

40 C.F.R. § 63.1252

Standards: General.

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

- (a) *Opening of a safety device.* Opening of a safety device, as defined in § 63.1251, is allowed at any time conditions require it to do so to avoid unsafe conditions.
- (b) Closed-vent systems. The owner or operator of a closed-vent system that contains bypass lines that could divert a vent stream away from a control device used to comply with the requirements in §§ 63.1253, 63.1254, and 63.1256 shall comply with the requirements of Table 4 to this subpart and paragraph (b)(1) or (2) of this section. Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and pressure relief valves needed for safety purposes are not subject to this paragraph.
- (1) Install, calibrate, maintain, and operate a flow indicator that determines whether vent stream flow is present at least once every 15 minutes. Records shall be maintained as specified in § 63.1259(i)(6)(i). The flow indicator shall be installed at the entrance to any bypass line that could divert the vent stream away from the control device to the atmosphere; or
- (2) Secure the bypass line valve in the closed position with a car seal or lock and key type configuration. A visual inspection of the seal or closure mechanism shall be performed at least once every month to ensure that the valve is maintained in the closed position and the vent stream is not diverted through the bypass line. Records shall be maintained as specified in § 63.1259(i)(6)(ii).
- (c) *Heat exchange systems*. Except as provided in paragraph (c)(2) of this section, owners and operators of affected sources shall comply with the requirements in paragraph (c)(1) of this section for heat exchange systems that cool process equipment or materials used in pharmaceutical manufacturing operations.
- (1) The heat exchange system shall be treated according to the provisions of § 63.104, except that the monitoring frequency shall be no less than quarterly.
- (2) For identifying leaking equipment, the owner or operator of heat exchange systems on equipment which meet current good manufacturing practice (CGMP) requirements of 21 CFR part 211 may elect to use the physical integrity of the reactor as the surrogate indicator of heat exchange system leaks around the reactor.
- (d) *Emissions averaging provisions*. Except as specified in paragraphs (d)(1) through (5) of this section, owners or operators of storage tanks or processes subject to the provisions of §§ 63.1253 and 63.1254 may choose to comply by using emissions averaging requirements specified in § 63.1257(g) or (h) for any storage tank or process.

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