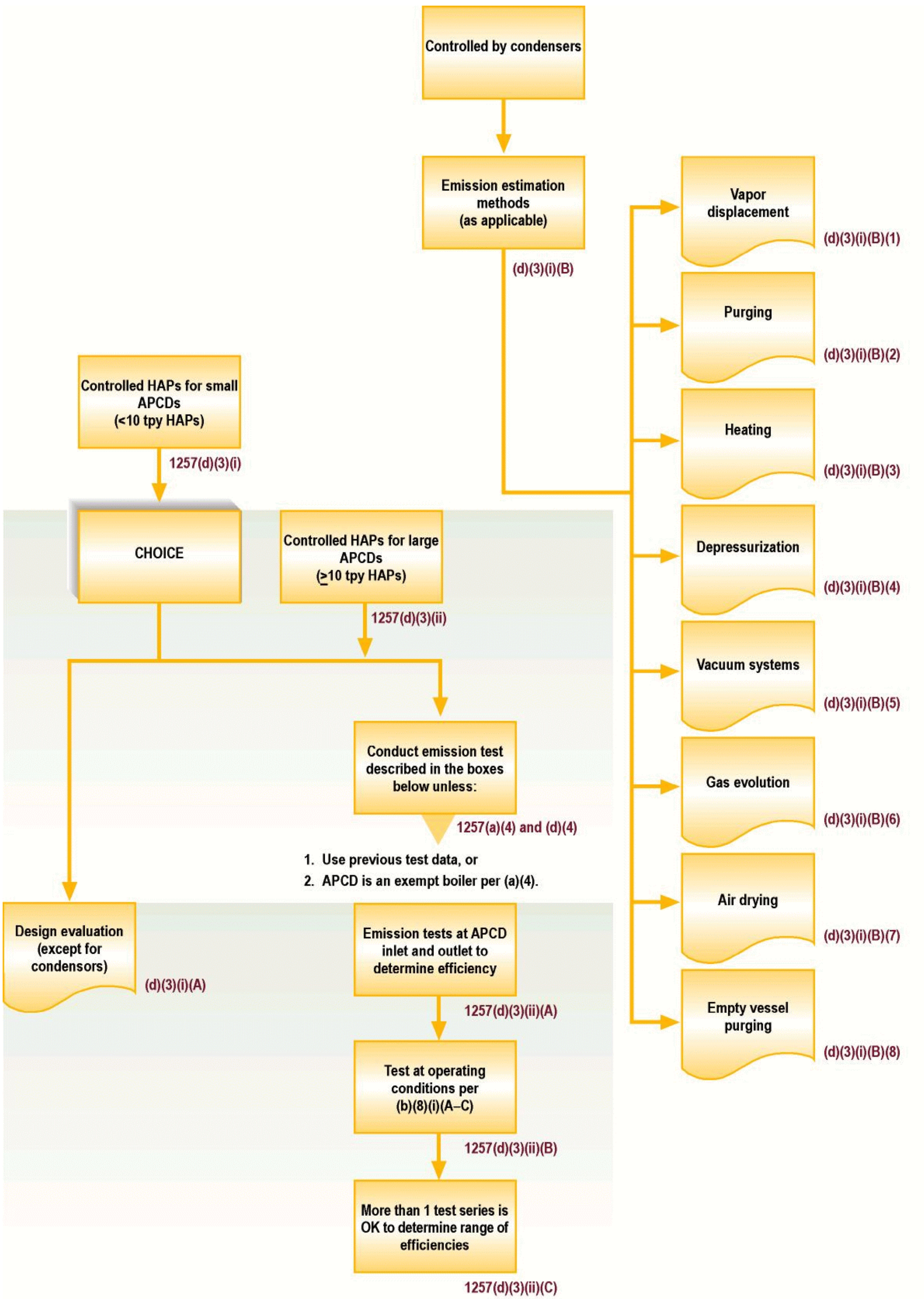


Figure 8-1b. Determining Controlled Emissions from Process Vents

What are the Engineering Assessments for Calculating Uncontrolled Emissions for Process Vents?

Engineering assessments are used primarily to calculate uncontrolled process vent emissions for emissions episodes that are NOT due to any of the activities described above under emissions estimations (i.e., vapor displacement, purging, heating, depressurization, vacuum operations, gas evolution, air drying, or empty vessel purging). Engineering assessments can also be used to calculate uncontrolled emissions for those 8 specific activities if the owner/operator believes the equations are not accurate or appropriate for his/her facility; the Administrator must approve such use of engineering assessments. In addition, modified versions of the emissions estimations methods under Section 63.1257 (d)(2)(ii) can be used if the owner/operator shows they have been used to meet other regulatory obligations and they do not affect applicability determinations or compliance determinations. Engineering assessments techniques are given below:

Engineering assessments can include...	Provided that...
Previous test data	**Tests are representative of current operating practices at the process unit.**
Bench-scale or pilot-scale test data	**Data are representative of the process under representative operating conditions.**
Maximum flow rate, HAP emission rate, concentration, or other relevant parameter	**Value is specified or implied within a permit limit applicable to the process vent.**
Design analysis based on accepted chemical engineering principles, measurable process parameters, or physical or chemical laws or properties (e.g., use of process stoichiometry to estimate maximum organic HAP concentrations, estimation of maximum flow rate based on physical equipment design such as pump or blower capacities, estimation of HAP concentrations based on saturation conditions.)	**All data, assumptions, and procedures used to support engineering assessments are documented.**

What are the Design Evaluation Techniques for Calculating <u>Controlled</u> Emissions for Process Vents?

The design evaluation must demonstrate how the control device being used achieves the needed percent reduction to comply with the rule. Design evaluations can be used for process vents ONLY if the control device controls less than 10 TPY (if $10 TPY, performance testing must be done unless control device is a condenser).

As shown in Figure 8-2, for each type of control device, EPA specifies what factors must be considered in conducting the design evaluation and what operating parameters must be established. Each design evaluation must consider the composition and concentration of all gases, vapors and liquids entering the control device.

For devices controlling process vents, the design evaluation must show compliance at absolute worst-case condition as determined from the emission profile (Information on conditions is provided later in this chapter). EPA's intent in requiring worst case conditions for testing is to document the reduction efficiency of the control device under the most challenging conditions. It is presumed that the device will work at least as well, and maybe better than, when conditions were at their worst. The emission profile should include the HAP loading rate in lb/hr and include all emissions episodes in a process that could contribute to the vent stack load. Production scheduling should be documented to ensure that all processes contributing to each vent are being considered.

What are the Emission Estimation Procedures for Calculating <u>Controlled</u> Emissions for Small Control Devices for Process Vents?

For small control devices, (controlling less than 10 tpy HAPs) equipped with a <u>condenser</u> operating as a control device, controlled emissions can be calculated using emission estimation equations. These techniques for the most part are similar to those previously discussed in uncontrolled emission estimation procedures with the exception that temperature values are those at the control device or receiver (condenser). A full presentation of equations and input variables is shown in Appendix EE.

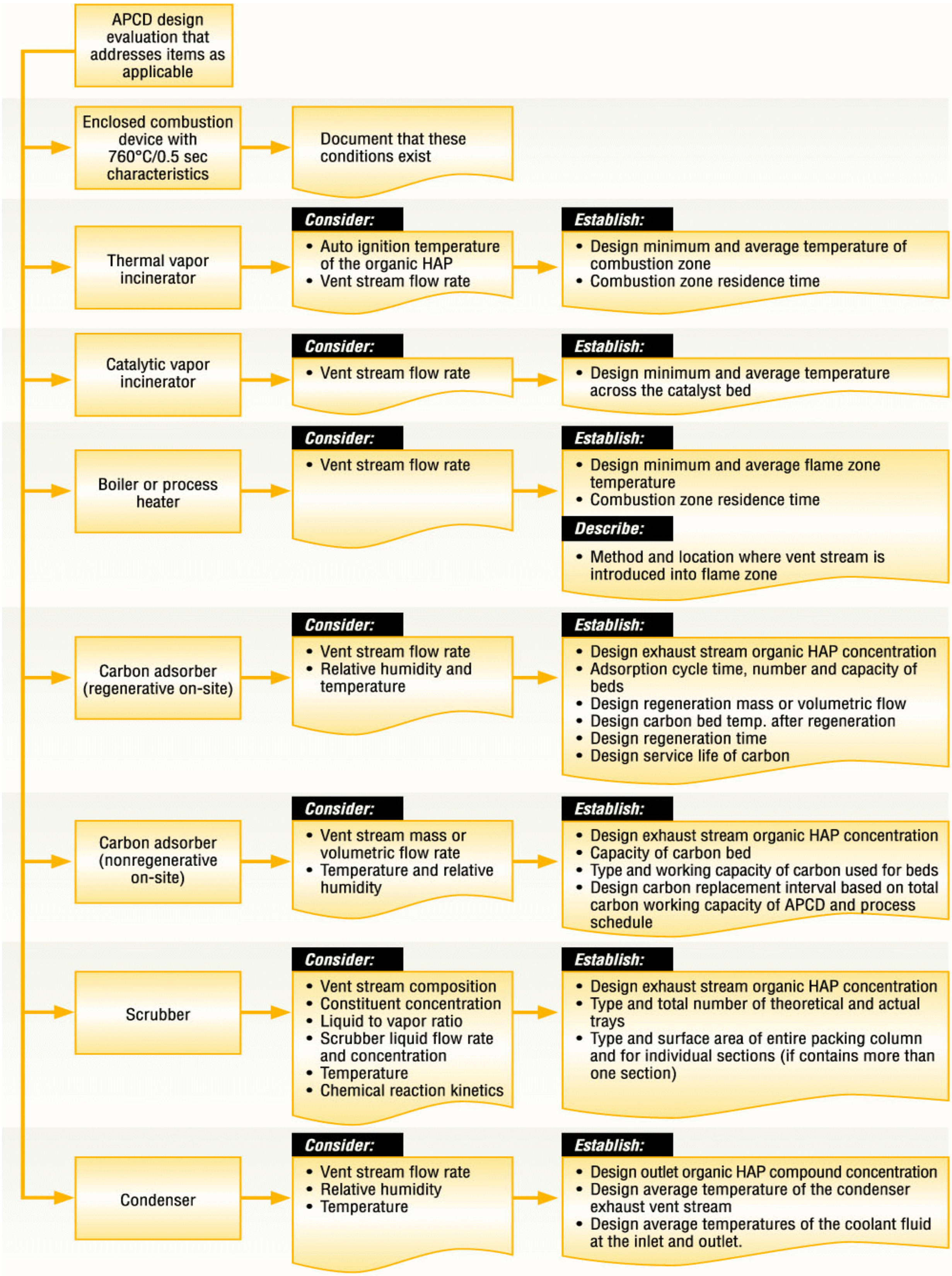


Figure 8-2. Emissions Control Device Design Evaluation Requirements

What is the Control Device Performance Testing for Process Vents?

Performance testing is required to demonstrate compliance for large control devices ($\geq$ 10 tpy HAPs). Previous test results may be used if the tests were conducted using the same procedures as provided by the rule at conditions typical of the appropriate worst case scenario. There are two primary objectives which must be considered in conducting performance tests:

- Demonstrate initial compliance, and
- Establish monitoring parameters for demonstrating on-going compliance.

Performance testing for demonstrating initial compliance can be broken down into the following tasks:

1. Test Plan Development and Submittal,
2. Testing, and
3. Report Writing and Submittal.

Test plans are to include the following information:

- Test program summary
  - List of sources to be tested
  - Test Methods
  - Test Conditions
- Test schedule
- Data quality objectives (precision, accuracy, and completeness of data)
- QA Programs - Internal (assessment of precision) and external (performance audits)

Further details on Performance testing are given in Appendix PT. Review the following Q and A boxes for more information on performance testing and emissions profiles.

Initial compliance demonstrations for condensers are based on how the condenser is used – as an air pollution control device or as a component of a process? For condensers used as APCDs: the owner/operator must determine controlled emissions by measuring exhaust gas temperatures and calculating emissions reduction for each batch emission episode within each unit operation. The owner/operator should use the equations for small devices for the eight specific procedures (vapor displacement, purging, heating, etc) or other approved equations, as discussed previously.

For condensers used as part of the process:

In configurations where the process condenser is not followed by an air pollution control device or the air pollution control device following the process condenser is not a condenser or is not meeting the alternative standard, the owner/operator must demonstrate that the process condenser is operating properly. This can be done by either:

1) measuring the exhaust gas temperature and showing that it is less than the boiling or bubble point of the substances in the vessel or

2) performing a material balance around the vessel and condenser to show that at least 99 percent of the material that vaporized during boiling is being condensed. The demonstration must be conducted for all appropriate operating scenarios. The owner/operator must document the results in the Notification of Compliance Report.

Q and A

Q. ***How do I demonstrate compliance with percent reduction standards?***

A. *The general equation for determining percent reduction requires the calculation of inlet and outlet mass rate of HAPs (or TOC) to the control device. Mass rate is calculated by multiplying HAP or TOC concentration by gas flow rate. As listed in Appendix PT, several test methods can be used for determining individual HAP concentrations, TOC concentration, and gas flow rate. However, each method has advantages and disadvantages and should be carefully reviewed before a selection is made.*

Q. ***What emissions test methods should be used?***

A. *Table 8-2 lists the emissions test methods to be used. These are taken from 40 CFR Part 60, Appendix A. Appendix PT describes these methods and discusses the advantages and disadvantages of each method.*

Q. ***Under what test conditions?***

A. *Test conditions for process vents, running in batch mode, should be at either absolute worst case or hypothetical worst case as defined in Table 8-3. These scenarios should be documented in an emissions profile. The owner or operator must prepare a site-specific test plan for approval 60 days prior to testing.* ***The test plan must include a description of proposed testing procedures as well as an emissions profile of the process.***

Testing storage tanks should be conducted during a reasonable maximum filling rate. Testing wastewater sources should be conducted under representative manufacturing process conditions and representative treatment operation.

Q, ***Do I need to determine uncontrolled emissions if I'm complying by using the outlet concentration standard or the Alternative Standard?***

A. *Yes, in the case of the outlet concentration standard. Uncontrolled emissions determination is needed to identify the worst case conditions for the performance test or design evaluation. It is <u>not</u> necessary to determine uncontrolled emissions if the Alternative Standard will be used because compliance is directly measured - no emissions profile is necessary.*

Table 8-2. EMISSIONS PERFORMANCE TEST METHODS

What's Being Measured	Method Number and Name (Appendix A of Part 60)
Sample and velocity traverse location	1 - Sample and Velocity Traverses for Stationary Sources OR 1A - Sample and Velocity traverses for stationary sources with small stacks or ducts
Velocity and volumetric flow rates	2 - Determination of stack gas velocity and volumetric flow rate (Type S pitot tube) OR 2A - Direct measurement of gas volume through pipes and small ducts OR 2C - Determination of stack gas velocity and volumetric flow rate in small stacks or ducts (standard pitot tube) OR 2D - Measurements of gas volumetric flow rates in small pipes and ducts
Gas analysis	3 - Gas analysis for carbon dioxide, oxygen, excess air, and dry molecular weight
Stack gas moisture	4 - Determination of moisture content in stack gases
HAP or TOC concentration *	25 - Total gaseous nonmethane organic emissions 26 or 26A - Determination of hydrogen chloride emissions, hydrogen halide and halogen from stationary sources 18 - Measurement of gaseous organic compound emissions by gas chromatography 25A - Determination of total gaseous organic concentration using a flame ionization analyzer. Can only be used for control efficiency determinations if any of the following conditions exist: 1. There is only one compound known to exist, 2. The organic compounds consist of only hydrogen and carbon, 3. Relative percentages of the compounds are known or can be determined and FID responses to the compounds are known, 4. A consistent mixture of the compounds exists both before and after the control device and only the relative concentrations are to be assessed, or The FID calibration gas used can be methane or the predominant HAP. The response from the high-level calibration gas must be at least 20 times the standard duration of the response from the zero calibration gas when the instrument is zeroed on the most sensitive scale. The span value of the analyzer must be less than 100 ppmv.

*** NOTE:** For determining speciated HAP concentrations, any method which has met EPA Method 301 validation criteria can also be used with the approval of the test administrator.

Q and A

Q. ***Who is the test administrator?***

A. *The test administrator is the regulator who has responsibility for approving the test plan, observing the tests, and accepting the test results. Typically, they are employees with the State or Local Air Pollution Agency who have jurisdiction over the facility through the issuance of air quality permits. In many cases, test objectives also include demonstrating compliance with air quality permit limits.*

Q. ***What should the emissions profile include?***

A. *The profile for the vent to the control device must describe the vent stream at the inlet to the control device under worst case conditions. The profile can be prepared using any one of the three following approaches:*

- ***By process**:*
  - include all emission episodes contributing to vent stack load
  - describe scheduling that reflects all contributing processes
  - describe the HAP load to the device that equals the highest sum of emissions from the episodes that can vent to the control device in any given hour
  - use uncontrolled emissions calculations (emissions estimation equations or engineering assessments) to calculate emissions per episode. If the episode is longer than 1 hour, divide the emissions figure by the duration of the episode.
- ***By equipment**:*
  - describe emissions that meet or exceed the highest emissions, in lb/hr, that would be expected under actual processing conditions
  - describe equipment configurations that yield the emission events described
  - include volatility of materials processed in the equipment
  - describe rationale used to identify and characterize the emissions (emissions may be based on a compound more volatile than compounds actually used in the process(es), and emissions may be generated from all equipment in the process(es) or only selected equipment.
- ***By capture and control device limitations**:*
  - describe the highest emissions, in lb/hr, that can be routed to the control device, based on maximum flowrate and concentrations possible because of limitations on conveyance and control equipment.

In order to show that large control devices (handle at least 10 tons/yr) are achieving the required reduction efficiencies, performance tests must be performed at worst-case conditions.

The owner or operator can choose to use absolute worst-case or hypothetical worst-case, as defined below in Table 8-3**.**

Table 8-3. DEFINITIONS OF TYPES OF PERFORMANCE TEST CONDITIONS

Type of Condition	Definition
Absolute Worst-Case	If the **maximum load rate is the most challenging condition** for the control device, then absolute worst case equals: 1) period in which **inlet will contain at least 50 percent of the maximum HAP load** (in lb) capable of being vented to the device over any 8-hr period OR 2) period in which **inlet will contain the highest HAP mass loading rate** (in lb/hr) capable of being vented to the device **over a 1-hr period** If **condition other than maximum load rate is the most challenging condition** for the control device, then absolute worst case equals: The period of time when the **HAP loading or stream composition (including non-HAP) is the most challenging** for the control device (e.g., periods when stream contains the highest combined VOC and HAP load in lb/hr, periods when stream contains HAP constituents that approach limit of solubility for scrubbing media, periods when stream contains HAP constituents that approach limit of adsorptivity for carbon adsorption systems).
Hypothetical Worst-Case	**Simulated test conditions** that, at a minimum, contain the **highest total average hourly HAP load** of emissions that would be predicted to be vented to the control device, considering information included in the emissions profile.

Devising a Compliance Strategy
-An Example-

The example provided below shows how an emissions profile can be used to develop a compliance strategy for a specific process.

Table 1 lists the series of emissions events in Process A, starting with a methanol (MeOH) charge to the weigh tank. This table lists the uncontrolled and controlled emissions of one batch of the existing process prior to implementation of the MACT rule. Some emissions are controlled by condensers and/or a carbon adsorber. Some of the emissions are not currently routed to a control device. As shown at the bottom of the table, uncontrolled emissions for one batch are 673.01 pounds (methanol and chloroform). The overall control efficiency is 74.57%; controlled emissions are 171.18 pounds total. The owner/operator will need to determine whether it makes sense to comply with the 2,000 lb/yr limits standard or the 93% emission reduction standard.

Table 2 shows one possibility for a control strategy. First, the owner/operator should determine whether any vents are subject to the individual vent control requirement for 98% reduction. The table indicates that no individual vents have uncontrolled emissions greater than 50,000/year (25 tons/yr), so no vents are subject to the 98% requirement. In this case, after determining that no vents are subject to the 98% requirement, the owner/operator decides to attempt compliance with the 93% emissions reduction standard.

The gray boxes indicate where previously uncontrolled streams will be vented to the carbon adsorber. With a 90% reduction efficiency for methanol and a 95% reduction efficiency for chloroform, the new annual controlled emissions are listed in the column on the far right side of the table. As shown at the bottom of that column, the new overall control efficiency is 93.13%, which meets the MACT standard.

To demonstrate that the carbon bed will be able to achieve the standard, it must be tested at the maximum loading rate. Table 3 provides the emissions profile data for the carbon bed. In looking at the column labeled "Total HAP sent to CA (lb/hr)" it is clear that the maximum load occurs during the drying process, with 34.14 lb/hr sent to the carbon adsorber. This happens 123 hours into the batch. The owner/operator will conduct performance tests of the carbon adsorber during the dryer emissions event.

TABLE 1. COMPLIANCE STRATEGY

Process	Emission Event	Vent I.D.	Flowrate (scfm)	Duration (hr)	Processing Time (hr)	Pollutant	Uncontrolled Emissions (lb)	Control Device	Efficiency (%)	Controlled Emissions (lb)	Reference
A	MeOH Charge to Weigh Tank	WT-1	0.9	0.25	0.25	MEOH	0.14	None	NA	0.14	Calculations
A	Fermenter Charge and Purge	Ferm-1	133	12.25	12.5	MEOH	10	None	NA	10	Calculations
A	Ferm Mix Charge to Holding Tank	TK-1	2.21	1.2	13.7	MEOH	0.08	None	NA	0.08	Calculations
A	Extraction	EX-1	0.8	30	33.7	MEOH CHC13	1.2 185.5	Condenser Condenser	65.00% 58.00%	0.42 77.65	Calculations Calculations
A	Charge Organic Phase to Hold Tank	HT-2	0.64	1	34.7	MEOH CHC13	0.14 2.23	None None	NA NA	0.14 2.23	Calculations Calculations
A	Charge Aqueous Phase to Hold Tank	HT-3	2.5	1	34.7	MEOH	0.03	None	NA	0.03	Calculations
A	Strip Aqueous Phase	SS-1	0.1	3	37.7	MEOH	0.03	None	NA	0.03	Calculations
A	Charge to Concentrate Receiver	CR-1	0.03	20	57.7	MEOH CHC13	3.7 0.27	None None	NA NA	3.7 0.27	Calculations Calculations
A	Concentration of Organic	EVAP to CX	0.5	20	57.7	MEOH CHC13	9.1 123.9	Condensers and Carbon Condensers and Carbon	99.20% 99.40%	0.07 0.7	Calculations Calculations
A	Distillate Receiver from EVAP	DR-1 to CX	0.0003	20	57.7	MEOH CHC13	0.00039 0.013	Condensers and Carbon Condensers and Carbon	92.82% 99.62%	2.8E-05 5E-05	Calculations Calculations
A	Reactor Charge with Solvent	R-1 to CX	0.7	0.5	58.2	MEOH CHC13	0.16 2.14	Condensers and Carbon Condensers and Carbon	98.90% 99.30%	0.0017 0.016	Calculations Calculations
A	Reactor Heatup	R-1 to CX	6E-05	4	62.2	MEOH CHC13	0.07 0.97	Condensers and Carbon Condensers and Carbon	98.70% 99.20%	0.0009 0.008	Calculations Calculations
A	Distillate Receiver from R-1	DR-2	0.003	0.25	62.2	MEOH CHC13	0.0002 0.0006	None None	NA NA	0.0002 0.0006	Calculations Calculations
A	Centrifuge	CEN-1	1.7	2	64.2	MEOH CHC13	1.97 26.5	None None	NA NA	1.97 26.5	Calculations Calculations
A	Dryer	DRY-1 to CX	50	8	72.2	MEOH CHC13	25.06 247.5	Carbon Carbon	90.00% 95.00%	2.51 12.4	Design Evaluations Design Evaluations
A	Filtrate Receiver	FIL-1	0.17	5	69.2	MEOH CHC13	1.95 30.36	None None	NA NA	1.95 30.36	Mass Balance Calcs Mass Balance Calcs
					TOTAL:		673.01		74.57%	171.18	

TABLE 2. COMPLIANCE STRATEGY

Compliance Strategy		Emission Event	Vent I.D.	Flowrate (scfm)	Duration (hr)	Annual Uncontrolled Emissions (lb/yr)	Annual Controlled Emissions (lb/yr)	98% Control Required? (Y/N) (a)	Control vent to achieve overall 93% (Y/N) (b)	New Anuual Emissions (lb/yr) (c)
Batches/yr: 75		MeOH Charge to Weigh Tank	WT-1	0.9	0.25	10.50	10.50	N	N	10.50
Carbon Control Eff.		Fermenter Charge and Purge	Ferm-1	133	12.25	750.00	750.00	N	N	750.00
MeOH: 90.00% CHC13: 95.00%		Ferm Mix Charge to Holding Tank	TK-1	2.21	1.2	6.00	6.00	N	N	6.00
		Charge Organic Phase to Hold Tank		0.64	1	10.50 167.25	10.50 167.25	N N	N N	10.50 167.25
		Charge Aqueous Phase to Hold Tank		2.5	1	2.25	2.25	N	N	2.25
		Strip Aqueous Phase		0.1	3	2.25	2.25	N	N	2.25
		Charge to Concentrate Receiver		0.03	20	277.50 20.25	277.50 20.25	N	N	277.50 20.25
		Extraction		0.8	30	90.00 13,912.50	31.50 5,823.75	See below See below	Y (d) Y (d)	3.15 582.37
		Concentration of Organic		0.5	20	682.50 9,292.50	5.25 52.50	See below See below	Y Y	5.25 52.50
		Distillate Receiver from EVAP		0.0003	20	0.03 0.98	0.00 0.00	See below See below	Y Y	0.00 0.00
		Reactor Charge with Solvent		0.7	0.5	12.00 160.50	0.13 1.20	See below See below	Y Y	0.13 1.20
		Reactor Heatup		0.00006	4	5.25 72.75	0.07 0.60	See below See below	Y Y	0.07 0.60
		Centrifuge		1.7	2	147.75 1,987.50	147.75 1,987.50	See below See below	Y Y	14.77 198.75
		Dryer		50	8	1,879.50 18,562.50	188.25 930.00	See below See below	Y Y	188.25 930.00
		Filtrate Receiver		0.17	5	146.25 2,277.00	146.25 2,277.00	See below See below		14.62 227.70

Compliance Strategy		Emission Event	Vent I.D.	Flowrate (scfm)	Duration (hr)	Annual Uncontrolled Emissions (lb/yr)	Annual Controlled Emissions (lb/yr)	98% Control Required? (Y/N) (a)	Control vent to achieve overall 93% (Y/N) (b)	New Anuual Emissions (lb/yr) (c)
		Distillate Receiver from R-1		0.003	0.25	0.02 0.05	0.02 0.05	N N	N N	0.02 0.05
		TOTALS				50,476.06	12,838.31			3,465.94
										93.13%

Gray boxes: Not currently controlled or require additional control

(a) Whether or not these requirements apply to the vent is determined using the TRE equation.

