

RULE 428. STERILIZERS AND AERATORS USING ETHYLENE OXIDE

Adopted: 11/06/91

A. PURPOSE

To comply with the Air Resources Board's Ethylene Oxide Toxic Control Measure for Sterilizers and Aerators, as required by California Health and Safety Code Section 39666.

B. DEFINITIONS

For the purposes of this section, the following definitions shall apply:

1. "Acute care facility" means any facility currently licensed by the California Department of Health Services as a general acute care hospital (as defined in Title 22, CCR, Section 70005), or any military hospital.
2. "Aeration" is the process during which residual ethylene oxide dissipates, whether under forced air flow, natural or mechanically assisted convection, or other means, from previously sterilized materials after the sterilizer cycle is complete.
3. "Aeration-only facility" means a facility which performs aeration on materials which have been sterilized with ethylene oxide at another facility.
4. "Aerator" means 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.
5. "Aerator exhaust stream" means all ethylene oxide contaminated air which is emitted from an aerator.
6. "Back-draft valve exhaust stream" is the air stream which results from collection of ethylene oxide-contaminated air which may be removed from the sterilizer through a back-draft valve or rear chamber exhaust system during unloading of the sterilized materials.
7. "Control device" means an article, machine, equipment, or contrivance which reduces the amount of ethylene oxide between its inlet and outlet and which is sized, installed, operated, and maintained according to good engineering practices, as determined by the district.

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8. "Control efficiency" is the ethylene oxide (EtO) mass or concentration reduction efficiency of a control device, as measured with ARB Test Method 431 (Title 17, CCR, Section 94143) according to the source testing requirements herein, and expressed as a percentage calculated across the control device as follows:

$$\frac{\text{EtO in} - \text{EtO out}}{\text{EtO in}} \times 100 = \% \text{ Control Efficiency}$$

9. "Ethylene oxide (EtO)" is the substance identified as a toxic air contaminant by the Air Resources Board in 17 CCR, Section 93000.
10. "Facility" means any entity or entities which: own or operate a sterilizer or aerator, are owned or operated by the same person or persons, and are located on the same parcel or contiguous parcels.
11. "Facility-wide pounds of ethylene oxide used per year" is the total pounds of ethylene oxide used in all of the sterilizers at the facility during a one-year period.
12. "Leak-free" refers to that state which exists when the concentration of sterilant gas measured 1 cm. 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 sterilant gas composed of 12% ethylene oxide/88% chlorofluorocarbon-12 by weight, and
  - 10 ppm for other compositions of sterilant gas, as determined by ARB Test Method 21 (Title 17, CCR, Section 94124) using a portable flame ionization detector, or a non-dispersive infrared analyzer, calibrated with methane, or an acceptable alternative method or analytical instrument approved by the district. A chlorofluorocarbon-12 specific audible detector using a metal oxide semiconductor sensor shall be considered an acceptable alternative for exhaust systems carrying a sterilant gas mixture of ethylene oxide and chlorofluorocarbon-12.
13. "Local medical emergency" means an unexpected occurrence in the area served by the acute care facility resulting in a sudden increase in the amount of medical treatments which require a significant increase in the operation of a sterilizer or aerator.
14. "Sterilant gas" means ethylene oxide or any combination of ethylene oxide and (an)other gas(es) used in a sterilizer.
15. "Sterilizer" means any equipment in which ethylene oxide is used as a biocide to destroy bacteria, viruses, fungi, and other unwanted organisms on materials. Equipment in which ethylene oxide is used to fumigate foodstuffs is considered a sterilizer.
16. "Sterilizer cycle" means the process which begins when ethylene oxide is introduced into the sterilizer, includes the initial purge or evacuation after

sterilization and subsequent air washes, and ends after evacuation of the final air wash.

17. "Sterilizer door hood exhaust stream" is 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.
18. "Sterilizer exhaust stream" is all ethylene oxide-contaminated air which is intentionally removed from the sterilizer during the sterilizer cycle.
19. "Sterilizer exhaust vacuum pump" means a device used to evacuate the sterilant gas during the sterilizer cycle, including any associated heat exchanger. A sterilizer exhaust vacuum pump is not a device used solely to evacuate a sterilizer prior to the introduction of ethylene oxide.

#### C. APPLICABILITY

Any person who owns or operates a sterilizer or an aerator must comply with this regulation.

#### D. NOTIFICATION

Any person subject to this regulation must provide the District with the following information, in writing, by December 6, 1991:

1. the name(s) of the owner and operator of the facility, and
2. the location of the facility, and
3. the number of sterilizers and aerators at the facility, and
4. an estimate of the total pounds of ethylene oxide and sterilant gas used by the facility, in all sterilizers, during the previous calendar year, as determined by a method approved by the district.

