

RULE 7021 ETHYLENE OXIDE - STERILIZERS AND AERATORS (Adopted December 19, 1991, Amended December 17, 1992)

1.0 Purpose

The purpose of this rule is to control the emissions of ethylene oxide from sterilizers and aerators. Recordkeeping, notification, reporting, and control requirements are specified. A compliance schedule is also included.

2.0 Applicability

The requirements of this rule shall apply to any person who uses ethylene oxide for sterilization or fumigation or who aerates products sterilized with ethylene oxide at another facility.

3.0 Definitions

3.1 Aeration: the process during which residual ethylene oxide dissipates by forced air flow, natural or mechanically assisted convection, or other means from previously sterilized materials after the sterilizer cycle is completed. Aeration is completed when materials that have previously undergone ethylene oxide sterilization can be handled in the same manner as similar materials that have not been sterilized with ethylene oxide.

3.2 Aeration-only Facility: a facility which performs aeration on materials which have been sterilized with ethylene oxide at another facility.

3.3 Aerator: any equipment or space in which materials previously sterilized with ethylene oxide are placed or remain for the purpose of aeration. An aerator is not any equipment or space in which materials that have previously undergone ethylene oxide sterilization and aeration can be handled, stored, and transported in the same manner as similar materials that have not been sterilized with ethylene oxide.

3.4 Back-draft Valve: a valve or rear chamber exhaust system for removal of ethylene oxide during unloading of sterilized materials.

3.5 Control Efficiency: The ethylene oxide (ETO) mass or concentration reduction efficiency of a control device, as measured with ARB Test Method 431 according to the source testing requirements herein, and expressed as a percentage calculated across the control device as follows:

$$\text{Control Efficiency}(\%) = \frac{ETO_{INPUT} - ETO_{OUTPUT}}{ETO_{INPUT}} \times 100$$

- 3.6 Ethylene Oxide: a colorless, flammable gas that has been identified as a suspected human carcinogen and a toxic air contaminant by the ARB.
- 3.7 Exhaust Stream: the ethylene oxide-contaminated effluent emitted from a sterilizer or aerator.
- 3.8 Facility-wide: the total pounds of ethylene oxides used in all of the sterilizers at the facility during a one (1) year period.
- 3.9 Leak-free: the state which exists when the concentration of sterilant gas measured one (1) centimeter away from any portion of the exhaust system of a sterilizer or aerator, during conditions of maximum sterilant gas mass flow, is less than 30 ppm (for a sterilant gas composition of 12% ethylene oxide and 88% CFC-12 by weight) or ten (10) ppm (for other compositions), as determined by a portable hydrocarbon detection instrument.
- 3.10 Portable Hydrocarbon Detection Instrument: a hydrocarbon analyzer which used the flame ionization detection or thermal conductivity methods and satisfies ARB Method 21. The instrument shall be calibrated on methane and shall sample at a rate of at least one (1) liter per minute.
- 3.11 Sterilization/Fumigation: the process where ethylene oxide or any combination of ethylene oxide and other gases are used to destroy bacteria, viruses, fungi, and other unwanted organisms on products. These products include, by way of illustration and not limitation, medical products, cosmetics, and foodstuffs.
- 3.12 Sterilizer: any chamber or related piece of equipment that uses ethylene oxide or an ethylene oxide mixture in any sterilization or fumigation process.
- 3.13 Sterilizer Gas: ethylene oxide or any combination of ethylene oxide and other gases used in a sterilizer.
- 3.14 Sterilizer Cycle: the process which begins when ethylene oxide is introduced into the sterilizer, includes the initial purge or evacuation after sterilization and subsequent air washer, and ends after evacuation of the final air wash.
- 3.15 Sterilizer Door Hood Exhaust Stream: the air stream which results from collection of fugitive ethylene oxide emissions, by means of an existing hood over the sterilizer door, during the time that the sterilizer door is open after the sterilizer cycle has been completed.
- 3.16 Sterilizer Exhaust Vacuum Pump: a device used to evacuate the sterilant gas during the sterilizer cycle, including any associated heat exchanger. A sterilizer exhaust pump is not a device used solely to evacuate a sterilizer prior to the introduction of ethylene oxide.

4.0 Exemptions

- 4.1 Any facility with a facility-wide usage of ethylene oxide less than or equal to 25 pounds per calendar year shall be exempt from the requirements of Section 5.0.
- 4.2 If control equipment is required solely to comply with the requirements of this rule, such equipment shall not be subject to Rule 2201 (New and Modified Stationary Source Review Rule) provided the system includes Best Available Control Technology (BACT).

5.0 Requirements

A person shall not operate a sterilizer or aerator unless all of the following requirements are satisfied:

- 5.1 No sterilizer exhaust vacuum pump working fluid is discharged to wastewater streams.
- 5.2 The exhaust stream including, but not limited to, any piping, ducting, fittings, valves, or conveyed from the sterilizer and aerator to the outlet of the control device is leak-free.
- 5.3 All of the control requirements shown in Table 1 for the applicable control category are met.
- 5.4 For facilities using more than 600 pounds of ethylene oxide per year, the back-draft valve is ducted to the control device that is used to control the sterilizer or aerator exhaust stream.
- 5.5 For facilities using more than 5,000 pounds of ethylene oxide per year, the sterilizer door hood exhaust stream is ducted to the control device that is used to control the aerator exhaust stream.

