RULE 1203
ETHYLENE OXIDE STERILIZERS AND AERATORS

WORKSHOP REPORT

A workshop notice was mailed to each company known to be involved in ethylene oxide sterilizing and aerating operations in San Diego County. Notices were also mailed to all Economic Development Corporations and Chambers of Commerce in San Diego County, sterilizer manufacturers, the U.S. Environmental Protection Agency (EPA), the California Air Resources Board (ARB), and other interested parties.

The workshop was held on January 17, 1991 and was attended by 28 people. Written comments were also received. The comments and District responses are as follows:

WORKSHOP COMMENT:

Section (e) - Recordkeeping requires that the weight of ethylene oxide used per cycle be recorded. Will manufacturer's specifications be acceptable for this requirement?

DISTRICT RESPONSE:

The rule has been revised to clarify that manufacturer's specifications outlining the ethylene oxide usage per cycle will be acceptable to comply with the requirements of Section (e).

WORKSHOP COMMENT:

Clarification of "key system operating parameters" is requested.

DISTRICT RESPONSE:

In general, "key system operating parameters" refers to the control system parameters which need to be monitored to ensure that the control levels are maintained on an ongoing basis. They may include, for example, catalyst temperature, flow rates, and pressures. The term "key operating parameters" has been clarified in the rule.

WORKSHOP COMMENT:

Section (d)(1)(ii) requires that the system be leak-free while Section (e)(4) requires daily records of key system operating parameters necessary to ensure compliance with Section (d). Since daily records are required, does that mean that the entire system must be checked for leaks on a daily basis?

DISTRICT RESPONSE:

As noted above, "key system operating parameters" refer strictly to the control equipment. Therefore, daily testing for leaks is not required. It is the District's understanding that most facilities test for leaks on a regular basis for health safety purposes and when repair work is done, while others have continuous monitors installed.

WORKSHOP COMMENT:

How often is verification of the emission reduction efficiency required? Is that also a daily requirement or will it be an annual requirement?

DISTRICT RESPONSE:

Once the control equipment is installed, it will be tested to verify the emission reduction efficiency. Daily recording of the key system operating parameters will be required. Depending on the reliability of the equipment and its performance, some of the equipment may randomly or periodically be re-tested to verify continued operation at the required destruction efficiency. Daily testing will not be required.

WORKSHOP COMMENT:

Who will conduct the testing for leaks? Is this an in-house test or is a third party required?

DISTRICT RESPONSE:

If a user has the capability to check for leaks, documentation of these tests will be sufficient. Facilities that have continuous monitoring systems may use their charts to demonstrate compliance with this provision of the rule. The user must ensure that the system is leak-free and can do this by either in-house or third party testing.

WORKSHOP COMMENT:

For some facilities, it will be a hardship to test all the piping and ductwork for leaks since, in many instances, it travels through several floors and providing access will be a problem. This piping and ductwork are under negative pressure.

DISTRICT RESPONSE:

The District will not perform or require a thorough examination of ductwork demonstrated to be under negative pressure.

WORKSHOP COMMENT:

Section (f)(1) requires installation of a recirculation pump within six months. Sections (d)(2) through (d)(4) allow between 12 and 24 months to install the necessary control equipment. Since the recirculation pump is usually part of the system design for the control equipment, the discrepancy in time frames would result in a considerable added expense and essentially obligate a facility to comply with the control requirements within six months also.

DISTRICT RESPONSE:

The rule has been revised to eliminate the six month requirement for recirculation pumps and instead incorporate it within the time frames specified in the control equipment compliance schedule.

WORKSHOP COMMENT:

The disposal of concentrated working fluid in the recirculating system results in ethylene glycol being introduced into the sewer. Must facilities contact the District to do this? Can the ethylene glycol be disposed of in the sewer or must it be hauled away?

