RULE 430 Sterilizers (Ethylene Oxide) - Adopted 7/13/92

I. **Definitions**

A. Aeration - A process during which residual ethylene oxide dissipates, whether under forced air flow, natural or mechanically assisted convection, or any other means, from previously sterilized materials after the sterilizer cycle is complete.

B. Aeration - Only Facility - A facility aerating materials sterilized with ethylene oxide at another facility.

C. Aerator - Any equipment or space in which materials previously sterilized with ethylene oxide are placed or remain for the purpose of aeration.

D. Aerator Exhaust Stream - All ethylene oxide-contaminated air emitted from an aerator, including the ethylene oxide-contaminated air removed from a sterilizer through a rear chamber exhaust system.

E. Commercial Facilities - All ethylene oxide-using facilities except hospitals and medical facilities.

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

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

G. Ethylene Oxide Sterilization Chamber - A chamber using ethylene oxide, or a combination of ethylene oxide and CFC-12 or other diluents, to destroy bacteria and viruses on medical products, food products, containers, or other materials.

H. Existing Facility - A facility operating a sterilizer or aerator installed and operated before (July 13, 1992).

I. Facility - Means all plants, processes, process lines, production units, or pieces of equipment operated or maintained by a person as part of a business on continuous or adjacent property.

J. Hospital Sterilizer - A sterilizer located at a hospital, medical clinic, dental clinic, veterinary clinic, or any other type of medical facility.

K. Leak-Free - Refers to that state which exists when the concentration of sterilant gas measured 1 centimeter away from any portion of the exhaust system of a sterilizer or aerator, during conditions of maximum sterilant gas mass flow, is less than 10 ppm, as determined by CARB Test Method 21 (Title 17, CCR, Section 94124) using a portable flame ionization detector calibrated with methane, or an equivalent method approved by the District.

L. Sterilization Cycle - The process which begins when ethylene oxide is introduced into a sterilizer, including the initial purge or evacuation after sterilization and subsequent air washes, and ending after evacuation of the final air wash.

M. Sterilizer Exhaust Street - All ethylene oxide-contaminated air intentionally removed from a sterilizer during the sterilization cycle. Ethylene oxide-contaminated air may also be removed from the sterilizer through a backdraft valve or rear chamber exhaust system during unloading of sterilized materials.

N. Sterilant Gas - Ethylene oxide or any combination of ethylene oxide and other gas(es) used in a sterilizer.

O. Vacuum Pump - A pump used to evacuate the sterilant gas during the sterilization cycle, including any associated heat exchanger.

II. **Requirements**

A. No person shall operate a commercial, or hospital ethylene oxide sterilization chamber after the adoption date of this Rule unless the sterilizer and aerator exhaust stream emissions are reduced to less than the following levels by a District-approved control device sized, installed, operated, and maintained in accordance with accepted engineering practices:

1. If facility-wide usage of ethylene oxide is 25 pounds per year or more but less than or equal to 600 pounds per year, sterilizer exhaust emissions shall be reduced by at least 99% by weight.

2. If facility-wide usage of ethylene oxide is more than 600 pounds per year and less than or equal to 5,000 pounds per year, sterilizer exhaust emissions shall be reduced by at least 99.9% by weight and by at least 95% by weight from aerators.

3. If facility-wide usage of ethylene oxide is more than 5,000 pounds per year, sterilizer exhaust stream emissions shall be reduced by at least 99.9% by weight and any sterilizer door hood exhaust stream shall be ducted to the control device used to control aerator exhaust stream emissions by at least 99% by weight.

B. No person shall operate an aeration-only facility unless aerate exhaust emission are reduced by at least 95%.

C. No person shall operate an ethylene oxide sterilization chamber unless the vacuum pump is of a recirculating design, or the chamber evacuation is otherwise designed such that no ethylene oxide is released in a wastewater stream.

D. For purposes of determining compliance with control efficiency requirements of Subsection II, if a reduction in the amount of ethylene oxide across the control device is determined, and the concentration of ethylene oxide measured in the outlet of the control device is less than 0.2 ppm, the facility shall be considered in compliance with these subsections.

E. Any sterilizer exhaust stream or exhaust stream subject to control efficiency requirements in Subsection II. shall be continuously vented to, and shall not bypass, the control device.

F. No person shall operate an ethylene oxide sterilization chamber or aerator unless the entire exhaust system, including, but not limited to, any piping, ducting, fittings, valves, or flanges, through which ethylene oxide-contaminated air is conveyed, is leak-free.

III. **Administrative Requirements**

A. Any person subject to this Rule shall maintain an operations log noting the date and time of each sterilization operation cycle and the quantity of EtO and/or sterilant gas used. Such log shall include the District's designated Permit to Operate number(s).

B. Any person subject to this Rule shall maintain records of all purchases of ethylene oxide and CFC-12.

C. Any person subject to this Rule shall maintain all records to demonstrate proper operation and maintenance of emission control equipment.

D. All records required by Subsection A, B, and C shall be retained at the facility for a minimum of two years and made available for inspection upon District request.

E. Any person subject to this Rule must provide the District with the following information, in writing, within 30 days of the date of adoption:

1. the name(s) of the owner and operator of the facility,

2. the location of the facility,

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.

A District may exempt a source from this requirement if the District maintains current equivalent information on the source.

IV. Test Methods

A. Emissions of ethylene oxide shall be measured as prescribed in CARB Test Method 431 (Title 17, CCR 60, Section 94143) or any method approved by the Executive Officer of the CARB in consultation with the Control Officer.

B. Testing shall be conducted in accordance with Subsection A, above of this Rule and:

1. A control device test for a sterilizer exhaust stream shall be run with a typical load, as approved by the District.

2. A control device test for an aerator exhaust stream shall be run with a typical load, as approved by the District.

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

4. Efficiency of each control device shall be determined under conditions of maximum ethylene oxide mass flow to the device, during normal operating conditions. To measure the control efficiency of the control device on the sterilizer exhaust stream, sampling shall be conducted 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 conducted 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 conducted during the entire duration of the first aerator evacuation after aeration begins.

5. During testing there shall be no dilution of the air stream between inlet and outlet test points.

V. Compliance Schedule

A. Any person subject to Section II shall, no later than 60 days from the date of adoption, perform a test to determine compliance, as specified in Section IV.

B. Any person operating an existing facility using 25 to 600 pounds of ethylene oxide in any consecutive 12 month period shall comply with the requirements of Subsection II.A.1. no later than six months after (July 13, 1992).

C. Any person operating an existing facility using-more than 600 pounds and not more than 5,000 pounds, of ethylene oxide in any consecutive 12 month period shall comply with the requirements of Subsection II.A.2. no later than 12 months after July 13, 1992.

D. Any person operating an existing facility using more than 5,000 pounds of ethylene oxide in any consecutive 12 month period shall comply with Subsection II.A.3. no later than 12 months after July 13, 1992.

E. Any person operating an existing aeration-only facility shall comply with the requirements of Section II no later than 18 months after July 13, 1992.

F. Any person installing or intending to install new equipment subject to this Rule shall comply with the applicable provisions of Section II of this Rule upon installation and start-up.

VI. **Exemptions**

A. All Sections of this Rule, except Section III, do not apply to a facility if the facility-wide usage of ethylene oxide is less than 25 pounds per year.

B. Provisions of this Rule do not apply to sterilizers of the liner-bag design using ampules of ethylene oxide, provided no more than one ounce is used in any one charge, and no more than 25 pounds is used annually.