

SAN LUIS OBISPO COUNTY AIR POLLUTION CONTROL DISTRICT

RULE 414 - ETHYLENE OXIDE - STERILIZATION AND AERATION*(Adopted 11/19/91)***A. APPLICABILITY**

The requirements of this Rule shall apply to any person who operates an ethylene oxide sterilizer and/or an aerator.

B. DEFINITIONS

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

1. "Aeration": The process during which residual ethylene oxide dissipates by forced air flow, through natural or mechanically assisted convection, or other means, from previously sterilized materials after the sterilization cycle is completed.
2. "Aerator": Any equipment, space, or room in which air is used to remove residual ethylene oxide from sterilized materials. An aerator is not any equipment, space, or room in which materials that have previously undergone ethylene oxide sterilization and aeration can be handled, stored, and transported in the same manner that have not been sterilized with ethylene oxide.
3. "Aerator Exhaust Stream": All ethylene oxide contaminated effluent gases which are emitted from an aerator.
4. "Back-Draft Valve Exhaust Stream": The effluent gas stream which results from the collection of ethylene oxide contaminated gases during unloading of the sterilizer and which is removed through a back-draft valve or rear chamber exhaust system.
5. "Control Efficiency": The ethylene oxide mass or volume concentration reduction efficiency of control equipment, as measured by ARB Test Method 431 and expressed as a percentage as follows:

$$\frac{\text{sum ETO}_{\text{in}} - \text{sum ETO}_{\text{out}}}{\text{sum ETO}_{\text{in}}} \times 100 = \% \text{ Control Efficiency}$$

6. "Ethylene Oxide (ETO, C₂H₄O)": A colorless, flammable gas that has been identified as a suspected human carcinogen and a toxic air contaminant by the California Air Resources Board.
7. "Leak": A concentration of sterilant gas measured one centimeter from the source equal to or greater than:
 - a. 30 ppm, as methane, for sterilant gas composed of 12 percent ethylene oxide and 88 percent chlorofluorocarbon-12 by weight; or
 - b. 10 ppm, as methane, for all other compositions of sterilant gas.

If a detector with an audible alarm is used, a leak shall be defined as a concentration of sterilant gas measured one centimeter from the source which causes the alarm to sound.

8. "Source-wide Use of Ethylene Oxide": The total weight of ethylene oxide used in all sterilizers at a stationary source during a calendar year, expressed as pounds per year.
9. "Sterilant Gas": Ethylene oxide or any combination of ethylene oxide and other gases used in a sterilizer.
10. "Sterilizer": Any equipment that uses ethylene oxide or an ethylene oxide mixture in any sterilization or fumigation process.
11. "Sterilizer Cycle": The process which begins when ethylene oxide is introduced to a sterilizer, includes the initial purge or evacuation after sterilization and subsequent air washes, and ends after evacuation of the final air wash.

12. "Sterilizer Door Hood Exhaust Stream": The effluent gas stream which results from the collection of fugitive ethylene oxide emissions by means of a hood over the sterilizer door, during the period in which the sterilizer door is open after the sterilizer cycle has been completed.
13. "Sterilizer Exhaust Stream": The ethylene oxide-contaminated effluent gases emitted from a sterilizer.
14. "Sterilizer Exhaust Vacuum Pump": A device (including any associated heat exchanger) used to evacuate sterilant gas during the sterilizer cycle but not a device used solely to evacuate a sterilizer prior to the introduction of ethylene oxide.

C. EXEMPTIONS

The provisions of Section D, Requirements, shall not apply to any sterilizer and/or aerator at a stationary source where the source-wide use of ethylene oxide is four (4) lb/yr or less, provided the requirements of Section E, Recordkeeping, are satisfied. This exemption applies only to stationary sources where a sterilizer is operated.

D. REQUIREMENTS

1. No person shall operate any sterilizer at a stationary source where the source-wide use of ethylene oxide is greater than four pounds per year (lb/yr), but no greater than 600 lb/yr, unless the sterilizer exhaust stream is vented to control equipment with a control efficiency of at least 99.0 percent.
2. No person shall operate any sterilizer and/or aerator at a stationary source where the source-wide use of ethylene oxide is greater than 600 lb/yr, but no greater than 5,000 lb/yr, unless all of the following requirements are satisfied:
 - a. The sterilizer exhaust stream shall be vented to control equipment with a control efficiency of at least 99.9 percent.
 - b. The aerator exhaust stream and back-draft valve stream shall be vented to control equipment with a control efficiency of at least 95.0 percent.
3. No person shall operate any sterilizer and/or aerator at a stationary source where the source-wide use of ethylene oxide is greater than 5,000 lb/yr, unless all of the following requirements are satisfied:
 - a. The sterilizer exhaust stream shall be vented to control equipment with a control efficiency of at least 99.9 percent.
 - b. The aerator exhaust stream, sterilizer door hood exhaust stream and back-draft valve exhaust stream shall be vented to control equipment with a control efficiency of at least 99.0 percent.
4. No person shall operate an aerator at a stationary source where products that have been sterilized at another stationary source are aerated, unless the aerator exhaust stream is vented to control equipment with a control efficiency of at least 95.0 percent.
5. Compliance shall be verified by source testing at least every 24 months, with the first source test being performed no later than the date specified pursuant to Section H, Compliance Schedule.
6. Any person who operates a sterilizer and/or aerator shall submit to the APCO a compliance plan no later than the date specified in Section H, Compliance Schedule. The compliance plan shall contain the following:
 - a. The name of the manufacturer, model number, and a description of the equipment which will be used to comply with the emission control requirements of this Subsection and with the requirements of Subsection D.8.a, Requirements.
 - b. The dates or estimated dates of the purchase, delivery, and installation of such equipment.
7. Any person who operates a sterilizer and/or aerator shall submit to the APCO a copy of the purchase order for the equipment necessary to comply with the emission control requirements of this Subsection no later

than the date specified pursuant to Section H, Compliance Schedule.