DISTRICT RESPONSE:

The California Regional Water Quality Control Board is the regulatory agency responsible for sewer discharge and should be contacted for information on disposal and handling of ethylene glycol. The District will consider the potential for VOC emissions from disposal when evaluating proposed control systems.

WORKSHOP COMMENT:

To install control equipment, a hospital will need to obtain permits from the Office of Statewide Health Planning and Development (OSHPD) in addition to the District's permits. This may create a problem if the state permits are not received in time to comply with the District's deadlines. Are allowances being made for this?

DISTRICT RESPONSE:

Applications to OSHPD for installation of control equipment should be submitted as soon as possible since this rule is very likely to be adopted by June 1991. If there are still problems with meeting deadlines, applicants can file for a variance with the Air Pollution Control District Hearing Board. The District cannot propose later compliance dates in the rule as such dates would be inconsistent with the State Airborne Toxic Control Measure (ATCM).

WORKSHOP COMMENT:

Testing the control equipment with an empty chamber rather than a maximum load is more challenging and less of an imposition for a source.

DISTRICT RESPONSE:

The test conditions are those given by the ATCM adopted by ARB and the District cannot deviate from them. However, ARB has advised the District it is reconsidering this test method. If there are any changes in the ATCM, the District will accordingly amend Rule 1203.

WORKSHOP COMMENT:

Facilities affected by this proposed rule are in favor of using Method 18 for testing of control equipment. Has this been discussed with ARB?

DISTRICT RESPONSE:

Yes, this has been discussed with ARB and at this time, ARB opposes using Method 18.

WORKSHOP COMMENT:

Testing of control efficiency for aeration operations may be difficult because the ethylene oxide concentrations are barely measurable.

DISTRICT RESPONSE:

ARB has determined that if the exhaust ethylene oxide concentration is not detectable (i.e., it is below the detection limit of 0.2 ppm), the equipment is considered to be in compliance with the rule. This provision has been incorporated into the rule.

WRITTEN COMMENT:

Allowances should be made for facilities installing equipment capable of recovering ethylene oxide. Since the EtO is recovered, the control tier for the facility should be based on actual loss of ethylene oxide (i.e., purchased quantities less recycled amounts).

DISTRICT RESPONSE:

The control tier for a facility in Rule 1203 is based on the actual usage (throughput) of ethylene oxide,.i.e. on the amount of ethylene oxide used for treatment of the material being sterilized. This amount depends on the capacity of a sterilizer and remains the same regardless of the amount of sterilant being recycled. The calculations show that providing credits for recycling will result in higher EtO emissions than the rule allows. This suggestion will not be incorporated.

WRITTEN COMMENT:

Subsection (c)(7)(ii) defines "leak-free" as a concentration of sterilant gas, other than a 12/88 CFC mixture, of less than 10 ppm. Is the technology for monitoring at this level available?

DISTRICT RESPONSE:

Various manufacturers have indicated they have hand-held leak detectors that will measure concentrations of EtO below 10 ppm. Some facilities have installed gas chromatographs that monitor continuously. These will certainly detect levels below 10 ppm.

WRITTEN COMMENT:

What is the need to distinguish between 12/88 mixtures and other mixtures in establishing concentration limits in Subsection (c)(7)(ii)?

DISTRICT RESPONSE:

Dichlorodifluoromethane (CFC-12) in the mixture with EtO (12% EtO + 88% CFC-12) interferes with EtO measurements if a flame ionization detector (FID) is used. Allowing for this interference, the concentration of EtO is approximately 10 ppm when the measured concentration of 12/88 mixture is 30 ppm. Other gases used for sterilant gas mixtures such as nitrogen or carbon dioxide do not interfere with FID measurements.

WRITTEN COMMENT:

Subsection (d)(1)(i) should specify there should be no discharge of "ethylene oxide laden" sterilizer exhaust vacuum pump working fluid. There are some "once through pumps" that never come in contact with ethylene oxide.

