

**Title 7 DNREC  
1100 Air Quality Management Section**

**1138 EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES**

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2/11/09

9.0 Emission Standards for Hospital Ethylene Oxide Sterilizers

9.1 Applicability.

9.1.1 The provisions of 9.0 of this regulation apply to each ethylene oxide sterilization facility at a hospital that is an area source of hazardous air pollutant emissions.

9.1.2 The provisions of 9.0 of this regulation apply to each new or existing affected source. The affected source is each ethylene oxide sterilization facility.

9.1.2.1 An affected source is existing if the owner or operator commenced construction or reconstruction of the affected source before November 6, 2006.

9.1.2.2 An affected source is new if the owner or operator commenced construction or reconstruction of the affected source on or after November 6, 2006.

9.1.3 The owner or operator of an area source subject to 9.0 of this regulation is exempt from the obligation to obtain a Title V operating permit under 7 **DE Admin Code** 1130 of State of Delaware “Regulations Governing the Control of Air Pollution”, if the owner or operator is not required to obtain a Title V operating permit under 3.1 of 7 **DE Admin Code** 1130 for a reason other than the owner or operator’s status as an area source under 9.0. Notwithstanding the previous sentence, the owner or operator shall continue to comply with the provisions of 9.0.

## 9.2 Definitions.

Unless defined below, all terms in 9.0 of this regulation have the meaning given them in the Act or in 3.0 of this regulation.

“**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 circumstances**” 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.

“**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 9.0 of this regulation, the term includes combination sterilization units.

### 9.3 Compliance Dates.

- 9.3.1 The owner or operator of an existing affected source shall be in compliance with the applicable provisions of 9.0 of this regulation by no later than February 11, 2009.
- 9.3.2 The owner or operator of a new or reconstructed affected source that has an initial startup on or before December 28, 2007 shall be in compliance with the applicable provisions of 9.0 of this regulation by no later than February 11, 2009.
- 9.3.3 The owner or operator of a new or reconstructed affected source that has an initial startup after December 28, 2007 shall be in compliance with the applicable provisions of 9.0 of this regulation immediately upon startup or February 11, 2009, whichever is later.

### 9.4 Standards.

- 9.4.1 The owner or operator of an affected source subject to 9.0 of this regulation shall comply with either 9.4.1.1 or 9.4.1.2 of this regulation.
  - 9.4.1.1 The owner or operator of an aeration unit or sterilization unit that is not equipped with an air pollution control device shall only sterilize full loads of items having a common aeration time, except under medically necessary circumstances, as that term is defined in 9.2 of this regulation.
  - 9.4.1.2 The owner or operation of an aeration unit or sterilization unit that is equipped with an air pollution control device shall reduce the ethylene oxide emissions discharged to the atmosphere in accordance with the applicable requirements in 9.4.1.2.1 or 9.4.1.2.2 of this regulation.
    - 9.4.1.2.1 The air pollution control device for a sterilization unit shall reduce the emissions of ethylene oxide to the atmosphere by 99 percent or greater.
    - 9.4.1.2.2 The air pollution control device for an aeration unit shall reduce the emissions of ethylene oxide to the atmosphere by 95 percent or greater.
- 9.4.2 The owner or operator of an affected source complying with 9.4.1.1 of this regulation shall also provide a permanent, legible, conspicuous label summarizing the sterilization unit loading and operating requirements.
- 9.4.3 The owner or operator of an affected source subject to 9.0 of this regulation shall develop and implement a written startup, shutdown, and malfunction plan that describes, in detail, procedures for operating and maintaining the affected source during periods of startup, shutdown, and malfunction and a program of corrective actions for malfunctioning process, control devices, and monitoring equipment used to comply with 9.0. At a minimum, this plan shall include the following:

- 9.4.3.1 Operating instructions for the proper loading, processing, venting, unloading and aeration of the sterilization facility.
- 9.4.3.2 The routine maintenance schedule and procedures in accordance with the manufacturer's recommendations.
- 9.4.3.3 The operational plan that describes, in detail, a program of corrective actions to be taken when equipment or process malfunctions occur.
- 9.4.3.4 The proper storage of ethylene oxide.

