

RULE 1203. ETHYLENE OXIDE STERILIZERS AND AERATORS

(Adopted 7/23/91; Rev. Effective 7/26/00)

(a) APPLICABILITY

This rule shall apply to any person who operates a sterilizer and/or aerator using ethylene oxide or mixtures containing ethylene oxide.

(b) EXEMPTIONS

(1) The provisions of Section (d) of this rule, except for Subsection (d)(1), shall not apply to facilities using less than twenty-five pounds of ethylene oxide in every consecutive twelve-month period. Any person claiming this exemption shall keep records in compliance with Section (f) of this rule. This exemption shall not apply to aeration-only facilities.

(2) The provisions of Sections (d) and (f) of this rule, except for Subsections (d)(1) and (d)(7), shall not apply to facilities subject to Title 17, California Code of Regulations (CCR) Section 93108.5 Ethylene Oxide Airborne Toxic Control Measure for Sterilizers and Aerators: Part 2, Commercial Sterilizers and Aerators. Any person claiming this exemption shall comply with the requirements of that Part.

(c) DEFINITIONS

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

(1) **"Aeration"** means any process by which residual ethylene oxide dissipates from sterilized materials after the sterilizer cycle is complete.

(2) **"Aeration-Only Facility"** means a facility which performs aeration on materials which have been sterilized with ethylene oxide at another facility.

(3) **"Aerator"** means any equipment or space in which materials previously sterilized with ethylene oxide are placed or remain for the purpose of aeration.

(4) **"Aerator Exhaust Stream"** means all ethylene oxide-contaminated air which is emitted from an aerator.

(5) **"Back-Draft Valve"** means a valve or rear chamber exhaust system for removal of ethylene oxide-contaminated air during unloading of sterilized materials from a sterilizer.

(6) **"Leak-Free"** means that state which exists when the concentration of ethylene oxide measured one centimeter away from any portion of the aerator, sterilizer, sterilant gas supply or ethylene oxide-contaminated air exhaust systems, is less than 10 parts per million by volume (ppmv) ethylene oxide.

(7) **"Sterilant Gas"** means ethylene oxide or any combination of ethylene oxide and other gas(es) used in a sterilizer.

(8) **"Sterilizer"** means any equipment in which sterilant gas is used as a biocide to destroy bacteria, viruses, fungi, and other unwanted organisms on materials.

(9) **"Sterilizer Cycle"** means the process which begins when sterilant gas is introduced into the sterilizer, includes the initial purge or evacuation after sterilization and subsequent air, steam or other washes, and ends after evacuation of the final air, steam or other washes, prior to aeration. For equipment which cycles directly from sterilization to aeration, the delineation of the two cycles shall be determined by the Air Pollution Control Officer.

(10) **"Sterilizer Door Hood Exhaust Stream"** means the exhaust stream which results from the collection, by means of a hood over the sterilizer door, of fugitive ethylene oxide-contaminated air during the time that the sterilizer door is open after the sterilizer cycle has been completed.

(11) **"Sterilizer Exhaust Stream"** means all ethylene oxide-contaminated air which is emitted from the sterilizer during the sterilizer cycle. The sterilizer exhaust stream does not include the door hood exhaust stream.

(12) **"Sterilizer Exhaust Vacuum Pump"** means a device used to evacuate the sterilant gas during the sterilizer cycle, including any associated heat exchanger.

(d) **STANDARDS**

(1) No person shall operate a sterilizer or aerator unless:

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

(ii) The sterilant gas supply, transfer, and exhaust systems, including, but not limited to, any piping, ducting, fittings, valves, or flanges through which sterilant gas or ethylene oxide-contaminated air is conveyed, are leak-free.

(2) No person shall operate a sterilizer at a facility using 25 pounds or more of ethylene oxide in any consecutive twelve-month period, but less than or equal to 600 pounds of ethylene oxide in every consecutive twelve-month period, unless the sterilizer exhaust stream is vented to emission control equipment with an ethylene oxide emission reduction efficiency of at least 99.0% by weight.