(b) Which vents to control (in addition to the vents already controlled) to achieve an overall HAP reduction of 93 percent is a judgement call.

(c) New annual emissions estimated by routing streams not currently controlled or streams that require additional control to a carbon adsorber which achieves 90 and 95 percent reduction of methanol and chloroform, respectively.

(d) This stream is currently controlled by a condenser. In order to achieve the required 93 percent overall reduction of HAPs the outlet gas will be routed to a carbon adsorber.

TABLE 3. COMPLIANCE STRATEGY

Emission Event	Pollutant	HAP (lb/yr)	Total HAP LOADING (lb/yr) (a)	HAP (lb/batch) (b)	Duration (hr/batch)	Total HAP sent to CA (lb/hr)	Batch Time (hrs) (d)
MeOH Charge to Weigh Tank					0.25		0.25
Fermenter Charge and Purge					12.25		12.5
Ferm Mix Charge to Holding Tank					1.2		13.7
Extraction	MeOH CHC13	31.50 5,823.75	5855.25	78.07	30	2.60	43.7
Charge Organic Phase to Hold Tank					1		44.7
Charge Aqueous Phase to Hold Tank					1		45.7
Strip Aqueous Phase					3		48.7
Concentration of Organic	MeOH CHC13	53.10 1,053.75	1106.85	14.76	20	0.74	68.7
Charge to Concentrate Receiver					20		88.7
Distillate Receiver from EVAP	MeOH CHC13	0.02 0.08	0.101	0.00	20	0.00	108.7
Reactor Charge with Solvent	MeOH CHC13	1.30 23.40	24.7	0.33	0.5	0.66	109.2
Reactor Heatup	MeOH CHC13	0.64 11.52	12.16	0.16	4	0.041	113.2
Distillate Receiver from R-1	MeOH CHC13				0.25		113.45
Centrifuge	MeOH CHC13	147.75 1,987.50	2135.25	28.47	2	14.24	115.45
Dryer	MeOH CHC13	1,882.50 18,600.00	20482.5	273.10	8	34.14	123.45
Filtrate Receiver	MeOH CHC13	146.25 2,280.00	2426.25	32.35	5	6.47	128.45

(a) requires combining multiple HAPs from single emission episodes in order to estimate total HAP to the control device
(b) estimated on a batch basis by dividing the annual amount by the number of batches in a year (75)
(c) the emissions profile must include average HAP loading (lb/hr) versus time for all emission episodes routed to the device (d) the rolling batch duration was used to account for the entire length of the batch in the emissions profile

Q and A

Q. ***Why are there two types of testing conditions - absolute worst-case and hypothetical worst-case?***

A. *The EPA regulations allow the owner/operator the flexibility to define worst-case in terms of HAP load, HAP mass loading rate, or other factors relating to the operation of the control device. Hypothetical worst-case allows the owner/operator to simulate the worst-case conditions, in the event that it is very difficult to find a period when the device actually is under worst-case conditions without artificially staging the test and perhaps causing significant interruptions in production.*

Q. ***Are there any restrictions on my operation based on the type of performance test I conduct?***

A. *Yes; the owner or operator cannot operate the facility under conditions that are worse than the conditions under which the performance test was conducted. If "worst-case" conditions were properly identified in the test design, however, there should not be many, if any, instances where this occurs. Recall that a violation of an operating limit does not necessarily constitute a violation of an emission standard, except for condensers. In fact, the owner/operator may choose to preset multiple parameter levels to account for variation in batch emission streams. The owner/operator has the opportunity to review operating logs during periods of exceedances to determine if operating conditions are different from those under which the device was tested. If this is the case, and the owner/operator has preset multiple parameter levels to account for these variable periods, the exceedance will not count as a violation.*

What are Acceptable Previous Test Results?

Previous test results are acceptable for compliance demonstrations if they were:

- Performed using acceptable test methods (as listed in Table 8-2)
- Performed over conditions typical of appropriate worst case as listed in Table 8-3 for process vents, reasonable maximum filling rate for tanks, and representative <u>manufacturing process</u> operation and representative <u>wastewater treatment</u> operation for wastewater sources.

What are the TOC Alternative Standards & Outlet TOC Standards for Compliance Demonstration for Process Vents, Storage Tanks, and Wastewater Sources?

Total Organic Compounds, TOC, are measured as the sum concentration of all organic compounds in a gas stream. The rule makes reference to two TOC standards - the **Alternative Standard** and, for the sake of discussion here, the **Outlet TOC Standard**. A comparison is shown below in Table 8-4.

The **Outlet TOC Standard** can be considered a surrogate of demonstrating compliance with the percent reduction standard, because it allows an owner/operator to show initial compliance by measuring TOC. For demonstrating on-going compliance, the owner/operator can set operating parameters, or continue to monitor TOC directly with a CEM. The **Alternative Standard**, however, “locks” the owner/operator into monitoring TOC with a CEM for on-going compliance if the owner/operator continues to choose the alternative standard option for compliance.

Table 8-4. Comparison of the Alternative Standard and the Outlet TOC Standard

	Alternative Standard	Outlet TOC standard
Standard	for combustion control devices, $\leq$20 ppmv TOC and $\leq$20 ppmv hydrogen halides/halogens[1];	$\leq$20 ppmv TOC and $\leq$20 ppmv hydrogen halides/halogens
	for noncombustion, <50 ppmv TOC and <50 ppmv hydrogen halides/halogens	$\leq$ 50 ppmv TOC and < 50 ppmv hydrogen halides/HCl
Standard is an option for	**storage tanks and process vents**	wastewater streams and process vents
Standard applies to	**control device**	process vents or wastewater stream
Initial compliance demonstration requirements	Use a CEM to meet TOC and HCl monitoring requirements in §63.1258(b)(5) by the initial compliance date.[2]	Use methods in 63.1257(b) to demonstrate 20 ppmv TOC
Monitoring on-going compliance	Continue TOC monitoring and hydrogen halide and halogen every 15 minutes during operation	Meet monitoring requirements in §63.1258(b)(1)-(4). Owner/operator sets monitoring parameters (e.g., combustion temp.) during initial performance test.

1. In lieu of achieving the 20 ppmv outlet hydrogen halide and halogen concentrations the owner/operator may control post-combustion device HCL emissions by 95%.

2. When using a post-combustion control device to comply with the 95% HCl control efficiency option available under the alternative standard, the owner/operator may use methods in 63.1257(b) to demonstrate HCl compliance in lieu of a CEM.

NOTE: When a combustion device is used to comply with the outlet concentration standard, the actual TOC, organic HAP, and hydrogen halide and halogen must be corrected to 3 percent oxygen if supplemental gases are added to the vent stream or manifold. The applicable equation for calculating the corrected concentration is at 63.1257 (a)(3).

8.6 Compliance Demonstration Procedures for Storage Tanks

Compliance demonstration procedures for storage tanks are listed in 1257(c). Procedures are given to comply with the following types of standards:

- Floating roof
- Percent reduction
- Alternative standard
- Vapor balancing

To determine mass emission rates and percent reduction, compliance demonstrations are done by conducting ***design evaluations***, (see page 8-10) or ***performance testing*** (see page 8-12). Compliance with the TOC alternative standard is accomplished using ***TOC monitoring*** (see page 8-22). These methods are identical to those described in section **8.5** for process vents. Please note that design evaluations can be used for calculating controlled emissions from storage tanks regardless of the quantity of emissions controlled (i.e., there is no <10 TPY restriction). Floating roof demonstration requirements are listed in the HON, § 63.119(b-d) and §63.120(a-c). Because few pharmaceutical facilities use floating roofs, a detailed discussion is not included here. The reader is referred to the HON Inspection Tool (EPA - 305-B-97-006, September, 1997). The reader is referred to Appendix HON for more details. A separate compliance demonstration for tanks is not necessary for a storage tank if emissions are routed to a control device being used for process vents, and a compliance demonstration will be done in accordance with the process vent regulations.

If the owner or operator uses the vapor balancing option, the following requirements apply. Railcars or tank trucks that deliver HAPs to an affected source must be reloaded at a facility that either:
1) controls emissions via a closed vent system with a device that reduces inlet emissions of HAP by at least 90% or
2) controls emissions by using a vapor balancing system to route the collected HAP vapor back to the storage tank from which the material was originally transferred.

If option 1 is used to control emissions, the owner or operator needs to secure information from the reloading/cleaning facility that demonstrates compliance with the 90% reduction standard. Either performance testing or design evaluations can be done. If option 2 is used, the owner or operator must keep records that show what procedures will be followed when reloading and when displacing vapors back to the original storage tank. He/she must document each time the vapor balancing system is used to comply with the standard.

8.7 Initial Compliance Demonstration Procedures for Wastewater Sources

The initial compliance demonstration procedures as listed in §63.1257(e) are basically separated into 3 parts:

- Determination of wastewater HAP concentration and load as it pertains to wastewater applicability criteria,
- Design Evaluation and Performance Test procedures for demonstrating compliance with wastewater treatment standards, and
- Design Evaluation and Performance Test procedures for demonstrating compliance with APCD requirements.

The following discussion will address these three items.

How do I Calculate the Annual Average Concentrations and Load?

This calculation determines if a wastewater meets applicability criteria (four affected source categories), and should be performed using either:

- Analytical techniques listed in 63.1257(b) (10) i- iv . They are:
  - Method 305-Fm (Fm = Fraction measured = theoretical proportion in wastewater that volatilizes into air; as listed in Table 8 in the rule);
  - Methods 624, 625, 1624, 1625, 1666, or 1671;
  - Method 8270 or 8260;
  - Other EPA Methods validated using Method 301, 40 CFR 63 Appendix A, or "Alternative Validation Procedure for EPA Waste Methods" in 40 CFR 63 Appendix D; or
  - Non-EPA Method validated using Method 301, 40 CFR 63, Appendix A.

  (For any above techniques chosen, prepare a sampling plan documenting procedures for determining recovery efficiency of PSHAPs and SHAPs and incorporating similar sample handling requirements as Method 25D to ensure that losses of organic compounds during sampling are minimized.)
- Calculation techniques based on process wastewater knowledge, or
- Bench scale or Pilot scale test data.

NOTE: As discussed in Chapter 7, an o/o is exempted from performing wastewater characterizations for applicability determinations if he designates the wastewater stream as affected. If an o/o designates a wastestream as affected, he assumes the wastewater is subject to the standards, and therefore does not need to determine concentration and load annually. Designated streams are subject to the same standards as characterized streams. Wastewater treatment options are limited, however, and do not include treatment to 50 ppmw PSHAP or 520 ppmw SHAP, or using enhanced biological treatment.

How Do I Demonstrate Compliance With the Wastewater Treatment Standards?

If the owner or operator opts to use enhanced biotreatment or a RCRA-regulated unit, neither performance testing nor design evaluations are required. For any other non-biological treatment process, the owner or operator must do performance testing or a design evaluation. For closed biological treatment processes, either performance testing or design evaluations are required. For open biological treatment processes, performance testing is required.

Wastewater Treatment Performance Testing

Wastewater treatment performance testing procedures are given for the following types of treatment standards:

- wastewater concentration limits (noncombustion treatment)
- wastewater mass removal/destruction efficiency limits

Table 8-5 summarizes analytical methods for determining applicability and demonstrating initial compliance for wastewater.

Table 8-5. Summary of Analytical Methods for Wastewater Applicability and Initial Compliance Demonstrations

If you are measuring concentration to...	According to procedures specified in ...	Using...	Then...
Determine characteristics of an affected wastewater stream defined in §63.1256 (a)(1)(i)	§63.1257 (e)(1)	Method 305	Divide the measured concentrations by the appropriate compound-specific Fm factors before comparing the sum to the applicability threshold.
		Any other method, as described in §63.1257 (b)(10)(ii) through (v)	Compare the sum of the measured concentrations directly to the applicability threshold.
Demonstrate initial compliance with the outlet concentration limit in §63.1256 (g)(8)(i) or (9)(i)	§63.1257 (e)(2)(iii)(B)	Method 305	Compare the sum of the measured concentrations directly with the PSHAP and/or SHAP limits.
		Any other method, as described in §63.1257 (b)(10)(ii) through (v)	You may elect to multiply the measured concentrations by the appropriate compound-specific Fm factors before comparing with the PSHAP and/or SHAP limit.
Demonstrate initial compliance with any of the percent mass removal/destruction options in §63.1256 (g)(8)(ii), (9)(ii), (11), (12).	§63.1257 (e)(2)(iii(C) through (G)	Method 305	Divide the measured concentrations by the appropriate compound-specific Fm factors before using to calculate the mass flow rate
		Any other method, as described in §63.1257 (b)(10)(ii) through (v)	Use the measured concentrations directly to calculate the mass flow rates

*Method 305 = Measurement of Emissions Potential if Individual Volatile Organic Compounds in Waste

Q and A

Q. ***If I choose the sampling/analysis option for determining wastewater applicability characteristics, where do I sample and at what frequency and duration ?***

A. *The rule states that the samples must be collected either at the POD or downstream of the POD. If downstream, the resulting HAP concentrations must be corrected to reflect expected values which would occur at the POD. As for the sampling frequency and duration, the only guideline given is that the resulting SHAP/PSHAP concentration and load values are annual averages. In other words, the concentration must reflect the total mass of SHAP/PSHAP constituents delivered to the wastewater stream in a calendar year divided by the total mass of wastewater occurring in the same year. Sampling frequency and duration must be sufficient to calculate a representative average of these parameters. Once the applicability determination is made, it does not need to be revisited unless there are process changes that would change wastewater concentrations and/or loading such that applicability of the rule could change.*

Q and A

Q. ***How is the degradation factor (F_{bio}) calculated and used?***

A. *The degradation factor (F_{bio}) is calculated using the procedures found in Appendix C to Part 63 (Determination of the Fraction Biodegraded in a Biological Treatment Unit). Procedures are given for using F_{bio} in the following 3 biological treatment configurations:*

- *mass destruction/removal efficiency is determined across a biological treatment system only*
- *mass destruction/removal efficiency is determined across a series of treatment processes where the inlet to the equalization tank <u>can be</u> considered the biological treatment system inlet*
- *mass destruction/removal efficiency is determined across a series of treatment processes where the inlet to the equalization tank <u>cannot be</u> considered the biological treatment system inlet*

If hard piping is used to transport wastewater and the equalization tank has a fixed roof/closed vent system vented to an APCD, the inlet to the equalization tank can be considered the biological treatment system inlet. Also, in a general sense, if hard piping is not used to transport wastewater, total plant mass destruction/removal efficiency has to be calculated as the sum of individual treatment process removal efficiencies. Further details on wastewater treatment compliance are given in Appendix WWT.

Q. ***How do I demonstrate compliance for wastewater that is either treated off site or treated on site by a treatment facility not owned or operated by the source ?***

A. *The wastewater treatment plant O/O is responsible for the bulk of the demonstration procedure. However, the O/O of the wastewater source must perform the following:*

- *Demonstrate compliance with vapor suppression standards for all equipment used to transport wastewater prior to treatment, and*
- *Submit a notice to the treatment facility and keep a record for himself stating the wastewater contains organic HAP and must be treated in accordance with this rule. The notice must be submitted for each shipment, or if shipment is continuous, then an initial notice and whenever there is a change in the required treatment, and*
- *Additionally, though not required, it may be prudent for the owner/operator to:*

Verify that the treatment facility is certified to manage this waste in accordance with:

1. Wastewater treatment and emissions regulation of this rule, §63.1256 (b)-(i) (vapor suppression standards, emissions control device standards, wastewater treatment standards, and delay of repair standards), or

2. Subpart D of this part, if an alternative emissions limitation has been granted to the source in accordance with Subpart D (Regulations Governing Compliance Extensions for Early Reductions of HAPs), or

3. §63.6(g) - Use of an alternative non-opacity emission standard

Wastewater Treatment Design Evaluations

Wastewater treatment design evaluations can be used to demonstrate compliance for nonbiological and closed biological treatment systems. (If open biological treatment is being used, then performance testing must be performed to demonstrate compliance.) A wastewater design evaluation should be completed according to §63.1257(e)(2)(ii).

The following guidelines are given:

- Base the design evaluation on operation at a wastewater flow rate and a concentration under which it would be most difficult to demonstrate compliance, and
- For closed biological treatment processes, use a mass balance conducted over the entire unit, including any emission control devices, to determine mass removal/destruction rates.

Q and A

Q. ***How do I demonstrate initial compliance with vapor suppression standards?***

A. *There are few initial compliance demonstration requirements listed in the rule for vapor suppression standards. However, in the Reporting Requirements listed in § 63.1260(f), Requirements for Notification of Compliance Status Report, the report must include where appropriate, among other items, a list of monitoring devices, monitoring frequencies, and values of monitored parameters established during the initial compliance demonstrations. Therefore, the types of I & M procedures required for wastewater management units (i.e., vapor suppression inspection routines- discussed in Section 7.4 and in Table 9-3) must be established and documented at the time of the initial compliance demonstration period. Certain vapor collection systems, closed-vent systems, fixed roofs, covers, and enclosures must receive an initial inspection in accordance with Method 21 to determine whether there are any leaks (readings greater than 500 ppm above background), per 63.1260(h)(2)(i)(A). Vapor collection systems operating under negative pressure are not subject to this requirement. The reporting provisions in 63.1260(f)(2) require that the results of the inspection be submitted in the notification of compliance status report.*

Note on choosing the biological demonstration procedure:

Closed Biological - If the O/O chooses closed biological treatment and demonstrates compliance using §63.1257(2)(iii)(E) or (F) (i.e., using a site-specific F_{bio}), then the treatment process is not subject to wastewater storage tank or surface impoundment vapor suppression standards.

Open Biological - If the O/O chooses open biological treatment, then the treatment process need not be covered and vented to a control device. As noted above, if compliance is being demonstrated by §63.1257(2)(iii)(E) or (F), the treatment process is not subject to wastewater storage tank or surface impoundment vapor suppression standards.

How Do I Demonstrate Compliance With the APCD Standards?

As with the wastewater treatment standards, the owner or operator must conduct performance testing or design evaluations to demonstrate that the air pollution control devices are operating efficiently and achieving the necessary control. The compliance demonstration requirements are summarized in Table 8-6.

Table 8-6. Compliance Demonstrations for APCDs used for Wastewater Sources

Compliance Demonstration for APCDs	Standard	Summary of Procedure
Performance Testing 63.1257(e)(3)(i)	95% reduction 20 ppmv outlet limit	Follow same general performance test procedures of 63.1257(e)(2)(iii)(A)(1)-(4): - demonstrate during representative process operating conditions - demonstrate during representative treatment process operating conditions - supplement perf. test results with modeling or engineering data, if necessary, to demonstrate performance over a range of conditions - sample at inlet and outlet of APCD - minimum of 3 1-hr test runs - Method 18 or other method validated via Method 301 - calculate concentration of TOC or total organic HAP (correct to 3% oxygen if combustion device) - calculate mass rate - compare mass destruction efficiency to 95% standard or compare outlet concentration to 20 ppmv standard
Design Evaluation	95% reduction or 20 ppmv outlet limit	Follow design evaluation requirements as described on page 8-10 and 8-11 of this chapter
Flare Demonstration 63.1257(e)(3)(iii)	Flare	Operate flare as provided under 63.11; no performance testing or TOC testing required for demonstration

Note: no compliance demonstration is necessary if APCD is a boiler or process heater with design heat input capacity of 44 megawatts or greater, a boiler or process heater in which the emission stream is burned with the primary fuel, or a RCRA-regulated unit.

8.8 Submittal of Compliance Demonstrations for All Affected Sources

The O/O must submit supporting data and analyses used in compliance demonstrations in either the Precompliance Report or in the Notice of Compliance Status Report, depending on the nature of the information being submitted. The following information must be included:

Table 8-7. COMPLIANCE DEMONSTRATION PLANS AND REPORTS

Precompliance Report	Notice of Compliance Status Report
Submit at least 6 months prior to compliance date	Submit no later than 150 days after the compliance date
Include**:** **Data and rationale** used to support an engineering assessment to calculate uncontrolled emissions from process vents **Data and information** used to support determination of annual average concentration in wastewater by process simulation**.** **Bench or pilot data** used to determine annual average concentration in wastewater**.**	Include: (1) The results of any **applicability determinations, emission calculations, or analyses used to identify and quantify HAP emissions** from applicable sources. (2) The results of **emissions profiles, performance tests, engineering analyses, design evaluations, or calculations used to demonstrate compliance.** For performance tests, results should include descriptions of sampling and analysis procedures and quality assurance procedures. (3) **Descriptions of monitoring devices, monitoring frequencies, and the values of monitored parameters** established during the initial compliance determinations, including data and calculations to support the levels established. (4) **Operating scenarios**. (5) **Descriptions of worst-case operating and/or testing conditions** for control devices.

NOTE: Additional information, other than compliance demonstration data, is required to be included in the above reports (See Chapter 13).

Using Operating Scenarios in Compliance Demonstrations

The term “operating scenario” is defined in 63.1251. In general, it is the collection of information that describes how a PMPU is operating at any one time to produce a product. It includes a description of what process equipment is used, what the emissions points are, what control standards the process is subject to, how the emissions are being controlled to the required standard, what monitoring is being conducted, as well as any other information that needs to be gathered to demonstrate compliance. A more complete list is on page 12-4. Documenting this information allows owners/operators to track all the elements that contribute to a compliance demonstration.

Chapter 9
Monitoring Procedures

9.1 Overview

The MACT regulations require that affected sources conduct monitoring to verify on-going continuous compliance. Monitoring can be done either by continuously measuring emission reductions directly or by continuously measuring a site-specific operating parameter(s). The site-specific operating parameters are established during the initial compliance demonstration. For devices that control greater than 1 ton per year, the operating parameters are monitored no less than every 15 minutes while the control device is operating. For devices that control less than 1 ton per year, daily verification that the device is operating properly is sufficient for monitoring purposes. An important aspect of a facility's monitoring program is the determination of the appropriate averaging period for each parameter measurement. An operator can choose to use either a daily (24-hour) or a block averaging period that covers the length of a process. For equipment leaks, periodic monitoring is conducted through implementation of the LDAR program (See Chapter 6). Monitoring requirements for the mass emissions limit standard are discussed in this chapter; monitoring requirements for those facilities using the pollution prevention option are covered in Chapter 10.

