

(Adopted December 21, 1990)(Amended January 4, 1991)

**RULE 1405. CONTROL OF ETHYLENE OXIDE AND
CHLOROFLUOROCARBON EMISSIONS FROM
STERILIZATION OR FUMIGATION PROCESSES**

(a) Purpose

The purpose of this rule is to protect public health by reducing ethylene oxide emissions from sterilization or fumigation operations in the South Coast Air Basin and to fulfill state requirements. Pursuant to the requirements of Health and Safety Code Section 39650 (AB 1807 Tanner), the Air Resources Board (ARB) adopted an Air Toxic Control Measure for Ethylene Oxide Emissions from Sterilizers and Aerators in May, 1990. The District is required to enact equivalent or more stringent requirements than this measure. This rule requires recovery or reclamation of chlorofluorocarbons at certain commercial facilities and eliminates the use of certain chlorofluorocarbons as diluents in sterilization processes by 1997.

(b) Applicability

This rule is applicable to persons that use ethylene oxide for sterilization or fumigation, or aerate products sterilized with ethylene oxide at another facility.

(c) Definitions

For the purpose of this rule, the following definitions apply:

- (1) AERATION is the process during which residual ethylene oxide dissipates by forced air flow, or through natural or mechanically assisted convection, or other means, from previously sterilized materials after the sterilization cycle is completed. Aeration is completed when materials that have previously undergone ethylene oxide sterilization can be handled, stored, and transported in the same manner as similar materials that have not been sterilized with ethylene oxide.
- (2) AERATION-ONLY FACILITY is any facility which performs aeration on materials which have been sterilized with ethylene oxide at another facility.
- (3) AERATOR is any equipment, space, or room in which air is used to remove residual ethylene oxide from sterilized materials.
- (4) BACK-DRAFT VALVE is a valve or rear chamber exhaust system for removal of ethylene oxide during unloading of sterilized materials.

- (5) CHLOROFLUOROCARBON (CFC) DILUENT is any of the five chlorinated fluorinated carbon compounds (CFC-11, CFC-12, CFC-113, CFC-114, or CFC-115), or combinations of these compounds, used in sterilant gas mixtures.
 - (6) ETHYLENE OXIDE (C₂H₄O) is a colorless, flammable gas that has been identified as a suspected human carcinogen and a toxic air contaminant by the ARB.
 - (7) EXHAUST STREAM is the ethylene oxide-contaminated effluent emitted from a sterilizer or aerator.
 - (8) PERSON is any firm, business establishment, association, partnership, corporation or individual, whether acting as principal, agent, employee or other capacity, including any governmental entity or charitable organization.
 - (9) RECOVER is to remove refrigerant in any condition from a system and store it in an external container, without necessarily testing or processing it in any way.
 - (10) RECLAIM is to process refrigerant to new product specifications.
 - (11) STERILIZATION/FUMIGATION is 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 materials. These materials include, by way of illustration and not limitation, medical products, cosmetics, and foodstuffs.
 - (12) STERILIZER is any chamber or related piece of equipment that uses ethylene oxide or an ethylene oxide mixture in any sterilization or fumigation process.
 - (13) STERILIZER EXHAUST VACUUM PUMP is a device (including any associated heat exchanger) used to evacuate sterilant gas during the sterilizer cycle, but is not a device used solely to evacuate a sterilizer prior to the introduction of ethylene oxide.
- (d) Requirements
- (1) The following requirements shall be met by December 21, 1992 by all persons who use a total of 400 pounds or less of ethylene oxide per calendar year:
 - (A) Sterilizer(s) shall be vented to control equipment with an efficiency of 99 percent or more, by weight.

