

YOLO-SOLANO AIR QUALITY MANAGEMENT DISTRICT

RULE 9.4 - ETHYLENE OXIDE STERILIZERS AND AERATORS

(Adopted June 23, 1993)

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100 GENERAL

101 PURPOSE: The purpose of this rule is to control the emissions of ethylene oxide from sterilizers and aerators in compliance with the Airborne Toxic Control Measure adopted by the California Air Resources Board (Title 17, California Code of Regulations (CCR), Section 93108).

102 APPLICABILITY: This rule applies to any person who owns or operates a ethylene oxide sterilizer or an aerator.

110 EXEMPTIONS:

110.1 The requirements set forth in Section 301 of this rule shall not apply to any facility which treats materials in a sterilizer and which uses a total of twenty-five (25) pounds or less of ethylene oxide per calendar year.

110.2 The District Hearing Board may grant an emergency variance from Items A and C in Table 1 of Section 301 to a person who owns or operates an acute care facility if response to a local medical emergency requires increased operation of a sterilizer or aerator such that the requirements cannot be met. 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 Regulation V, PROCEDURE BEFORE THE HEARING BOARD, regarding the issuance of emergency variances for such occurrences, including the requirement that the emergency variance shall not remain in effect longer than thirty (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.

200 DEFINITIONS

201 **ACUTE CARE FACILITY:** 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.

202 **AERATION:** 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.

203 **AERATION-ONLY FACILITY:** A facility which performs aeration on materials which have been sterilized with ethylene oxide at another facility.

204 **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.

205 **AERATOR EXHAUST STREAM:** All ethylene oxide-contaminated air which is emitted from an aerator.

206 **BACK-DRAFT VALVE EXHAUST STREAM:** The air stream which results from the 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 sterilizer materials.

207 **CONTROL DEVICE:** 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 Air Pollution Control Officer.

208 **CONTROL EFFICIENCY:** The ethylene oxide (EtO) mass or concentration reduction efficiency of a control device, as measured with California Air Resources Board (CARB) Test Method 431 according to the source testing requirements herein, and expressed as a percentage calculated across the control device as follows:

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

209 **DATE OF COMPLIANCE:** The time from District adoption of regulations enacting this control measure until a facility must be in compliance with the specific requirements of this rule.

210 ETHYLENE OXIDE (EtO): The substance identified as a toxic air contaminant by the California Air Resources Board in Title 17, CCR, Section 93000.

211 FACILITY: 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.

212 FACILITY-WIDE POUNDS OF ETHYLENE OXIDE USED PER YEAR: The total pounds of ethylene oxide used in all the sterilizers at the facility during a one calendar year period.

213 LEAK-FREE: 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: thirty (30) ppm for sterilant gas composed of 12% ethylene oxide/88% chlorofluorocarbon-12 by weight; and ten (10) ppm for other compositions of sterilant gas, as determined by CARB Test Method 21 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 Air Pollution Control Officer. A chlorofluorocarbon-12 specific audible detector using a metal oxide semi-conductor sensor shall be considered an acceptable alternative for exhaust systems carrying a sterilant gas mixture of ethylene oxide and chlorofluorocarbon-12.

214 LOCAL MEDICAL EMERGENCY: An unexpected occurrence in the area served by the acute care facility resulting in a sudden increase in the amount of medical treatments which requires a significant increase in the operation of a sterilizer or aerator.

215 STERILANT GAS: Ethylene oxide or any combination of ethylene oxide and (an)other gas(es) used in a sterilizer.

216 STERILIZER: Any equipment in which ethylene oxide is used as a biocide to destroy bacterias, viruses, fungi, and other unwanted organisms on materials. Equipment in which ethylene oxide is used to fumigate foodstuffs is considered a sterilizer.

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

218 STERILIZER DOOR HOOD EXHAUST SYSTEM: 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.

219 STERILIZER EXHAUST STREAM: All ethylene oxide-contaminated air which is intentionally removed from the sterilizer during the sterilizer cycle.

220 STERILIZER EXHAUST VACUUM PUMP: 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.

300 STANDARDS

301 REQUIREMENTS: No person shall operate a sterilizer or aerator after the applicable date shown in Item D, **Table 1** of this Section, unless all of the following requirements are satisfied:

301.1 There is no discharge of sterilizer exhaust vacuum pump working fluid to wastewater streams; and

301.2 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

301.3 All of the control requirements shown in **Table 1** of this Section for the applicable control category are met; and

301.4 For facilities using more than 600 pounds of ethylene oxide per calendar year, the back-draft valve is ducted to the control device used to control the sterilizer exhaust stream or the aerator exhaust stream; and

301.5 For facilities using more than 5000 pounds of ethylene oxide per calendar year, the sterilizer door hood exhaust stream is ducted to the control device used to control the aerator exhaust stream.

