

TABLE 1 OF SECTION 63.360—GENERAL PROVISIONS APPLICABILITY TO SUBPART O—Continued

Reference	Applies to sources using 10 tons in subpart O <sup>a</sup>	Applies to sources using 1 to 10 tons in subpart O <sup>a</sup>	Comment
63.10(e)(3)(vi)–(viii) .....		Yes	Opacity monitors are not required for these standards.
63.10(e)(4) .....		No	
63.10(f) .....		Yes	
63.11 .....		Yes	
63.12–63.15 .....		Yes	

<sup>a</sup> See definition.

(b) Sterilization sources using less than 1 ton (see definition) are not subject to the emissions standards in § 63.362. The recordkeeping requirements of § 63.367(c) apply.

(c) This subpart does not apply to beehive fumigators.

(d) This subpart does not apply to research or laboratory facilities as defined in section 112(c)(7) of title III of the Clean Air Act Amendment of 1990.

(e) This subpart does not apply to ethylene oxide sterilization operations at stationary sources such as hospitals, doctors offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals.

(f) If you are an owner or operator of an area source subject to this subpart, you are exempt from the obligation to obtain a permit under 40 CFR part 70 or 71, provided you are not required to obtain a permit under 40 CFR 70.3(a) or 71.3(a) for a reason other than your status as an area source under this subpart. Notwithstanding the previous sentence, you must continue to comply with the provisions of this subpart applicable to area sources.

(g) The owner or operator shall comply with the provisions of this subpart as follows:

(1) All sterilization chamber vents subject to the emissions standards in § 63.362 with an initial startup date before December 6, 1998, no later than December 6, 1998.

(2) All sterilization chamber vents subject to the emissions standards in § 63.362 with an initial startup date on or after December 6, 1998, immediately upon initial startup of the source.

(3) All sterilization chamber vents at sources using less than 1 ton of ethylene oxide that increase their ethylene oxide usage after December 6, 1998 such

that the sterilization chamber vent becomes subject to the emissions standards in § 63.362(c), immediately upon becoming subject to the emission standards.

(4) All aeration room vents subject to the emissions standards in § 63.362 with an initial startup date before December 6, 2000, no later than December 6, 2000.

(5) All aeration room vents subject to the emissions standards in § 63.362 with an initial startup date on or after December 6, 2000, immediately upon initial startup of the source.

(6) All aeration room vents at sources using less than 10 tons that increase their ethylene oxide usage after December 6, 2000, such that the aeration room vents become subject to the emissions standards in § 63.362, immediately upon becoming subject to the emission standards.

(7)–(10) [Reserved]

[59 FR 62589, Dec. 6, 1994, as amended at 61 FR 27788, June 3, 1996; 63 FR 66994, Dec. 4, 1998; 64 FR 67793, Dec. 3, 1999; 64 FR 69643, Dec. 14, 1999; 66 FR 55582, Nov. 2, 2001; 70 FR 75345, Dec. 19, 2005]

**§ 63.361 Definitions.**

Terms and nomenclature used in this subpart are defined in the Clean Air Act (the Act) as amended in 1990, §§ 63.2 and 63.3 of subpart A of this part, or in this section. For the purposes of subpart O, if the same term is defined in subpart A and in this section, it shall have the meaning given in this section.

*Aeration room* means any vessel or room that is used to facilitate off-gassing of ethylene oxide at a sterilization facility.

*Aeration room vent* means the point(s) through which the evacuation of ethylene oxide-laden air from an aeration room occurs.

*Baseline temperature* means a minimum temperature at the outlet from the catalyst bed of a catalytic oxidation control device or at the exhaust point from the combustion chamber of a thermal oxidation control device.

*Chamber exhaust vent* means the point(s) through which ethylene oxide-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes.

*Compliance date* means the date by which a source subject to the emissions standards in § 63.362 is required to be in compliance with the standard.

*Deviation* means any instance in which an affected source, subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limitation (including any operating limit) or work practice standard;

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit; or

(3) Fails to meet any emission limitation (including any operating limit) or work practice standard in this subpart during startup, shutdown, or malfunction, regardless of whether or not such failure is permitted by this subpart.