Chapter 9 at a Glance

9.2 Structure of the Regulation

The monitoring section of the Pharmaceutical MACT is structured as follows:

§63.1258(a)	Sources shall provide evidence of continued compliance
§63.1258(b)	Monitoring for control devices
§63.1258(c)	Monitoring for emission limits
§63.1258(d)	Monitoring for equipment leaks
§63.1258(e)	Pollution prevention

§63.1258(f) Emissions averaging

§63.1258(g) Inspection and monitoring of waste management units and treatment processes

§63.1258(h) Leak inspection provisions for vapor suppression equipment

NOTE: Because this document contains specific chapters on equipment leaks, pollution prevention, and emissions averaging, the monitoring provisions relating to those topics will be covered in those specific chapters.

9.3 Basis for Monitoring Control Devices

As noted in the overview, owners and operators must use some sort of monitoring to confirm that the control devices being used are actually achieving the required reductions.

Instead of measuring HAP levels and calculating emission reductions, however, the owner or operator can establish parametric monitoring levels, which if met, indicate that the control device is operating to achieve the required emission reduction. These parameters could include, for example: temperature (in the case of condensers), liquid flow rates (for liquid scrubbers), time interval between carbon replacement (for non-regenerative carbon adsorbers). The table below describes the basis for selecting monitoring parameters for different kinds of monitoring programs. The different kinds of monitoring programs are based on the size of the control device (i.e., quantity of HAPs controlled per year), or the mode of operation (i.e., batch or continuous), or the whether the alternative TOC standard will be used.

Table 9-1. BASIS FOR MONITORING PARAMETERS

Nature of Process or Control Device	Basis for Establishing Monitoring Parameters
Devices controlling **less than 1 tpy HAP emissions before control**	Monitoring consists of **daily verification** that device is operating properly. Verification may be on a per batch basis. The verification method is determined by the owner/operator and must be identified in the Precompliance Report.
Devices controlling **>1 tpy but < 10 tpy**	Establish **parametric monitoring levels based on design evaluation** conducted for the initial compliance demonstration. IF a performance test was conducted, follow information directly below for devices controlling ≥ 10 tpy.
Devices controlling ≥ **10 tpy**	Establish maximum or minimum **parametric value(s) based on the average of values from each of three performance test runs.** Test results are not required over the entire operating range. If the O/O wants to set levels for conditions other than worst case, information from engineering assessments and manufacturer's recommendations can be used to supplement the performance tests. This information must be submitted in the Precompliance Report for approval.

Nature of Process or Control Device	Basis for Establishing Monitoring Parameters
Devices controlling emissions from **batch processes** (for devices controlling $\geq$ 10 tons/yr)	If owner/operator selects to control more than one batch emission episode, then use the initial compliance demonstration to establish either: a) a **single parametric level for the batch process**, or b) **separate parametric levels for each batch emission episode or groups of emission episodes.** If separate monitoring levels are chosen (b), the operator must record which episode is being monitored and when the parameter being monitored changes levels. The operator must record at least one reading at the "new" level for the monitored parameter(s).
Devices controlling emissions from process vents and/or tanks for which the O/O has selected the **"alternative standard"**	Use direct measure of **TOC, and hydrogen chloride and halogens** (if present in the gas stream) as indicated by a CEM. (See Page 9-6 for additional details)

9.4 Establishing Operating Parameters for Monitoring Control Devices

Table 9-2 lists the required monitoring parameters for emissions control devices, provides a monitoring schedule, and lists other instructions and specifications particular to each kind of control device, such as calibration schedules.

The regulations also allow an owner or operator to request approval to monitor alternative parameters for control devices. This request can be made by following the procedures in §63.8(f) or included in the Precompliance Report.

For devices controlling less than 10 TPY, the parameter values can be determined from the design evaluation conducted as part of the initial compliance demonstration. For devices controlling at least 10 TPY, performance testing will be required for the initial compliance demonstration. The owner or operator can use engineering assessments and manufacturer's recommendations to supplement performance tests, in establishing the parametric monitoring level(s). The owner or operator must describe in the Precompliance Report:

- rationale for the specific level for each parameter, including data and calculations used to establish level(s)
- why the level(s) indicate proper operation of the control device

The Administrator must approve the determination of parametric monitoring levels as outlined in the Precompliance Report.

Table 9-2. OPERATING PARAMETERS FOR DEVICES CONTROLLING > 1 TPY

If the control device used is a ...,	For each device, must establish the following operating parameter(s)...,	And monitor parameters on the following schedule.[*]	Other Instructions and Specifications
liquid scrubber	1) minimum scrubber liquid flow rate or pressure drop, based on conditions anticipated under worst-case conditions, 2) **if** caustic used, minimum pH of effluent liquid	1) every 15 minutes while scrubber is operating, 2) once a day[1]	Device monitoring flow rate or pressure drop must be certified by manufacturer to be accurate within ± 10 percent of design flowrate or maximum pressure drop measured. Calibrate monitoring device annually.
condenser	maximum condenser outlet gas temperature	every 15 minutes while condenser is functioning in achieving the required HAP reduction[2]	Temperature monitoring device must be accurate to within ± 2% of temp. or within ± 2.5EC, whichever is greater. Calibrate monitoring device annually.
regenerative carbon adsorber	under absolute worst-case conditions - 1) minimum regeneration frequency, 2) minimum temp. to which bed is heated during regen., 3) maximum temp. to which bed is cooled, measured within 15 minutes of completing cooling phase, and 4) minimum regen. stream flow	record 4 regeneration cycle characteristics for each cycle	Use temp. monitoring device that is accurate to within ± 2% of temp. or within ± 2.5EC, whichever is greater. Use stream flow monitoring device accurate to within ± 10 percent of the established value. Calibrate temp. and flow monitoring devices annually. Conduct yearly check for bed poisoning.
non-regenerative carbon adsorber	maximum time interval between replacement, based on anticipated worst-case conditions	at each replacement	
flare	presence of pilot flame(s)	every 15 minutes while the flare is functioning	
thermal incinerator	maximum temperature of gases exiting the combustion chamber	every 15 minutes while the device is functioning	Monitoring device must be accurate to within ± 0.75% of temp. or ± 2.5EC, whichever is greater. Calibrate monitoring device annually.

If the control device used is a ...,	For each device, must establish the following operating parameter(s)...,	And monitor parameters on the following schedule.*	Other Instructions and Specifications
catalytic incinerator	minimum temperature of gas stream immediately before the catalyst bed and minimum temperature difference across the catalyst bed	temp. of gas stream immediately before and after the catalyst bed, every 15 minutes while the device is functioning	Monitoring device must be accurate to within ± 0.75 % of temp. or ± 2.5EC. Calibrate monitoring device annually.
process heater and boiler	minimum temperature of gases exiting combustion chamber EXEMPT IF ALL VENT STREAMS INTRODUCED WITH PRIMARY FUEL OR DESIGN HEAT INPUT CAPACITY IS 44 MEGAWATTS OR GREATER.	every 15 minutes while the device is functioning	Monitoring device must be accurate to within ± 0.75 % of temp. or ± 2.5EC. Calibrate monitoring device annually.

* Monitoring frequencies listed are minimum required frequencies.
1. Liquid scrubbers used to control HCl emissions during periods of planned routine maintenance for centralized combustion control devices (CCCD) must be monitored once a day to ensure scrubber effluent pH $\geq$ 9.
2. This also applies to condensers receiving HAP emissions during periods of planned routine maintenance for a CCCD.

Using a Continuous Emissions Monitor for HAP or TOC

As an alternative to the parameters listed above, an owner or operator may elect to install a continuous emissions monitoring system (CEMS) to monitor:

- the outlet HAP concentration, OR
- both the outlet TOC concentration and outlet hydrogen halide and halogen concentration.

Monitoring must be conducted every 15 minutes while the control device is functioning in achieving the HAP removal required by the regulations. If the owner or operator knows that the emission stream does not contain hydrogen halides or halogens, it is not necessary to monitor for them. The monitor must meet the performance standards in Part 60, specifically Performance Specification 8 or 9 of Appendix B. The monitor must be installed, calibrated, and maintained according
to the regulations at §63.8 - Monitoring requirements in General Provisions. The text of Part 60, Appendix B- Performance Specification 8 and 9, and the text of §63.8 are provided in Appendix PS of this document. The QA/QC plan must include provisions for quarterly cylinder gas audits, at a minimum.

Monitoring alternative parameters

If an owner or operator prefers to monitor parameters other than those listed in Table 9-2, he/she may submit a request for approval, following the procedures in §63.8(f) (Monitoring requirements - Use of an alternative monitoring method). For example, an owner/operator could examine the manufacturing process to determine if any parameters, or combinations of parameters, such as raw materials, feed rates, operating pressures, process type, etc., could be monitored to demonstrate continuing compliance.

Monitoring for the "alternative" standard

Monitoring for the alternative standard requires measuring the outlet TOC concentration and the outlet hydrogen halide and halogen concentration every 15 minutes while the APCD is functioning. (Operate a TOC monitor that meets Performance Specifications 8, 9, or 15 of 40 CFR Part 60 Appendix B. Perf. Spec. 8 - QA and calibration criteria for VOC CEMs such as Method 25A instruments; Perf. Spec. 9 - QA and calibration criteria for GC analyses such as those called for by Method 18.)

For monitoring HCl, the owner/operator has some options:

- use a FTIR CEMS that meets performance specification 15 of appendix B of Part 60, or
- any other CEMS capable of measuring HCl. If a Performance Specification has not been promulgated in appendix B of Part 60 for the subject monitoring method, the owner/operator must prepare a monitoring plan and submit it for approval per §63.8.
- for monitoring halogenated vent streams controlled by a combustion device followed by a scrubber, the owner/operator may elect to monitor scrubber operating parameters that demonstrate the HCl emissions are reduced by at least 95% by weight, in lieu of operating a CEMS.

It is not necessary to measure hydrogen halide and halogen if the owner or operator knows that the emission stream does not contain them.

If the owner/operator is using the alternative standard (emissions routed to device that achieves 20 ppmv TOC and 20 ppmv hydrogen halides and halogens (50 ppmv TOC/ 50 ppmv hydrogen halides/halogens if non-combustion device is used), and **supplemental gases** are added to the vents or manifolds, the regulations impose some specific instructions for monitoring.

The owner/operator must:

- For combustion devices, correct for supplemental gases (correct to 3% oxygen as directed by §63.1257 (a)(3)(i)) or track residence time and firebox temperature. Monitoring residence time can be done by measuring flowrate into the combustion chamber:
  - If complying with the alternative standard in lieu of **95% reduction for affected existing process vents and/or storage tanks**, minimum residence time is **0.5 seconds** at minimum temperature of **760º C**.
  - If complying with the alternative standard in lieu of **98% reduction for affected new process vents and/or storage tanks**, minimum residence time is **0.75 seconds** at minimum temperature of **816º C**.
- For noncombustion devices that are used to control emissions from dense gas systems (conveyance system is

operated to limit oxygen levels to below 2 percent), the owner or operator can monitor flowrate as detailed below.

- For noncombustion devices that are used to control emissions from systems <u>other than</u> dense gas systems, 63.1257 (a)(3)(ii) provides the equation for correcting the actual concentration for supplemental gases. Process knowledge and representative operating data can be used to determine the fraction of the flow due to supplemental gases.

Measuring flowrate for dense gas systems

As part of complying with the alternative standard, if the owner or operator opts to monitor flowrate in noncombustion devices controlling emissions from dense gas systems, the following provisions apply:

1. Determine annual emissions entering the control device, based on the most representative emissions inventory data submitted within the five-year period before the Notification of Compliance Status report is due.

2. Install and operate a monitoring system for measuring system flowrate, recording the flowrate into the control device at least once per hour. Calculate the system flowrate as the average of all values measured during each 24-hour operating day. The monitoring device must be accurate to within 5 percent of the system flowrate setpoint. It must be calibrated annually.

3. Calculate the system flowrate setpoint at which the average concentration is 5,000 ppmv TOC using the following equation :

$$Fs = \frac{721xEan}{5,000}$$

where

Fs = system flowrate setpoint, scfm

Ean = annual emissions entering the control device, lbmols / yr

NOTE: These first three steps actually are part of the initial compliance demonstration.

4. Recalculate the system flowrate setpoint once every five years using the annual emissions from the most representative inventory data submitted during the past five years. If the emissions inventory data is calculated using procedures other than those at §63.1257(d) for initial compliance demonstrations for process vents, 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.

5. Submit the initial calculation in the Notification of Compliance Status report; submit the recalculated values in the next Periodic report after each

Supplemental gases *- 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 ppm 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.*

recalculation. In the Notification of Compliance Status report, if desired, the owner or operator can specify a maximum daily average operating flowrate limit above the flowrate setpoint and a reduced outlet concentration limit corresponding to that limit. Use the following equation to correlate the elevated flowrates and the outlet concentration limits:

$$Ca = \frac{Fs}{Fa} x50$$

where:

Ca = adjusted outlet concentration limit, dry basis, ppmv

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

Fs = system flowrate setpoint, scfm

Fa = actual system flowrate limit, scfm

6. Each time that a new operating scenario is implemented, evaluate the volumetric flowrate of supplemental gases and the volumetric flowrate of all gases, based on process knowledge and representative operating data. Include the procedures used to evaluate the flowrates and the resulting correction factor in the Notification of Compliance Status report and in the next Periodic report after the operating scenario changes.

Monitoring closed vent systems with bypass lines

If a closed vent system has bypass lines that could divert a vent stream from a control device, the owner/operator must do one of the following:

C install, calibrate, maintain, and operate a flow indicator that indicates whether vent stream flow is present, at least once every 15 minutes. The flow indicator must be installed at the entrance to any bypass line that could divert the gas stream to the atmosphere. The owner/operator must keep hourly records of whether the flow indicator was operating and whether any diversions were detected. He/She must also record the times and durations of any periods where the stream was diverted or when the flow indicator was not operating.

OR

C secure the bypass line valve in the closed position with a car seal or lock and key. He/She must conduct a monthly visual inspection to ensure that the valve is closed and the vent stream is not diverted. The owner/operator must record that the monthly inspection was done, as well as document any occurrences of broken seal mechanisms, changes in the position of the valve, or periods when the key is checked out (if a lock and key system is used).

9.5 Establishing Averaging Periods for Monitoring

The owner/operator must establish averaging periods for parametric monitoring levels according to the following:

C On a daily (24 hour) or block average basis
  - a 24 hour period can be from midnight to midnight or any other continuous 24 hour period,
  - a block average is equal to the period of time, at a

maximum, from beginning to end of a batch process. A block may range from a very short period of time (e.g., 10 minutes) to a long range of time (e.g., two weeks), depending on the nature of the batch process.

- A daily or block average is calculated as the average of all values for a monitored parameter recorded during the operating day or block.

    - Monitoring data from control devices not operating (as indicated by no flow) is **not included** in the average
    - To identify periods of inoperation, the owner/operator must operate a flow indicator at either the inlet or outlet of the control device. The flow indicator must be calibrated annually.

The averaging period that will be used, operating day or block, must be defined in the Notification of Compliance Status Report.

9.6 Monitoring for the Mass Emissions Limit Standard - 900 kg/yr (2,000 lb/yr)

Owners/operators electing to use the 900 kg and/or 1,800 kg/yr limit emission standard for process vents must demonstrate on-going compliance. **For each process** for which the mass emission standard will be applied, the owner/operator must daily calculate a 365-day rolling summation of emissions. Remember that this option limits emissions from process vents using this option to 1,800 kg/yr total per facility, for existing sources. For new sources, the total facility limit is 900 kg/yr, with no PMPU limit.

An owner/operator may comply with the mass emissions limit using a combination of controlled and uncontrolled vents. If vents are controlled, initial and on-going compliance demonstrations (i.e., performance testing and monitoring) must be conducted for those vents. If a centralized combustion device is being used to achieve the mass emissions limit standard, the owner or operator must calculate the controlled emissions during periods of planned routine maintenance assuming the control efficiency is 93 percent.

If an owner/operator elects to switch from the 93% or 98% reduction requirement to the 900 kg/yr method, the rolling summations must include emissions from the past 365 days (i.e., include data from days when the owner/operator was using the 93% or 98% standard). Please note that an owner/operator cannot switch from the 900 kg/yr standard to the percent reduction standard until at least one year has passed.

9.7 Wastewater Monitoring Procedures

The following section presents a brief summary of monitoring requirements for demonstrating on-going compliance with wastewater provisions. As with process vents, storage tanks, and equipment leaks, owners/operators of wastewater facilities at affected sources must provide evidence of continued compliance with the standard. Process operation and associated waste management units must therefore be monitored to ensure on-going compliance.

In addition to the monitoring requirements listed in §63.1258, it is important to review record keeping and reporting requirements that relate to the choice of parameters to be monitored. For example, one of the record keeping requirements for wastewater {§63.1259(b)(6)} is to maintain a record of the initial demonstration of wastewater concentration per POD or process.

The following task list can be used to assist the O/O in developing a list of parameters to monitor:

1. **Determine Inspection and Maintenance procedures for wastewater vapor suppression requirements.** The O/O must implement I & M procedures at the required frequencies for demonstrating continued compliance with vapor suppression standards. These procedures are shown in Table 9-3.

2. **Determine monitoring parameters that are indicators of emissions control.** The O/O must monitor parameters which are indicators of emissions control compliance. These include:

   - APCD operation/performance monitoring parameters, or

   - Alternative parameters - Any parameters needed to calculate emissions based on correlations with performance testing, engineering calculations, design evaluations, etc. These can be alternative APCD parameters (those not listed in the rule) or process operation parameters (raw materials, feed rates, operating temperatures and pressures, process type, etc). These monitoring parameters are the same as those discussed above in section 9.2 - Establishing Operating Parameters for Monitoring Control Devices.

3. **Determine wastewater characterization/treatment monitoring parameters**. Procedures for monitoring on-going compliance with wastewater treatment standards are contained in §63.1258(g).
   For **biological** treatment processes:
   - TSS, BOD, and biomass concentration must be monitored at a frequency approved by the permitting authority. Alternative monitoring parameters may be approved if proposed in the Precompliance report.

   For **non-biological** treatment processes:
   - A statement must be made in the Precompliance Report regarding the parameters that will be monitored.

   For recordkeeping purposes, §63.1259(b)(1) requires recordkeeping for measurements of treatment process parameters.

4. **Establish monitoring frequency and averaging time for each monitored parameter.** Refer to sections 9.3 and 9.4 for information on averaging time and monitoring frequency for parametric and TOC monitors.

Table 9-3. INSPECTION AND MONITORING REQUIREMENTS FOR VAPOR SUPPRESSION

Vapor Suppression Equipment	Inspection and Monitoring Procedure	
	Procedure Description	**Frequency**
All Wastewater Management Units:		
Closed Vent System - Hard Piping*	- Method 21 leak detections - Visible, audible, or olfactory leak detection	- Initially - Annually
Closed Vent System - Ductwork*	- Method 21 leak detections - Visible, audible, or olfactory leak detection	- Initially & annually - Annually
APCD	- Inspect APCD visually for cracks, gaps, tears or holes	- Initially & semi-annually
Tanks:		
Fixed Roof	- Inspect for Improper Work Practices (IWP) such as leaving open any access doors or Control Equipment Failures (CEF) such as inspect for cracks, gaps, or breakage in cover, lid, joint, door or gasket. - Inspect APCD and Closed Vent System as discussed above under "All Wastewater Management Units" -Inspect roof, cover and opening visually for leaks.	- Initially & semi-annually -(see above) - Initially & semi-annually
Internal Floating Roof	- Visual observations for wear in material - Inspect for IWPs and CEF as listed in §63.1256(b)(8)(i)(A)-(H) - Inspect for cracks, gaps, or breakage in cover, lid, joint, door or gasket.	-per .120(a)2&3 -per .120(a)2&3 - Initially and semi-annually
	- Seal Gap Measurements per §63.120(b)(2)(i) - (b)(4) - Primary seal gaps - Secondary seal gaps - If the floating roof is determined to be unsafe, measure seal gaps or inspect wastewater tank, or empty and close the tank per §1256(b)(6)(ii) within 45 days - Inspect for IWPs and CEFs as listed in §1256(b)(8)(i)(A)-(H) - Inspect for cracks, gaps, or breakage in cover, lid, joint, door or gasket.	- Initially & once every 5 years (annually if no secondary seal) - Initially & semi-annually - Within 30 days of determination - Initially & semi-annually - Initially & semi-annually

Table 9-3. INSPECTION AND MONITORING REQUIREMENTS FOR VAPOR SUPPRESSION

Vapor Suppression Equipment	Inspection and Monitoring Procedure	
	Procedure Description	**Frequency**
Surface Impoundments:		
Cover or Floating membrane	- Inspect for IWPs such as leaving open any access hatches and CEFs such as joint, lid, cover or door has a crack, gap or is broken - Inspect APCDs and Closed Vent System as listed above - Inspect cover and openings visually for leaks	- Initially & semi-annually - Initially & semi-annually - Initially & semi-annually
Containers:		
Covers	- Inspect for IWPs such as leaving open any access hatch and CEFs such as any time cover or door has a gap or crack or is broken - Inspect APCDs and Closed Vent System as listed above - Inspect covers or openings visually for leaks	Initially & semi-annually
Individual Drain Systems:		
Cover	- Inspect for IWPs such as leaving open any access hatch and CEFs such as any time a cover or door has a gap or crack or is broken - Inspect APCDs and Closed Vent System as listed above	Initially & semi-annually
Water Seal	- Verify that sufficient water is present	Initially & semi-annually
Cap or Plug	- Inspect for cracks, gaps, or holes in cap or plug	Initially & semi-annually
Junction Box	- Inspect for cracks, gaps, or holes in cover	Initially & semi-annually
Unburied Sewer Lines	- Inspect for cracks or gaps, or holes that may result in emissions	Initially & semi-annually
Oil-Water Separators:		
Fixed Roof	- Inspect Fixed Roof and openings for leaks - Inspect APCDs and Closed Vent System as listed above	Initially & semi-annually
	Measure Seal Gaps according to 40 CFR 60.696(d)(1) - primary seal gaps -secondary seal gaps	- Initially - Once every 5 yrs -Initially and Annually

Table 9-3. INSPECTION AND MONITORING REQUIREMENTS FOR VAPOR SUPPRESSION

Vapor Suppression Equipment	Inspection and Monitoring Procedure	
	Procedure Description	**Frequency**
Oil-Water Separator (general)	-Inspect for IWPs such as leaving open or ungasketed any access door or other opening, - Inspect for CEFs such as those listed in 1256(f)(5)(i)(A-F) {floating roof related} - Inspect for additional CEFs such as gaskets, joints, lids or covers for cracks or gaps, or breakage.	- Initially & semi-annually - as listed above -Initially & semi-annually

*Instead of these inspection and monitoring procedures, per §63.1258(h)(10), an owner/operator may choose to design a closed-vent system to operate at a pressure below atmospheric pressure. If such a system is used, it must have a gauge that can be read from a readily accessible location to verify that negative pressure is being maintained when the associated control device is operating.

9.8 Exceedances of Operating Parameters, Excursions, and Violations

It is important to understand what constitutes noncompliance with the MACT regulations. To do this, it is necessary to know how EPA defines "exceedances of operating limits", "exceedances of emissions limitations" and/or "excursions".

For the pharmaceutical MACT, the emissions standard is composed of two parts (1) emissions limitations, and (2) operating limits. In some cases, an exceedance of an operating limit is directly tied to an emission limitation, whereas in other cases, it is not. If the operating limit is not directly tied to the emissions limit, it still constitutes a separably enforceable commitment which is representative of proper operation of the control device on an ongoing basis. The adjacent charts list how EPA defines exceedance and excursions.

Exceedances of Operating Parameters
The parameter, averaged over the operating day or block, is **below the minimum value** established during the initial compliance demonstration.
The parameter, averaged over the operating day or block, is **above the maximum value** established during the initial compliance demonstration.
For flares, each **loss of all pilot flames.**

Excursions
When the control device operates for **4 hours or more** in an operating day AND data are insufficient to constitute a valid hour of data[1] for at least **75 percent of the operating hours**.
When the control device operates for **less than 4 hours** in an operating day AND **more than one of the hours** does not constitute a valid[1] hour of data.

[1]**Valid hour of data** = measured values are available for all of the four 15-minute periods within the hour.