- (B) If ethylene oxide emissions from aeration are greater than four pounds per calendar year, the aerator(s) shall be vented to control equipment with an efficiency of 95 percent or more, by weight.
 - (C) If the exhaust streams from the equipment identified in (1)(A) and (B) are vented to the same control equipment, the combined efficiency must be 98.8 percent or more, by weight.
- (2) The following requirements shall be met by June 21, 1992 by all persons who use a total of more than 400 and less than or equal to 4,000 pounds of ethylene oxide per calendar year:
- (A) Sterilizer(s) shall be vented to control equipment with an efficiency of 99.9 percent or more, by weight.
 - (B) Aerator(s) shall be vented to control equipment with an efficiency of 95 percent or more, by weight.
 - (C) Back-draft exhaust valve(s) shall be vented to control equipment with an efficiency of 95 percent or more, by weight.
 - (D) If the exhaust streams from the equipment identified in (2)(A), (B), and (C) are vented to the same control equipment, the combined efficiency must be 99.6 percent or more, by weight.
- (3) The following requirements shall be met by December 21, 1991 by all persons who use a total of more than 4,000 pounds of ethylene oxide per calendar year:
- (A) Sterilizer(s) shall be vented to control equipment with an efficiency of 99.9 percent or more, by weight.
 - (B) Aerator(s) and sterilizer door hood exhaust stream(s) shall be vented to control equipment with an efficiency of 99 percent or more, by weight.
 - (C) Back-draft exhaust valve(s) shall be vented to control equipment with an efficiency of 99 percent or more, by weight.
 - (D) If the exhaust streams from the equipment identified in (3)(A), (B), and (C) are vented to the same control equipment, the combined efficiency must be 99.8 percent or more, by weight.
- (4) Persons owning or operating aeration-only facilities where more than four pounds of ethylene oxide are emitted per calendar year shall install control equipment with an efficiency of 95 percent or more, by weight, by June 21, 1992.

- (5) Sterilizers, aerators, control equipment, and emissions collection systems shall be leak free effective December 21, 1990. The maximum sterilant gas mass flow shall be less than 30 parts per million ethylene oxide for sterilant gas composed of 12 percent ethylene oxide/88 percent chlorofluorocarbon-12, by weight, and less than 10 parts per million ethylene oxide for other compositions of sterilant gas, as measured one (1) centimeter away from any portion of a sterilizer, aerator, or control equipment that could have an ethylene oxide leak. Leak tests shall be conducted during conditions of maximum sterilant gas mass flow. Leak tests shall be conducted every six months, as specified in paragraph (f), Test Methods.
- (6) All persons subject to this rule shall conduct source tests on control equipment within 60 days after the initial operation of the equipment to verify compliance with control efficiency requirements, as specified in paragraph (f), Test Methods. Thereafter, annual source tests shall be conducted on catalytic oxidation, carbon, or solid bed control equipment. More frequent source tests, or source tests on other control equipment, may be required at the District's discretion.
- (7) A person shall not discharge any sterilizer exhaust vacuum pump working fluid to the wastewater stream.
- (8) By July 1, 1992, all persons who use more than 30,000 pounds of chlorofluorocarbons per calendar year for ethylene oxide sterilization, except at hospitals, shall vent the sterilizer exhaust to recovery or reclamation equipment with an efficiency of 70 percent or more, by weight.
- (9) A person shall not use chlorofluorocarbon diluents in ethylene oxide sterilization, effective January 1, 1997.

(e) **Record Keeping**

Any person subject to this rule shall maintain written records for a minimum of two years and shall make them available to the District upon request. Records shall include:

- (1) Documentation and results of leak tests; and either
- (2) The number of sterilizer cycles and the pounds of ethylene oxide (measured or calculated) used per cycle for each sterilizer each day; or
- (3) The total pounds of ethylene oxide purchased and used per calendar year, provided that monthly totals are also kept.

(f) Test Methods

- (1) Source tests shall be conducted according to ARB Test Method 431 or an acceptable source test method approved by the ARB and the District. In addition, the following requirements shall be met:
 - (A) Tests on control equipment shall be run with a typical load in the sterilizer or aerator.
 - (B) The inlet and outlet of the control equipment shall be sampled simultaneously during testing to measure the control efficiency.
 - (C) The efficiency of control equipment shall be determined under normal operating conditions. To measure the control efficiency on the sterilizer exhaust stream, sampling shall be done during the entire duration of the first sterilizer evacuation and subsequent air washes after ethylene oxide has been introduced. To measure the control efficiency 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 equipment 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.
- (2) Leak tests shall be conducted by ARB 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 District. A chlorofluorocarbon-12 detector with an audible signal 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.

(g) Exemptions

The provisions of paragraph (d), "Requirements," of this rule shall not apply to any person who uses less than or equal to four pounds of ethylene oxide per calendar year.