9.5 Initial compliance demonstration.

9.5.1 For affected sources electing to comply with 9.4.1.1 of this regulation.

9.5.1.1 The owner or operator shall demonstrate initial compliance with 9.4 of this regulation by submitting an initial notification of compliance status certifying that the owner or operator is sterilizing full loads of items having a common aeration time, except under medically necessary circumstances, and is in compliance with all other applicable requirements in 9.4.

9.5.1.2 The owner or operator shall demonstrate initial compliance with 9.4 of this regulation immediately upon startup or no later than **120** calendar days after the compliance date of the affected source, whichever is later.

9.5.2 For affected sources electing to comply with 9.4.1.2 of this regulation.

The owner or operator shall conduct a performance test to demonstrate initial compliance with the applicable emission limitations in 9.4.1.2 of this regulation. The owner or operator shall conduct the performance testing in accordance with the requirements in 3.7 of this regulation and permit conditions established in 9.11.2 of this regulation.

9.5.3 [Reserved]

9.5.4 [Reserved]

9.6 Monitoring requirements.

9.6.1 For affected sources electing to comply with 9.4.1.1 of this regulation.

The owner or operator shall demonstrate ongoing compliance with the requirements of 9.4.1.1 of this regulation 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.

9.6.2 For affected sources electing to comply with 9.4.1.2 of this regulation.

The owner or operator shall demonstrate ongoing compliance with the requirements of 9.4.1.2 of this regulation by recording the date and time of each sterilization cycle and by conducting monitoring in accordance to the permit conditions established under 9.11.2 of this regulation.

9.6.3 On the first day of each month, the owner or operator of an affected source subject to 9.0 of this regulation shall calculate and record the previous month ethylene oxide consumption and the rolling 12-month total ethylene oxide consumption.

9.7 Notification requirements.

9.7.1 For affected sources electing to comply with 9.4.1.1 of this regulation.

9.7.1.1 The owner or operator shall submit an initial notification of compliance status, signed by a responsible official who shall certify its accuracy, providing the information required in 9.7.1.1.1 through 9.7.1.1.7 of this regulation.

9.7.1.1.1 The name and address of the owner or operator.

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

9.7.1.1.3 An identification of the standard and other applicable requirements in 9.0 of this regulation that serve as the basis of the notification and the source's compliance date.

9.7.1.1.4 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, if any, and typical number of sterilization cycles per year.

9.7.1.1.5 A statement that the affected source is an area source.

9.7.1.1.6 A statement certifying that the owner or operator is sterilizing full loads of items having a common aeration time, except under medically necessary circumstances, and is in compliance with all other applicable requirements in 9.4 of this regulation.

9.7.1.1.7 A statement that all information contained in the notification is true and accurate.

9.7.1.2 The owner or operator shall submit the initial notification of compliance status to the Department no later than 120 calendar days after the compliance date of the affected source.

9.7.2 For affected sources electing to comply with 9.4.1.2 of this regulation.

9.7.2.1 The owner or operator shall submit an initial notification of compliance status no later than 60 calendar days following completion of the compliance demonstration required in 9.5.2 of this regulation in accordance with 3.9.8 of this regulation. The initial notification of compliance status shall be signed by the responsible official who shall certify its accuracy, attesting to whether the source is in compliance with applicable provisions of 9.4 of this regulation.

9.7.2.2 The owner or operator shall submit a notification of a performance test in accordance with 3.9.5 of this regulation.

9.7.3 In addition to submitting the initial notification of compliance status to the Department, the owner or operator of an affected source subject to 9.0 of this regulation shall submit the initial

notification of compliance status to the EPA Regional Office specified in 3.13.1 of this regulation.

9.7.4 The owner or operator shall also submit a copy of the initial notification of compliance status to EPA's Office of Air Quality Planning and Standards. The owner or operator shall send this notification via either of the following:

9.7.4.1 Electronic-mail to CCG-ONG@EPA.GOV or

9.7.4.2 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.

9.8 Recordkeeping requirements.

9.8.1 The owner or operator of an affected source subject to 9.0 of this regulation shall keep the records specified in 9.8.1.1 through 9.8.1.9 of this regulation.

9.8.1.1 A copy of the initial notification of compliance status that the owner or operator submitted to comply with 9.7 of this regulation.

9.8.1.2 Records required by 9.6.1 of this regulation, if applicable, for each sterilization unit not equipped with an air pollution control device.