What constitutes a violation of the operating limit?*	What constitutes a violation of the emission limit?
Exceedances of monitored parameters for such devices as scrubbers, regenerative carbon adsorbers, nonregenerative carbon adsorbers, flares, thermal incinerators, catalytic incinerators, and process heaters and boilers.	Exceedances of the monitored parameter (temperature) for condensers.
Excursions (defined in chart above)	Exceedances of the outlet concentrations for HAP or TOC/hydrogen halide and halogen.
Exceedances of monitored parameters and/or excursions do not constitute a violation if they occur during startup, shutdown, or malfunction (SSM), and the facility follows its SSM plan.	Exceedances of monitored parameters and/or excursions do not constitute a violation if they occur during startup, shutdown, or malfunction (SSM), and the facility follows its SSM plan.
	Exceedances of the emission limit as measured during the initial performance test or subsequent performance tests.
	Exceedances of the annual kg/kg factor, as determined from the baseline kg/kg factor, used in the pollution prevention option.
	Exceedances of the 900 kg/yr per process, as determined by the daily 365-day rolling summation

How are violations of operating limits counted?	How are violations of emissions limits counted?
For episodes occurring more than once per day, exceedances of parameters or excursions count as one violation per operating day for each monitored item of equipment utilized in the process.	For episodes occurring more than once per day, exceedances of the temperature or outlet concentrations or excursions will count as one violation per operating day for each item of equipment required to be monitored in the process.
For control devices used for more than one process in an operating day, exceedances of parameters or excursions will count as one violation per operating day, per control device, for each process for which the control device is being used.	For control devices used for more than one process in an operating day, exceedances of parameters or excursions will count as one violation per operating day, per control device, for each process for which the control device is being used.
	Exceedances of the "alternative" standard, averaged over the operating day, count as one violation per day per control device.

*This chart lists only those violations specifically discussed in the rule. It does not attempt to explicitly define all of the situations that could constitute a violation.

Chapter 10
Pollution Prevention

10.1 Overview

The pharmaceutical MACT rule allows the owner or operator of a manufacturing operation to use pollution prevention techniques to comply with the rule instead of installing traditional air pollution control devices. Essentially, the owner or operator demonstrates a 75% reduction (or a 50% with an additional 25% reduction achieved via traditional control devices) from a baseline amount, when adjusted for production. Rolling averages of the production-indexed consumption factor are calculated monthly and compared to the baseline value to confirm compliance with the pollution prevention standard.

Owners/operators of processes run in batch mode can demonstrate compliance with the pollution prevention standard on a schedule set according to the number of batches run per year. Any HAPs that are generated in the PMPU, and therefore not accounted for in the consumption factor, must be controlled according to the traditional standards for process vents, storage tanks, equipment leaks, and wastewater. The standard also contains restrictions regarding VOC consumption, as discussed further below, to avoid substituting VOC for HAP. The pollution prevention option is available only for existing sources; any unit which began production after April 2, 1997 is not eligible.

10.2 Structure of the Regulation

The pollution prevention standard is provided at §63.1252(e). The initial compliance demonstration requirements are described in §63.1257(f). These provisions describe how the baseline and annual factors are to be calculated for continuous and batch processes. In addition, these regulations describe the required elements for a pollution prevention (P2) demonstration summary, which must be submitted as part of the Precompliance Report (§63.1260(e)(4)). The monitoring requirements are contained in §63.1258(e) and pertain primarily to the calculation of rolling averages. Recordkeeping requirements are in §63.1259(b)(2).

Chapter 10 at a Glance

10.3 Applicability

As mentioned in the Overview, the pollution prevention standard can be used only for existing sources. This is because it is impossible to calculate a baseline for a new source with no operating records. It makes sense to apply P2 planning concepts to new sources too, however.

The production-indexed consumption factor, on which the P2 standard is based, must be calculated at the PMPU level. The source should evaluate all components included in each PMPU to receive the maximum credit for emission reductions achieved within the PMPU. Additionally, the PMPU against which P2 is measured must begin with the same starting materials and end with the same products as the process for which the baseline was calculated. In other words, the source may not comply with the P2 option simply by eliminating steps by transferring the step off-site. For assistance in defining the PMPUs at a production site, the reader is referred to ° **Chapter 3 - Applicability**.

The owner or operator can choose to use the pollution prevention option for a series of processes, including situations where multiple processes are merged, as long as the processes were merged after the baseline period (single year no earlier than 1992) into an existing process or processes.

Definition of Baseline

To calculate the baseline annual consumption factor (kg HAP consumed per kg product made), the owner or operator must use consumption and production values averaged over the period from either:

1) startup of the process until the present time (if the process has been in operation for at least a year) OR
2) the first 3 years of operation (beginning no earlier than 1987), whichever is the **shorter time period**.

If the time period used is less than three years, the data must represent at least 1 year's worth of data.

10.4 Standards

The P2 regulations provide two options for the standard:

Pollution Prevention Options	
Option 1: Reduce the production-indexed consumption factor by at least **75%** from the baseline.	**Option 2**: Reduce the production-indexed consumption factor by at least **50%** from the baseline AND achieve additional reductions in emissions from control devices to yield at least a **75% overall reduction** in the consumption factor.

The difference in the two options is that traditional end-of-pipe emissions controls are being used to reach part of the 75% reduction in Option 2, while the 75% reduction in Option 1 is achieved entirely by using pollution prevention techniques.

The regulations specify which kinds of control devices may be used under Option 2. These are:

- combustion control devices such as incinerators, process flares, or process heaters,
- control devices such as condensers

and carbon adsorbers whose recovered product is destroyed or shipped offsite for destruction,
- any control device that does not allow for recycling of material back to the PMPU, or
- any control device for which the owner or operator can demonstrate that the use of the device will not affect the production-indexed consumption factor for the PMPU.

VOC Restrictions

To ensure that owner/operators do not achieve HAP emissions reductions merely by substituting VOC-containing materials for HAPs, the standard includes restrictions on VOCs. Therefore, if the HAP being reduced is classified as a VOC, then an equivalent reduction in the VOC consumption factor is also required. If a HAP being reduced is not also classified as a VOC, the VOC consumption factor cannot be increased.

Restriction on Generated HAP

If the manufacturing process itself generates HAP during the process, there is no way that these HAPs can be accounted for in the production-indexed consumption factor. Therefore, the owner or operator must control emissions of these “generated HAPs” according to the other, traditional standards for process vents, storage tanks, equipment leaks, and wastewater. Hydrogen halides that are generated as a result of control devices that use combustion must be controlled to 95% or to a concentration less than or equal to 20 ppmv.

Consumption

The definition of consumption in the regulations specifies that it is 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 solvents and other additives as well as reactants. If the same HAP component is generated in the process as well as added as a raw material, consumption shall include the quantity generated in the process and the excess reactant, as calculated assuming 100 percent theoretical conversion. The pollution prevention option does not apply to HAPs used as reactants and totally consumed in the reaction.

10.5 Compliance Demonstration

For each process for which the P2 standard will be attempted, the owner or operator must:

1. **Calculate the baseline** as mentioned above in section 10.1, using at least one year’s worth of data, beginning no earlier than 1987. Divide the annual consumption of total HAPs (or VOCs) by the annual production rate:

Baseline HAP consumption factor =

$$\frac{annual\ \ kg\ \ total\ \ HAP\ \ consumed}{annual\ \ kg\ \ product\ \ made}$$

Baseline VOC consumption factor =

$$\frac{annual\ kg\ total\ VOC\ consumed}{annual\ kg\ product\ produced}$$

If more than one year of data will be used in calculating the baseline, take the average of the annual factors calculated.

2. **Calculate the annual consumption factor** after the implementation of P2 techniques as follows:

   For continuous processes - calculate the annual factor every 30 days for the 12-month period preceding the 30th day (i.e., calculate a 30-day rolling average).

   For batch processes - calculate the annual factor 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..

3. **Demonstrate compliance** by showing that the baseline consumption factor has been reduced by 75% for Option 1. Case Study 1, on page 10-9 illustrates the use of the HAP consumption factor calculation, the VOC consumption factor calculation, and their evaluation to determine compliance. The case study is based upon a compilation of research and facility evaluations that EPA conducted in developing the rule and this plain English guide.

   If using Option 2 (add-on controls achieving balance of 75% reduction), the owner or operator must calculate the baseline HAP consumption factor and demonstrate a 50% reduction in consumption. In addition, the owner or operator must show that the yearly reduction achieved with the add-on controls (kg HAP/yr) is equal to or greater than the mass of HAP calculated using the following equation:

$$M=[kg/kg]_b \ x\ (0.75 - P_R)(M_{prod})$$

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 $P_R \geq 0.5$ and < 0.75.

The owner or operator must calculate the annual reduction achieved with the add-on devices using the methods described in §63.1257(d) in the process vents regulations (see o **Chapter 8 - Compliance Demonstrations and Testing Procedures**).

To show that the add-on control devices used meet the criteria for allowable devices, the owner or operator must describe the control device and the material streams entering and exiting the control device.

Example Scenario for a Batch Operation - Using the same equipment, an operator follows an annual production cycle as shown below. All three processes use methanol in several wash cycles. The owner's pollution prevention strategy is two-fold: re-examine the process to determine if one of the wash cycles can be eliminated or done with a different material and install a closed-loop distillation unit to recover methanol, which will be reused in the same processes. The owner hopes to achieve a 75% reduction after implementation of his strategy. How does the owner determine whether he is in compliance with the standard?

	Process 1	**Process 2**	**Process 3**
production	5 batches	3 batches	4 batches
1. Determine baseline	20 kg methanol consumed/kg product produced	10 kg/kg	1 kg/kg
2. After installation of in-line methanol recovery device, calculate annual consumption factor	1kg/kg produced	.5 kg/kg	.5 kg/kg
3. Calculate percentage reduced	19/20 = 95 % reduction	9.5/10 = 95 % reduction	.5/1 = 50 % reduction
4. Was P2 goal achieved for process?	yes	yes	no; need to install additional controls to achieve 75% reduction

Note that the P2 goal must be assessed **for each process, not for the set of equipment**. Because each process has less than 10 batches per year, the annual consumption factor must be calculated with less than 10 batches. For purposes of calculating the baseline consumption factor and the annual consumption factor after implementation of the P2 plans, the operator must **track methanol consumption in each process separately**. To do this, the operator keeps a log book that tallies gallons of virgin methanol used in each process, on a daily, monthly, and annual basis. After the gallons of virgin methanol used per process is converted to kilograms, the operator can divide by the kilograms of finished product made per process. As a rough check on the virgin methanol figure, the operator could compare the annual consumption sums of the three processes to purchasing/inventory records that show how much methanol was purchased that year.

P2 Demonstration Summary

If an owner or operator uses the P2 option to achieve compliance with the MACT rule, he/she must prepare a P2 demonstration summary that contains:

- descriptions of the methodologies and forms used to measure and record daily consumption of HAP compounds
- descriptions of the methodologies and forms used to measure and record daily production of products
- supporting documentation for the descriptions above (e.g., operator log sheets, copies of daily, monthly, and annual inventories of materials and products)

10.6 Monitoring, Recordkeeping, and Reporting

Owners or operators electing to use the P2 option must prepare monthly calculations to demonstrate continued compliance with the P2 standard. The calculations are the same as those done to determine initial compliance. For continuous processes, the owner or operator must calculate monthly, on a rolling average basis, the HAP consumption factor and the VOC consumption factor. For batch processes, the owner or operator must calculate the annual factor every 10 batches, for the 12-month period preceding the 10th batch. The HAP consumption factor must be compared to the 75% or 50% reduction level (determined from the baseline) to confirm continued compliance. The VOC consumption factor must be compared to the baseline VOC consumption factor to confirm that it either does not go up (if the HAP being reduced is not a VOC) or that it is reduced (if the HAP being reduced is also a VOC). Each rolling average kg/kg consumption factor that exceeds the reduction value or the applicable VOC restriction is considered a violation of the emission limit.

Owners and operators must record the consumption, production, and rolling average values of the production-indexed HAP and VOC consumption factors used to demonstrate compliance with the pollution prevention standard. The P2 demonstration summary must be submitted as part of the precompliance report.

Q and A

Q. ***If an owner or operator makes changes to a process, such that it is considered a "new source," is that process no longer eligible for the pollution prevention option?***

A. *If the process is considered a "new source," it is not eligible for the pollution prevention option. (Please note that making changes to a process does not necessarily constitute a new source.)*

Q. ***If a process operates only six months of the year, how is the baseline calculated?***

A. *EPA's intent in using a year's worth of data to calculate the baseline is to ensure that the consumption and production figures are representative of the process and do not reflect anomalies and sensitivity in measurements. If the process routinely is conducted over a six-month period, however, and the operation is representative of how the process will be run in the future, it may be reasonable to calculate the baseline using the six-month period. In the P2 Demonstration Summary provided in the Precompliance Report, the owner/operator should describe why a baseline calculated with less than twelve months of data is legitimate for the intended purpose of calculated reductions achieved via pollution prevention.*

Q. ***What was EPA's rationale behind specifying the types of devices that can be used to achieve the balance of the 75% reduction in Option*** **2?**

A. *EPA's intent is to ensure that control devices that allow recycling of solvent back into the process would not be used to make up the balance of the required 75% reduction, so that the results of using the control device aren't double-counted. For example, if a condenser's control efficiency is considered part of the reduction achieved by using add-on controls, the owner/operator should not also get credit for returning the recovered solvent back to the process. This would be double-counting the impact of the condenser.*

10.7 Examples

There are several different types of pollution prevention technologies applicable to the pharmaceutical manufacturing industry, including:

- material substitution - substituting raw materials to reduce the volume and/or toxicity of wastes,
- process modification - alteration of process or equipment to reduce wastes generated,
- good operating practices - adopting practices, such as employee training, improved maintenance programs, more rigorous inventory control, that will result in fewer material losses and generated wastes, and

- recycling, recovery, and reuse - in-process recycling of a material such that a smaller amount of the chemical is consumed and emissions are reduced.

Table 10-1 provides some examples of how different pollution prevention technologies have been applied successfully at pharmaceutical manufacturing plants. These examples are from the Sector Notebook prepared by EPA's Office of Compliance. Other examples of P2 in the pharmaceutical industry can be found in the sector notebook, *Profile of the Pharmaceutical Industry*, EPA 310-R-97-005, September, 1997.

For more reading on pollution prevention technologies, their application, and costing procedures for making decisions about using P2, the reader is referred to EPA's Enviroene website: http://es.epa.gov. The sector notebook referenced earlier in this chapter can be downloaded from this site:

http://es.epa.gov/comply/sector/index.html

Table 10-1. EXAMPLES OF POLLUTION PREVENTION EFFORTS

Pollution Prevention Examples	
Material Substitution	C Riker Laboratories (Northbridge, CA) replaced several different organic solvent coating materials with a water-based coating materials, resulting in 24 tons per year reduction in organic solvent emissions. C Glaxo-Wellcome eliminated the use of methylene chloride, isopropyl alcohol, methanol, and ethanol in a coating process by substituting aqueous-based materials. The new system reduced VOC emissions to the air from almost 15,000 pounds per year to zero.
Process Modification	C To reduce the use of methanol in a cleanout process during product changeover, Hoffman La Rouche converted to a two-stage water -based cleaning system, before a final methanol rinse. This facility reduced the amount of methanol used from 110,000 gallons to 30,000 gallons per year. C Merck replaced their steam jets used in a process vessel with liquid ring vacuum pumps. This reduced air emissions of dichloromethane which had been mixed with steam in the steam jets. Additional reductions in dichloromethane emissions were achieved by keeping the vacuum pump seal fluid at subzero temperatures such that the dichloromethane vapor was condensed and then reused. C Sandoz Pharmaceutical Co. changed processes in its reactors to reduce solvent usage. In the new process, an inert atmosphere above the reaction mixture protects the reaction from exposure to oxygen. In the previous process, nitrogen flowed continuously over the mixture and carried away solvent vapors. The new system makes use of a non-flowing nitrogen layer that releases only a very small amount of nitrogen and solvent.
Good Operating Practices	C A computerized inventory system in a central warehouse at a Schering-Plough Pharmaceuticals plant eliminates excess raw material wastes and ensures that only the exact amounts needed are used. Materials are weighed according to batch requirements, labeled, and sent to the appropriate process area.
Recycling, Recovery, and Reuse	C Nycomed, Inc. Installed closed loop distillation units to recover all of its methanol from washes and methanol-containing wastewater. The recovered methanol is used in the same process. The company is reducing consumption of about one million pounds of methanol per year. C A Pharmacia and Upjohn facility reuses more than 195 million pounds of solvent annually. The facility employs both in-process reuse and distillation. The company's efforts earned a National Performance Review Environmental Champion Award, given by Al Gore in 1995.

Case Study 1: 75% Reduction of HAP Consumption for and Existing Pharmaceutical Manufacturing Process Unit (PMPU)

The following case study is intended to illustrate the process for documenting compliance with the pollution prevention alternative standard. For this case, the manufacturer seeks to document that they have met the requirement for Option 1 (75% reduction) of the pollution prevention alternative standard.

Background:

Manufacturer A uses dichloromethane (methylene chloride) to produce an intermediate that is then processed elsewhere into a product. The intermediate manufacturing process is the only process that relies upon dichloromethane. Dichloromethane is used as a solvent in several steps of the manufacturing process. The entire intermediate manufacturing process is considered as single pharmaceutical manufacturing process unit (PMPU) that runs continuously throughout the year. The plant has the capacity to run several lines that all produce the same intermediate product. The data collected for the plant is inclusive off all lines running during the baseline period as well as subsequent monitoring.

Demonstrating Compliance:

Ø Manufacturer A reviews its dichloromethane consumption and intermediate production data to determine a baseline. The data is used to develop a Hazardous Air Pollutant (HAP) consumption factor. Since the process operates continuously, the manufacturer develops the baseline using monthly consumption and production rates and averages the HAP consumption factor over the three-year period.

The calculation is performed using the amounts of dichloromethane consumed by the process (i.e., recycled solvent is not included in the calculation if it is reused in the process). The HAP consumption factors are calculated for each year using the following equation and then averaged:

$HAP_{Consumption\ Factor}$ = $HAP_{Consumed}$ (kg)/Product (kg)

Sample Calculation:

1987: 6.2M kg $MeCl_2$ used 2.5M kg of product $HAP_{Consumption\ Factor}$ = 6.2/2.5 = 2.48kg/kg

1988: 5.9M kg $MeCl_2$ used 2.5M kg of product $HAP_{Consumption\ Factor}$ = 5.9/2.5 = 2.36kg/kg

1989: 6.4M kg $MeCl_2$ used 2.8M kg of product $HAP_{Consumption\ Factor}$=6.4/2.8 = 2.36kg/kg

The average $HAP_{Consumption\ Factor}$= 2.4kg of HAP consumed/kg of product

To document compliance, the manufacturer must also demonstrate that the total VOC consumed in this process does not increase as a result of pollution prevention alternatives that eliminate HAPs. As such, the manufacturer must also baseline and track total VOC consumption using a similar ratio of $VOC_{Consumption\ Factor}$ = $VOC_{Consumed}$ / Product. For our case, the $VOC_{Consumption\ Factor}$ ratios for 1987-89 are as follows:

1987: $VOC_{Consumption\ Factor}$ = 11.4M kg/2.5M kg = 4.56

1988: $VOC_{Consumption\ Factor}$ = 10.8M kg/2.5M kg = 4.32

1989: $VOC_{Consumption\ Factor}$ = 12.3M kg/2.8M kg = 4.39

The average $VOC_{Consumption\ Factor}$ for 1987-89 = 4.42kg VOC/kg of product

Pollution Prevention Approaches Selected

The manufacturer implemented the following pollution prevention alternatives over the period from 1987 through 1999:

1988 - install recyclable seal water vacuum pumps
1990 - initiate procedure to steam strip aqueous waste streams and process still bottoms to recovery dichloromethane.
1991-92 - test use of less dichloromethane in the process within FDA approved manufacturing limits. Test demonstrate that reductions in the amount of solvent used will not impact purity or quality. Reduction are implemented within FDA approved ranges.
1991-92 - Test and propose use of recycled dichloromethane in intermediate manufacturing process. Approval from FDA allows additional uses of recycled dichloromethane in manufacturing
1993-94 - upgrade carbon absorption system
1994 - map vents and attach all vents that receive dichloromethane to the carbon adsorption unit.
1995-96- change handling of intermediate products to ensure all volatilized dichloromethane is recovered.
1998-99 - segregate and capture all dichloromethane aqueous wastes and process through steam stripper and carbon absorption unit.

Ù Manufacturer A computes the monthly $HAP_{Consumption\ Factor}$ for the PMPU. The monthly values are averaged into an annual value. The values for 1997-99 for $HAP_{Consumption\ Factor}$ and $VOC_{Consumption\ Factor}$ are presented below.

1997: 2.48M kg $MeCl_2$ used 5.0 M kg of product $HAP_{Consumption\ Factor}$= 2.48/5.0 = 0.50kg/kg

1998: 3.52M kg $MeCl_2$ used 6.25M kg of product $HAP_{Consumption\ Factor}$= 3.52/6.25 = 0.56kg/kg

1999: 2.88M kg $MeCl_2$ used 7.0M kg of product $HAP_{Consumption\ Factor}$= 2.88/7.0 = 0.41kg/kg

The percent reduction of the $HAP_{Consumption\ Factor}$ is 79.2%, 76.6%, and 82.9% for 1997, 98, and 99, respectively. Manufacturer A must also demonstrate that their pollution prevention activities have not resulted in increased consumption of VOCs:

1997: $VOC_{Consumption\ Factor}$ = 21.5M kg/5.0M kg = 4.3

1988: $VOC_{Consumption\ Factor}$ = 25.5M kg/6.25M kg = 4.08

1999: $VOC_{Consumption\ Factor}$ = 28.7M kg/7.0M kg = 4.10

Each of these values is below the three-year average for the $VOC_{Consumption\ Factor}$ and meets the requirement. Having not increased VOC consumption, Manufacturer A has met the numeric reduction standard for $HAP_{Consumption\ Factor}$ of 75% to claim the pollution prevention alternate standard.

Ú To document and demonstrate on-going compliance, Manufacturer A must provide all of the information identified in the rule and summarized on page 10-6 of this document.

Chapter 11
Emissions Averaging

11.1 Overview

The rule allows for limited emissions averaging of HAP emission sources (process vents and storage tanks). The requirements contain restrictions similar to those imposed for other Part 63 standards. For example, credits are discounted by 10 percent, and restrictions on averaging sources already controlled by State rules or prior to 1990 are in effect.

Chapter 11 at a Glance

11.2 Structure of the Regulation

- Requirements are located in §61.1252(d)
- Compliance Demonstration §63.1257(g) and (h)
- Monitoring §63.1258
- Recordkeeping §63.1259(e)
- Reporting §63.1260(h)

11.3 Applicability

Emissions averaging can be done only for some processes and tanks. The following process vents and tanks can be included in averaging groups:

$ Two or more processes subject to 93 percent control requirement in §63.1254(a)(1)(i).

$ Two or more storage tanks subject to 90 or 95 percent control requirement in §63.1253(b)(1) or §63.1253(c)(1)(i).

- Process vents that meet the individual vent criteria for 98% control but have grandfathered control devices due to the level of control achieved before April 12, 1997.

Exclusions

$ States have the option not to allow emissions averaging

$ Control of emissions before November 15, 1990 or control due to State regulations cannot be used as emission credits in averaging, except where control is increased after November 15, 1990 and above what is required by the State

$ Rule excludes emission points that:

1. Are permanently shutdown or out of HAP service
2. Are controlled using equipment,

such as

-- Floating roofs,

-- Grandfathered storage tanks as described in §63.1253(c)(1)(ii),

-- Boilers, incinerators, or flares as described in §63.1254(a)(1)(ii)

3. Are controlled to the 20 ppmv concentration standard or alternative standard

- Processes complying with 2,000 lb/yr emission limit as described in §63.1254(a)(2) cannot be used in emissions averaging
.

- Averaging groups for processes are limited to 20 processes, and averaging groups for tanks are limited to 20 tanks at an affected source at any one time.

11.4 Standards

The control requirements (R) for emissions averaging are as follows.

Processes

- The overall percent reduction efficiency, R, for all processes included in an average must equal 93 percent or greater.

Tanks

- The overall percent reduction efficiency, R, for all tanks requiring 90 percent control in an average must equal 90 percent or greater

- The overall percent reduction efficiency, R, for all tanks requiring 95 percent control in an average must equal 95 percent or greater.

Note: If the operator is complying with the planned routine maintenance provisions for centralized combustion control devices in 1252(h), the process vents cannot be used in emissions averaging during the periods of planned routine maintenance.