8. No person shall operate any sterilizer or aerator unless all of the following requirements are satisfied:
 - a. No working fluid from the sterilizer exhaust vacuum pump shall be discharged to any wastewater stream.
 - b. No sterilant gas shall leak from any portion of any sterilant, aerator, control equipment, or emission collection system including, but not limited to any piping, fittings, valves, or flanges through which ethylene oxide is conveyed.

E. RECORDKEEPING

1. Any person who operates a sterilizer shall maintain monthly records of the amount of ethylene oxide purchased, used, and returned. In addition, records showing the results of all source tests shall be maintained.
2. All records except source test records shall be retained for at least two years. Source test records shall be maintained for at least four years. All records shall be made available to the APCO upon request.

F. REPORTING REQUIREMENTS

Any person who operates a sterilizer and/or an aerator shall submit to the APCO the following information in writing by December 19, 1991:

1. The name, address, and phone number of the owner and operator of any stationary source where a sterilizer and/or an aerator is operated.
2. The number of sterilizers and aerators at the stationary source.
3. The total weight of ethylene oxide and sterilant gas used in all sterilizers at the stationary source during the year of 1990.

G. TEST METHODS

1. Source tests to determine compliance with the emission reduction requirements of Section D, Requirements, shall be conducted using ARB Test Method 431. If a reduction in the amount of ethylene oxide across the control equipment is demonstrated, but the control efficiency cannot be determined because the concentration of ethylene oxide measured at the outlet of the control equipment is below 0.2 ppm, the control equipment shall be deemed in compliance with the emission reduction requirements of Section D, Requirements. 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 of 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 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.
 - d. There shall be no dilution of the air stream between the inlet and outlet test points during the source test.

2. Leak determinations shall be conducted using 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 APCO. A detector with an audible alarm using a metal oxide semi-conductor sensor and with a detection level of five ppm or less for ethylene oxide shall be considered an acceptable alternative.

H. COMPLIANCE SCHEDULE

1. Any person subject to the provisions of Section D.1, Requirements, shall satisfy the following compliance schedule:
 - a. Submit to the APCO a compliance plan pursuant to Section D, Requirements, by September 1, 1992.
 - b. Submit to the APCO a complete application for an Authority to Construct for any sterilizer, aerator, and associated control equipment by January 1, 1993.
 - c. Submit to the APCO a copy of the purchase order specified pursuant to Subsection D.7, Requirements, by July 1, 1993.
 - d. Demonstrate compliance with the requirements for Subsection D.1 through source testing, by November 19, 1993.
2. Any person subject to the provisions of Subsection D.2, Requirements, shall satisfy the following compliance schedule:
 - a. Submit to the APCO a compliance plan pursuant to Subsection D.6, Requirements, by March 1, 1992.
 - b. Submit to the APCO a complete application for an Authority to Construct for any sterilizer, aerator, and associated control equipment by July 1, 1992.
 - c. Submit to the APCO a copy of the purchase order specified pursuant to Subsection D.7, Requirements, by January 1, 1993.
 - d. Demonstrate compliance with the requirements of Subsection D.2 through source testing, by May 19, 1993.
3. Any person subject to the provisions of Subsection D.3, Requirements, shall satisfy the following compliance schedule:
 - a. Submit to the APCO a compliance plan pursuant to Subsection D.6, Requirements, by March 1, 1992.
 - b. Submit to the APCO a complete application for an Authority to Construct for any sterilizer, aerator, and associated control equipment by July 1, 1992.
 - c. Submit to the APCO a copy of the purchase order specified pursuant to Subsection D.7, Requirements, by September 1, 1992.
 - d. Demonstrate compliance with the requirements of Subsection D.3, Requirements, through source testing, by November 19, 1992.
4. Any person subject to the provisions of Subsection D.4, Requirements, shall satisfy the following compliance schedule:
 - a. Submit to the APCO a compliance plan pursuant to Subsection D.6., Requirements, by March 1, 1992.

- b. Submit to the APCO a complete application for an Authority to Construct for any sterilizer, aerator, and associated control equipment by July 1, 1992.
 - c. Submit to the APCO a copy of the purchase order specified pursuant to Subsection D.7., Requirements, by January 1, 1993.
 - d. Demonstrate compliance with the requirements of Subsection D.3. through source testing, by May 19, 1993.
5. All Subsections of this Rule shall apply to any new facility or source obtaining a District Permit to Operate on or after November 19, 1991.
 - a. Submit to the APCO a complete application for an Authority to Construct for any sterilizer, aerator, and associated equipment prior to equipment purchase.
 - b. Submit to the APCO a copy of the purchase order pursuant to Subsection D.7, Requirements, at least thirty (30) calendar days prior to installation.
 - c. Demonstrate compliance with the requirements of Subsection D, Requirements, through source testing within sixty (60) calendar days after installation or as directed in the Permit to Operate for the sterilizer or aerator.