AIR POLLUTION CONTROL DISTRICT
COUNTY OF SAN DIEGO

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Air Pollution Control District
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May 12, 2000

TO: Workshop Participants
Other Interested Parties

FROM: Richard J. Smith
Assistant Director

PROPOSED AMENDMENTS TO DISTRICT RULE 1203 - ETHYLENE OXIDE STERILIZERS AND AERATORS AND IMPLEMENTATION OF THE STATEWIDE AIRBORNE TOXIC CONTROL MEASURE (ATCM) FOR ETHYLENE OXIDE COMMERCIAL STERILIZERS AND AERATORS

WORKSHOP REPORT

On March 21, 2000, the District conducted a public workshop to discuss proposed amendments to District Rule 1203 - Ethylene Oxide Sterilizers and Aerators, and implementation of the Airborne Toxic Control Measure (ATCM) Part 2 for Commercial Ethylene Oxide Sterilizers and Aerators. Three people attended the workshop. The workshop report and fnal draft of the rule are attached.

If you have any questions or comments, please call Laura Yannayon at (858) 694-3326.

Richard J. Smith

RICHARD J. SMITH
Assistant Director

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Attachment

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AIR POLLUTION CONTROL DISTRICT
SAN DIEGO COUNTY

PROPOSED AMENDMENTS TO DISTRICT RULE 1203 - ETHYLENE OXIDE STERILIZERS AND AERATORS AND IMPLEMENTATION OF THE STATEWIDE AIRBORNE TOXIC CONTROL MEASURE (ATCM) FOR ETHYLENE OXIDE COMMERCIAL STERILIZERS AND AERATORS

WORKSHOP REPORT

A workshop notice was mailed to all businesses and government entities in San Diego County that are involved in ethylene oxide sterilization and aeration. In addition, notices were mailed to all local Chambers of Commerce, all local Economic Development Corporations, the U. S. Environmental Protection Agency (EPA), the California Air Resources Board (ARB), and other interested parties.

The workshop was held on March 21, 2000, and was attended by three people. The workshop comments and District responses are as follows:

1. WORKSHOP COMMENT

ARB has acknowledged that Part 2 of the ATCM, applicable to commercial sterilization facilities, contains some errors and omissions. The District has addressed these errors and omissions by developing an "informational copy" of Part 2 of the ATCM, with corrections contained in brackets [ ]. This informational copy will be placed in Appendix A of the District Rules and Regulations. Why has ARB not addressed these corrections?

DISTRICT RESPONSE

ARB has submitted this ATCM to EPA for an equivalency determination, which, if granted as expected, will streamline requirements for commercial sterilization facilities. Prior to the equivalency determination, it is not expedient to modify the ATCM. Once the equivalency review process is complete, ARB intends to make administrative corrections to the ATCM. If necessary during the interim, ARB will provide a written statement to assist in implementing those sections of the regulation where the meaning is unclear.

2. WORKSHOP COMMENT

ARB has acknowledged an error in the threshold ethylene oxide annual throughput listed in Subsections (f)(1)(C) and (f)(2). Rather than 20,000 pounds, requirements are triggered at 2,000 pounds. There are several additional subsections in the ATCM where requirements are linked to the 20,000-pound threshold. Has ARB acknowledged any additional corrections related to the 20,000-pound throughput?

DISTRICT RESPONSE

The District's informational copy of the ATCM provided for the workshop includes all corrections acknowledged by ARB. In response to the above comment, the District has consulted further with ARB and confirmed that the 20,000-pound threshold contained in Subsections (f)(5) and Appendix 1 Subsections (b)(4) and (e) is correct.

3. ARB COMMENT

For clarification and to provide consistency with ARB's ATCM, the District should add definitions of "commercial facility" and "control efficiency."

DISTRICT RESPONSE

The District disagrees. There is no longer a specific need to define "commercial facility" because, as discussed in the answer to comment 4, below, the District has simplified the records retention requirements within amended Rule 1203 by not distinguishing between commercial and non-commercial facilities. Secondly, within Part 2 of the ATCM, Subsection (b) Applicability, the District explains, through information inserts, that Part 2 is not applicable to either research and development facilities or medical service providers. With this explanation, no additional definition is necessary.

"Control efficiency" is addressed adequately both in amended Rule 1203 Subsection (g)(2) and in Part 2, by requiring the use of Test Method 431 to determine control efficiency for compliance with the rule. This test method prescribes the procedure for determining control efficiency; therefore, the definition is not necessary.

4. ARB COMMENT

Section (f) requires sources to maintain records for five years. To relieve the burden on non-commercial facilities and provide consistency with the ATCM, ARB recommends that the District reduce the five-year recordkeeping requirement for non-commercial facilities to two years.

DISTRICT RESPONSE

The District is aware that the five-year record retention requirement in the amended ATCM is applicable only to commercial sterilization facilities. Proper implementation of this requirement, however, requires that the rule contain several additional definitions which complicates the rule unnecessarily, while providing little regulatory relief to non-commercial facilities. Therefore, the District proposes to retain the five-year record retention requirement.

5. ARB COMMENT

Section (g) specifies test methods to be used to determine compliance with standards contained in Section (d), but it is not clear which test methods apply to which processes. For clarification, ARB recommends that Section (g)(1) be modified as follows: "For the requirements of Section (d)(1)(ii), ARB Test Method 21 . . .," and that Section (g)(2) be modified as follows: "For the requirements of Sections (d)(2), (d)(3), (d)(4), and (d)(5), ARB Test Method 431 . . ."

DISTRICT RESPONSE

The District agrees. A reference to the applicable process has been added for each test method.