11.5 Compliance Demonstration

R is calculated in the following equation:

E_{unc} = total yearly uncontrolled emissions from sources in processes or from tanks

$$R = \frac{E_{unc} - (D)(E_{cont})}{E_{unc}}(100\%)$$

E_{cont} = total yearly emissions after control from sources in processes or tanks

D = 1.1, the discounting factor

Averaging example for processes

An example for averaging of processes is presented in Table 11-1. In example 1, three processes are included in an emissions average. From the table, there are several emission points within each process that are controlled. For example, process A has three vents, two controlled by condensers and one directed to a boiler. In processes B and C, vents are controlled using a thermal oxidizer (throx).

In this example, three processes are evaluated to include an emissions average. In an emissions average, no credit is allowed for emission points controlled to comply with a State (or Federal) rule unless the level of control has been increased after November 1990 above the State requirement. In Table 11-1, several vents are controlled by State rules (vent H is controlled to 98% while other vents are controlled to less than 93%). Since the State RACT are all less than 93% and vent H complies with the State Air Toxic rule, there are no credits from processes A and C. Since there are no credits from process C and it is already controlled to > 93%, there is no reason to include process C in the emissions average.

R is calculated in the following equation:

$$R = 96\% = \frac{57{,}900 - 1.1(2{,}055)}{57{,}900}(100\%)$$

The emissions average complies with the requirements of §63.1252(d)(8) because the annual percent reduction efficiency is greater than or equal to 93 percent.

Averaging example for Tanks

An example for averaging of tanks is presented in Table 11-2. In this example, 5 tanks out of 14 are included in the emissions average and the average entirely excludes tanks that are already controlled to the level required by State and/or Federal rules and/or using devices installed prior to November 1990.

The average complies with the requirements of §63.1252(d)(7) because the annual percent reduction efficiency is greater than or equal to 90 percent.

11.6 Recordkeeping

The emissions averaging provisions also require a rolling quarterly calculation of the annual percent reduction efficiency.

The results of the quarterly calculation are required to be reported in either every other semiannual report, or every 4th quarterly report, if a quarterly report is required.

NOTE: Quarterly reports are not required by the averaging provisions, but they may be for other reasons, as described in §63.1260(g)(1).

11.7 Reporting

Implementation Plan

An implementation plan must be submitted 6 months prior to the compliance date. The plan is described in §63.1259(e) and must include:

- $ the identification of all process vents and tanks in the average,
- $ the uncontrolled and controlled emissions of HAP and the overall reduction efficiency,
- $ supporting calculations used to obtain uncontrolled and controlled HAP emissions and overall percent reduction efficiency,
- $ estimated values for monitoring parameters, and
- $ a certification statement.

Additionally, the implementation plan should contain a Hazard or Risk Equivalency Determination that should be made to the satisfaction of the operating permit authority. The plan should address the points excluded from control via the emissions averaging provisions.

Periodic reports

Periodic reports must be submitted on a semiannual basis; they can be part of the periodic reports submitted for the standard. The periodic report must include the calculations of overall percent reduction efficiency for the reporting period. Every second semiannual report must demonstrate that the overall percent reduction efficiency for the year has been met. Other items to be submitted in the periodic report include any changes to the emission sources included in the average, or any changes in the methodology used to calculate uncontrolled or controlled emissions.

11.8 Hazard or Risk Equivalency Determination

Definitions

Hazard assessments address toxicity but not exposure. Hazard refers to the intrinsic toxic properties of a pollutant, such as potency or the types of toxic endpoints of concern (e.g., cancer, development effects).

Risk is an integration of hazard and human exposure to the pollutant used to estimate the type and likelihood of toxic effects associated with a specific pollutant release.

NOTE: Under this the implementing agency can consider either of these factors in determining whether an averaging plan should be approved.

Applicability

Hazard or risk equivalency determinations need only be conducted when inter-pollutant trading occurs (i.e., the overcontrol of one or more HAP is used to offset required reductions of one or more different HAP).

Risk Determination

The implementing agency should specify the level of detail and desired output of the risk analysis to be conducted. Most State agencies have established procedures for health-based screening for air toxics; these procedures could also be used for this analysis.

Table 11.1. EMISSIONS AVERAGING EXAMPLE - PROCESSES

Process vents	**Process A**			**Total for Process A**	**Process B**				**Total for Process B**	**Process C**				**Total for Process C**
	A	**B**	**C**		**D**	**E**	**F**	**G**		**H**	**I**	**J**	**K**	
Annual emissions (lb/yr) (before control)	1,000	500	1,000	2,500	25,000	100	100	30,000	55,200	40,000	100	50	50	40,200
Control requirements														
PhRM MACT (93% average)	93	93	93		93	93	93	93		93	93	93	93	
State/RACT	60	50	None		90	None	None	None		None	None	None	None	
State AirToxic	None	None	None		None	None	None	None		98	None	None	None	
BACT/other	None	None	None		None	None	None	None		None	None	None	None	
Actual control, percent device	70 Condenser	50 Condenser	NA Boiler		98 Throx	None	None	98 Throx		98 Throx	None	None	None	
Year installed	1991	1985	1992		1992			1992		1992				
Annual emissions, lb/yr (after control)	300	250	NA	550	500	100	100	600	1,300	800	100	50	50	1,000
Current control efficiency, per process, percent				63.3					97.6					97.5
Uncontrolled, lb/yr[1] Emissions from **eligible** emissions sources	1,000	500	1,000	2,500	25,000	100	100	30,000	55,200	800	100	50	50	200
Controlled, lb/yr Emissions from **eligible** emissions sources	300	250	0	550	500	100	100	600	1,300	800	100	50	50	200
Uncontrolled, lb/yr		57,900												
Controlled, lb/yr		1,850												
Overall percent reduction efficiency		96												

Table 11-2. EMISSIONS AVERAGING EXAMPLE - TANKS

Tank identification	**Storage Tanks**													
	A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**	**M**	**N**
Capacity, gallon	20,000	15,000	15,000	20,000	55,100	12,500	8,500	14,000	8,500	11,000	13,000	13,000	15,000	15,000
VP/HAP, psia	0.5	1.5	2.7	3.1	1.8	2.9	2.1	1.6	0.4	6.6	0.8	2.6	0.5	2.6
Annual emissions, lb/yr (before control)	200	500	300	400	700	300	50	100	100	300	200	400	200	300
Control requirements														
PhRM	None	None	90	95	None	90	None	None	None	90	None	90	None	90
MACT	None	None	None	95	95	None	None	None	None	None	None	None	None	None
State/RACT	None	None	None	95	95	None	None	None	None	None	None	None	None	None
State Air Toxic	None	None	None	95	95	None	None	None	None	None	None	None	None	None
BACT/other	None	None	None	95	95	None	None	None	None	None	None	None	None	None
NSPS Kb														
Actual control, percent device	60 Condenser	None	62 Condenser	95 Condenser	95 Condenser	98 Throx	98 Throx	None	None	98 Throx	None	98 Throx	None	98 Throx
Year installed	1992		1992	1992	1992	1994	1994			1994		1994		1994
Annual emissions, lb/yr (after control)	80	500	114	20	35	6	1	100	100	6	200	8	200	6
Eligible for emissions averaging	N	N	Y	N	N	Y	N	N	N	Y	N	Y	N	Y
Uncontrolled, lb/yr			300			300				300		400		300
Controlled, lb/yr			114			6				6		8		6

Uncontrolled emissions from **eligible** tanks subject to 90% control 1,600 Controlled emissions from **eligible** tanks subject to 90% control 140
Uncontrolled emissions from **eligible** tanks subject to 95% control 0 Controlled emissions from **eligible** tanks subject to 95% control NA
Overall percent reduction efficiency 90.4

Chapter 12
Recordkeeping

12.1 Overview

The recordkeeping requirements associated with the pharmaceutical MACT ensure that a written record will be established to document compliance with the provisions of the regulation. Because of the variability in product lines and schedules in pharmaceutical manufacturing operations, it is essential that detailed, accurate recordkeeping be done to document the details of the process emitting HAPs, the control devices in use, and the level of control achieved.

12.2 Structure of the Regulation

The recordkeeping regulations are contained in the regulations primarily in §63.1259. The General Provisions of Part 63 that also apply to pharmaceutical manufacturing operations are listed in Table 1 of the regulations. Some of these provisions relate to recordkeeping.

12.3 Recordkeeping Requirements from the General Provisions

The following table outlines some of the recordkeeping requirements in Part 63 that apply to pharmaceutical manufacturing operations.

Chapter 12 at a Glance

General Provisions Recordkeeping

Data Retention - 63.10(b)(1) - all records and reports must be retained for at least five years (for at least two of these years, the records must be kept on-site).
Applicability Determinations - 63.10(b)(3) - stationary sources that determine they are not subject to the pharmaceutical MACT must keep records of their applicability determinations.
Application for Construction or Reconstruction - 63.5 - for new affected sources, comply with normal new source application process, except for §63.5(d)(1)(ii)(H) - technical information on new source and emissions values; §63.5(d)(2) - more technical information on new source; and §63.5(d)(3)(ii) - description of emissions control equipment.
Recordkeeping for Performance Testing -63.7 - retain records or results of performance tests and other data needed to determine emissions from an affected source.

Table 12-1. MACT Recordkeeping

For the following events, processes, or devices....	....keep the following records on-site
Startup, Shutdown, or Malfunction (SSM) (§63.1259(a)(3))	• procedures for operating and maintaining affected source during SSM • program for corrective action for 1) process, 2) air pollution control, and 3) monitoring equipment • occurrence and duration of each malfunction of 1) the process operation or 2) air pollution control equipment, 3) continuous monitoring system • documentation for each SSM event that shows plan provisions were followed, as specified in §63.6(e)(3)(iii) (alternatively, the O/O must record any actions taken that are NOT consistent with the plan) • SSM plan and superseded versions • description (and any updates) of maintenance procedures for management of wastewater generated from the emptying and purging of equipment during temporary shutdowns for inspections, maintenance, and repair and during periods that are not shutdowns (i.e., routine maintenance).
Continuous Monitoring System (CMS) (§63.1259 (a)(4) and (b)(3))	• records of all required CMS measurements (including data recorded during unavoidable CMS breakdowns and out-of-control periods) • date and times when CMS is inoperative, except for zero (low-level) and high-level checks • date and duration of each period of excess emissions and parameter monitoring exceedances that occurs 1) during SSMs of the affected source and 2) during periods other than SSMs of the affected source • note the nature and cause of any malfunction, if known • note corrective action taken or preventive measures adopted • record nature of repairs or adjustments to CMS that was inoperative or out of control • total process operating time during the reporting period • all procedures that are part of a quality control program for the CMS (developed under §63.8(d)) • records documenting calibration checks and maintenance

For the following events, processes, or devices....	....keep the following records on-site
Equipment Operation (§63.1259(b))	C each required measurement of operating parameters monitored for control devices C each required measurement of a treatment parameter monitored for biological and non-biological wastewater treatment C for processes using the pollution prevention standard, records of consumption, production, and the rolling average values of the production-indexed HAP and VOC consumption factors C for CMS, records documenting the completion of calibration checks and maintenance of CMS. C for processes complying with the 900 kg/yr standard: - daily records of the rolling annual total emissions - number of batches per year for each batch process - the operating hours per year for continuous processes - standard batch uncontrolled and controlled emissions for each process -actual controlled emissions for each batch operated during periods of planned routine maintenance of a CCCD - actual uncontrolled and controlled emissions for each non-standard batch - a record of whether each batch operated was a "standard batch" C for processes complying with the percent reduction standard(s), with vents controlled to less than the required % reduction (but not individual "large" vents): - uncontrolled and controlled emissions per standard batch for each process, - actual uncontrolled and controlled emissions for each non-standard batch - a record of whether each batch operated was a "standard batch" C wastewater concentration per POD or process, except for "designated" wastewaters C number of storage tank turnovers per year, if used in an emissions average C daily schedule or log of each operating scenario prior to its operation C description of worst-case operating conditions for control devices, as required in §63.1257(b)(8) C periods of planned routine maintenance for storage tanks C for storage tanks complying by installation of a floating roof, records of each seal gap measurement and inspection, in

For the following events, processes, or devices....	....keep the following records on-site
Operating Scenarios (§63.1259(c) and Definitions in §63.1251)	• for storage tanks complying with the vapor balancing option, records of the DOT certification required by 63.1253(f)(2) and the pressure relief vent setting and leak detection records specified in 63.1253(f)(5). C per PMPU, records of each operating scenario - - a description of the process and the type of process equipment used - identification of related process vents and their associated emissions episodes and durations - identification of wastewater PODs - identification of storage tanks - the applicable control requirements, including the level of control for each vent (e.g., identify which vents are subject to 98% control) - the control or treatment devices used, including a description of operating and/or testing conditions for any associated control device - the process vents, wastewater PODs, and storage tanks (including those from other processes) that are simultaneously routed to the control or treatment device - the applicable monitoring requirements and any parametric level that assures compliance for all emissions routed to the control or treatment device - calculations and engineering analyses required to demonstrate compliance - verifications 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. (63.1260 (g)(2)(vii)) • a record should be kept showing which scenarios are being operated at any given time. Changes in any of the elements of the operating scenario (except for the listing of process vents, wastewater PODs, and storage tanks that are simultaneously routed to the control or treatment device) constitute a new operating scenario.
Equipment Leak Detection and Repair (§63.1259(d))	See recordkeeping requirements in Equipment Leak chapter.

For the following events, processes, or devices....	....keep the following records on-site
Emissions Averaging (§63.1259(e))	C *Implementation Plan* - - all process vents and storage tanks in each emissions average - uncontrolled and controlled emissions of HAP and overall percent reduction efficiency, and calculations used to obtain these figures - estimated values for all parameters required to be monitored for each process and storage tank included in the average - a statement that all applicable compliance demonstrations, monitoring, inspection, recordkeeping, and reporting requirements will be implemented on the date of compliance C *Risk Equivalency Demonstration* showing that emissions averaging will not result in greater risk than if the tanks and process vents had been controlled separately (see chapter on Emissions Averaging for more details)
Delay of Repair for Wastewater Equipment (§63.1259(f))	**When delay of equipment repair is necessary due to unavailability of parts, record:** **C a description of the failure** **C the reason additional time was necessary to get the needed part(s) and why the parts were not on-site** **C date the repair was completed**
Wastewater Stream or Residual Transfer (§63.1259(g))	Notice sent to the treatment operator stating that the wastewater stream or residual contains organic HAP that must be managed according to the MACT regulations.
Extensions for Wastewater Equipment (§63.1259(h))	When the owner/operator delays draining a tank for which the floating roof is unsafe or delays correcting an Improper Work Practice or Control Equipment Failure beyond the allowed time, document: C a description of the failure C that alternative storage capacity is unavailable C a schedule of actions that will ensure that the control equipment will be repaired and the tank emptied as soon as practical

For the following events, processes, or devices....	....keep the following records on-site
Consistency with other regulations for wastewater (§63.1250(h)(5))	If affected wastewater also subject to 40 CFR Parts 260-272, owner/operator may opt to comply with the more stringent control requirements and the more stringent testing, monitoring, recording, and recordkeeping requirements that overlap with Subpart GGG. If the site consolidates the two wastewater programs, the owner/operator must keep a record of the information used to determine which requirements are more stringent. This recordkeeping is not required if a site opts to comply with both standards separately.

For the following events, processes, or devices....	....keep the following records on-site
Inspections (§63.1259(i))	C documentation that each waste management unit was inspected as required under §63.1256(b)-(f). C documentation that inspections for control devices required by §63.1256(h) were conducted. C results of seal gap measurements required for floating roofs, including the date of measurement, raw data, and the calculations described in §63.120(b)(2) - (4) C identification of all parts of the vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated as **unsafe** to inspect; an explanation of why it is unsafe and the plan for checking the equipment C identification of all parts of the vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated as **difficult** to inspect; an explanation of why it is difficult and the plan for checking the equipment C for each vapor collection system or closed-vent system containing bypass lines that could divert a vent stream away from the control device, either 1) hourly records of whether the flow indicator was operating and whether a diversion was detected at any time during the hour, as well as a record of period when stream was diverted or flow indicator was not operating, or 2) monthly records of visual inspections of seal or closure mechanism, including periods when seal mechanism was broken, bypass line valve position was changed, the key for a lock-and-key was checked out, or the car-seal was broken. C For inspections of vapor suppression systems for leaks, if leaks are detected: - identification of the leaking equipment - the instrument identification number and operator name or initials, if the instrument method was used - if the leak was detected by sensory observations, a record noting that - date the leak was detected and date of first attempted repair - maximum instrument reading measured by the method in §63.1258(h)(4) after the leak is repaired or determined to be nonrepairable

For the following events, processes, or devices....	....keep the following records on-site
Inspections, cont.	- any incidences of delay of repair and the reason for the delay if a leak is not repaired within 15 calendar days of detection - name or initials of owner or operator (or designee) who decided repair could not be done without a shutdown - expected date of successful repair if not repaired within 15 calendar days of detection - dates of shutdown that occur while the equipment is unrepaired - date of successful repair C For inspections of vapor suppression systems during which no leaks are detected, the date of the inspection and a statement that no leaks were detected. C For visual inspections of hard-piped vapor collection systems or closed-vent systems, or visual inspections of fixed roofs, covers, or enclosures, during which no leaks are detected, a record that the inspection was done, the date of the inspection, and a statement that no leaks were detected.

12.4 Purpose of Keeping Records of "Operating Scenarios"

The information recorded as part of the "operating scenario," along with the monitoring information recorded under "equipment operation," (see the table above) will serve to help owners/operators and regulating agencies track compliance with the standards. The information recorded in the operating scenario is on a per PMPU basis because the emissions standards are in terms of processes, rather than specific pieces of equipment. The operating scenario, in tandem with the operating log or diary, and when overlaid with the parameter monitoring information, shows how emissions are being controlled for any given manufacturing set-up or process configuration. The reporting requirements in §63.1260, including the Notification of Compliance Status report and the Periodic reports, ensure that the monitoring information and the listings of operating scenarios are submitted to the regulating agency on a schedule that allows for compliance checks and explanation of data submitted in the periodic reports.

Chapter 13
Reporting

13.1 Overview

The reporting requirements in the pharmaceutical MACT regulations include three basic kinds of reporting: Precompliance reporting, Notification of Compliance Status reporting, Periodic reporting, and three types of notices: Initial Notifications, Notifications of Continuous Monitoring System Performance Tests, and Application for Approval of Construction or Reconstruction. In addition, pharmaceutical manufacturing operations are subject to some of the reporting requirements in Part 63 - General Provisions. Reporting provisions ensure that regulating agencies are aware of facilities subject to the MACT regulations and can monitor initial and ongoing compliance.

Chapter 13 at a Glance

13.2 Structure of the Regulation

The reporting requirements are contained in the regulations primarily at §63.1260. Additionally, the requirements from the General Provisions of Part 63 that also apply to pharmaceutical manufacturing operations are listed in Table 1 of the regulations .

13.3 Reporting Requirements from the General Provisions, Subpart A

The following table outlines the reporting requirements in Part 63, Subpart A that apply to pharmaceutical manufacturing operations.

Table 13-1. GENERAL PROVISIONS REPORTING APPLICABLE TO THE PHARMACEUTICAL MACT

Subject	**Citation**	**Requirement** (refer to regulatory language for more details)
Initial Notification	§63.9(b) or (d)	Notify the Administrator that the affected source is subject to a relevant standard (in this case, pharmaceutical MACT). Includes area sources that become major sources due to increased emissions of HAPs or potential to emit increased HAP. Notification includes 1) name and address of owner or operator, 2) address of manufacturing operation, 3) identification of the relevant standard and the affected source's compliance date, 4) brief description of the nature, size, design, and method of operation of the source, including design capacity and identification of each point of emissions for each HAP, or preliminary identification of anticipated points of emission. Notification is due 120 days after the effective date.
Application for Approval of Construction or Reconstruction	§63.5(b)(3) and (d)	Application for construction of a new major affected source, reconstruction of a major affected source, or the reconstruction of a major affected source such that it becomes a major affected source subject to the standards must be prepared in accordance with §63.5(d) [except for §63.5(d)(1)(ii)(H) - technical information on new source and emissions values; §63.5(d)(2) - more technical information on new source; and §63.5(d)(3)(ii) - description of emissions control equipment.]
Notification of CMS Performance Evaluation	§63.8(e)(2)	If owner/operator complies via continuous emission monitoring or by the alternative or if required by Administrator to conduct a performance evaluation of a continuous monitoring system (CMS), notify the Administrator of the evaluation date at least 60 days prior to the evaluation. Coordinate notification of evaluation of CMS with notification of performance test of APCD, if required.

13.4 Reporting Requirements From the Pharmaceutical MACT, Subpart GGG

The following tables provides a comprehensive list of reporting requirements in §63.1260.

Table 13-2. PRECOMPLIANCE REPORT (§63.1260(e))

PRECOMPLIANCE REPORT	
When is Submittal Required?	At least 6 months prior to the compliance date of the standard (for existing sources, the date was April 21, 2002). For new sources, submit Precompliance report with application for approval of construction or reconstruction. For area sources that become major sources, the Precompliance Report is due within 30 months of becoming a major source.
What Must be Included?	- Requests for approval to use alternative monitoring parameters for 63.1258(b)(1)(ii)-(ix) and 63.1258(g)(2), or requests to set monitoring parameters according to 63.1258(b)(4) -Requests for approval to monitor appropriate parameters, monitoring frequency, and planned recordkeeping/reporting for non-biological treatment units pursuant to 63.1258(g)(3) - Descriptions of the daily or per batch demonstrations to verify that control devices controlling < 1 ton/year are operating as designed - A description of test conditions, monitoring parameter values established during performance testing for devices controlling >10 tons per year, and supplemental data to support parameter values not obtained during initial compliance demonstration. - A P2 demonstration summary, as required under §63.1257(f), if applicable - The data and rationale used to support an engineering assessment to calculate uncontrolled emissions from process vents - Data and other information supporting the determinations of annual average concentrations for PSHAP and/or SHAP in wastewater, via process simulation - Bench-scale or pilot-scale test data and the rationale if used in the process simulation to determine annual average concentrations in wastewater

Table 13-3. NOTIFICATION OF COMPLIANCE STATUS REPORT (§63.1260(f))

NOTIFICATION OF COMPLIANCE STATUS REPORT	
When is Submittal Required?	No later than 150 days after the compliance date (March 21, 2003 for existing sources or 150 days after start-up of new sources). For area sources that become major sources the report is due 150 days after the compliance date.
What Must be Included?	- Results of applicability determinations, emissions calculations, or analyses used to identify/quantify HAP emitted from the affected source - Results of emissions profiles, performance tests, engineering analyses, design evaluations, or calculations used to demonstrate compliance - For performance tests, descriptions of sampling and analysis procedures and QA procedures - Descriptions of monitoring devices, frequencies, and values of monitored parameters established during the initial compliance demonstrations, including data and calculations used to support the levels established - A listing of all operating scenarios (see Recordkeeping chapter for discussion on operating scenarios) - Descriptions of worst-case operating and/or testing conditions for control devices - Identification of emissions points subject to overlapping requirements in other MACT standards, RCRA regulations, NSPS (Subpart Kb), Subpart I, Subpart PP and/or other NESHAPs; and identification of authority under which owner or operator will comply -For tanks, election to use vapor balancing and certification that pressure relief devices have been set at $2.5 psig -Determination of predominant use for storage tanks -Annual average concentration of SHAP and PSHAP if determined through mass balance or wastewater solubility, per 1257 (e)(1)(ii)(B). -Averaging periods for parametric monitoring levels (daily or batch cycle) -For the LDAR program: • process group identification • approximate number of each equipment type in organic HAP service, excluding that in vacuum service • method of compliance with the standard • products or product codes subject to LDAR • planned schedule for pressure testing -Process condenser evaluation results -For noncombustion devices used to control emissions from dense gas systems, if owner/operator not correcting for supplemental gases, initial calculation for flowrate -Anticipated periods of planned routine maintenance of CCCD, during which emissions are subject to 63.1252(h). If applicable, for large vents that exceed the flowrate criteria, the rationale for why the planned maintenance must be performed while the large vent is operating.

