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Compliance Assistance Tool for
Clean Air Act Regulations: Subpart
GGG of 40 CFR NESHAPS for
Source Category Pharmaceutical
Production

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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.

9.2 Structure of the Regulation

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

§63.1258(a) Sources shall provide

Chapter 9 at a Glance

9.1	<i>Overview</i>
9.2	<i>Structure of the Regulation</i>
9.3	<i>Basis for Monitoring Control Devices</i>
9.4	<i>Establishing Operating Parameters for Monitoring Control Devices</i>
9.5	<i>Establishing Averaging Periods for Monitoring</i>
9.6	<i>Monitoring for the Mass Emissions Limit Standard (2,000 lb/yr)</i>
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	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 ≥ 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 $\pm 2\%$ of temp. or within $\pm 2.5\text{EC}$, 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 $\pm 2\%$ of temp. or within $\pm 2.5\text{EC}$, 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 $\pm 0.75\%$ of temp. or $\pm 2.5\text{EC}$, 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 ± 2.5 EC. 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 ± 2.5 EC. 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 ≥ 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:

- S** use a FTIR CEMS that meets performance specification 15 of appendix B of Part 60, or
- S** 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.
- S** 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:
 - S** 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 **760° C**.
 - S** 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 **816° 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 other than 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 :

$$F_s = \frac{721 \times E_{an}}{5,000}$$

where

F_s = system flowrate setpoint, scfm

E_{an} = 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

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.

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

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:

6. Each time that a new operating scenario is implemented, evaluate the

$$Ca = \frac{Fs}{Fa} \times 50$$

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

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.

- C 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 separately 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 <u>operating limit</u>?*	What constitutes a violation of the <u>emission limit</u>?
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 <u>operating limits</u> counted?	How are violations of <u>emissions limits</u> 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.