DISTRICT RESPONSE:

The intent of the rule is to prevent discharge of ethylene oxide into wastewater streams. If it is demonstrated there is no ethylene oxide being discharged, this would comply with the rule.

WRITTEN COMMENT:

Revise Subsection (d)(3)(iii) and (iv) to read "the back-draft valve, if present, is vented..." since these are generally found only on large industrial sterilizers.

DISTRICT RESPONSE:

The rule states that back-draft valves must be vented to control equipment. It does not, however, state that sterilizers must have back-draft valves. Provisions in rules that are clearly not applicable are not enforced.

WRITTEN COMMENT:

Subsection (e)(1) requires that records be kept of the weight of ethylene oxide used per cycle. This is not practical and it is recommended that consumption based on calculations be allowed.

DISTRICT RESPONSE:

The District has recognized the difficulty in recording actual weight of ethylene oxide used per cycle. A clarification has been added to Subsection (e)(1) to allow for weights based on manufacturer's specifications.

WRITTEN COMMENT:

No frequency for source or leak testing requirements has been given in Subsections (g)(1) and (2). Initial testing within 30 days of start up and annual testing thereafter, or upon major control device repair is suggested.

DISTRICT RESPONSE:

No frequency has been specified for either source or leak testing. It is the District's understanding that most facilities test for leaks on a regular basis for health safety purposes and when repair work is done, while others have continuous monitors installed. It is in the source's best interest to ensure the system is maintained leak-free at all times since enforcement inspections usually occur unannounced. The frequency of source testing required will depend upon the types of controls installed, their reliability and the adequacy of maintenance observed. Source testing frequencies will be established by the District taking into account the characteristics of the system installed.

ARB COMMENT:

Subsection (g)(1) states that measurements of sterilant gas emissions shall be conducted in accordance with EPA Method 18 or ARB Test Method 431. Any method, other than ARB Method 431, must be approved by the Executive Officer of the Air Resources Board.

DISTRICT RESPONSE:

EPA Method 18 has been deleted as an alternative to ARB Test Method 431 in Subsection (g)(1).

ARB COMMENT:

Subsection (d)(1)(i) should specify that there shall be sterilizer exhaust vacuum pump working fluid discharge into the wastewater streams.

DISTRICT RESPONSE:

This clarification has been made in the rule.

Proposed New Rule 1203 is added to Regulation XII to read as follows:

RULE 1203 ETHYLENE OXIDE STERILIZERS AND AERATORS

(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), ~~and~~ (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 ~~(date of Workshop)~~ (*date of Adoption*).

(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 ~~(date of Workshop)~~ (*date of Adoption*).

(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 <u>to wastewater streams</u>; 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.

~~(e)~~(f) **COMPLIANCE SCHEDULE**

~~(1) Any person operating an existing facility using twenty-five pounds or more of ethylene oxide in any consecutive twelve month period shall comply with the requirements of Subsection (d)(1) no later than (*6 months after date of adoption*).~~

~~(2)~~(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 Subsection (d)(2) no later than (*24 months after date of Adoption*).

~~(3)~~(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 Subsection (d)(3) no later than (*18 months after date of Adoption*).

~~(4)~~(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 Subsection (d)(4) no later than (*12 months after date of Adoption*).

~~(5)~~(4) Any person operating an existing aeration-only facility shall comply with the requirements of Subsection (d)(5) no later than (*18 months after date of Adoption*).

~~(6)~~(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.

~~(7)~~(6) Any person installing new equipment shall comply with the applicable provisions of Section (d) upon initial installation and startup.

~~(f)~~(g) **TEST METHODS**

(1) Measurements of sterilant gas emissions subject to Section (d) of this rule shall be conducted in accordance with ~~EPA Method 18 (40 CFR 60, Appendix A) or~~ ARB Test Method 431 (Title 17, CCR 60, Section 94143) as ~~they~~ it exists on (*date of Adoption*). 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 eqipment is below 0.2 parts per million.