Table 13-4. PERIODIC REPORTS (§63.1260(g))

	PERIODIC REPORTS	
When is Submittal Required?	**Semi-annually** (except as provided in 63.1260(g)(1)(i)-(iii))	Submit the first report no later than 240 days after the Notification of Compliance Status Report is due (For existing sources, November 21, 2003). It should cover the 6-month period beginning on the date the Notification of Compliance Status Report is due.
	Quarterly	(1) when the source experiences exceedance of temperature limit for APCD condensers or outlet concentration for TOC or hydrogen halide/halogens. Quarterly reporting will continue until a request for a reduced frequency (back to semi-annually) is approved. If the owner or operator has made such a request, the provisions of §63.10(e)(3)(ii) applies as follows : - For a full year (4 quarterly or 12 monthly reporting periods), the affected source must be in compliance with the standard, - The owner/operator must continue to comply with all recordkeeping and monitoring requirements, and - The Administrator does not object to a reduced reporting frequency (2) if a new operating scenario has been followed since the last report, quarterly reports must be submitted. (3) if the Administrator determines on a case-by-case basis that more frequent reporting is necessary to accurately access compliance
What Must be Included?		- Company name and address of affected source - List of HAPs monitored at the site - Beginning and ending dates of the reporting period - A brief description of the process units - The emissions limitations and operating parameter limits applicable at the facility - Monitoring equipment manufacturer(s) and model number(s)

	PERIODIC REPORTS	
	Emission Data Summary	- Date of the latest CMS certification or audit - Total operating time of the affected source during the report period - Emission data summary including - the total duration of excess emissions during the reporting period, - the total duration of excess emissions expressed as a percent of the total source operating time during that reporting period. - a breakdown of the total duration of excess emissions during the reporting period into those that are due to startup/shutdown, control equipment problems, process problems, other known causes, and other unknown causes.
	CMS Information	- Name, title, and signature of the responsible official certifying the accuracy of the report - Date of the report - A CMS performance summary including - the total CMS downtime during the reporting period, - the total duration of the CMS downtime expressed as a percent of the total source operating time during the reporting period, - a breakdown of the total CMS downtime during the reporting period into periods that are due to monitoring equipment malfunctions, nonmonitoring equipment malfunctions, QA/QC control calibrations, other known causes, and other unknown causes - Description of any changes in CMS, processes, or controls since the last reporting period.

	PERIODIC REPORTS	
What Must be Included?	If the total duration of **excess emissions, parameter exceedances, or excursions** for the reporting period is $1 percent of the total operating time, OR the total CMS downtime for the reporting period is $5 percent of the total operating time, include ö	- Monitoring data, including 15-minute as well as daily average values, for all operating days when the average values were outside the ranges established in the Notification of Compliance Status report or operating permit, - Duration of excursions - Daily schedule or operating logs and operating scenarios for all operating scenarios for all operating days when the values were outside the levels established in the Notification of Compliance Status report or operating permit, - If a CMS is used, the information required in §63.10(c)(5)-(13): C date and times when CMS is inoperative, except for zero (low-level) and high-level checks C date and times when CMS was out of control, as defined in §63.8(c)(7) C date and time of commencement and completion of each period of excess emissions and parameter monitoring exceedances that occurs 1) during SSMs of the affected source and 2) during periods other than SSMs of the affected source C nature and cause of any malfunction, if known C corrective action taken or preventive measures adopted C nature of repairs or adjustments to CMS that was inoperative or out of control C total process operating time during the reporting period

	PERIODIC REPORTS	
What Must be Included?	For each inspection of a vapor collection system, closed-vent system, fixed roof, cover and enclosure, during which a **leak is detected**, include ö	- the instrument identification numbers; operator name or initials; identification of the equipment - date the leak was detected and date of first attempted repair - maximum instrument reading measured by the method in §63.1258(h)(4) after the leak is successfully repaired or determined to be nonrepairable - any incidences of delay of repair and the reason for the delay if a leak is not repaired within 15 calendar days after discovery of leak - name or initials of owner or operator (or designee) who decided repair could not be done without a shutdown - expected date of repair if not repaired within 15 calendar days of detection - dates of shutdown that occur while the equipment is unrepaired - date of successful repair
	For each vapor collection system or closed-vent system with a bypass line, for periods when vent stream is diverted and a **flow indicator** is being used, include ö	- Hourly records of whether the flow indicator was operating and whether the diversion was detected, as well as records of the times and durations of all periods when the vent stream was diverted from the control device or the flow indicator was not operating
	For each vapor collection system or closed-vent system with a bypass line, for periods when **seal mechanism** is broken, the **bypass valve** position has changed, or the key to unlock the bypass line valve was checked out, include ö	- Records of monthly visual inspection of the seal or closure mechanism and records of all periods when the seal mechanism was broken, the bypass line valve position changed, or the key for the lock-and-key type lock was checked out, and records of any car-seal that was broken

	PERIODIC REPORTS	
What must be included?	Statement(s), if applicable	- No excess emissions - No exceedances of a parameter - No excursions - No CMS has been inoperative, out of control, repaired, or adjusted
	For each **storage tank** subject to control, include ö	- Periods planned maintenance during which the control device does not meet the control requirements -For a CCCD subject to 63.1252(h), period of planned routine maintenance during the current reporting period and anticipated maintenance during the next reporting period. If not included in the NOCSR, or if different from the rationale provided in the NOCSR, the rationale for why planned routine maintenance must be performed while a large vent that exceeds the flowrate criteria will be operating. - Change in predominant use for storage tank(s). - If using a floating roof, submit information per 40 CFR 63.122(d)-(f), as appropriate.
	For the **initial Periodic Report**, include ö	- Each operating scenario for each process operated since the due date of t he Notification of Compliance Status Report
	For each **subsequent Periodic Report**, include ö	- Description of any new operating scenarios operated since the time period covered by the last Periodic Report and verification that operating conditions for any associated control or treatment device have not been exceeded and that any required calculations and engineering analyses have been done - Whenever a process change (defined as start up of a new process) is made or information in the Notification of Compliance Status Report changes, include a brief description of the process change (also includes startup of a new process), a description of any modifications to standard procedures or QA procedures, revisions to any of the information in the original Notification of Compliance Status Report under 63.1260(f), and information required by the Notification of Compliance Status Report on changes involving the addition of processes or monitoring equipment

	PERIODIC REPORTS	
	For emissions averaging, include ö	- Any changes of the processes or storage tanks included in the average - Calculation of the overall percent reduction efficiency for the reporting period. - Changes to the Implementation Plan that affect the calculation methodology of uncontrolled or controlled emissions or the hazard or risk equivalency demonstration. - Rolling quarterly calculation of annual percent reduction efficiency, submitted every second semiannual or fourth quarterly report, to demonstrate emissions averaging provisions are satisfied.

Table 13-5. OTHER REPORTING REQUIREMENTS (§63.1260(h)-(m))

	Other Reporting Requirements	
Change in Activity Covered by Precompliance Report or **Change in Size of Control Device**		Submit a report 60 days before the planned implementation date of (1) any change in the activity covered by the Precompliance report or (2) a change in the status of a control device from small to large. Results of performance test for large device must be reported in the Periodic Report.
Startup, Shutdown, and Malfunction Reports for SSM events that occurred during the reporting period	Submit on same schedule as Periodic Reports and include ö	- Occurrence and duration of each malfunction of (1) the process operations or air pollution control equipment or (2) CMS - A statement for each SSM event that plan provisions were followed. - Name, title, and signature of the owner or operator, or other responsible official certifying report's accuracy
Actions Inconsistent with the SSM Plan	Telephone call or fax within 2 working days of commencing action inconsistent with SSM plan, followed by a letter within 7 working days after the end of the event. Include ö	- Name, title, and signature of the owner or operator, or other responsible official certifying report's accuracy - Circumstances of event and reasons for not following SSM plan - Whether any excess emissions and/or parameter monitoring exceedances are believed to have occurred

	Other Reporting Requirements	
LDAR Programs		Follow reporting requirements of §63.1255, described in more detail in ° **Chapter 6, section 6.3**. Retain copies of reports for 5 years.
Emissions Averaging: Implementation Plan	Submit implementation plan 6 months prior to compliance date. Include ö	- Implementation Plan: - identification of all process vents and storage tanks in each emissions average - uncontrolled and controlled emissions of HAP and overall percent reduction efficiency, and calculations used to obtain these figures - estimated values for all parameters required to be monitored for each process and storage tank included in the average - a statement that all applicable compliance demonstrations, monitoring, inspection, recordkeeping, and reporting requirements will be implemented on the date of compliance - Hazard or Risk Equivalency Demonstration showing that emissions averaging will not result in greater hazard and/or risk than if the tanks and process vents had been controlled separately
Notification of **Performance Test and Test Plan**		60 days before planned date of performance test: - notify Administrator - submit the test plan (§63.7(c)) (**ö see Appendix PT** for more details) - submit the emissions profile (§63.1257(b)(8)(ii)) (**ö see Section 8.3** for more information on emissions profiles)
Request for **Extension of Compliance**	Allow up to 1 additional year to comply with standards	- Submit request no later than 120 days prior to compliance dates. May submit after that point if need for the extension arose after that date and before the otherwise applicable compliance date, and the need arose due to circumstances beyond the operator's control. Include data described in §63.6(i)(6)(i)(A)-(D).
Flowrate Recalculations for Dense Gas Systems	Submit once every five years on when operating scenario changes	Recalculated flowrate for dense gas systems when not correcting for supplemental gases, per 63.1258(b)(5)(ii)(B).

Appendix EE

Emissions Estimation Procedures for Process Vents

The following paragraphs briefly summarize the techniques for calculating uncontrolled and controlled emissions by emission estimation procedures for the following emission episodes:

- Vapor Displacement
- Purging
- Heating
- Depressurization
- Vacuum Systems
- Gas Evolution
- Air Drying
- Empty Vessel Purging

Uncontrolled emissions calculations for the above source types are given in sections 63.1257(d)(2)(i) (A) through (H), respectively, and controlled emissions techniques in 63.1257(d)(3)(i)(B) (1) through (8), respectively. If the owner or operator determines that these equations are not appropriate for his/her operations, the regulations at 63.1257(d)(2)(ii) allow for the use of other engineering assessments to determine uncontrolled HAP emissions. If alternative equations or engineering assessments will be conducted, the owner or operator must document all data, assumptions, and procedures in the Precompliance Report.

The following discussion refers to equation numbers found in 63.1257(d) (Numbers 11 - 43). Except where variations are noted, individual HAP partial pressures in multicomponent systems shall be determined by the following methods: If the components are miscible in one another, use Raoult's law to calculate the partial pressures; if the solution is a dilute aqueous mixture, use Henry's law to calculate partial pressures; if Raoult's law or Henry's law are not appropriate or available, use experimentally obtained activity coefficients or models such as the group-contribution models, to predict activity coefficients, or assume the components of the system behave independently and use the summation of all vapor pressures from the HAP as the total HAP partial pressure. Chemical property data can be obtained from standard reference texts.

Vapor Displacement-Uncontrolled Emissions: Calculating HAP emissions from vapor displacement due to material transfer is accomplished according to Equation 11. The following values are needed:

- <u>Volume</u> of Gas displaced by vessel (V),
- <u>Temperature</u> of vessel vapor space (T),
- <u>Partial Pressure</u> of each HAPs (may be calculated using Raoult's Law) (P_i),
- <u>Molecular Weight</u> of each HAP (MW_i),

- Universal gas constant (R), and
- Total number of HAPs (n).

Vapor Displacement-Controlled Emissions: Same as above (using equation 11) except T = temperature of the receiver and the HAP partial pressures are determined at the temperature of the receiver.

Purging-Uncontrolled Emissions: Calculating HAP emissions from purging is accomplished according to Equation 12. The following values are needed:

- Purge flow rate at the temperature and pressure of the vessel vapor space (V),
- Temperature of the vessel vapor space; absolute (T).
- Partial pressure of the individual HAP (P_i), which may be calculated using Raoult's Law
- Partial pressure of individual condensable VOC compounds (including HAP) (P_j), which may be calculated using Raoult's Law
- Pressure of the vessel vapor space (P_T), which may be set to 760 mmHg for atmospheric conditions
- Molecular weight of the individual HAP (MW_i),
- Time of purge (t),
- Number of HAP compounds in the emission stream (n),
- Number of condensable VOC compounds (including HAP) in the emission stream (m), and
- Ideal gas law constant (R).

HAP vapor concentration must be assumed to be 25% of the saturated value when the purge rate is greater than 100 standard cubic feet per minute (scfm).

Purging - Controlled Emissions: Same as above (using equation 12) except T = temperature of the receiver and HAP partial pressures determined at the temperature of the receiver.

Heating - Uncontrolled Emissions: There are three methods given in Section 63.1257(d)(2)(i)C for calculating HAP emissions from heating a vessel. For heating processes where the vessel contents are heated to ≤ 10^oK below the content's boiling point (Scenario 1), equation 13 or 14 or 18 must be used. For heating processes where the vessel contents are heated to within 10^oK of the content's boiling point (but below the boiling point) (Scenario 2), equation 13 or 14 or 18 must be used. However, in equations 13 and 14, T_2 must be 10^oK below the boiling point. For Scenario 2, the O/O can use Equation 14 to calculate two increments. If the contents are heated to boiling, the vessel must be operated with a properly operated process condenser. A demonstration that the process condenser is properly operated is required if: (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). HAP emissions are assumed to be zero if a process condenser is properly operated and documented as follows:

- show that the exhaust gas temperature is less than the boiling point of the substance(s) in the vessel, or
- perform a material balance around the condenser and show that at least 99% of the material vaporized while boiling is condensed.

Several calculation options are given for each of the 2 heating scenarios described above. The owner/operator should review the equations and decide which is best for his given situation. These procedures are summarized below:

Equation No.	Description
13 or 14 or 18	*Scenario* 1 = Final Temp is $\leq$ 10°K below HAP boiling point - These equations are similar and the choice of which to use is left up to the owner/operator. Both of them calculate HAP emissions based on initial & final pressure of the vessel, initial & final temperatures, average HAP MW calculated by weighting each HAP's MW by the respective HAP partial pressure (Eq. 14 only), HAP vapor pressure & mole fraction in the liquid phase, and condensable VOC vapor pressure & mole fraction in the liquid phase. Equation 18 calculates HAP emissions based on initial and final HAP partial pressures, total pressure of the vessel, initial and final temperatures, average HAP MW and the volume of free space in the vessel.
15 - 17	Supporting equations for 13 & 14. NOTE: Eq. 17 supports Eq. 14 only.
19-20	Supporting equations for 18.
	Scenario 2 = Final Temp is > 10°K below HAP boiling point - The Owner/Operator has a choice of 4 calculation methods for this scenario as follows:
13, or	1. Use equation 13 with parameters (vapor pressures, T_2, Pa_2) determined at 10°K below the boiling point.
14, or	2. Use equation 14 with parameters (HAP partial pressures, T_2, Pa_2) determined at 10°K below the boiling point
14	3. Use Equation 14 to calculate emissions as the sum of emissions for 2 discrete temperature increments (i.e, (initial temp to 10°K below BP) + (10°K below BP to the lower of the final temperature or 5°K below the

	BP)	
18	4.	Same as above.

Heating - Controlled Emissions: Use equation 13 or 37. In equation 13 HAP vapor pressures shall be determined at the temperature of the receiver. In equation 13 and 37, the average HAP molecular weight shall be calculated using the HAP partial pressures at the temperature of the receiver.

Depressurization - Uncontrolled Emissions: There is a choice of three techniques for calculating HAP emissions from depressurization events. The owner/operator should review the equations and decide which is best for his given situation. These procedures are summarized below:

21-26, 17 — 1. The first technique calculates HAPs emissions using the ideal gas law as a function of the volume of non-condensable gas produced, ratio of moles of non-condensable gas to moles of HAPs, HAP MW, pressure, temperature and universal gas constant. Equation input parameters include free volume of the vessel, condensable VOC (including HAPs) vapor pressure & mole fraction, HAP vapor pressure & mole fraction, and initial & final pressure of the vessel. The HAP partial pressure may be calculated using Raoult's Law.

27-31, 23-24 — 2. HAPs emissions are calculated by this method by multiplying the average HAP-to-non-condensable gas mole ratio by the number of moles of non condensable gas released during the event. Equation inputs are initial & final pressure, temperature, condensable VOC vapor pressure & mole fraction, mole fraction of HAPs, and average HAP molecular weight.

32 — 3. Equation 32 presents another approach to calculating HAPs emissions from depressurization. Parameter inputs include vessel volume, temperature, initial & final pressure, partial pressure of individual HAP compounds, molecular weight of individual HAP compounds.

Depressurization - Controlled Emissions: Use equation 38 with the initial and final volumes of noncondensable gas in the vessel, adjusted to the pressure of the receiver, calculated using equations 39 and 40. Initial and final partial pressures of noncondensable gas in the vessel are calculated using equations 41 and 42.

Vacuum Systems - Uncontrolled Emissions: HAPS emissions from vacuum systems may be calculated using equation 33 if the air leakage rate is known or can be calculated. Values needed are

- Absolute pressure of receiving vessel or ejector outlet conditions (P_{system}),
- Partial pressure of HAP at receiver temperature (P_i), or the ejector outlet conditions
- Partial pressure of condensable at receiver temperature (P_j) or the ejector outlet conditions
- Total air leak rate in the system (La),
- Molecular weight of non-condensable gas (MW_{nc}),
- Molecular weight of the individual HAP with partial pressures calculated at receiver or ejector outlet temperature, as appropriate (MW_i),
- Time of the vacuum operation.

Vacuum Systems - Controlled Emissions: Use equation 33 to calculate controlled emissions from vacuum systems.

Gas Evolution - Uncontrolled Emissions: Use equation 12 with Volumetric Flow (V) determined by equation 34. Parameter inputs are:

- Mass flow rate of gas evolution (W_g),
- Temperature at the exit, absolute (T),
- Vessel pressure (P_T),
- Molecular weight of the evolved gas (MW_g)
- Ideal gas law constant (R),

Gas Evolution - Controlled Emissions: Use equation 12 with V calculated using equation 34 and T set to equal the temperature of the receiver and the HAP partial pressures determined at the receiver temperature. The term for time, t in equation 12, is not need for the purposes of this calculation.

Air Drying - Uncontrolled Emissions: Use equation 35 to calculate HAPs emissions per batch of air dried solids with parameter inputs as follows:

- Mass of dry solids (B),
- HAP in material entering dryer, weight percent (PS_1), and
- HAP in material exiting dryer, weight percent (PS_2)

Air Drying - Controlled Emissions: Same as above (use equation 11) with V equal to the air flow rate and P_i determined at the temperature of the receiver.

Empty Vessel Purging - Uncontrolled Emissions: Use equation 36 with the following inputs:

- Volume of empty vessel (V),
- Temperature of the vessel vapor space (T),
- Partial pressure of the individual HAP at the beginning of the purge (P_i),
- Flowrate of the purge gas (F), and
- Duration of the purge (t)

Note that the term $e^{-Ft/v}$ can be assumed to be zero.

Empty Vessel Purging - Controlled Emissions: Use equation 43 with the following inputs:

- Volume of empty vessel (V),
- Temperature of the vessel vapor space at beginning of purge (T_1)
- Temperature of the receiver (T_2),
- Partial pressure of the individual HAP at the beginning of the purge $(P_i)_{T1}$,
- Partial pressure of the individual HAP at the receiver temperature $(P_i)_{T2}$,
- Flowrate of the purge gas (F), and
- Duration of the purge (t)

Emissions Estimation Equations for Uncontrolled Sources (11-36) and Controlled Sources (37-43)

No.	Equation
11	Vapor Displacement $$E = \frac{(V)}{(R)(T)} \times \sum_{i=1}^{n} (P_i)(MW_i)$$ E = mass of HAP emitted V = volume of gas displaced from the vessel R = ideal gas law constant T = temperature of the vessel vapor space; absolute P_i = partial pressure of the individual HAP MW_i = molecular weight of the individual HAP n = number of HAP compounds in the emission stream i = identifier for a HAP compound

Emissions Estimations Equations for Uncontrolled Sources (11-36) and Controlled Sources (37-43) (continued)

No.	Equation
12	$$E = \sum_{i=1}^{n} P_i\, MW_i \times \frac{(V)(t)}{(R)(T)} \times \frac{P_T}{P_T - \sum_{j=1}^{m} (P_j)}$$ Purging: E = mass of HAP emitted V = purge flow rate at the temperature and pressure of the vessel vapor space R = ideal gas law constant T = temperature of the vessel vapor space; absolute P_i = partial pressure of the individual HAP

	P_j = partial pressure of individual condensable VOC compounds (including HAP) P_T = pressure of the vessel vapor space MW_i = molecular weight of the individual HAP t = time of purge i = identifier for a HAP compound j = identifier for a condensable compound n = number of HAP compounds in the emission stream m = number of condensable VOC compounds (including HAP) in the emission stream
13	Heating (1) $$E = \frac{\sum_{i=1}^{n}((P_i^*)(x_i)(MW_i))}{760 - \sum_{j=1}^{m}((P_j^*)(x_j))} \times \Delta n$$ E = mass of HAP vapor displaced from the vessel being heated x_i = mole fraction of each HAP in the liquid phase x_j = mole fraction of each condensable VOC (including HAP) in the liquid phase (P_i^*) = vapor pressure of each HAP in the vessel headspace, mmHg (P_j^*) = vapor pressure of each condensable VOC (including HAP) in the vessel headspace, mmHg 760 = atmospheric pressure, mmHg MW_i = molecular weight of the individual HAP n = number of HAP compounds in the displaced vapor m = number of condensable VOC compounds (including HAP) in the displaced vapor Δ_n = number of moles of non-condensable gas displaced, as calculated using Equation 15 of this subpart i = identifier for a HAP compound
14	$$E = \frac{\frac{\sum_{i=1}^{n}(P_i)_{T1}}{Pa_1} + \frac{\sum_{i=1}^{n}(P_i)_{T2}}{Pa_2}}{2} \times \Delta n \times MW_{HAP}$$ Pa_n = partial pressure of non-condensable gas in the vessel headspace at the initial (n=1) and final (n=2) temp. $(Pi)_{Tn}$ = partial pressure of each HAP in the vessel headspace at initial (T_1) and final (T_2) temperature. [For use in Equation 13, replace $(Pi)_{T1}$ + $(Pi)_{T2}$ with Pi at the temperature used to calculate vapor pressure of HAP in Equation 13.] Heating (2) (same as Equation 13)

15	$$\Delta h = \frac{V}{R}\left[\left(\frac{Pa_1}{T_1}\right)-\left(\frac{Pa_2}{T_2}\right)\right]$$ Heating (3) θη = number of moles of gas displaced V = volume of free space in the vessel R = ideal gas law constant Pa_1 = initial noncondensable gas pressure in the vessel, as calculated using Equation 16 Pa_2 = final noncondensable gas pressure in the vessel, as calculated using Equation 16 T_1 = initial temperature of vessel, absolute T_2 = final temperature of vessel, absolute
16	$$Pa_n = P_{atm} - \sum_{j=1}^{m}(P_j)_{Tn}$$ Heating (4): Pa_n = partial pressure of noncondensable gas in the vessel headspace at initial (n=1) and final (n=2) temperature P_{atm} = atmospheric pressure (when θ? is used in Equation 13 of this subpart, P_{atm} may be set equal to 760 mmHg for any vessel) $(P_j)_{Tn}$ =partial pressure of each condensable volatile organic compound (including HAP) in the vessel headspace at the initial temperature (n=1) and final (n=2) temperature m = number of condensable VOC compounds (including HAP) in the displaced vapor j = identifier for a condensable compound
17	$$MW_{HAP} = \sum_{i=1}^{n}\frac{((P_i)_{T_i} + (P_i)_{T_2})\,MW_i}{\sum_{i=1}^{n}((P_i)_{T_1} + (P_i)_{T_2})}$$ Heating (5): MW_{HAP} = average molecular weight of HAP in the displaced gas $(P_i\ *)$ = vapor pressure of each HAP in the vessel headspace at any temperature between the initial and final heatup temperatures, mmHg $(Pi)_{Tn}$ = partial pressure of each HAP in the vessel headspace at initial (T_1) and final (T_2) temperature [For use in Equation 13, replace $(Pi)_{T1}$ + $(Pi)_{T2}$ with Pi at the temperature used to calculate vapor pressure of HAP in Equation 13] MW_i = molecular weight of each HAP n = number of HAP compounds in the emission stream
18	

	$$E = MW_{HAP} \times \left(N_{avg} \times \ln \left(\frac{P_T - \sum_{i=1}^{n} (P_{i,1})}{P_T - \sum_{i=1}^{n} (P_{i,2})} \right) - (n_{i,2} - n_{i,1}) \right)$$ Heating (6): E = mass of HAP vapor displaced from the vessel being heated N_{avg} = average gas space molar volume during the heating process P_T = total pressure in the vessel $P_{i,1}$ = partial pressure of the individual HAP compounds at T_1 $P_{i,2}$ = partial pressure of the individual HAP compounds at T_2 MW_{HAP} = average molecular weight of the HAP compounds $n_{i,1}$ = number of moles of condensable in the vessel headspace at T_1 $n_{i,2}$ = number of moles of condensable in the vessel headspace at T_2 n = number of HAP compounds in the emission stream
19	$$N_{avg} = \frac{VP_T}{2R} \left(\frac{1}{T_1} + \frac{1}{T_2} \right)$$ Heating (7): N_{avg} = average gas space molar volume during the heating process V = volume of free space in vessel P_T = total pressure in the vessel R = ideal gas law constant T_1 = initial temperature of the vessel T_2 = final temperature of the vessel
20	$$(n_{i,2} - n_{i,1}) = \frac{V}{(R)(T_2)} \sum_{i=1}^{n} P_{i,2} - \frac{V}{(R)(T_1)} \sum_{i=1}^{n} P_{i,1}$$ Heating (8): V = volume of free space in vessel R = ideal gas law constant T_1 = initial temperature in the vessel T_2 = final temperature in the vessel $P_{i,1}$ = partial pressure of the individual HAP compounds at T_1 $P_{i,2}$ = partial pressure of the individual HAP compounds at T_2 n = number of HAP compounds in the emission stream
21	Depressurization (1): $$V_{nc1} = \frac{VP_{nc_1}}{760}$$ V_{nc1} = initial volume of noncondensable gas in the vessel

