apcd
County of San Diego

R. J. Sommerville
Air Pollution Control Officer

NOTICE OF WORKSHOP
FOR DISCUSSION OF NEW PROPOSED RULE 1203 ETHYLENE OXIDE STERILIZERS AND AERATORS

The San Diego County Air Pollution Control District will hold a public meeting to consider the adoption of a new rule, Rule 1203 - Ethylene Oxide Sterilizers and Aerators. Comments regarding the proposed rule may be submitted in writing before, or made at the workshop, which is scheduled as follows:

DATE: January 17, 1991

TIME: 2:30 p.m.

PLACE: Farm Advisor's Conference Room
County Operations Center
Building #4
San Diego, CA 92123

Rule 1203 is a new rule designed to reduce emissions of ethylene oxide from commercial and medical sterilizers and aerators using pure or blended ethylene oxide as a sterilant gas. Ethylene oxide is a suspected human carcinogen and has been identified through the state Tanner (AB 1807) process as a toxic air contaminant. In May 1990, the California Air Resources Board adopted an Air Toxic Control Measure (ATCM) for ethylene oxide sterilizers and aerators. Rule 1203 is similar to the ATCM. State law requires that local air pollution control districts adopt regulations no less stringent than the ATCM within a specified time after adoption by the Air Resources Board.

Proposed Rule 1203 will prohibit measurable leaks of ethylene oxide into the atmosphere from all sterilizers and aerators and the discharge of wastewater contaminated with ethylene oxide. For facilities using less than or equal to 600 lbs of ethylene oxide per year, the rule requires installation of emission control devices to reduce ethylene oxide emissions from sterilizers by 99% by weight. For facilities using more than 600 lbs of ethylene oxide per year, the rule requires the installation of emission control devices to reduce ethylene oxide emissions from sterilizers by 99.9% by weight and from aerator exhausts by 95% by weight. Facilities using more than 5000 lbs of ethylene oxide per year will be required to control ethylene oxide emissions from sterilizers by 99.9% and from aerators by 99%.

A schedule for compliance with these requirements is also being proposed in Rule 1203. That schedule will require compliance with the gas leak and wastewater discharge standards within six months of adoption and compliance with the emission control standards within 12 to 24 months, depending upon the magnitude of facility emissions.

If you would like a copy of the proposed Rule 1203, please call Juanita Ogata at (619) 694-3307. If you have any questions concerning the proposal, please call Natalie Zlotin at (619) 694-3312 or me at (619)694-3303.

Richard J. Smith

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Deputy Director

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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) 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 Notice of Workshop*).

(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 Notice of Workshop*).

(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; 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 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.

(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).

(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) **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) Any person operating an existing facility using 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) 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) 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) 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) 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) Any person installing new equipment shall comply with the applicable provisions of Section (d) upon initial installation and startup.

(f) **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 exist 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.