TABLE 1
Control and Compliance Requirements

CONTROL CATEGORY	REQUIREMENTS		
Facility-wide Pounds of Ethylene Oxide used per year	Exhaust Streams to be Controlled	Exhaust Streams to be tested	Control Efficiency %
Less than or equal to 25	None	None	None
More than 25 and less than or equal to 600	Sterilizer	Sterilizer	99.0
More than 600 and less than or equal to 5,000	Sterilizer; Aerator; Back-Draft Valve	Sterilizer; Aerator	99.9 95.0
More than 5,000	Sterilizer; Aerator; Sterilizer Door Hood Back-Draft Valve	Sterilizer; Aerator	99.9 99.0 N/A
Aeration-only Facilities	Aerator	Aerator	95.0

5.6 If a reduction in the amount of ethylene oxide across the control device is demonstrated, but the control efficiency cannot be affirmatively demonstrated because the concentration of ethylene oxide measured in the outlet of the control device is below 0.2 parts per million ethylene oxide, the facility shall be considered to be in compliance with this requirement.

6.0 Administrative Requirements

6.1 Recordkeeping

Any person who owns or operates a sterilizer or aerator shall maintain a log of the date and time of each sterilizer operation cycle and record all ethylene oxide purchases. These records shall be retained for two years and made available to the District upon request.

6.2 Test Methods

Emissions of ethylene oxide shall be determined by ARB Test Method 431. The source test shall be conducted in the following manner:

6.2.1 The test on a control device for a sterilizer exhaust stream shall be run with a typical load in the sterilizer.

- 6.2.2 The test on a control device for an aerator exhaust stream shall be run with a typical load in the aerator.
- 6.2.3 The inlet and outlet of the control device shall be sampled simultaneously during testing to measure the control efficiency.
- 6.2.4 The efficiency of each control device shall be determined under conditions of maximum ethylene oxide mass flow to the device, under normal operating conditions.
 - 6.2.4.1 to measure the control efficiency of the control device on the sterilizer exhaust stream, sampling shall be done during the entire duration of the first sterilizer evacuation after ethylene oxide has been introduced.
 - 6.2.4.2 to measure the control efficiency of the control device on an aerator exhaust stream with a constant air flow, sampling shall be done during a period of at least 60 minutes, starting 15 minutes after aeration begins.
 - 6.2.4.3 to measure the control efficiency of the control device on an aerator exhaust stream with a non-constant air flow, sampling shall be done during the entire duration of the first aerator evacuation after aeration begins.
- 6.2.5 There shall be no dilution of the air stream between the inlet and outlet test points during testing.

6.3 Notification

Any person who owns or operates a sterilizer or aerator must submit by February 1, 1991 the following information:

- 6.3.1 The name(s) of the owner and operator of the facility.
- 6.3.2 The location of the facility.
- 6.3.3 The number of sterilizers and aerators at the facility.
- 6.3.4 An estimate of the total pounds of ethylene oxide and sterilant gas used by the facility during the 1990 calendar year.

6.4 Reporting

Any person who owns or operates a sterilizer shall furnish a written report to the district by March 1 of the following year. This report shall include one (1) of the following:

- 6.4.1 The number of sterilizer cycles and the pounds of ethylene oxide purchased, used, and returned in the previous calendar year.
- 6.4.2 The total pounds of sterilant gas and the total pounds of ethylene oxide purchased, used, and returned in the previous calendar year.

7.0 Compliance Schedule

- 7.1 The owner or operator of a sterilizer or aerator which is subject to the provisions of this rule and was installed prior to January 1, 1992 shall comply with the following applicable compliance schedule:
 - 7.1.1 If the facility-wide usage of ethylene oxide is greater than 5,000 pounds per year, full compliance shall be met by December 1, 1992.
 - 7.1.2 If the facility-wide usage of ethylene oxide is greater than 600 but less or equal to 5,000 pounds per year, full compliance shall be met by June 1, 1993.
 - 7.1.3 If the facility-wide usage of ethylene oxide is greater than 25 but less than or equal to 600 pounds per year, full compliance shall be met by December 1, 1993.
 - 7.1.4 If the facility-wide usage of ethylene oxide is less than or equal to 25 pounds per year, full compliance shall be met by December 1, 1993.
- 7.2 The owner or operator of a sterilizer or aerator which is subject to the provisions of this rule and which is installed or constructed on or after January 1, 1992 shall be in full compliance with the provisions of this rule at the time of initial operation.
- 7.3 The owner or operator of a sterilizer or aerator which loses their exemption provided by Section 4.0 shall be in full compliance 12 months from the date the exemption was lost.