	V_{nc2} = final volume of noncondensable gas in the vessel V = free volume in the vessel being depressurized P_{nc1} = initial partial pressure of the noncondensable gas, as calculated using Equation 23 of this subpart, mmHg P_{nc2} = final partial pressure of the noncondensable gas, as calculated using Equation 24 of this subpart, mmHg 760 = atmospheric pressure, mmHg
22	$$V_{nc2} = \frac{VP_{nc_2}}{760}$$ Depressurization (2): (same as equation 21)
23	$$P_{nc1} = P_1 - \sum_{j=1}^{m} (P_j^*)(x_j)$$ Depressurization (3): P_{nc1} = initial partial pressure of the noncondensable gas P_{nc2} = final partial pressure of the noncondensable gas P_1 = initial vessel pressure P_2 = final vessel pressure P_j^* = vapor pressure of each condensable VOC (including HAP) in the emission stream x_j = mole fraction of each condensable VOC (including HAP) in the emission stream m = number of condensable VOC compounds (including HAP) in the emission stream
24	$$P_{nc2} = P_2 - \sum_{j=1}^{m} (P_j^*)(x_j)$$ Depressurization (4): (same as equation 23)
25	$$n_{Ri} = \frac{\left(\frac{P_{nc1}}{\sum_{i=1}^{n} (P_i^*)(x_i)} + \frac{P_{nc2}}{\sum_{i=1} ton(P_i^*)(x_i)} \right)}{2}$$ Depressurization (5): 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 20 of this subpart P_{nc2} = final partial pressure of the noncondensable gas, as calculated using Equation 21

	of this subpart P_i^* = vapor pressure of each individual HAP x_i = mole fraction of each individual HAP in the liquid phase
26	$$E = (V_{nc1} - V_{nc2}) \text{ x } \frac{P_{atm}}{RT} \text{ x } \sum_{i=1}^{n} \frac{MW_i}{n_{Ri}}$$ Depessurization (6): 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
27	$$n_{HAP} = \frac{(Y_{HAP})(V)(P_1)}{R\ T}$$ Depressurization (7): Y_{HAP} = mole fraction of HAP (the sum of the individual HAP fractions, SY_i) V = free volume in the vessel being depressurized P_1 = initial vessel pressure R = ideal gas law constant T = vessel temperature, absolute
28	$$n_1 = \frac{VP_{nc_1}}{RT}$$ Depressurization (8): n_1 = initial number of moles of noncondensable gas in the vessel n_2 = final number of moles of noncondensable gas in the vessel V = free volume in the vessel being depressurized P_{nc1} = initial partial pressure of the noncondensable gas, as calculated using Equation 23 of this subpart P_{nc2} = final partial pressure of the noncondensable gas, as calculated using Equation 24 of this subpart R = ideal gas law constant T = temperature, absolute
29	Depressurization (9):

	$$n_2 = \frac{VP_{nc_2}}{RT}$$ same as equation 28)
30	Depressurization (10): $$n_{HAP} = \frac{\left(\frac{n_{HAP,1}}{n_1} + \frac{n_{HAP,2}}{n_2}\right)}{2}[n_1 - n_2]$$ n_{HAP} = moles of HAP emitted n_1 = initial number of moles of noncondensable gas in the vessel, as calculated using Equation 28 of this subpart n_2 = final number of moles of noncondensable gas in the vessel, as calculated using Equation 29 of this subpart
31	$$E = n_{HAP} * MW_{HAP}$$ Depressurization (11): E = mass of HAP emitted n_{HAP} = moles of HAP emitted, as calculated using Equation 30 of this subpart MW_{HAP} = average molecular weight of the HAP as calculated using Equation 17 of this subpart
32	$$E = \frac{V}{(R)(T)} \text{ x } \ln\left(\frac{P_1 - \sum_{j=1}^{m}(P_j)}{P_2 - \sum_{j=1}^{m}(P_j)}\right) \text{ x } \sum_{i=1}^{n}(P_i)(MW_i)$$ Depressurization (12): V = free volume in vessel being depressurized R = ideal gas law constant T = temperature of the vessel, absolute P_1 = initial pressure in the vessel P_2 = final pressure in the vessel P_j = partial pressure of the individual condensable compounds, including HAP MW_i = molecular weight of the individual HAP compounds n = number of HAP compounds in the emission stream m = number of condensable compounds (including HAP) in the emission stream i = identifier for a HAP compound j = identifier for a condensable compound
33	Vacuum Systems:

	$$E = \frac{(La)(t)}{MW_{nc}} \left(\frac{\sum_{i=1}^{n} P_i MW_i}{P_{system} - \sum_{j=1}^{m} P_j} \right)$$ E = mass of HAP emitted P_{system} = absolute pressure of receiving vessel or ejector outlet conditions, if there is no receiver P_i = partial pressure of the HAP at the receiver temperature or the ejector outlet conditions P_j = partial pressure of condensable (including HAP) at the receiver temperature or the ejector outlet conditions La = total air leak rate in the system, mass/time MW_{nc} = molecular weight of noncondensable gas t = time of vacuum operation MW_i = molecular weight of the individual HAP in the emission stream, with HAP partial pressures calculated at the temperature of the receiver or ejector outlet, as appropriate
34	$$V = \frac{(W_g)(R)(T)}{(P_T)(MW_g)}$$ Gas Evolution: V = volumetric flow rate of gas evolution W_g = mass flow rate of gas evolution R = ideal gas law constant T = temperature at the exit, absolute P_T = vessel pressure MW_g = molecular weight of the evolved gas
35	$$E = B \text{ x} \left(\frac{PS_1}{100 - PS_1} - \frac{PS_2}{100 - PS_2} \right)$$ Air Drying: E = mass of HAP emitted B = mass of dry solids PS_1 = HAP in material entering dryer, weight percent PS_2 = HAP in material exiting dryer, weight percent
36	Empty Vessel Purging:

	$$E = \left(\frac{V}{RT} \times \left(\sum_{i=1}^{n} (P_i)(MW_i) \right) (1 - e^{-Ft/v}) \right)$$ V = volume of empty vessel R = ideal gas law constant T = temperature of the vessel vapor space; absolute P_i = partial pressure of the individual HAP at the beginning of the purge (MW_i) = molecular weight of the individual HAP F = flowrate of the purge gas t = duration of the purge n = number of HAP compounds in the emission stream i = identifier for a HAP compound (Note: The term $e^{-Ft/v}$ can be assumed to be 0)
37	$$E = \Delta h \times \frac{\sum_{i=1}^{n} P_i}{P_T - \sum_{j=1}^{m} P_j} \times MW_{HAP}$$ Heating (controlled emissions): E = mass of HAP emitted θ? = moles of noncondensable gas displaced P_T = pressure in the receiver P_i = partial pressure of the individual HAP at the receiver temperature P_j = partial pressure of condensable VOC (including HAP) at the receiver temperature n = number of HAP compounds in the emission stream MW_{HAP} = the average molecular weight of HAP in vapor exiting the receiver, as calculated using Equation 17 of this subpart m = number of condensable VOC (including HAP) in the emission stream
38	$$E = (V_{nc}1 - V_{nc}2) \times \frac{\sum_{i=1}^{n} (P_i)}{P_T - \sum_{j=1}^{m} (P_j)} \times \frac{P_T}{RT} \times MW_{HAP}$$ Depressurization (controlled emissions, 1): E = mass of HAP vapor emitted V_{nc1} = initial volume of noncondensable in the vessel, corrected to the final pressure, as calculated using Equation 39 of this subpart V_{nc2} = final volume of noncondensable in the vessel, as calculated using Equation 40 of this subpart

	P_i = partial pressure of each individual HAP at the receiver temperature P_j = partial pressure of each condensable VOC (including HAP) at the receiver temperature P_T = receiver pressure T = temperature of the receiver R = ideal gas law constant MW_{HAP} = the average molecular weight of HAP calculated using Equation 17 of this subpart with partial pressures determined at the receiver temperature n = number of HAP compounds in the emission stream m = number of condensable VOC (including HAP) in the emission stream
39	$$V_{nc}1 = \frac{VP_{nc_1}}{P_T}$$ Depressurization (controlled emissions, 2): V_{nc1} = initial volume of noncondensable gas in the vessel V_{nc2} = final volume of noncondensable gas in the vessel V = free volume in the vessel being depressurized P_{nc1} = initial partial pressure of the noncondensable gas, as calculated using Equation 41 of this subpart P_{nc2} = final partial pressure of the noncondensable gas, as calculated using Equation 42 of this subpart P_T = pressure of the receiver
40	Depressurization (controlled emissions, 3): $$V_{nc}2 = \frac{VP_{nc_2}}{P_T}$$ (same as equation 39)
41	$$P_{nc}1 = P_1 - \sum_{j=1}^{m} P_j$$ Depressurization (controlled emissions, 4): P_{nc1} = initial partial pressure of the noncondensable gas in the vessel P_{nc2} = final partial pressure of the noncondensable gas in the vessel P_1 = initial vessel pressure P_2 = final vessel pressure P_j = partial pressure of each condensable VOC (including HAP) in the vessel m = number of condensable VOC (including HAP) in the emission stream
42	Depressurization (controlled emissions, 5): $$P_{nc}2 = P_2 - \sum_{j=1}^{m} P_j$$

	(Same as equation 41)
43	Empty Vessel Purging (controlled emissions): $$E = \frac{V}{R}\left(\left(\sum_{i=1}^{n}\frac{(P_i)_{T_1}(MW_i)}{T_1}\right)\left(-e^{-Ft/V}\right)-\left(\sum_{i=1}^{n}\frac{(P_i)_{T_2}(MW_i)}{T_2}\right)\left(\ln\left(\frac{\sum_{i=1}^{n}(P_i)_{T_2}}{\sum_{i=1}^{n}(P_i)_{T_1}}\right)+1\right)\right)$$ V = volume of empty vessel R = ideal gas law constant T_1 = temperature of the vessel vapor space at beginning of purge T_2 = temperature of the receiver, absolute $(P_i)_{T1}$ = partial pressure of the individual HAP at the beginning of the purge $(P_i)_{T2}$ = partial pressure of the individual HAP at the receiver temperature MW_i = molecular weight of the individual HAP F = flowrate of the purge gas t = duration of the purge n = number of HAP compounds in the emission stream i = identifier for a HAP compound

Appendix PT

Emissions Performance Testing - Test Methods and Approach

Overview

In complying with emissions control requirements for process vents, tanks, and wastewater emission sources, the O/O has a choice of demonstrating compliance with standards for:

- Organic HAP Mass Removal/Destruction Efficiency,
- TOC Mass Removal/Destruction Efficiency, or
- Outlet TOC concentration.

Organic HAP

Organic HAP mass removal/destruction efficiency is determined by comparing the mass rate of organic HAPs leaving the air pollution control device (APCD) to the mass rate entering the APCD. Mass rates are calculated by multiplying organic HAP concentrations by the gas flow rate. Total organic HAP concentration is typically defined as the sum of individual organic HAP compounds (for APCDs controlling solely wastewater emission sources, Organic HAP includes only SHAP and PSHAP compounds).

TOC

TOC concentration is the sum of all organic compounds minus concentrations of methane and ethane. TOC concentrations can be used for calculating efficiency or to demonstrate compliance with the 20 ppmv TOC concentration limit (TOC is almost always referred to in conjunction with demonstrating compliance to 20 ppm TOC standard)

Structure of this Appendix

The list of applicable test methods for demonstrating compliance with the Pharmaceutical MACT standards is listed below. Summaries of each test method are presented. The benefits of selecting a particular method are then discussed.

Demonstrating Compliance with Percent Reduction Standards

For demonstrating compliance with percent reduction standards, the following methods can be used:

- Method 18 - (HAP or TOC) - all control devices
- Method 25 - (HAP or TOC) - only from combustion sources,
- Methods 26 or 26A - (HAPs with HCl; TOC with hydrogen halides HCl, HBr and HF or halogens Cl_2 and Br_2)
- Method 25A - (HAP or TOC) - only under any of the following limited conditions:
    1. There is only one compound known to exist,
    2. Where the organic compounds consist of only hydrogen and carbon,

3. Where relative percentages of the compounds are known or can be determined and FID responses to the compounds are known,
4. Where a consistent mixture of the compounds exist both before and after the control device and only the relative concentrations are to be assessed, or
5. Where the FID can be calibrated against mass standards of the compounds emitted (i.e., predominant HAP compound)

Demonstrating Compliance with <u>TOC Standards</u>

For demonstrating compliance with TOC standard, the following methods can be used:

- Method 18- conforming to performance specification 9 (40 CFR 60 App B),
- Method 25A - calibrated with either methane or the predominant HAP and meeting performance specification 8, or
- Method 26 - for measuring hydrogen halide concentrations (if present)

Q and A

Q Do I have to use one of the listed methods for determining concentrations of HAP or TOC?

A. No. Any method which has been validated by EPA validation Method 301 (§40 CFR 63 Appendix A) can also be used. This is especially the case for certain HAPs that cannot be measured by Method 18 or 25A. Formaldehyde, for example, does not respond well to a FID used in Method 25A and sometimes in Method 18. Phenol is another example of a compound very difficult to sample and analyze using Method 18 procedures.

Method 18

Method 18 (Measurement of Gaseous Organic Compound Emissions by Gas Chromatography [discrete GC analyses for individual HAPs conducted either on-site or off-site]) is suitable for measuring concentrations of many organic HAPs. The method uses Gas Chromatography (GC) coupled with any suitable detector. By using the GC separation capability, Method 18 can quantify concentrations of <u>individual</u> compounds. Sample procedures are listed as follows:

- Integrated Bag Sampling. Configurations include evacuated container, direct pump sample, or other (heated, or diluted bag configurations, etc.)

C Direct Interface (heated tubing from stack to instrument)
C Dilution Interface, or
C Sorbent Tube

There is no criterion for how quickly the sample must be analyzed, so for bag (container) sampling, it is possible to analyze samples off-site (However, extensive QA procedures must be performed showing that analytical recoveries are not biased by this lapse in time). Typically, analyses are conducted on-site, during sampling.

The method is only semi-continuous at best, because even with direct interface sampling which calls for extracting a continuous sample stream from the stack, each analyses takes several minutes to conduct.

NOTE: TOC, organic HAP, hydrogen halide and halogen concentrations from combustion control devices must be corrected to 3% O_2, if supplemental gases are added to the vent stream or manifold:

$$C_c = C_m \left(\frac{17.9}{20.9 - \%O_2} \right)$$

Where C_c = concentration of TOC, 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

$\%0_{2d}$ = concentration of oxygen measured in vented gas stream, dry basis, percent by volume

Supplemental gases are defined in §63.1251 and include gases that are not defined as process vents, or closed-vent systems from wastewater units, storage tanks, or equipment components; they contain less than 50 ppmv TOC. Air required to operate combustion device burners is not considered a supplemental gas.
Concentration values to be used as an intermediates for calculating mass rates for efficiency determinations do not need to be corrected 3% O_2.

NOTE: TOC, organic HAP, or hydrogen halide and halogen concentrations from non-combustion devices must be corrected if supplemental gases are added:

$$C_a = C_m \left(\frac{V_s + V_a}{V_a} \right)$$

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 halide 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

Method 18 Calibration and QA Criteria

Calibration: A minimum of 3 gas standards/compound must be used to prepare calibration curves. Duplicate analyses of each standard must agree to within 5% of their mean. Standards must be analyzed both before and after sample analyses. Use an average of the 2 curves to determine sample concentration. If the 2 curves differ by more than 5% from their mean, report final results using both curves (resulting in 2 sample data sets)

Sample Analyses:- Final bag analyses concentration equals the average of 2 replicate analyses. Replicate peak areas must agree within 5% of their average (maybe difficult for direct interface if process is changing and at least several minutes lapse between analyses)

Dilution System Check: For dilution systems, a single calibration gas (high) must be directed through entire dilution system. Resulting values should be within 10% of expected.

Performance Audits: Audit analyses of 2 gases (high and low) must be within 10% of true value. If results are not within 10%, the audit superviser determines corrective action (correct instrumental problems and re-run audit, numerically correct biased data set, etc).

Recovery Study: For direct interface and dilution systems, direct mid level calibration gases through entire system. Replicate analyses should agree to within 5% of their mean and within 10% of the reading determined when gas are challenged directly to analyzer (sample bias). For bag sampling, spike a sample bag, to 40-60% of average sample concentration or 5 times the MDL (if sample not detected). From these results, the calculated a R value should be within 0.7 - 1.3. R is calculated as shown in Section 7.6.2 of Method 18. For sorbent tubes, 2 sample probes (tubes) are located adjacently in the stack and a sample taken. One is spiked with liquid or gaseous compounds while the other is not. From these results, the calculated R value should be within 0.7 - 1.3.

Additional Method 18 calibration and QA criteria when used for the 20 ppm TOC Standard (per Performance Specification 9, 40 CFR 60 Appendix B)

Calibration Gases: Low level 40-60% of measured concentratin (or 4-5x MDL),
Mid level 90-110% of measured concentration
High level 140-160% of measured concentration

Calibration Error: Calibration error checks must be performed for each target compound every 24 hours for each of the 3 standards. Observed concentration must be within 10% of actual value.

Calibration Precision and Linearity: Standards must be analyzed in triplicate. All must be within 5% of mean and an R^2 of > 0.995

Measurement Frequency: Sample time constant, T, must be less than 5 minutes or the sample frequency specified in the applicable regulation. T is calculated using equation 3 in PS 9.

Performance Audits: Same as above

Q and A

Q ***Does an O/O really have to conduct all the pre-test method development listed in Method 18 ?***

A *The objectives of the Method 18 preliminary method development are to 1) determine all target compounds. 2) optimize GC operating parameters and 3) develop acceptable QA procedures. Much of the method development information and QA procedures can be determined from past testing experience and existing laboratory methods. Potential target compounds can be revealed by interviewing plant personnel who have knowledge of the process being tested. However, during testing, compounds with GC peaks that have peak areas greater than 5% of the total peak area must be identified. Therefore, it is extremely important to develop the test method, prior to conducting the test, that will adequately quantify all possible target compounds. However, as long as the final Method 18 calibration and QA criteria are met during the test program, most administrators will not require such an extensive pre-test work up as is written up in the method.*

Method 25A

Method 25Adoes not have the capability of separating and quantifying individual compounds. It measures total organic gas concentration on a continuous basis using a flame ionization detector (FID). The FID is calibrated using a single calibration compound. The Pharmaceutical MACT allows the O/O to use either methane or the most predominant HAP as a calibration gas. Methane is used routinely for Method 25A calibrations (TOC/Methane). However, TOC/Methane results can be relatively high when compared with other calibration techniques due to differences in various compound FID relative response factors (RRF) as discussed below:

- TOC/Methane concentrations respond to a hydrocarbon compound at 1 ppm per 1 ppm of compound multiplied the number of carbon atoms in the compound. For example 4 ppm of benzene (C_6H_6) would respond as 24 ppm methane (4 x 6 carbon atoms/molecule) . If the HAPs do not consist strictly of hydrogen and carbon (i.e, contain alcohols, aldehydes, nitrogen, halogens, or other) the TOC/Methane RRF will be somewhat less than the 1 per number of carbon atoms/molecule. For example, if 20 ppm ethanol (C_2H_5OH) were present, a methane calibrated analyzer would respond at ~30 ppm TOC/methane (RRF – 1.5 ppm methane/ppm ethanol).
- Method 25A can be calibrated using the predominant HAP. For

the above benzene scenario, if TOC was determined by Method 25A calibrated with benzene, the resulting TOC/Benzene value would be 4 ppm (vs 24 ppm as TOC/Methane) ,

In determining which calibration gas to use, it should be remembered that calibration gases are not available for all HAP compounds, and the prices of non-methane calibration gases can be high.

Q and A

Q ***What are the requirements for using the predominant HAP as the Method 25A calibration gas ?***

A *The following criteria must be met in order to use the predominant HAP as the Method 25A calibration gas:*

- *The HAP is the single organic HAP representing the large percent by volume*
- *The response from the high calibration gas is at least 20 times the standard deviation of the response from the zero calibration gas when the instrument is zeroed on the most sensitive scale*
- *The span value of the analyzer must be less than 100 ppmv*

Measuring Methane & Ethane Concentrations

For TOC determinations, concentrations of methane and ethane should be subtracted from the total organic concentration. Some of the newer Method 25A analyzers can incorporate this into their operation, however, if methane values are substantial it may be better to analyze for methane and ethane separately using Method 18 or other technique (there is no required method listed in the rule for determining methane concentrations for calculating nonmethane organic concentrations, however, the planned procedure should be approved by the test plan administrator). Methane concentrations can also be approximated by techniques such as filtering the Method 25A sample stream through a charcoal tube (to remove all compounds but methane). Some sources, especially combustion sources fired on natural gas, may contain a considerable amount of methane (>50% of TOC). Quantities of ethane are usually not as high. If test costs include a methane determination by Method 18, it may be a good idea to include speciated organics in the analysis as well. In this way, if the

TOC/Methane values do not demonstrate compliance, the O/O may be able recalculate TOC using Method 18 data.
WARNING: If any changes are made to any performance testing procedures during the test program, the data <u>may not</u> be accepted by the regulatory agency. However, if the test engineer explains the logic behind the changes to the observer and has him/her "sign off" on the changes (in a log book, etc), the test results <u>may</u> be accepted.

Easy Calculation: TOC concentrations are calculated as the sum concentrations of all organics in the gas stream minus those of methane and ethane. However, if TOC is determined by Method 25 or 25A, the resulting measurement values already reflect total organic concentration, so that no sums have to be taken. Only methane and ethane concentrations need to be subtracted from these values.

Method 25A Calibration and QA criteria:
Calibration: A minimum of 4 gas standards concentrations as follows:

- zero gas = < 0.1 ppmv organics or < 0.1% span,(which ever is greater)
- low level = 25-35% of span
- mid level = 45-55% of span
- high level = 80-90% of span

Zero Drift: Introduce zero level gases after every test, or hourly during test. Must be less than ± 3% of span (gas directed through entire sample system)
Calibration Drift: Introduce mid level gases after every test, or hourly during test. Must be less than ± 3% of span (gas directed through entire sample system)

Calibration Error: Introduce low and mid level gases before start of test. Must be less than ± 5% of calibration gas value (gas directed through entire sample system)
Corrective Action: If CE is unacceptable, do not start testing until problem is corrected and CE is acceptable. If CD is unacceptable, either invalidate test results or recalibrate instrument and report results using both sets of calibration data**.**
Response Time: Measured 1/test program

Additional Calibration and QA criteria when used for the 20 ppm TOC standard (per Performance Specification 8, 40 CFR 60 Appendix B).
Data Recorder Scale: For uncontrolled sources = 1.25 to 2 times the average potential level, For controlled sources = 1.5 times the pollutant concentration corresponding to the emissions standard
Calibration Drift: ± 2.5% of span (gas directed through entire sample system)
Relative Accuracy: < 20 % mean value of the reference method test data in units of the applicable emissions standard, or 10% of the applicable standard, whichever is greater.