#### E. REPORTING

Any person who owns or operates a sterilizer shall furnish a written report to the District annually in December. This report shall include the total pounds of sterilant gas and the total pounds of ethylene oxide purchased, used, and returned in the previous calendar year, as shown on invoices.

#### F. REQUIREMENTS

No person shall operate a sterilizer or aerator after the applicable date shown in column (d), Table I, unless all of the following requirements are satisfied:

1. there is no discharge of sterilizer exhaust vacuum pump working fluid to wastewater streams, and

2. the exhaust systems including, but not limited to, any piping, ducting, fittings, valves, or flanges, through which ethylene oxide-contaminated air is conveyed from the sterilizer and aerator to the outlet of the control device are leak-free, and
3. all of the control requirements shown in Table I below for the applicable control category are met; and
4. for facilities using more than 600 pounds of ethylene oxide per year, the back-draft valve is ducted to the control device used to control the sterilizer exhaust stream or the aerator exhaust stream; and
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 used to control the aerator exhaust stream.

#### G. EXEMPTIONS

1. The requirements set forth in subsection F above, do not apply to any facility which treats materials in a sterilizer and which uses a total of 25 pounds or less of ethylene oxide per calendar year.
2. The District Hearing Board may grant an emergency variance from items (a) and (c) in Table I of subsection F, Requirements, to a person who owns or operates an acute facility if response to a local medical emergency requires increased operation of a sterilizer or aerator such that the requirements cannot be met.
3. The demonstrated need for such increased operation shall constitute "good cause" pursuant to Health and Safety Code Section 42359.5. The emergency variance shall be granted in accordance with this section and any applicable district rule regarding the issuance of emergency variances for such occurrences, including the requirement that the emergency variance shall not remain in effect longer than 30 days; however, the emergency variance shall be granted only for the period of time during which increased operation of a sterilizer or aerator is necessary to respond to the local medical emergency.

#### H. COMPLIANCE

The facility shall be in compliance with all provisions specified in subsection F, Requirements, no later than the date specified in column (d) of Table I.

1. For the purpose of determining compliance with the control efficiency requirement shown in column (c) of Table I, subsection F, 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.

I. ALTERNATE COMPLIANCE DATE

The owner or operator of any facility which uses more than 600 pounds of ethylene oxide per year may choose this alternate compliance option which addresses the date for compliance with the requirements of subsection F. If this compliance option is chosen, the owner or operator shall:

1. by February 6, 1992, comply with the requirements shown in subsection F.1 and F.2, and demonstrate a control efficiency of 99.9% for the sterilizer exhaust stream, in accordance with the source testing requirements set forth in subsection J; and
2. by May 6, 1992, submit to the District a plan to discontinue operation of all sterilizers and aerators or comply with the district requirements to submit a plan to comply with the requirements of subsections F.3, F.4, and F.5; and
3. by May 6, 1993, do one of the following:
  - a. demonstrate to the satisfaction of the District that operating of all sterilizers and aerators at the facility has been permanently discontinued; or
  - b. demonstrate compliance with the requirements of subsections F.3, F.4, and F.5, in accordance with the source testing provisions set forth in subsection J, below.

TABLE I  
CONTROL AND COMPLIANCE REQUIREMENTS

CONTROL CATEGORY	REQUIREMENTS			
	(a)	(b)	(c)	(d)
Facility-wide Pounds of Ethylene Oxide Used per Year	Exhaust Streams to be Controlled	Control to be Tested	Efficiency (%)	Date of Compliance Months
less than or equal to 25	None	None	None	
more than 25 and less than or equal to 600	Sterilizer	Sterilizer	99.0	24
more than 600 and less than or equal to 5,000	Sterilizer	Sterilizer	99.0	18
	Aerator	Aerator	95.0	
	Back-draft Valve		N/A*	
more than 5,000	Sterilizer	Sterilizer	99.9	12
	Aerator & Sterilizer Door Hood	Aerator	99.0 N/A*	
	Back-draft Valve		N/A*	
Aeration-Only Facilities	Aerator	Aerator	95.0	18

\* Not Applicable

J. SOURCE TESTING

Source testing shall be conducted according to ARB Test Method 431 (Title 17, CCR, Section 95143) and the method evaluations cited therein or an acceptable source test method approved by the Executive Officer of the Air Resources Board. Specific requirements for application are given below:

1. The test on a control device for a sterilizer exhaust stream shall be run with a typical load, as approved by the district, in the sterilizer.
2. The test on a control device for an aerator exhaust stream shall be run with a typical load, as approved by the district, in the aerator.
3. The inlet and outlet of the control device shall be sampled simultaneously during testing to measure the control efficiency.
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. 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. 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. 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.
5. There shall be no dilution of the air stream between the inlet and outlet test points during testing.

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