RULE 336. CONTROL OF ETHYLENE OXIDE EMISSIONS. (Adopted 12/12/1989)

A. Applicability

This rule applies to any stationary source which uses or emits ethylene oxide.

B. Definitions

For the purposes of this rule, the following definitions shall apply:

1. "**Across the control device**" means the ratio of controlled outlet emissions to the atmosphere, compared to uncontrolled inlet emissions, calculated as follows:

$$\frac{\text{(Uncontrolled Emissions - Controlled Emissions)}}{\text{Uncontrolled Emissions}} * 100$$

2. "**Ethylene oxide sterilizer**" means any equipment which uses ethylene oxide as a biocide to destroy bacteria, viruses, fungus and other unwanted organisms. For the purposes of this rule, any vacuum pump or other equipment used to evacuate ethylene oxide from a sterilization chamber, as well as any aeration activities, shall be considered as part of the ethylene oxide sterilizer.

3. "**Existing**" means any operation or facility which was operating, constructed, or under construction as of December 12, 1989.

4. "**Sterilant gas**" means ethylene oxide or any combination of ethylene oxide and other gases (such as dichlorodifluoromethane (CFC-12) or carbon dioxide) used in an ethylene oxide sterilizer.

5. "**Vacuum pump**" means any pump used to evacuate ethylene oxide from a sterilization chamber after the sterilization process is complete, along with any associated heat exchanger.

C. Requirements

1. No person shall operate any ethylene oxide sterilizer unless the sterilization chamber sterilant gas evacuation process conforms to one of the following requirements:

   a. If a liquid sealed vacuum pump is used to evacuate the chamber, the pump shall be a mechanically sealed closed loop (recirculating) pump, with oil used as the recirculating fluid.

   b. If a liquid sealed vacuum pump is not used to evacuate the chamber, the sterilant gas evacuation process shall be designed to ensure that ethylene oxide is not released in wastewater streams.

2. Except as provided in Section C.4, no person shall operate any ethylene oxide sterilizer unless all ethylene oxide evacuated from the sterilization chamber is vented to an emission control device with an ethylene oxide emission reduction efficiency of 99.9% by weight or greater, across the control device.

3. Except as provided in Section C.4, no person shall operate any ethylene oxide sterilizer unless all ethylene oxide emissions at a stationary source, other than the emissions evacuated from the sterilization chamber, are vented to an emission control device with an ethylene oxide emission reduction efficiency of 99% by weight or greater, across the control device.

4. No person shall operate any ethylene oxide sterilizer at a stationary source where all ethylene oxide emissions at the source are vented to a single emission control device unless the ethylene oxide emission reduction efficiency is 99.8% by weight or greater, across the control device.

5. No person shall operate any stationary source which emits greater than 0.5 pounds per hour or 1.5 pounds per day of ethylene oxide.

D. Exemptions

Any stationary source which emits less than 4 pounds per calendar year shall be exempt from the provisions of Sections C.2, C.3 and C.4 of this rule.

E. Test Methods

Emission source testing shall be conducted in accordance with California Air Resources Board Test Method 431 (Determination of Ethylene Oxide Emissions from Stationary Sources) or other test methods approved by the Control Officer. Emission source testing shall be conducted annually in accordance with a District-approved emission source test plan. If any emission source test indicates that a source is, or has the potential to be, operated in violation of Section C of this rule, the District may require more frequent emission source testing.

F. Recordkeeping

The owner or operator of any ethylene oxide sterilizer shall maintain a log of the following information for each sterilization cycle at every ethylene oxide sterilizer:

1. The date and time that the sterilizer was loaded.

2. The date and time that the sterilizer was unloaded.

3. A description of the sterilized items, including the materials of construction.

4. The number and duration of ethylene oxide evacuation operations.

5. The date and time that aeration of the sterilized items was completed.

6. The amount of total sterilant gas used, in pounds, and the amount of ethylene oxide used, in pounds.

The log shall be maintained on site for a minimum period of three years after the date of the last entry in the log and shall be made available to the District upon request.

G. Reporting

The owner or operator of any ethylene oxide sterilizer shall file a written report on or before February 1, May 1, August 1, and November 1 of each year, detailing the following information for the previous calendar quarter:

1. The amount of total sterilant gas purchased, in pounds, and the composition of the sterilant gas, specifically identifying the amount of ethylene oxide in the sterilant gas, in pounds.

2. The amount, location, and intended purpose of any ethylene oxide stored by the owner or operator within the District.

3. The following information for each sterilization cycle at every ethylene oxide sterilizer:

a. The date and time that the sterilizer was loaded.

b. The date and time that the sterilizer was unloaded.

c. A description of the sterilized items, including the materials of construction.

d. The number and duration of ethylene oxide evacuation operations.

e. The date and time that aeration of the sterilized items was completed.

f. The amount of total sterilant gas used, in pounds, and the amount of ethylene oxide used, in pounds.

H. Compliance Schedule

1. The owner or operator of any new ethylene oxide sterilizer shall comply with this rule when the sterilizer is first operated.

2. The owner or operator of any existing ethylene oxide sterilizer which emits greater than 250 pounds of ethylene oxide per year shall comply with Sections C.1 through C.4 of this rule not later than December 12, 1990. In addition, the owner or operator shall comply with the following schedule:

   a. Submit an application for an Authority to Construct for installation and/or modification of equipment necessary to comply with the requirements of Sections C.1 through C.4 of this rule, by January 12, 1990.

   b. Submit an emission source test plan for approval by the District not later than 1 month after the District approves the Authority to Construct.

   c. Arrange for District-approved source testing and District inspection prior to the submittal of an application for a Permit to Operate.

3. The owner or operator of any existing ethylene oxide sterilizer which emits 250 pounds of ethylene oxide per year or less shall comply with Sections C.1 through C.4 of this rule not later than December 12, 1991. In addition, the owner or operator shall comply with the following schedule:

   a. Submit an application for an Authority to Construct for installation and/or modification of equipment necessary to comply with the requirements of Sections C.1 through C.4 of this rule, by September 12, 1990.

   b. Submit an emission source test plan for approval by the District not later than 1 month after the District approves the Authority to Construct.

   c. Arrange for District-approved source testing and District inspection prior to the submittal of an application for a Permit to Operate.

4. The owner or operator of any stationary source which emits ethylene oxide shall comply with Section C.5 on the date of adoption of this rule.