Method 25

Method 25 measures Total Gaseous Nonmethane Organic Emissions as Carbon. A sample of gas is extracted from the stack, pulled thorough a cryogenic trap to collect the higher molecular weight organic compounds, and then into an evacuated canister, to collect the lower molecular weight organic compounds. In principle, the analysis is then completed on both fractions in the following steps:

1. Measure sample methane and CO_2 and concentration (background)
2. Oxidize all organics to CO_2 and H_2O,
3. Catalytically reduce CO_2 to CH_4, and
4. Measure residual CH_4 concentration.

The difference between the background CH_4 concentration from the oxidized/reduced CH_4 fraction is attributable to the concentrations of organic compounds in the gas stream. This method does not have a response factor bias as does Method 25A, but has a detection limit of 50 ppmC (parts per million carbon, same as ppm as methane). For many process/control device situations, this detection limit is too high to allow control efficiency compliance to be demonstrated.

Method 26

Method 26, Determination of Hydrogen Chloride from Stationary Sources, uses aqueous absorbing solutions to collect and quantify hydrogen chloride (HCl). It cannot be used for measuring concentrations of organics. It can be used for determining removal efficiencies of HCl in control efficiency demonstrations or halogenated compounds for the 20 ppm TOC/halogen halide concentration requirements.

Q and A

Q ***Which parameters (Organic HAP or TOC) should an O/O use to demonstrate compliance ?***

A *The selection of whether to use Organic HAP removal efficiency standard or TOC concentration standard to demonstrate APCD compliance is case specific. For some cases where the APCD is functioning well and is controlling TOC to levels much lower than 20 ppm TOC/Methane, then TOC as measured by Method 25A is the simplest and least costly choice. For cases where the margin of compliance is closer, it may be a "safer bet" to measure Total Organic HAP at the inlet and outlet for removal efficiency determinations.*

Compounds not Included in Wastewater APCD Tests

For wastewater sources, the total Organic HAPs method target compounds need not include compounds not used or produced, compounds in wastewater POD that are < 1 ppmw, or compounds which are not detected in wastewater when detection limits are not greater than < 1 ppmw.

How is gas flow rate measured ?

Flow Rate Determinations

Vent gas flow rate must be measured for determining Organic HAP mass rates. Section 1257(b) states that EPA Method 2, 2A, 2C or 2D must be used for measuring volumetric flow rates. However, some of these methods may not be appropriate for low flow or batch processes as discussed below.

Method 2

Method 2 incorporates the use of an S type pitot tube to measure velocity pressure drop and gas velocity. The gas velocity is then multiplied by the duct cross sectional area to determine flow rate. Incorporated into Method 2 are measurements of O_2/CO_2 concentrations, gas temperature, and gas moisture content. Method 2 works well for measuring fairly stable flows with a measurable pressure drop (not too low). If velocity pressures are lower than 0.05 inches water column (in. wc), a more sensitive pressure gauge than what is described in Method 2 must be used (or use a different flow measurement technique). Method 2 is conducted manually with discrete measurements taken periodically. If flow rate fluctuates, periodic measurements may not capture all flow rate episodes which could result in a biased flow rate average.

Method 2A - 2E

Method 2A -2E are alternative flow measurement methods for situations where Method 2 is not recommended. They are entitled as follows:

- 2A = Direct measurement of gas volume through pipe and small ducts (volume meters),
- 2B = Determination of exhaust gas volume flow from gasoline vapor incinerators
- 2C = Determination of gas velocity and volumetric flow rate in small stacks or ducts (standard pitot)
- 2D = Measurement of gas volumetric flow rates in small pipes or ducts (orifice plates, rotameters, other),
- 2E = Determination of gas: gas production flow rate

Alternative Flow Monitoring Techniques

The above alternative Method 2 procedures are suitable for many situations. Most of them incorporate visual observation of pressure other measurement. For batch processes having very variable flow rate, it may be necessary to use the above methods with an automated measuring device capable of sending the measurement signal to a continuous data acquisition system (i.e., pressure transducer, temperature thermocouple, anemometer, etc). Continuous readings of flow rate could then be acquired and accurate averages calculated. If the test firm is using a continuous emissions monitoring systems (CEMS) for Method 25A tests, it is not much more difficult to incorporate continuous flow monitoring into their data acquisition system. Alternative flow rate measurement techniques may be approved as well. For batch processes, tracer gas injection (SO_2, CO, etc) with dilution monitoring works well and provides continuous flow rate data (per Alternative EPA Method Alt-012).

Cyclonic Flow Measurements

For instances of cyclonic flow, EPA Method 1 recommends that EPA Method 2 not be used for determining flow rate. In these cases, there are alternative methods which can be used, if approved by the administrator (i.e, Draft Method 2F- Alternative Method ATM-015).

O_2/CO_2 Measurements

Oxygen and carbon dioxide concentrations must be measured to incorporate into gas flow rate calculations (if velocity pressure flow measurement technique is used). Also, if the TOC compliance option is being used on a combustion APCD, TOC values must be corrected to 3% O_2. Section 63.1257(b)(3) states that EPA Method 3 must be used for gas analysis. EPA Method 3 determines O_2 and CO_2 using either a Fyrite™ or an Orsat™ analyzer. If the O_2 measurement is needed for TOC correction to 3% O_2, then a Fyrite™ can not be used. Using an Orsat™ analyzer for O_2 measurements can be time consuming and has potential for error due to leaks and operator error. It is more simple and technically sound to conduct O_2 measurements using CEMS by EPA Method 3A.

Moisture Determination

Gas moisture content is incorporated into flow rate calculations (if velocity pressure flow measurement techniques are used) and Method 18 & 25A analyses (to correct TOC values from a wet basis to a dry basis). EPA Method 4 should be used to determine moisture. This procedure calls for extracting a gas stream from the duct and bubbling it through chilled water and pre-weighed silica gel desiccant. Moisture is determined by comparing the volume of moisture collected by the water and silica gel to the volume of gas sampled. If the stream is saturated, moisture content is determined by measuring gas temperature and using a psychometric chart or saturation vapor pressure tables. Approximation techniques such as wet-bulb/dry bulb procedures can only be used if it is shown to be within 1% of Method 4 techniques.

EPA Web Site

Further details can be found in the EPA reference methods which can be downloaded from the EPA TTN bulletin board at http://www.epa.gov/ ttn/emc promgate.html.

General Approach to Performance Testing

If the facility is required to conduct performance testing, it is important to understand the distinct areas of responsibility. Some tasks should be handled by the vendor, however, the ultimate responsibility is with the plant engineer. The discussion provides a set of steps that can be followed in planning and conducting a performance test.

Steps in Planning and Conducting a Performance Test Program

Planning, Operating Conditions:

1. Select how the process(es) will be operated during the test program (i.e., absolute worst-case, or hypothetical worst-case)
   - If the above entails precise timing of multiple process events, verify that the approach is feasible,
2. Select how the APCD or wastewater treatment equipment will be operated during the test program,
3. Select which process, APCD, and wastewater treatment parameters to monitor,
4. Determine how the above parameters will be monitored and which ones are candidate parameters for monitoring on an on-going basis.

Planning, Test Objectives:

5. Determine pollutant concentration test methods and detection limits,
6. Verify detection limits are sufficient for demonstrating compliance,
7. Select flow monitoring methods and devices,
8. Verify that expected costs for above scope are within a reasonable testing budget.

Executing the Pre-Test Survey:

12. Meet on-site with the vendor to confirm approach on all of the above,
13. Discuss and confirm all Health & Safety precautions and required procedures,
14. Confirm vendors needs for mobile lab parking, access to sample sites, utilities, process coordination (start and stop times),
15. Confirm what type of process data will be collected and who will collect it, and,
16. Walkthrough facility examining sample sites and process data collection points.

Executing the Test Program:

17. Confirm expected testing schedule and logistics with vendor on equipment set-up day,
18. Conduct test program,
19. Verify collection of all process data, and
20. Collect copies of field data sheets & sample log or chain of custody.

Data Reduction and Reporting:

21. Verify receipt of samples by laboratory
22. Confirm expected sample analysis date and preliminary report date,
23. Reduce all on-site data (flows, sample volumes, process data),
24. Incorporate analytical data and prepare preliminary report,
25. Review preliminary report,
26. Incorporate comments and finalize report.

Selecting the Testing Firm

There are many testing firms highly qualified to conduct sampling and analyses for gas phase and water phase pollutants. In selecting a vendor the following items should be considered:

1. Determine if the testing firm should provide engineering services in addition to testing. If so, should they include both process engineering as well as control device/treatment equipment engineering ?

2. Prepare scope of work for the RFP and be explicit in:
    - what are the target compounds,
    - what test methods are not suitable
    - What detection limits are needed (provide expected concentrations and flow rates),
    - What is the available testing window is (hours of the day),
    - Whether the vendor should provide a process interface person for process data collection (do not expect the vendor to provide this without him costing it in)
    - What type of data reduction/reporting is desired (i.e., deliver two types of reports - sanitized and unsanitized, what types of averages should be calculated for complex scenarios, how to combine process data and emissions data, graphics, etc.)

3. Have vendors submit cost proposals including costs for baseline scope of work and on-site field team costs ($/hr) for possible add-on tasks.

4. Review proposals and select testing firm.

Note on Detection limits - Make sure the vendor states what the detection limits will be (concentration and mass rate for a given flow rate) and see if these values will suit your needs. For example, if your inlet loading to an APCD is estimated to be 20 lbs/hr HAPs, and your detection limit at the outlet is < 5 lbs/hr, the highest removal efficiency that can be demonstrated is 75%. If this is the case, a different test method with a lower detection may be needed at the APCD outlet.

Note on Process Data Collection: There always seems to be confusion surrounding the role of process/testing interface person. The plant people know the facility best however, the test people know how the testing will be conducted (timing). It is important to establish what roles will be played by whom.

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Appendix WWT

Wastewater Treatment Performance Testing - Test Methods and Approach Overview

Wastewater Treatment (WWT) performance testing must be used to demonstrate compliance for open biological treatment systems. Either WWT testing or WWT design evaluation can be used for closed biological or nonbiological treatment systems. There are six wastewater performance test procedures stipulated in §63.1257(e)(2)(iii) B-G listed as follows:

- C wastewater concentration limits (**noncombustion** treatment)[§63.1257(e)(2)(iii)(B)]
- C wastewater mass removal/destruction efficiency limits:
  - **noncombustion & non biological** treatment [§63.1257(e)(2)(iii)(C)]
  - **combustion** treatment [§63.1257(e)(2)(iii)(D)]
  - **biological (open or closed)** [§63.1257(e)(2)(iii)(E & F)]
  - **closed biological** only [§63.1257(e)(2)(iii)(G)]

The six performance testing procedures are similar in that they require:

- C three 1-hour test runs,
- C grab wastewater sampling or integrated wastewater sampling at approximately equally spaced time intervals during each hour of the three 1-hour tests,
- C wastewater sampling per §63.1257(b)(10)(vi), that calls for sampling procedures that minimize emissions, such as 40 CFR 60 Appendix A Method 25D sampling guidelines (collecting the sample through a cooling coil into a jar containing Polyethylene Glycol, PEG)
- C wastewater flow measurements concurrent with concentration sampling,
- C Separate inlet and outlet flow measurements, if the outlet flow is higher. If the outlet flow is not greater than the inlet, then a single flow measurement is satisfactory, at either the inlet or outlet.

F_{bio}

For **biological** treatment demonstrations, the mass removal/destruction efficiency determinations incorporate the use of a site specific degradation factor F_{bio} (closed biological can use either methods in §63.1257(e)(2)(iii)(E) & (F), which incorporate F_{bio} , or G which does not). F_{bio} is an indication of what fraction of total organics in solution biodegrade, as opposed to being emitted or remaining in the effluent. The first step in determining F_{bio} is to measure the compound-specific degradation rate f_{bio} using procedures found in Appendix C to Part 63. These are:

1A. M304A - Determine site specific, biodegradation factor using bench scale laboratory set up/ air vent (use instead of 304B when compounds react or hydrolyze in the scrubber of Method 304B).

1B. M304B - Same as previous w/ scrubber and is not vented (when Henry's Law constants are not known.)

2. Site specific performance data with and without biodegradation used to calculate F_{bio}.

3. Any of the above 3 methods or using inlet and outlet concentration measurements coupled with calculation such as a computer model (i.e, Water7, TOXCHEM, BASTE, etc).

4. Batch treatability tests

NOTE: For non-enhanced bio treatment, use f_{bio} method 1, 2, or 4 above. For enhanced bio treatment, use f_{bio} method 1, 2, 3, or 4 for PSHAPs. For SHAPs use K_1 = Table 9 values & follow Appendix C, Form III or use f_{bio} methods 1, 2, 3, or 4.

The total stream F_{bio} is then determined by multiplying each compound specific f_{bio} by the compound mass flow rate in the wastewater stream, summing all compound specific f_{bio} x mass flow products and then dividing by the total organic mass flow in the wastewater stream. Further details can be found in the Appendix C reference methods which can be downloaded from the EPA TTN bulletin board at http://www.epa.gov/ ttn/emc/ promgate.html.

For further guidance on "thoroughly mixed" biological treatment units, see guidance at http://www.epa.gov/ttn/oarpg/t3/reports/guidfn.pdf.

Note on choosing biological treatment compliance demonstration procedure:
Closed Biological -If the O/O chooses closed biological treatment and demonstrates compliance using §63.1257(2)(iii)(E) or (F), then the treatment process is not subject to wastewater storage tank or surface impoundment vapor suppression standards.

Open Biological - -If the O/O chooses open biological treatment, the treatment process need not be covered and vented to a control device. Also, if compliance is demonstrated by §63.1257(2)(iii)(E) or (F), the treatment process is also not subject to wastewater storage tank or surface impoundment vapor suppression standards.

Mass Removal/Destruction Efficiency for Biological Systems

Procedures are given for determining mass removal/destruction efficiency from the following 2 biological treatment configurations:

1. mass destruction/removal efficiency is determined across a biological treatment system only, or
2. mass destruction/removal efficiency is determined across a series of treatment processes

Compliance is demonstrated if destruction/removal efficiency, E, is 95% or greater. For case 1 above, mass removal/destruction efficiency (E) is equal to F_{bio}. In the second case, use the equation below. (Equation 50 from the rule.)

$$E = \frac{\text{Nonbiotreatment HAP load removal} + \text{Biotreatment HAP load removal}}{\text{Total influent HAP load}}$$

$$= \frac{\left(\sum_{i=1}^{n}\left(QMW_{a,i} - QMW_{b,i}\right)\right) + QMW_{bio} \times F_{bio}}{QMW_{all}}$$

$QMW_{a,i}$ = the soluble and/or partially soluble HAP load entering a treatment process segment

$QMW_{b,i}$ = the soluble and/or partially soluble HAP load exiting a treatment process segment

n = the number of treatment process segments

i = identifier for a treatment process element

QMW_{bio} = the inlet load of soluble and/or partially soluble HAP to the biological treatment process. The inlet is defined in accordance with 63.1257 (e)(2)(iii)(A)(6). If complying with 63.1257 (e)(2)(iii)(A)(6)(ii) (i.e., the inlet to the equalization tank is considered to be the inlet to the biological treatment process) of this section, QMW_{bio} is equal to $QMW_{b,n}$

F_{bio} = site-specific fraction of soluble and/or partially soluble HAP compounds biodegraded.

QMW_{all} = the total soluble and/or partially soluble HAP load to be treated.

If wastewater is conveyed by hard piping, mass removal/destruction efficiency is determined across the combination of all treatment processes. Owners/operators may conduct the performance test across each series of treatment processes (§63.1257(e)(2)(iii)(A)(5)(i)) OR conduct the test over each individual treatment process in the series of processes and sum them together (§63.1257(e)(2)(iii)(A)(5)(ii)). If wastewater is not conveyed by hard piping, efficiency must be determined across each treatment process with total efficiency equal to the sum of efficiencies from each component process. In this manner, the owner or operator does not get credit for fugitive emissions that may occur between treatment process segments.

Equalization Tank The inlet to the biological process may be considered the inlet to the equalization tank if:

- Wastewater is conveyed by hard piping from last treatment process or POD to equalization tank, or
- Wastewater is conveyed by hard piping from equalization tank to biological treatment process, or
- Equalization tank is equipped with a fixed roof/closed vent system/APCD.

Test Plan A site specific test plan must be prepared addressing the following:

- Test program summary,
- Test schedule,
- Data quality objectives (pretest expectations of precision, accuracy and completeness of data),
- Internal and External QA programs (internal QA includes assessment of data precision, external includes activities such as performance audits), and
- An emission profile must also be included if tests are being conducted on a control device which controls process vents from a batch process.

The test plan must be submitted to the administrator at least 60 days before the scheduled test date.

Sample Plan All compliance procedures listed above require a sample plan to be developed and kept on-site. The sample handling procedures must be aimed at minimizing the loss of volatiles from the sample solution. In summary, the following tasks must be considered:

- Use Procedures in Chapter 9 of SW-846 for developing sampling plan,
- Sample location should be representative of unexposed waste (where waste has minimum opportunity to volatilize to atmosphere)

- Collect the sample through a tap or use a submerged container (if a tap is impractical)
- Distinguish sampling procedures for single phase or well mixed waste versus multi-phase waste
- Collected through a chilled coil into a chilled polyethylene glycol (PEG) solution or chilled VOA tubes
- Determine target compound recovery efficiency during sample analyses

Three, 1-hour long sample runs must be performed at representative process unit operation and representative treatment process. The owner/operator may collect grab samples or composite samples. If the treatment process operates at multiple representative conditions, testing at each condition is not necessary. Calculations or engineering evaluations can be used to supplement test results to demonstrate compliance over the entire range of operation.

Analytical Summary Analyses should be completed using Method 305, 624, 625, 8270, 1624, 1625, 1666, 1671 or other validated method. For demonstrating compliance with wastewater concentration limits, either Method 305 should be used or another method with the results multiplied by the compound specific fraction Measured (Fm) values. For the purposes of this discussion, these types of wastewater concentrations will be known as wastewater Emission Potential Concentrations (EPC). Analytical techniques for concentrations to be used in calculating mass rates are not EPC values. If Method 305 is used for a mass rate concentration type, the result must be divided by the appropriate Fm value. Results from other analytical techniques are not adjusted. Fm values are listed in the following Table. (See page 8-27 for a table on use of Fm values).

TABLE WWT-2 TO SUBPART GGG. FRACTION MEASURED (F_m) FOR HAP COMPOUNDS IN WASTEWATER STREAMS

Chemical name	CAS No.[a]	F_m
Acetaldehyde	75070	1.00
Acetonitrile	75058	0.99
Acetophenone	98862	0.31
Acrolein	107028	1.00
Acrylonitrile	107131	1.00
Allyl chloride	107051	1.00
Benzene	71432	1.00
Benzyl chloride	100447	1.00

TABLE WWT-2 TO SUBPART GGG. FRACTION MEASURED (F_m) FOR HAP COMPOUNDS IN WASTEWATER STREAMS

Chemical name	CAS No.[a]	F_m
Biphenyl	92524	0.86
Bromoform	75252	1.00
Butadiene (1,3-)	106990	1.00
Carbon disulfide	75150	1.00
Carbon tetrachloride	56235	1.00
Chlorobenzene	108907	0.96
Chloroform	67663	1.00
Chloroprene (2-Chloro-1,3-butadiene)	126998	1.00
Cumene	98828	1.00
Dichlorobenzene (p-1,4-)	106467	1.00
Dichloroethane (1,2-) (Ethylene dichloride)	107062	1.00
Dichloroethyl ether (Bis(2-Chloroethyl ether))	111444	0.76
Dichloropropene (1,3-)	542756	1.00
Diethyl sulfate	64675	0.0025
Dimethyl sulfate	77781	0.086
Dimethylaniline (N,N-)	121697	0.00080
Dimethylhydrazine (1,1-)	57147	0.38
Dinitrophenol (2,4-)	51285	0.0077
Dinitrotoluene (2,4-)	121142	0.085
Dioxane (1,4-) (1,4-Diethyleneoxide)	123911	0.87
Epichlorohydrin(1-Chloro-2,3-epoxypropane)	106898	0.94
Ethyl acrylate	140885	1.00
Ethylbenzene	100414	1.00
Ethyl chloride (Chloroethane)	75003	1.00
Ethylene dibromide (Dibromomethane)	106934	1.00
Ethylene glycol dimethyl ether	110714	0.86
Ethylene glycol monobutyl ether acetate	112072	0.043
Ethylene glycol monomethyl ether acetate	110496	0.093
Ethylene oxide	75218	1.00

TABLE WWT-2 TO SUBPART GGG. FRACTION MEASURED (F_m) FOR HAP COMPOUNDS IN WASTEWATER STREAMS

Chemical name	CAS No.[a]	F_m
Ethylidene dichloride (1,1-Dichloroethane)	75343	1.00
Hexachlorobenzene	118741	0.97
Hexachlorobutadiene	87683	0.88
Hexachloroethane	67721	0.50
Hexane	110543	1.00
Isophorone	78591	0.47
Methanol	67561	0.85
Methyl bromide (Bromomethane)	74839	1.00
Methyl chloride (Chloromethane)	74873	1.00
Methyl ethyl ketone (2-Butanone)	78933	0.99
Methyl isobutyl ketone (Hexone)	108101	0.98
Methyl methacrylate	80626	1.00
Methyl tert-butyl ether	1634044	1.00
Methylene chloride (Dichloromethane)	75092	1.00
Naphthalene	91203	0.99
Nitrobenzene	98953	0.39
Nitropropane (2-)	79469	0.99
Phosgene	75445	1.00
Propionaldehyde	123386	1.00
Propylene dichloride (1,2-Dichloropropane)	78875	1.00
Propylene oxide	75569	1.00
Styrene	100425	1.00
Tetrachloroethane (1,1,2,2-)	79345	1.00
Tetrachloroethylene (Perchloroethylene)	127184	1.00
Toluene	108883	1.00
Toluidine (o-)	95534	0.15
Trichlorobenzene (1,2,4-)	120821	1.00
Trichloroethane (1,1,1-) (Methyl chloroform)	71556	1.00

TABLE WWT-2 TO SUBPART GGG. FRACTION MEASURED (F_m)
FOR HAP COMPOUNDS IN WASTEWATER STREAMS

Chemical name	CAS No.[a]	F_m
Trichloroethane (1,1,2-) (Vinyl Trichloride)	79005	0.98
Trichloroethylene	79016	1.00
Trichlorophenol (2,4,5-)	95954	1.00
Triethylamine	121448	1.00
Trimethylpentane (2,2,4-)	540841	1.00
Vinyl acetate	108054	1.00
Vinyl chloride (Chloroethylene)	75014	1.00
Vinylidene chloride (1,1-Dichloroethylene)	75354	1.00
Xylene (m-)	108383	1.00
Xylene (o-)	95476	1.00
Xylene (p-)	106423	1.00

[a]CAS numbers refer to the Chemical Abstracts Service registry number assigned to specific compounds, isomers, or mixtures of compounds.

Flow Measurement

Wastewater (and vent gas) flow measurements are needed to calculate HAP mass rates. Flow measurements should be made during the same period that concentration samples are being collected. If samples are being collected over an hour-long period, enough flow measurements should be taken during that hour so that an accurate flow rate average can be calculated. If flow is constant, the flow may only need to be measured once per test run. However, if flow rate is variable, multiple flow measurements may need to be taken. Separate wastewater inlet and outlet flow measurements must be made unless a) the inlet flow is higher, then a single flow measurement device is satisfactory at either the inlet or outlet or b) the treatment process is an open or closed biological process then only the inlet flow must be measured for the performance test (§63.1257(e)(2)(iii)(E)(2) and (G). Gas flow rate must be measured by methods stipulated in the rule as discussed in Appendix PT. No wastewater flow measurement methods are stipulated in the rule.

Q. **How should treatment device residence time be considered ?**

A. Unlike an emissions control device, which has a residence time of a few seconds, the residence time of a wastewater stream flowing through a treatment plant may be much longer. In order to determine treatment efficiency, the treatment plant inlet and outlet PSHAP and SHAP mass rates must be measured on the same "slug" of wastewater flowing through the treatment plant. For example, if the residence time is 30 minutes, the outlet sample should not be collected until after 30 minutes have elapsed since collection of the inlet sample. An even more complicated scenario is when wastewater flow is not constant. Calculations should be made to determine the volume of wastewater which flows by the inlet sample point during inlet sampling, determine the exact treatment plant residence time, and commence outlet sampling after that residence time has elapsed.

Exempt Compounds For wastewater sources, the total Organic HAPs method target compounds need not include compounds not used or produced, compounds in wastewater that are < 1 ppmw, or compounds that are not detected in wastewater when detection limits are not greater than < 1 ppmw. Also, as for control devices controlling only wastewater emissions, the target compounds are only PSHAPs and SHAPs and do not include other HAPs.