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§63.364 Monitoring requirements.

(a)(1) The owner or operator of a source subject to emissions standards in §63.362 shall comply with the monitoring requirements in §63.8 of subpart A of this part, according to the applicability in Table 1 of §63.360, and in this section.

(2) Each owner or operator of an ethylene oxide sterilization facility subject to these emissions standards shall monitor the parameters specified in this section. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.

(b) For sterilization facilities complying with §63.363 (b), (d), or (e) through the use of an acid-water scrubber, the owner or operator shall either:

(1) Sample the scrubber liquor and analyze and record once per week the ethylene glycol concentration of the scrubber liquor using the test methods and procedures in §63.365(e)(1). Monitoring is required during a week only if the scrubber unit has been operated; or

(2) Measure and record once per week the level of the scrubber liquor in the recirculation tank. The owner or operator shall install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (i.e., a marker on the tank wall, a dipstick, a magnetic indicator, etc.).

(c) For sterilization facilities complying with §63.363(b), (c), (d), or (e) through the use of catalytic oxidation or thermal oxidation, the owner or operator shall continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion chamber using the temperature monitor described in paragraph (c)(4) of this section.

(1) For the sterilization chamber vent, a data acquisition system for the temperature monitor shall compute and record an average oxidation temperature over the length of the cycle (based on the length of the cycle used during the performance test in §63.365(b)(2)) and a three-cycle block average every third cycle.

(2) For the aeration room vent, a data acquisition system for the temperature monitor shall compute and record an average oxidation temperature each hour and a 3-hour block average every third hour.

(3) For the chamber exhaust vent, a data acquisition system for the temperature monitor shall compute and record an average oxidation temperature over the length of the cycle (based on the length of the cycle used during the performance test in §63.365(d)(2)).

(4) The owner or operator shall install, calibrate, operate, and maintain a temperature monitor accurate to within ±5.6 °C (±10 °F) to measure the oxidation temperature. The owner or operator shall verify the accuracy of the temperature monitor twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested.

(d) For sterilization facilities complying with §63.363(b), (c), (d), or (e) through the use of a control device other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator shall monitor the parameters as approved by the Administrator using the methods and procedures in §63.365(g).

(e) For sterilization facilities complying with §63.363(c)(3)(i) or (e)(2)(i) through the use of direct measurement of ethylene oxide concentration, the owner or operator shall follow either paragraph (e)(1) or (2) of this section:

(1) Measure and record once per hour the ethylene oxide concentration at the outlet to the atmosphere from the aeration room vent after any control device according to the procedures specified in §63.365(c)(1). The owner or operator shall compute and record a 3-hour average every third hour. The owner or operator will install, calibrate, operate, and maintain a gas

chromatograph consistent with the requirements of performance specification (PS) 9 in 40 CFR part 60, Appendix B, to measure ethylene oxide. The daily calibration requirements of section 7.2 of PS 9 are required only on days when ethylene oxide emissions are vented to the control device from the aeration room vent.

(2) Measure and record the ethylene oxide concentration in the sterilization chamber immediately before the chamber exhaust is activated according to the procedures specified in § 63.365(c)(2). The owner or operator shall install, calibrate, operate, and maintain a gas chromatograph consistent with the requirements of PS 9 to measure ethylene oxide concentration. The daily calibration requirements of section 7.2 of PS 9 are required only on days when the chamber exhaust is activated.

(f) For sterilization facilities complying with § 63.363(d)(1) or (e)(1) by manifolding emissions from the chamber exhaust vent to a control device controlling emissions from another vent type, the owner or operator shall monitor the control device to which emissions from the chamber exhaust vent are manifolded using the appropriate monitoring requirements in paragraphs (a) through (e) of this section and record the monitoring data.

§ 63.365 Test methods and procedures.

(a) *Performance testing.* The owner or operator of a source subject to the emissions standards in § 63.362 shall comply with the performance testing requirements in § 63.7 of subpart A of this part, according to the applicability in Table 1 of § 63.360, and in this section.

(b) *Efficiency at the sterilization chamber vent.* The following procedures shall be used to determine the efficiency of all types of control devices used to comply with § 63.362(c), sterilization chamber vent standard.

(1) *First evacuation of the sterilization chamber.* This procedure shall be performed on an empty sterilizer for the duration of the first evacuation under normal operating conditions (i.e., sterilization cycle pressure and temperature) and charging a typical amount of ethylene oxide to the sterilization chamber.

(i) The amount of ethylene oxide loaded into the sterilizer (W_c) shall be determined by either:

(A) Weighing the ethylene oxide gas cylinder(s) used to charge the sterilizer before and after charging. Record these weights to the nearest 45 g (0.1 lb). Multiply the total mass of gas charged by the weight percent ethylene oxide present in the gas.

(B) Installing calibrated rotameters at the sterilizer inlet and measuring flow rate and duration of sterilizer charge. Use the following equation to convert flow rate to weight of ethylene oxide:

$$W_c = F_v \times t \times \%EO_v \times \left(\frac{MW}{SV}\right)$$

where:

W_c=weight of ethylene oxide charged, g (lb)

F_v=volumetric flow rate, liters per minute (L/min) corrected to 20 °C and 101.325 kilopascals (kPa) (scf per minute (scfm) corrected to 68 °F and 1 atmosphere of pressure (atm)); the flowrate must be constant during time (t)

t=time, min

$\%EO_V$=volume fraction ethylene oxide

SV=standard volume, 24.05 liters per mole (L/mole)=22.414 L/mole ideal gas law constant corrected to 20 °C and 101.325 kPa (385.32 scf per mole (scf/mole)=359 scf/mole ideal gas law constant corrected to 68 °F and 1 atm).

MW=molecular weight of ethylene oxide, 44.05 grams per gram-mole (g/g-mole) (44.05 pounds per pound-mole (lb/lb-mole)), or

(C) Calculating the mass based on the conditions of the chamber immediately after it has been charged using the following equation:

$$W_c = \frac{MW \times \%EO_v \times P \times V}{R \times T}$$

where:

P=chamber pressure, kPa (psia)

V=chamber volume, liters (L) (ft^3)

R=gas constant, 8.313 L•kPa/g-mole•(10.73 psia•ft^3/mole°R)

T=temperature, K (°R)