RULE 1203. ETHYLENE OXIDE STERILIZERS AND AERATORS

(Adopted and Effective 7/23/91)

(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

The provisions of Sections (d), (f) and (g) of this rule 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 (e) of this rule. This exemption shall not apply to aeration-only facilities.

(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 during unloading of sterilized materials from a sterilizer.

(6) **"Existing Facility"** means a facility operating a sterilizer or aerator which was installed and operating before July 23, 1991.

(7) **"Leak-Free"** means that state which exists when the concentration of sterilant gas measured 1 centimeter away from any portion of the aerator, sterilizer, or their exhaust systems, during conditions of maximum sterilant gas mass flow, is less than:

(i) 30 ppm for sterilant gas composed of 12% ethylene oxide/88% dichlorodifluoromethane (CFC-12) by weight; or

(ii) 10 ppm for other compositions of sterilant gas.

(8) **"New Equipment"** means a sterilizer or aerator installed after July 23, 1991**.**

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

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

(11) **"Sterilizer Cycle"** means the process which begins when sterilant gas is introduced in the sterilizer, includes the initial purge or evacuation after sterilization and subsequent air washes, and ends after evacuation of the final air wash.

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

(13) **"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 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 designated discharge to the atmosphere are leak-free.

(2) No person shall operate a sterilizer at a facility using more than 25 pounds 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 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 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 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 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 control equipment.

(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 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 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 control equipment.

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

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

(e) **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 sterilizer manufacturer's specifications or total pounds of sterilant gas and the total pounds of ethylene oxide purchased on a monthly basis.

(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 Section (d)(2) through (d)(5), including, but not limited to, temperatures, flow rates and pressures.

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

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

(f) **COMPLIANCE SCHEDULE**

(1) Any person operating an existing facility using more than 25 pounds but less than or equal to 600 pounds of ethylene oxide in any consecutive twelve-month period shall comply with the requirements of Subsections (d)(1)(i) and (d)(2) no later than July 23, 1993.

(2) Any person operating an existing facility using more than 600 pounds but less than or equal to 5,000 pounds of ethylene oxide in any consecutive twelve-month period shall comply with the requirements of Subsections (d)(1)(i) and (d)(3) no later than January 23, 1993.

(3) Any person operating an existing facility using more than 5,000 pounds of ethylene oxide in any consecutive twelve-month period shall comply with the requirements of Subsections (d)(1)(i) and (d)(4) no later than July 23, 1992.

(4) Any person operating an existing aeration-only facility shall comply with the requirements of Subsection (d)(5) no later than January 23, 1993.

(5) Any person operating an existing facility required to install control equipment pursuant to this rule shall submit an application for Authority to Construct and Permit to Operate no later than eight months prior to the final compliance date specified in this section.

(6) Any person installing new equipment shall comply with the applicable provisions of Section (d) upon initial installation and startup.

(g) **TEST METHODS**

(1) Measurements of sterilant gas emissions subject to Section (d) of this rule shall be conducted in accordance with ARB Test Method 431 (Title 17, CCR 60, Section 94143) as it exists on July 23, 1991. These tests shall be conducted in accordance with the following requirements:

(i) Tests on control equipment shall be run with a maximum ethylene oxide charge in the sterilizer and maximum load in the aerator.

(ii) The inlet and outlet of the control equipment shall be sampled simultaneously during testing to measure the control efficiency.

(iii) To measure the control efficiency of the 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 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 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.

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

(2) Measurements of sterilant gas emissions for the purpose of determining leak-free conditions shall be conducted by ARB Test Method 21 (Title 17, CCR, Section 94124) using a portable flame ionization detector calibrated with methane, or alternative test equipment previously approved in writing by the Air Pollution Control Officer. A CFC-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 CFC-12, provided that the alarm level of the detector is not more than 30 ppm of CFC-12.

(3) A facility shall be considered to be in compliance with Subsections (d)(2) through (d)(5) if a reduction in the amount of ethylene oxide across the control equipment is demonstrated, but the control efficiency cannot be affirmatively demonstrated because the concentration of ethylene oxide measured in the outlet of the control equipment is below 0.2 parts per million.