TABLE 1
CONTROL AND COMPLIANCE REQUIREMENTS

CONTROL CATEGORY		REQUIREMENTS			
ITEM	A	B	C	D	
FACILITY-WIDE POUNDS OF ETHYLENE OXIDE USED PER YEAR	EXHAUST STREAMS TO BE CONTROLLED	EXHAUST STREAMS TO BE TESTED	CONTROL EFFICIENCY (%)	DATE OF COMPLIANCE (MONTHS)	
LESS THAN OR EQUAL TO 25	NONE	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 5000	STERILIZER	STERILIZER	99.9	18	
	AERATOR	AERATOR	95.0		
	BACK-DRAFT VALVE		N/A*		

MORE THAN 5000	STERILIZER	STERILIZER	99.9	12
	AERATOR	AERATOR	99.0	
	STERILIZER DOOR HOOD		N/A*	
	BACK-DRAFT VALVE		N/A*	
AERATION-ONLY FACILITIES	AERATOR	AERATOR	95.0	18

* NOT APPLICABLE

400 ADMINISTRATIVE REQUIREMENTS

401 NOTIFICATION: Any person subject to this rule shall provide the District with the following information, in writing, within 30 days of (date of adoption):

401.1 The name(s) of the owner and operator of the facility; and

401.2 The location of the facility; and

401.3 The number of sterilizers and aerators at the facility; and

401.4 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 Air Pollution Control Officer. The District may exempt a source from this requirement if the District has received written records that provide current information on the source.

402 COMPLIANCE: The facility shall be in compliance with all provisions specified in Section 301 of this rule no later than the date specified in Item D of **Table 1**.

402.1 For the purpose of determining compliance with the control efficiency requirement shown in Item C of **Table 1**, Section 301, 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.

403 ALTERNATE COMPLIANCE DATE: The owner or operator of any facility which uses more than 600 pounds of ethylene oxide per calendar year may choose this alternate option which addresses the date of compliance with the requirements of Section 301 of this rule. If this compliance option is chosen, the owner or operator shall:

403.1 Within three (3) months of (date of adoption), comply with the requirements shown in Sections 301.1 and 301.2 and demonstrate a control efficiency of 99.9% for the sterilizer exhaust stream, accordance with the source testing requirements set forth in Section 502 of this rule; and

403.2 Within six (6) months of (date of adoption), submit a plan to the Air Pollution Control Officer to discontinue the operation of all sterilizers and aerators or comply with the requirements of Sections 301.3, 301.4, and 301.5 of this rule; and

403.3 Within three (3) months of (date of adoption) do one of the following:

- a. Demonstrate to the satisfaction of the Air Pollution Control officer that operation of all sterilizers and aerators at the facility have been permanently discontinued; or
- b. Demonstrate compliance with the requirements of Sections 301.3, 301.4, and 301.5 of this rule, in accordance with the source testing provisions set forth in Section 502 of this rule.

500 MONITORING AND RECORDS

501 REPORTING: Any person who owns or operates a sterilizer shall furnish a written report to the Air Pollution Control Officer annually on the date specified by the Air Pollution Control Officer, or at his discretion, shall maintain such a report and make it available upon request. This report shall include one of the following, as determined by the Air Pollution Control Officer:

501.1 The number of sterilizer cycles and pounds of ethylene oxide used per cycle for each sterilizer during the reporting period, as determined by a method approved by the Air Pollution Control Officer; or

501.2 The total pounds of sterilant gas and the total pounds of ethylene oxide purchased, used and returned in the previous calendar year, as determined by a method approved by the Air Pollution Control Officer.

502 SOURCE TESTING: Source testing shall be conducted according to CARB Test Method 431 and the method evaluations cited therein or an acceptable source test method approved in writing by the Executive Officer of the California Air Resources Board. Specific requirements for application are as follows:

502.1 The test on a control device for a sterilizer exhaust stream shall be run with a typical load in the sterilizer, as approved by the Air Pollution Control Officer.

502.2 The test on the control device for an aerator exhaust stream shall be run with a typical load in the aerator, as approved by the Air Pollution Control Officer.

502.3 The inlet and outlet of the control device shall be sampled simultaneously during testing to measure control efficiency.

502.4 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 of an aerator exhaust stream with a constant air flow, sampling shall be done during a period of at least sixty (60) minutes, starting fifteen (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.

502.5 There shall be no dilution of the air stream between the inlet and outlet test points during testing.