9.8.1.3 Records required by 9.6.2 of this regulation, if applicable, for each sterilization unit equipped with an air pollution control device.

9.8.1.4 Records associated with the calculation and results of the rolling 12-month total ethylene oxide consumption determined on the first day of each month as specified in 9.6.3 of this regulation.

9.8.1.5 Records to document that the inspection and maintenance required by the startup, shutdown, and malfunction plan in 9.4.3 of this regulation have taken place. The record can take the form of a checklist and should identify the equipment inspected, the date of inspection, a brief description of the working condition, and any actions taken to correct deficiencies found during the inspection.

9.8.1.6 Records of all maintenance performed on the affected source.

9.8.1.7 Records of the occurrence, duration, and cause (if known) of each malfunction of the equipment.

9.8.1.8 Records of actions taken during periods of malfunction when such actions are inconsistent with the startup, shutdown, and malfunction plan.

9.8.1.9 Other records, which may take the form of checklists, necessary to demonstrate conformance with the provisions of the startup, shutdown, and malfunction plan in 9.4.3 of this regulation.

9.8.2 The owner or operator shall keep records in a form suitable and readily available for expeditious review.

- 9.8.3 The owner or operator shall keep each record for 5 years following the date of each record.
- 9.8.4 The owner or operator shall keep each record onsite for at least 2 years after the date of each record. The owner or operator may keep the records offsite for the remaining 3 years.

9.9 Reporting requirements.

- 9.9.1 The owner or operator of each affected source subject to 9.0 of this regulation shall fulfill all reporting requirements outlined in 3.0 and 9.9 of this regulation, according to the applicability of 3.0 of this regulation, as identified in Table 9-1 of this regulation. All reports shall be submitted to the Department and to the EPA Regional Office specified in 3.13.1 of this regulation.
- 9.9.2 At a minimum, the owner or operator of an affected source subject to 9.0 of this regulation shall submit in writing the following reports.
  - 9.9.2.1 Startup, shutdown, and malfunction reports in accordance with 3.10.4.5 of this regulation.
  - 9.9.2.2 No later than the first day of February of each year the consumption of ethylene oxide for the previous calendar year as determined in 9.6.3 of this regulation.
- 9.9.3 At a minimum, the owner or operator of an affected source, which elected to comply with 9.4.1.2 of this regulation, shall submit in writing the following reports.
  - 9.9.3.1 The results of performance tests in accordance with 3.10.4.2 of this regulation.
  - 9.9.3.2 The excess emissions and continuous monitoring system performance report and summary report in accordance with 3.10.5 of this regulation.

9.10 Applicability of general provisions.

The owner or operator of an affected sources subject to the provisions of 9.0 of this regulation shall also be in compliance with the provisions in 3.0 of this regulation, that are applicable to 9.0 as specified in Table 9-1 of this regulation.

9.11 Additional compliance requirements.

- 9.11.1 If the owner or operator of an affected source elects to comply with 9.4.1.2 of this regulation, the owner or operator shall:
  - 9.11.1.1 Submit to the Department a startup, shutdown and malfunction plan consistent with the requirements of 9.4.3 of this regulation.
  - 9.11.1.2 Submit to the Department recommended performance testing procedures and protocols necessary to demonstrate compliance with the requirements of 9.4.1.2 of this regulation.
  - 9.11.1.3 Submit to the Department an application under 7 **DE Admin Code** 1102 of State of Delaware “Regulations Governing the Control of Air Pollution” that proposes monitoring,

recordkeeping and reporting requirements needed to demonstrate ongoing compliance with the provisions of 9.0 of this regulation.

- 9.11.2 The operation of the control technology shall be made federally enforceable in a permit issued pursuant to 7 **DE Admin Code** 1102 or 1130 of State of Delaware “Regulations Governing the Control of Air Pollution.”