(3) No person shall operate a sterilizer or aerator at a facility using more than 600 pounds of ethylene oxide in any consecutive twelve-month period, but less than or equal to 5,000 pounds of ethylene oxide in every consecutive twelve-month period unless:

(i) The sterilizer exhaust stream is vented to emission control equipment with an ethylene oxide emission reduction efficiency of at least 99.9% by weight; and

(ii) The aerator exhaust stream is vented to emission control equipment with an ethylene oxide emission reduction efficiency of at least 95.0% by weight; and

(iii) The back-draft valve is vented to either the sterilizer exhaust stream or the aerator exhaust stream emission control equipment; or

(iv) In lieu of (i) and (ii) above, a person may vent the sterilizer and aerator exhaust streams simultaneously to emission control equipment with an ethylene oxide emission reduction efficiency of at least 99.7% by weight.

(4) No person shall operate a sterilizer or aerator at a facility using more than 5,000 pounds of ethylene oxide in any consecutive twelve-month period unless:

(i) The sterilizer exhaust stream is vented to emission control equipment with an ethylene oxide emission reduction efficiency of at least 99.9% by weight; and

(ii) The aerator exhaust stream is vented to emission control equipment with an ethylene oxide emission reduction efficiency of at least 99.0% by weight; and

(iii) The sterilizer door hood exhaust stream is ducted to the aerator exhaust stream emission control equipment; and

(iv) The back-draft valve is vented to either the sterilizer exhaust stream or the aerator exhaust stream emission control equipment.

(5) No person shall operate an aeration-only facility unless the aerator exhaust stream is vented to emission control equipment with an ethylene oxide emission reduction efficiency of at least 95.0% by weight.

(6) A facility shall be considered to be in compliance with Subsections (d)(2) through (d)(5) of this rule if the concentration of ethylene oxide measured in the outlet of the emission control equipment is below 0.2 ppmv.

(7) No person shall discharge liquids from an ethylene oxide recovery system to any system open to the atmosphere unless the concentration of ethylene oxide in the liquid is:

(i) 30 micrograms per milliliter or less for liquid discharges associated with the sterilizer cycle; and

(ii) 10 micrograms per milliliter or less for liquid discharges associated with the aeration cycle for those facilities where aeration emission control is required.

(e) **RESERVED**

(f) **RECORDKEEPING**

Any person operating an ethylene oxide sterilizer or aerator shall maintain the following records:

(1) The date and time of each sterilizer operation cycle and the weight of ethylene oxide used per cycle. The weight of ethylene oxide used per cycle may be determined based on either:

(i) The sterilizer manufacturer's specifications; or

(ii) The quantity of ethylene oxide purchased per month in pounds.

(2) Monthly amounts of ethylene oxide used.

(3) Total amount of ethylene oxide used in every consecutive twelve-month period.

(4) Daily records of key system operating parameters for ethylene oxide emission control equipment. Key system operating parameters are those necessary to ensure compliance with Subsections (d)(2) through (d)(5), including, but not limited to, temperatures, flow rates and pressures.

(5) Inspection and ongoing maintenance schedules for the emission control equipment.

These records shall be maintained on-site for five years and made available to the District upon request.

(g) **TEST METHODS**

To determine compliance with Section (d) of this rule, measurement of ethylene oxide concentrations shall be conducted in accordance with:

(1) California Air Resources Board (ARB) Test Method 21 for detection of leaks using an ethylene oxide-specific, metal-oxide detector or alternative test equipment previously approved in writing by the Air Pollution Control Officer; and

(2) ARB Test Method 431 for determination of control efficiency during the initial performance test, or an acceptable source test method approved in writing by the Air Pollution Control Officer with the concurrence of ARB. These tests shall be conducted in accordance with the following requirements:

(i) Tests of the emission control equipment efficiency shall be run with a maximum ethylene oxide charge in the sterilizer and maximum load in the aerator, as applicable.

(ii) The inlet concentration may be measured or calculated in accordance with ARB Test Method 431. If the emission reduction efficiency is determined by inlet and outlet sampling, the inlet and outlet of the emission control equipment shall be sampled simultaneously during testing to measure the emission reduction efficiency.

(iii) To measure the control efficiency of the emission control equipment 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 emission control equipment on an aerator exhaust stream with a constant air flow, sampling shall be done during a period of at least 60 consecutive minutes, starting 15 minutes after aeration begins. To measure the control efficiency of the emission 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.

(iv) There shall be no dilution of either the aerator or sterilizer exhaust stream between the inlet and outlet test points during testing.