Title 40: Protection of Environment

Subpart WWWWW—National Emission Standards for Hospital Ethylene Oxide Sterilizers

Source: 72 FR 73623, Dec. 28, 2007, unless otherwise noted.

Applicability and Compliance Dates

§ 63.10382 Am I subject to this subpart?

(a) You are subject to this subpart if you own or operate an ethylene oxide sterilization facility at a hospital that is an area source of hazardous air pollutant (HAP) emissions.

(b) The affected source subject to this subpart is each new or existing sterilization facility.

(1) An affected source is existing if you commenced construction or reconstruction of the affected source before November 6, 2006.

(2) An affected source is new if you commenced construction or reconstruction of the affected source on or after November 6, 2006.

§ 63.10384 What are my compliance dates?

(a) *Existing source.* If you have an existing affected source, you must comply with applicable requirements in this subpart no later than December 29, 2008.

(b) *New source.* If you start up a new affected source on or before December 28, 2007, you must comply with applicable requirements in this subpart by December 28, 2007.

(c) *New source.* If you start up a new affected source after December 28, 2007, you must comply with applicable requirements in this subpart upon startup of your affected source.

Standards

§ 63.10390 What management practice standard must I meet?

You must sterilize full loads of items having a common aeration time, except under medically necessary circumstances, as that term is defined in §63.10448.

Initial Compliance Requirements

§ 63.10400 How do I demonstrate initial compliance?

(a) Except as provided in paragraphs (b) and (c) of this section, you must demonstrate initial compliance with the management practice standard in §63.10390 by submitting an Initial Notification of Compliance Status certifying that you are sterilizing full loads of items having a common aeration time except under medically necessary circumstances.

(b) If you operate your sterilization unit(s) with an air pollution control device pursuant to a State or local regulation, you may demonstrate initial compliance with §63.10390 by submitting an Initial Notification of Compliance Status certifying that you are operating the sterilization unit in accordance with your State or local regulation and following control device manufacturer's recommended procedures.

(c) If you operate your sterilization unit(s) with an air pollution control device but are not subject to any State or local regulation, you may demonstrate initial compliance with §63.10390 by submitting an Initial Notification of Compliance Status certifying that you are venting the ethylene oxide emissions from each sterilization unit to an add-on air pollution control device. You must certify that you are operating the control device during all sterilization processes and in accordance with manufacturer's recommended procedures.

§ 63.10402 By what date must I demonstrate initial compliance?

You must demonstrate initial compliance with §63.10390 upon startup or no later than 180 calendar days after your compliance date, whichever is later.

Monitoring—Continuous Compliance Requirements

§ 63.10420 How do I demonstrate continuous compliance with the management practice requirements?

For each sterilization unit not equipped with an air pollution control device, you must demonstrate continuous compliance with the management practice standard in §63.10390 by recording the date and time of each sterilization cycle, whether each sterilization cycle contains a full load of items, and if not, a statement from a hospital central services staff, a hospital administrator, or a physician that it was medically necessary.

Notifications, Reports, and Records

§ 63.10430 What notifications must I submit and by when?

(a) You must submit an Initial Notification of Compliance Status that includes the information required in paragraphs (a)(1) through (5) of this section and the applicable certification in §63.10400.

(1) The name and address of the owner or operator.

(2) The address (i.e., physical location) of the affected source.

(3) An identification of the standard and other applicable requirements in this subpart that serve as the basis of the notification and the source's compliance date.

(4) A brief description of the sterilization facility, including the number of ethylene oxide sterilizers, the size (volume) of each, the number of aeration units, if any, the amount of annual ethylene oxide usage at the facility, the control technique used for each sterilizer, and typical number of sterilization cycles per year.

(5) A statement that the affected source is an area source.

(b) You must submit the Initial Notification of Compliance Status to the appropriate authority(ies) specified in §63.9(a)(4). In addition, you must submit a copy of the Initial Notification of Compliance Status to EPA's Office of Air Quality Planning and Standards. Send your notification via e-mail to *CCG-ONG@EPA.GOV* or via U.S. mail or other mail delivery service to U.S. EPA, Sector Policies and Programs Division, Coatings and Chemicals Group (E143–01), Attn: Hospital Sterilizers Project Leader, Research Triangle Park, NC 27711.

(c) You must submit the Initial Notification of Compliance Status no later than 180 calendar days after your compliance date, consistent with §63.10402.

§ 63.10432 What records must I keep?

You must keep the records specified in paragraphs (a) and (b) of this section.

(a) A copy of the Initial Notification of Compliance Status that you submitted to comply with this subpart.

(b) Records required by §63.10420 for each sterilization unit not equipped with an air pollution control device.

§ 63.10434 In what form and for how long must I keep my records?

(a) Your records must be in a form suitable and readily available for expeditious review.

(b) You must keep each record for 5 years following the date of each record.

(c) You must keep each record onsite for at least 2 years after the date of each record. You may keep the records offsite for the remaining 3 years.

Other Requirements and Information

§ 63.10440 What parts of the General Provisions apply to me?

Table 1 to this subpart shows which parts of the General Provisions in 40 CFR 63.1 through 63.16 apply to you.

§ 63.10442 Who implements and enforces this subpart?

(a) This subpart can be implemented and enforced by us, the U.S. EPA, or a delegated authority such as your State, local, or tribal agency. If the U.S. EPA Administrator has delegated authority to your State, local, or tribal agency, then that agency has the authority to implement and enforce this subpart. You should contact your U.S. EPA Regional Office to find out if this subpart is delegated to your State, local, or tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a State, local, or tribal agency under 40 CFR part 63, subpart E, the authorities contained in paragraph (c) of this section are retained by the Administrator of the U.S. EPA and are not transferred to the State, local, or tribal agency.