9.12 [Reserved]

Table 9-1 – Applicability of 3.0 to 9.0 of this Regulation

General Provisions Reference	Applies to 9.0	Comments
3.1.1.1-3.1.1.4	Yes	
3.1.1.5	No	
3.1.1.6	Yes	
3.1.1.7-3.1.1.9	No	
3.1.1.10-3.1.1.12	Yes	
3.1.1.13-3.1.1.14	No	
3.1.2.1	Yes	
3.1.2.2	Yes	
3.1.2.3	Yes	
3.1.3.1-3.1.3.2	Yes	9.1.3 of this regulation exempts affected sources from the obligation to obtain Title V operating permits for purposes of being subject to this regulation.
3.1.3.3-3.1.3.4	No	
3.1.3.5	No	
3.1.4	No	
3.1.5	Yes	
3.2	Yes	
3.3	Yes	
3.4.1-3.4.1.2	Yes	
3.4.1.3-3.4.1.5	No	
3.4.2-3.4.2.2	Yes	
3.4.2.3	No	
3.4.3	Yes	
3.5.1-3.5.2.1	Yes	
3.5.2.2	No	
3.5.2.3-3.5.2.4	Yes	
3.5.2.5	No	
3.5.2.6	Yes	
3.5.3	No	
3.5.4.1-3.5.4.1.2.8	Yes	
3.5.4.1.2.9	No	
3.5.4.1.2.10-3.5.6.1.1	Yes	
3.5.6.1.2-3.5.6.1.4	No	
3.5.6.2	Yes	
3.6.1-3.6.2.5	Yes	
3.6.2.6	No	
3.6.2.7-3.6.3	Yes	
3.6.3.1	Yes	Except that 9.3.1 of this regulation provides the compliance date for existing sources.

Table 9-1 - Continued

General Provisions Reference	Applies to 9.0	Comments
3.6.3.2	Yes	
3.6.3.3-3.6.3.4	No	
3.6.3.5	Yes	
3.6.4	No	
3.6.5-3.6.5.1	Yes	
3.6.5.2	No	
3.6.5.3	Yes	
3.6.6	Yes	Except 3.6.6 that does not apply to affected sources which elected to comply with 9.4.1.1 of this regulation
3.6.7-3.6.8	No	
3.6.9-3.6.9.6.1.2.1	Yes	
3.6.9.6.1.2.2	No	
3.6.9.6.1.2.3-	Yes	
3.6.9.6.1.2.4		
3.6.9.6.1.3-3.6.9.6.1.4	No	
3.6.9.6.2-3.6.9.14	Yes	
3.6.9.15	No	
3.6.9.16-3.6.10	Yes	
3.7.1.1-3.7.1.2	Yes	Except 3.6.6 that does not apply to affected sources which elected to comply with 9.4.1.1 of this regulation
3.7.1.2.1-3.7.1.2.8	No	
3.7.1.3-3.7.5	Yes	
3.7.6	No	
3.7.7-3.7.7.1	Yes	
3.7.7.2	No	
3.7.7.3-3.7.8	Yes	
3.8.1.1-3.8.1.2	Yes	
3.8.1.3	No	
3.8.1.4-3.8.5	Yes	
3.8.6	No	
3.8.7	Yes	
3.9.1-3.9.1.3	Yes	
3.9.1.4.1	No	
3.9.1.4.2	Yes	
3.9.2-3.9.2.2.5	Yes	
3.9.2.3	No	
3.9.2.4-3.9.2.4.1	Yes	
3.9.2.4.2-3.9.2.4.4	No	
3.9.2.4.5-3.9.2.5	Yes	
3.9.3	Yes	

Table 9-1 - Continued

General Provisions Reference	Applies to 9.0	Comments
3.9.1.4.2	Yes	
3.9.2-3.9.2.2.5	Yes	
3.9.2.3	No	
3.9.2.4-3.9.2.4.1	Yes	
3.9.2.4.2-3.9.2.4.4	No	
3.9.2.4.5-3.9.2.5	Yes	
3.9.3	Yes	
3.9.4-3.9.5	Yes	
3.9.6	No	
3.9.7-3.9.8.3	Yes	
3.9.8.4	No	
3.9.8.5-3.9.10	Yes	
3.10.1-3.10.1.3	Yes	
3.10.1.4.1	No	
3.10.1.4.2	Yes	
3.10.1.5-3.10.1.7	Yes	
3.10.2.1	Yes	
3.10.2.2-3.10.3.1	Yes	
3.10.3.2-3.10.3.4	No	
3.10.3.5-3.10.3.8	Yes	
3.10.3.9	No	
3.10.3.10-3.10.5.3.1.2	Yes	
3.10.5.3.1.3	No	
3.10.5.3.2-3.10.6.6	Yes	
3.11	No	9.0 of this regulation does not require flares.
3.12-3.15	Yes	