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(b) *Applicability of emission limits.* The emission limitations of paragraphs (c), (d), and (e) of this section apply during sterilization operation. The emission limitations do not apply during periods of malfunction.

(c) *Sterilization chamber vent at sources using 1 ton.* Each owner or operator of a sterilization source using 1 ton shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.

(d) *Aeration room vent at sources using 10 tons.* Each owner or operator of a sterilization source using 10 tons shall reduce ethylene oxide emissions to the atmosphere from each aeration room vent to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, from each aeration room vent.

(e) (1) *Chamber exhaust vent at sources using 10 tons.* Each owner or operator of a sterilization source using 10 tons shall either reduce ethylene oxide emissions to the atmosphere by manifolding emissions from each chamber exhaust vent to a control device used to comply with paragraphs (c) or (d) of this section or shall reduce ethylene oxide emissions by at least 99 percent from each chamber exhaust vent (without manifolding).

(2) *Chamber exhaust vent at sources using 1 to 10 tons.* Each owner or operator of a sterilization source using 1 to 10 tons shall limit ethylene oxide emissions from the chamber exhaust vent to the atmosphere to a maximum concentration of 5,300 ppmv from each chamber exhaust vent. If the owner or operator chooses to limit emissions to 5,300 ppmv concentration through the use of a control device, the owner or operator may choose either to manifold ethylene oxide emissions from each chamber exhaust vent to a control device used to comply with paragraph (c) of this section or to reduce ethylene oxide emissions by at least 99 percent (without manifolding).

§ 63.363 Compliance and performance testing.

(a) (1) The owner or operator of a source subject to emissions standards in § 63.362 shall conduct an initial performance test using the procedures listed in § 63.7 of subpart A of this part

according to the applicability in Table 1 of § 63.360, the procedures listed in this section, and the test methods listed in § 63.365.

(2) The owner or operator of all sources subject to these emissions standards shall complete the performance test within 180 days after the compliance date for the specific source as determined in § 63.360(g).

(b) The following procedures shall be used to determine compliance with the emission limits under § 63.362(c), the sterilization chamber vent standard:

(1) During the performance test required in paragraph (a) of this section, the owner or operator shall determine the efficiency of control devices used to comply with § 63.362(c) using the test methods and procedures in § 63.365(b)(1). The owner or operator shall also determine the following:

(i) For facilities with acid-water scrubbers, the owner or operator shall establish as a site-specific operating parameter during the test methods and procedures in § 63.365(b)(1) either:

(A) The maximum ethylene glycol concentration using the procedures described in § 63.365(e)(1); or

(B) The maximum liquor tank level using the procedures described in § 63.365(e)(2).

(ii) For facilities with catalytic oxidizers or thermal oxidizers, the owner or operator shall establish as a site-specific operating parameter the baseline temperature during the performance test in § 63.365(b)(2) using the procedures described in § 63.365(f)(1).

(2) Following the date on which the initial performance test is completed, the owner or operator shall comply with one of the following provisions:

(i) For facilities with acid-water scrubbers, operation of the facility with an ethylene glycol concentration in the scrubber liquor in excess of the maximum ethylene glycol concentration or the liquor tank level in excess of the maximum liquor tank level shall constitute a violation of the sterilization chamber vent standard.

(ii) For facilities with catalytic oxidizers or thermal oxidizers, operation of the facility with the oxidation temperature, averaged over three cycles, more than 5.6 °C (10 °F) below the baseline temperature shall constitute a

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violation of the sterilization chamber vent standard.

(c) The following procedures shall be used to determine compliance with the emission limits under § 63.362(d), the aeration room vent standard:

(1) During the performance test required in paragraph (a) of this section, the owner or operator shall determine either:

(i) The concentration of ethylene oxide emitted from the aeration room into the atmosphere (after any control device used to comply with § 63.362(d)) using the methods in § 63.365(c)(1); or

(ii) The efficiency of the control device used to comply with § 63.362(d) using the test methods and procedures in § 63.365(d)(1).

(2) For facilities seeking to comply with paragraph (c)(1)(ii) of this section with catalytic oxidizers or thermal oxidizers, the owner or operator must also establish as a site-specific operating parameter the baseline temperature using the procedures described in § 63.365(f)(2).

(3) Following the date on which the initial performance test is completed, the owner or operator of a facility shall comply with one of the following provisions:

(i) For facilities continuously measuring the ethylene oxide concentration emitted from the aeration room (after any control device), operation of the facility with a 3-hour average ethylene oxide concentration in excess of the 1 ppmv ethylene oxide concentration limit shall constitute a violation of the aeration room vent standard.

(ii) For facilities with catalytic oxidizers or thermal oxidizers, operation of the facility with the oxidation temperature, averaged over three hours, more than 5.6 °C (10 °F) below the baseline temperature shall constitute a violation of the aeration room vent standard.

(d) The following procedures shall be used to determine compliance with the emission limits under § 63.362(e)(1), the chamber exhaust vent standard for sources using 10 tons:

(1) For facilities manifolding emissions from the chamber exhaust vent to a control device controlling emissions from the sterilization chamber vent and/or the aeration room vent, the

owner or operator shall comply with the appropriate compliance provisions for that vent type and control device (see paragraphs (b) and (c) of this section).

(2) For facilities not manifolding emissions from the chamber exhaust vent (to a control device used to comply with § 63.362(c) or (d)), the owner or operator shall comply with the following:

(i) During the performance test required in paragraph (a) of this section, the owner or operator shall determine the efficiency of control devices used to comply with § 63.362(e)(1) using the test methods and procedures in § 63.365(d)(2) as well as the following:

(A) For facilities with acid-water scrubbers, the owner or operator shall establish as a site-specific operating parameter either:

(1) The maximum ethylene glycol concentration using the procedures described in § 63.365(e)(1); or

(2) The maximum liquor tank level using the procedures described in § 63.365(e)(2).

(B) For facilities with catalytic oxidizers or thermal oxidizers, the owner or operator shall establish as a site-specific operating parameter the baseline temperature using the procedures described in § 63.365(f)(3).

(ii) Following the date on which the initial performance test is completed, the owner or operator of a facility shall comply with one of the following provisions:

(A) For facilities with acid-water scrubbers, operation of the facility with an ethylene glycol concentration in the scrubber liquor in excess of the maximum ethylene glycol concentration or the liquor tank level in excess of the maximum liquor tank level shall constitute a violation of the chamber exhaust vent standard for sources using 10 tons.

(B) For facilities with catalytic oxidizers or thermal oxidizers, operation of the facility with the oxidation temperature, averaged over the cycle, more than 5.6 °C (10 °F) below the baseline temperature shall constitute a violation of the chamber exhaust vent standard for sources using 10 tons.

(e) The following procedures shall be used to determine compliance with the

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emission limits under § 63.362(e)(2), the chamber exhaust vent standard for sources using 1 to 10 tons:

(1) For facilities manifolding emissions from the chamber exhaust vent to a control device controlling emissions from the sterilization chamber vent, the owner or operator shall comply with the appropriate compliance provisions for the appropriate control technology (see paragraph (b) of this section).

(2) For facilities not manifolding emissions from the chamber exhaust vent (to a control device used to comply with § 63.362(c)), during the performance test required in paragraph (a) of this section, the owner or operator shall either:

(i) Determine the concentration of ethylene oxide in the sterilization chamber immediately prior to the operation of the chamber exhaust using the test methods and procedures in § 63.365(c)(2); or

(ii) Determine the efficiency of control devices used to comply with § 63.362(e)(2) using the test methods and procedures in § 63.365(d)(2) as well as the following:

(A) For facilities with acid-water scrubbers, the owner or operator shall establish as a site-specific operating parameter either:

(1) The maximum ethylene glycol concentration using the procedures described in § 63.365(e)(1); or

(2) The maximum liquor tank level using the procedures described in § 63.365(e)(2).

(B) For facilities with catalytic oxidizers or thermal oxidizers, the owner or operator shall establish as a site-specific operating parameter the baseline temperature using the procedures described in § 63.365(f)(3).

(3) Following the date on which the initial performance test is completed, the owner or operator of a facility shall comply with one of the following provisions:

(i) For facilities determining the ethylene oxide concentration, operation of the facility with the ethylene oxide concentration in the sterilization chamber (immediately prior to activation of the chamber exhaust) in excess of the 5,300 ppmv ethylene oxide concentration standard shall constitute a

violation of the chamber exhaust vent standard for sources using 1 to 10 tons.

(ii) Following the date on which the initial performance test is completed, the owner or operator of a facility shall comply with one of the following provisions:

(A) For facilities with acid-water scrubbers, operation of the facility with an ethylene glycol concentration in the scrubber liquor in excess of the maximum ethylene glycol concentration or the liquor tank level in excess of the maximum liquor tank level shall constitute a violation of the chamber exhaust vent standard for sources using 1 to 10 tons.

(B) For facilities with catalytic oxidizers or thermal oxidizers, operation of the facility with the oxidation temperature, averaged over the cycle, more than 5.6 °C (10 °F) below the baseline temperature shall constitute a violation of the chamber exhaust vent standard for sources using 1 to 10 tons.

(f) For facilities complying with the emissions limits under § 63.362 with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers:

(1) The owner or operator of the facility shall provide to the Administrator information describing the design and operation of the air pollution control system including recommendations for the operating parameters to be monitored to indicated proper operation and maintenance of the air pollution control system. Based on this information, the Administrator will determine the site-specific operating parameter(s) to be established during the performance test. During the performance test required in paragraph (a) of this section using the methods approved in § 63.365(g), the owner or operator shall determine the site-specific operating parameter(s) approved by the Administrator.

(2) Operation of the facility in a manner that exceeds a site-specific parameter established as a maximum requirement or falls below a site-specific parameter established as a minimum requirement (depending on the parameters monitored) shall constitute a violation of the applicable emissions standard under § 63.362.