(c) The authorities that will not be delegated to State, local, or tribal agencies include approval of alternatives to the applicability requirements under 40 CFR 63.10382, the compliance date requirements in 40 CFR 63.10384, and the management practice standards as defined in 40 CFR 63.10390.

§ 63.10446 Do title V permitting requirements apply to area sources subject to this subpart?

You are exempt from the obligation to obtain a permit under 40 CFR part 70 or 40 CFR part 71, provided you are not otherwise required by law to obtain a permit under 40 CFR 70.3(a) or 40 CFR 71.3(a). Notwithstanding the previous sentence, you must continue to comply with the provisions of this subpart.

§ 63.10448 What definitions apply to this subpart?

Terms used in this subpart are defined in the Clean Air Act (CAA), in 40 CFR 63.2, and in this section as follows:

Aeration process means any time when ethylene oxide is removed from the aeration unit through the aeration unit vent or from the combination sterilization unit through the sterilization unit vent, while aeration or off-gassing is occurring.

Aeration unit means any vessel that is used to facilitate off-gassing of ethylene oxide.

Air pollution control device means a catalytic oxidizer, acid-water scrubber, or any other air pollution control equipment that reduces the quantity of ethylene oxide in the effluent gas stream from sterilization and aeration processes.

Combination sterilization unit means any enclosed vessel in which both the sterilization process and the aeration process occur within the same vessel, i.e., the vessel is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing and is followed by off-gassing of ethylene oxide.

Common aeration time means that items require the same length of time to off-gas ethylene oxide.

Full load means the maximum number of items that does not impede proper air removal, humidification of the load, or sterilant penetration and evacuation in the sterilization unit.

Hospital means a facility that provides medical care and treatment for patients who are acutely ill or chronically ill on an inpatient basis under supervision of licensed physicians and under nursing care offered 24 hours per day. Hospitals include diagnostic and major surgery facilities but exclude doctor's offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals on an outpatient basis.

Hospital central services staff means a healthcare professional, including manager and technician, who is either directly involved in or responsible for sterile processing at a hospital.

Medically necessary means circumstances that a hospital central services staff, a hospital administrator, or a physician concludes, based on generally accepted medical practices, necessitate sterilizing without a full load in order to protect human health.

State or local regulation means a regulation at the State or local level that requires a hospital to reduce the quantity of ethylene oxide emissions from ethylene oxide sterilization units.

Sterilization facility means the group of ethylene oxide sterilization units at a hospital using ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing.

Sterilization process means any time when ethylene oxide is removed from the sterilization unit or combination sterilization unit through the sterilization unit vent.

Sterilization unit means any enclosed vessel that is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing. As used in this subpart, the term includes combination sterilization units.

Table 1 to Subpart WWWWW of Part 63—Applicability of General Provisions to Subpart WWWWW

As required in §63.10440, you must comply with the requirements of the General Provisions (40 CFR part 63, subpart A) shown in the following table:

Citation	Subject	Applies to subpart WWWWW	Explanation
§63.1(a)(1)–(4), (6), (10)–(12), (b)(1), (3)	Applicability	Yes	
§63.1(a)(5), (7)–(9)	[Reserved]		
§63.1(b)(2)	[Reserved]		
§63.1(c)(1)–(2)	Applicability of this part after a relevant standard has been set	Yes	§63.10446 of this subpart exempts affected sources from the obligation to obtain title V operating permits for purposes of being subject to this subpart.

§63.1(c)(3)–(4)	[Reserved]		
§63.1(c)(5)	Subject to notification requirements	No	
§63.1(d)	[Reserved]		
§63.1(e)	Emission limitation by permit	Yes	
§63.2	Definitions	Yes	
§63.3	Units and abbreviations	Yes	
§63.4	Prohibited activities	Yes	
§63.5	Construction/reconstruction	No	
§63.6(a), (b)(1)–(5), (7)	Compliance with standards and maintenance requirements	Yes	
§63.6(b)(6)	[Reserved]		
§63.6(c)(1)	Compliance dates for existing sources	Yes	Subpart WWWWW requires compliance 1 year after the effective date.
§63.6(c)(2), (5)	Compliance dates for CAA section 112(f) standards and for area sources that become major	No	
§63.6(c)(3)–(4)	[Reserved]		
§63.6(d)	[Reserved]		
§63.6(e)–(h)	Alternative nonopacity emission standard	No	
§63.6(i)–(j)	Compliance extension	Yes	
§63.7	Performance testing requirements	No	
§63.8	Monitoring requirements	No	
§63.9(a)	Applicability and initial notifications addressees	Yes	
§63.9(b)	Initial notifications	No	
§63.9(c)	Request for extension of compliance	Yes	
§63.9(d)–(j)	Other notifications	No	
§63.10(a)(1)–(2)	Recordkeeping and reporting requirements, applicability	Yes	
§63.10(a)(3)–(4)	General information	Yes	
§63.10(a)(5)–(7)	Recordkeeping and reporting requirements, reporting schedules	No	
§63.10(b)(1)	Retention time	Yes	
§63.10(b)(2)–(f)	Recordkeeping and reporting requirements	No	
§63.11	Control device requirements	No	
§63.12	State authority and delegations	Yes	

§§63.13–63.16	Addresses, Incorporations by Reference, availability of information, performance track provisions	Yes	