*Effective date* means the date of promulgation in the FEDERAL REGISTER notice.

*Initial startup date* means the date when a source subject to the emissions standards in § 63.362 first begins operation of a sterilization process.

*Manifolding emissions* means combining ethylene oxide emissions from two or more different vent types for the purpose of controlling these emissions with a single control device.

*Maximum ethylene glycol concentration* means any concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

*Maximum liquor tank level* means any level of scrubber liquor in the acid-water scrubber liquor recirculation tank established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

*Oxidation temperature* means the temperature at the outlet point of a catalytic oxidation unit control device or at the exhaust point from the combustion chamber for a thermal oxidation unit control device.

*Source(s) using less than 1 ton* means source(s) using less than 907 kg (1 ton) of ethylene oxide within all consecutive 12-month periods after December 6, 1996.

*Source(s) using 1 ton* means source(s) using 907 kg (1 ton) or more of ethylene oxide within any consecutive 12-month period after December 6, 1996.

*Source(s) using 1 to 10 tons* means source(s) using 907 kg (1 ton) or more of ethylene oxide in any consecutive 12-month period but less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

*Source(s) using less than 10 tons* means source(s) using less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

*Source(s) using 10 tons* means source(s) using 9,070 kg (10 tons) or more of ethylene oxide in any consecutive 12-month period after December 6, 1996.

*Sterilization chamber* means any enclosed vessel or room that is filled with ethylene oxide gas, or an ethylene oxide/inert gas mixture, for the purpose of sterilizing and/or fumigating at a sterilization facility.

*Sterilization chamber vent* means the point (prior to the vacuum pump) through which the evacuation of ethylene oxide from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.

*Sterilization facility* means any stationary source where ethylene oxide is used in the sterilization or fumigation of materials.

*Sterilization operation* means any time when ethylene oxide is removed from the sterilization chamber through the sterilization chamber vent or the

**Environmental Protection Agency**

**§ 63.363**

chamber exhaust vent or when ethylene oxide is removed from the aeration room through the aeration room vent.

*Thermal oxidizer* means all combustion devices except flares.

[59 FR 62589, Dec. 6, 1994, as amended at 66 FR 55583, Nov. 2, 2001]

**§ 63.362 Standards.**

(a) Each owner or operator of a source subject to the provisions of this subpart shall comply with these requirements on and after the compliance date specified in §63.360(g). The standards of this section are summarized in Table 1 of this section.

**TABLE 1 OF SECTION 63.362—STANDARDS FOR ETHYLENE OXIDE COMMERCIAL STERILIZERS AND FUMIGATORS**

Existing and new sources	Source type	Sterilization chamber vent	Aeration room vent	Chamber exhaust vent
Source size .....	<907 kg (<1 ton) .....	No control required; minimal recordkeeping requirements apply (see §63.367(c)).		
	≥907 kg and <9,070 kg (≥1 ton and < 10 tons).	99% emission reduction (see §63.362(c)).	No control .....	No control.
	≥9,070 kg (≥10 tons) ....	99% emission reduction (see §63.362(c)).	1 ppm maximum outlet concentration or 99% emission reduction (see §63.362(d)).	No control.

(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) [Reserved]

[59 FR 62589, Dec. 6, 1994, as amended at 66 FR 55583, Nov. 2, 2001]

**§ 63.363 Compliance and performance provisions.**

(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 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 procedures in paragraphs (b)(1) through (3) of this section shall be used to determine initial compliance with the emission limits under §63.362(c), the sterilization chamber vent standard and to establish operating limits for the control devices:

(1) 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).

(2) For facilities with acid-water scrubbers, the owner or operator shall establish as an operating limit either:

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

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

(3) For facilities with catalytic oxidizers or thermal oxidizers, the operating limit consists of the recommended minimum oxidation temperature provided by the oxidation unit manufacturer for an operating limit.

(4) Facilities with catalytic oxidizers shall comply with one of the following work practices: