

**Environmental Protection Agency**

**§ 63.360**

General provisions reference	Applies to subpart N	Comment
63.9(b)(1)(i)–(ii)	No	§ 63.343(a)(3) of subpart N requires area sources to comply with major source provisions if an increase in HAP emissions causes them to become major sources.
63.9(b)(1)(iii)	No	§ 63.347(c)(2) of subpart N specifies initial notification requirements for new or reconstructed affected sources.
63.9(b)(2)	No	§ 63.347(c)(1) of subpart N specifies the information to be contained in the initial notification.
63.9(b)(3)	No	§ 63.347(c)(2) of subpart N specifies notification requirements for new or reconstructed sources that are not major affected sources.
63.9(b)(4)	No	
63.9(b)(5)	No	
63.9(c)	Yes	This paragraph only references “§ 63.6(i)(4) through § 63.6(i)(6)” for compliance extension provisions. But, § 63.343(a)(6) of subpart N also contains provisions for requesting a compliance extension. Subpart N provides a different timeframe for submitting the request than § 63.6(i)(4).
63.9(d)	Yes	This paragraph only references “the notification dates established in paragraph (g) of this section.” But, § 63.347 of subpart N also contains notification dates.
63.9(e)	No	Notification of performance test is required by § 63.347(d) of subpart N.
63.9(f)	No	
63.9(g)	No	Subpart N does not require a performance evaluation or relative accuracy test for monitoring devices.
63.9(h)(1)–(3)	No	§ 63.347(e) of subpart N specifies information to be contained in the notification of compliance status and the timeframe for submitting this information.
63.9(h)(5)	No	Similar language has been incorporated into § 63.347(e)(2)(iii) of subpart N.
63.9(h)(6)	Yes	
63.9(i)	Yes	
63.9(j)	Yes	
63.10(a)	Yes	
63.10(b)(1)	Yes	
63.10(b)(2)	No	§ 63.346(b) of subpart N specifies the records that must be maintained.
63.10(b)(3)	No	Subpart N applies to major and area sources.
63.10(c)	No	Applicable requirements of § 63.10(c) have been incorporated into § 63.346(b) of subpart N.
63.10(d)(1)	Yes	
63.10(d)(2)	No	§ 63.347(f) of subpart N specifies the timeframe for reporting performance test results.
63.10(d)(3)	No	Subpart N does not contain opacity or visible emissions standards.
63.10(d)(4)	Yes	
63.10(d)(5)	No	§ 63.342(f)(3)(iv) and § 63.347(g)(3) of subpart N specify reporting associated with malfunctions.
63.10(e)	No	§ 63.347(g) and (h) of subpart N specify the frequency of periodic reports of monitoring data used to establish compliance. Applicable requirements of § 63.10(e) have been incorporated into § 63.347(g) and (h).
63.10(f)	Yes	
63.11	No	Flares will not be used to comply with the emission limits.
63.12–63.15	Yes	

[60 FR 4963, Jan. 25, 1995, as amended at 61 FR 27787, June 3, 1996; 70 FR 75345, Dec. 19, 2005]

**Subpart O—Ethylene Oxide Emissions Standards for Sterilization Facilities**

SOURCE: 59 FR 62589, Dec. 6, 1994, unless otherwise noted.

**§ 63.360 Applicability.**

(a) All sterilization sources using 1 ton (see definition) in sterilization or

fumigation operations are subject to the emissions standards in § 63.362, except as specified in paragraphs (b) through (e) of this section. Owners or operators of sources using 1 ton (see definition) subject to the provisions of this subpart must comply with the requirements of subpart A, of this part according to the applicability of subpart A of this part to such sources in Table 1 of this section.

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

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
63.1(a)(1) .....		Yes	Additional terms defined in § 63.361; when overlap between subparts A and O occurs, subpart O takes precedence.
63.1(a)(2) .....		Yes	
63.1(a)(3) .....		Yes	
63.1(a)(4) .....		Yes	
63.1(a)(5) .....		No	
63.1(a)(6) .....		Yes	
63.1(a)(7) .....		Yes	
63.1.1(a)(8) .....		Yes	
63.1(a)(9) .....		No	
63.1(a)(10) .....		Yes	
63.1(a)(11) .....		Yes	
63.1(a)(12)–(14) .....		Yes	Subpart O clarifies the applicability of each paragraph in subpart A to sources subject to subpart O.
63.1(b)(1)–(2) .....		Yes	
63.1(b)(3) .....		No	
63.1(c)(1) .....		Yes	Reserved.
63.1(c)(2) .....		Yes	§ 63.366(a) of subpart O also allows report submissions via fax and on electronic media.
63.1(c)(3) .....		No	§ 63.367 clarifies the applicability of recordkeeping requirements for sources that determine they are not subject to the emissions standards.
63.1(c)(4) .....		Yes	
63.1(c)(5) .....		No	Subpart O clarifies the applicability of each paragraph in subpart A to sources subject to subpart O in this table.
63.1(d) .....		No	
63.1(e) .....		Yes	§ 63.360(f) exempts area sources subject to this subpart from the obligation to obtain Title V operating permits.
63.2 .....		Yes	
63.3 .....		Yes	Reserved.
63.4(a)(1)–(3) .....		Yes	§ 63.360 specifies applicability.
63.4(a)(4) .....		No	
63.4(a)(5) .....		Yes	Reserved.
63.4(b) .....		Yes	
63.4(c) .....		Yes	§ 63.366(b)(1) contains applicability requirements for constructed or reconstructed sources.
63.5(a) .....		No	
63.5(b)(1) .....	Yes .....	No.	Reserved.
63.5(b)(2) .....		No	
63.5(b)(3) .....		No	See § 63.366(b)(2).
63.5(b)(4) .....	Yes .....	No.	
63.5(b)(5) .....	Yes .....	No.	Reserved.
63.5(b)(6) .....	Yes .....	No.	
63.5(c) .....		No	See § 63.366(b)(3).
63.5(d)(1)–(2) .....		No	
63.5(d)(3)–(4) .....	Yes .....	No.	See § 63.366(b)(4).
63.5(e) .....	Yes .....	No.	
63.5(f)(1)–(2) .....		No	§ 63.360 specifies applicability.
63.6(a)(1) .....		Yes	
63.6(a)(2) .....		No	§ 63.360(g) specifies compliance dates for sources.
63.6(b)–(c) .....		No	
63.6(d) .....		No	Reserved.
63.6(e) .....		No	
63.6(f)(1) .....		No	Subpart O does not contain any operation and maintenance plan requirements.
63.6(f)(2)(i) .....		Yes	
			§ 63.362(b) specifies when the standards apply.

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	
63.6(f)(2)(ii) .....		No	§ 63.363 specifies parameters for determining compliance.	
63.6(f)(2)(iii)–(iv) .....		Yes		
63.6(f)(2)(v) .....		No	Subpart O does not contain any opacity or visible emission standards.	
63.6(f)(3) .....		Yes		
63.6(g) .....		Yes		
63.6(h) .....		No		
63.6(i)(1)–(14) .....		Yes		
63.6(i)(15) .....		No		Reserved
63.6(i)(16) .....		Yes		
63.6(j) .....		Yes		
63.7(a)(1) .....		Yes		
63.7(a)(2) .....		Yes		
63.7(a)(3) .....		Yes		
63.7(b) .....		Yes		
63.7(c) .....	Yes .....	No.	§ 63.365 also contains test methods specific to sources subject to the emissions standards.	
63.7(d) .....	Yes .....	No.		
63.7(e) .....		Yes	Reserved	
63.7(f) .....		Yes		
63.7(g)(1) .....		Yes		
63.7(g)(2) .....		No		
63.7(g)(3) .....		Yes		
63.7(h) .....		Yes		
63.8(a)(1) .....		Yes		
63.8(a)(2) .....		Yes		
63.8(a)(3) .....		No		Reserved
63.8(a)(4) .....		Yes		
63.8(b)(1) .....		Yes		
63.8(b)(2) .....		Yes		
63.8(b)(3) .....		No		
63.8(c)(1) (i)–(ii) .....		No	A startup, shutdown, and malfunction plan is not required for these standards.	
63.8(c)(1)(iii) .....		Yes		
63.8(c)(2)–(3) .....		Yes	Frequency of monitoring measurements is provided in § 63.364; opacity monitors are not required for these standards.	
63.8(c)(4)–(5) .....		No		
63.8(c)(6) .....		No		
63.8(c)(7)(i)(A)–(B) .....		No	Performance specifications for gas chromatographs and temperature monitors are contained in § 63.365.	
63.8(c)(7)(i)(C) .....		No		
63.8(c)(7)(ii) .....		No	Opacity monitors are not required for these standards.	
63.8(c)(8) .....		No		
63.8(d) .....	Yes .....	No.	Performance specifications for gas chromatographs and temperature monitors are contained in § 63.365.	
63.8(e)(1) .....		Yes		
63.8(e)(2) .....		Yes		
63.8(e)(3) .....	Yes .....	No.		
63.8(e)(4) .....		Yes		
63.8(e)(5)(i) .....		Yes		
63.8(e)(5)(ii) .....		No		
63.8(f)(1)–(5) .....		Yes		Opacity monitors are not required for these standards.
63.8(f)(6) .....		No		
63.8(g)(1) .....		Yes		
63.8(g)(2) .....		No		
63.8(g)(3)–(5) .....		Yes		
63.9(a) .....		Yes		
63.9(b)(1)–(i) .....		Yes		

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	
63.9(b)(1)(ii)–(iii) .....		No	§ 63.366(c)(1)(i) contains language for sources that increase usage such that the source becomes subject to the emissions standards.	
63.9(b)(2)–(3) .....		Yes		
63.9(b)(4)–(5) .....		No		
63.9(c) .....		Yes	§ 63.366(c)(3) contains additional information to be included in the initial report for existing and new sources.	
63.9(d) .....		No		
63.9(e) .....		Yes		
63.9(f) .....		No		
63.9(g)(1) .....		Yes		
63.9(g)(2)–(3) .....		No		
63.9(h)(1)–(3) .....		Yes	Opacity monitors are not required for these standards.	
63.9(h)(4) .....		No		
63.9(h)(5) .....		No		
63.9(h)(6) .....		Yes	Opacity monitors and relative accuracy testing are not required for these standards.	
63.9(i) .....		Yes		
63.9(j) .....		Yes		
63.10(a) .....		Yes		
63.10(b)(1) .....		Yes		
63.10(b)(2)(i) .....		No		
63.10(b)(2)(ii) .....		Yes		
63.10(b)(2)(iii) .....		No		
63.10(b)(2)(iv)–(v) .....		No		
63.10(b)(2)(vi)–(xii) .....		Yes		
63.10(b)(2)(xiii) .....		No	Reserved.	
63.10(b)(2)(xiv) .....		Yes		
63.10(b)(3) .....		No		
63.10(c)(1) .....		Yes		
63.10(c)(2)–(4) .....		No	§ 63.366(c)(2) instructs sources to submit actual data.	
63.10(c)(5) .....		Yes		
63.10(c)(6) .....		No	Not applicable due to batch nature of the industry.	
63.10(c)(7) .....		No		
63.10(c)(8) .....		Yes		
63.10(c)(9) .....		No		
63.10(c)(10)–(13) .....		Yes		
63.10(c)(14) .....	Yes .....	No.		
63.10(c)(15) .....		No		
63.10(d)(1) .....		Yes		A startup, shutdown, and malfunction plan is not required for these standards.
63.10(d)(2) .....		Yes		
63.10(d)(3) .....		No		
63.10(d)(4) .....		Yes	Subpart O does not contain opacity or visible emissions standards.	
63.10(d)(5) .....		No		
63.10(e)(1) .....		Yes	A startup, shutdown, and malfunction plan is not required for these standards.	
63.10(e)(2)(i) .....		Yes		
63.10(e)(2)(ii) .....		No		
63.10(e)(3)(i)–(iv) .....		Yes	Opacity monitors are not required for these standards.	
63.10(e)(3)(v) .....		No		
			§ 63.366(a)(3) specifies contents and submittal dates for excess emissions and monitoring system performance reports.	

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.