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

August 2002

Office of Enforcement and Compliance Assurance
Office of Enforcement
Compliance Assessment and Media Programs Division
Air, Hazardous Waste and Toxics Branch

Table of Contents

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))	C procedures for operating and maintaining affected source during SSM C program for corrective action for 1) process, 2) air pollution control, and 3) monitoring equipment C occurrence and duration of each malfunction of 1) the process operation or 2) air pollution control equipment, 3) continuous monitoring system C 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) C SSM plan and superseded versions C 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))	C records of all required CMS measurements (including data recorded during unavoidable CMS breakdowns and out-of-control periods) C date and times when CMS is inoperative, except for zero (low-level) and high-level checks C 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 C note the nature and cause of any malfunction, if known C note corrective action taken or preventive measures adopted C record nature of repairs or adjustments to CMS that was inoperative or out of control C total process operating time during the reporting period C all procedures that are part of a quality control program for the CMS (developed under §63.8(d)) C 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.