6. ARB COMMENT

Section (g)(2) specifies ". . . ARB Test Method 21 or an acceptable source test method approved in writing by the Air Pollution Control Officer." For amended Rule 1203 to be acceptable to ARB, this section must also specify that the alternate test method must be approved by ARB Executive Officer.

DISTRICT RESPONSE

The District has added language to require ARB approval of an alternate test method for initial performance testing, without specifying the Executive Officer, in particular, to be consistent with other District rules.

7. ARB COMMENT

Part 2, Section (b) exempts ethylene oxide sterilization operations at sources whose primary purpose is to conduct research and development. To provide consistency with the ATCM and acceptability to ARB, this exemption should be deleted.

DISTRICT RESPONSE

The discussion regarding research and development facilities and medical service providers provides clarity with regard to the applicability of Part 2 of the ATCM. The District does not agree that this discussion can be interpreted to exempt sources from District Rule 1203, which implements Part 1 of the ATCM. However, in response to this comment, the District agrees to add a statement that facilities exempt from Part 2 of the ATCM are required to comply with the requirements of amended Rule 1203.

SAN DIEGO AIR POLLUTION CONTROL DISTRICT

PROPOSED AMENDMENTS TO RULE 1203

Amendments are 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

(1) The provisions of Sections (d)~~, (f) and (g)~~ of this rule, except for Subsection (d)(1), 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 (f)~~(e)~~ of this rule. This exemption shall not apply to aeration-only facilities.

(2) The provisions of Sections (d) and (f) of this rule, except for Subsections (d)(1) and (d)(7), shall not apply to facilities subject to California Code of Regulations (CCR) Section 93108.5 Ethylene Oxide Airborne Toxic Control Measure for Sterilizers and Aerators: Part 2, Commercial Sterilizers and Aerators. Any person claiming this exemption shall comply with the requirements of that Part.

(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-contaminated air 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 July 23, 1991.~~

~~(7)~~(6) **"Leak-Free"** means that state which exists when the concentration of ethylene oxide ~~sterilant gas~~ measured one ~~1~~ centimeter away from any portion of the aerator, sterilizer, sterilant gas supply or ethylene oxide-contaminated air exhaust systems, ~~or their air exhaust systems, during conditions of maximum sterilant gas mass flow,~~ is less than~~:~~ 10 parts per million by volume (ppmv) ethylene oxide.

~~(i) 30 ppm for sterilant gas composed of 12% ethylene oxide/88% dichlorodifluoromethane (CFC-12) by weight; or~~

~~(ii) 10 ppmv for other compositions of sterilant gas.~~

~~(8) **"New Equipment"** means a sterilizer or aerator installed after July 23, 1991.~~

~~(9)~~(7) **"Sterilant Gas"** means ethylene oxide or any combination of ethylene oxide and other gas(es) used in a sterilizer.

~~(10)~~(8) **"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)~~(9) **"Sterilizer Cycle"** means the process which begins when sterilant gas is introduced into the sterilizer, includes the initial purge or evacuation after sterilization and subsequent air, steam or other washes, and ends after evacuation of the final air, steam or other washes, prior to aeration. For equipment which cycles directly from sterilization to aeration, the delineation of the two cycles shall be determined by the Air Pollution Control Officer.

(10) **"Sterilizer Door Hood Exhaust Stream"** means the exhaust stream which results from the collection, by means of a hood over the sterilizer door, of fugitive

ethylene oxide-contaminated air during the time that the sterilizer door is open after the sterilizer cycle has been completed.

~~(12)~~(11) **"Sterilizer Exhaust Stream"** means all ethylene oxide-contaminated air ~~gaseous mixtures~~ which is emitted from the sterilizer during the sterilizer cycle. The sterilizer exhaust stream does not include the door hood exhaust streams.

~~(13)~~(12) **"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 to wastewater streams; and

(ii) The sterilant gas supply, transfer, and exhaust systems, including, but not limited to, any piping, ducting, fittings, valves, or flanges through which sterilant gas or 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 or more of ethylene oxide in any consecutive twelve-month period, 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 emission 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 of ethylene oxide in any consecutive twelve-month period, 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 emission 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 emission 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 emission control equipment.; or

(iv) In lieu of (i) and (ii) above, a person may vent the sterilizer and aerator exhaust streams simultaneously to emission control equipment with an ethylene oxide emission reduction efficiency of at least 99.7% by weight.

(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 emission 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 emission 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 emission control equipment; and.

(iv) The back-draft valve is vented to either the sterilizer exhaust stream or the aerator exhaust stream emission control equipment.

(5) No person shall operate an aeration-only facility unless the aerator exhaust stream is vented to emission control equipment with an ethylene oxide emission reduction efficiency of at least 95.0% by weight.

(6) A facility shall be considered to be in compliance with Subsections (d)(2) through (d)(5) of this rule if the concentration of ethylene oxide measured in the outlet of the emission control equipment is below 0.2 ppmv.

(7) No person shall discharge liquids from an ethylene oxide recovery system to any system open to the atmosphere unless the concentration of ethylene oxide in the liquid is:

(i) 30 micrograms per milliliter or less for liquid discharges associated with the sterilizer cycle; and

(ii) 10 micrograms per milliliter or less for liquid discharges associated with the aeration cycle for those facilities where aeration emission control is required.

(e) **RESERVED**

~~(e)~~(f) **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 either: ~~sterilizer manufacturer's specifications, or total pounds of sterilant gas and the total pounds of ethylene oxide purchased on a monthly basis.~~

(i) The sterilizer manufacturer's specifications; or

(ii) The quantity of ethylene oxide purchased per month in pounds.

(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 Subsections (d)(2) through (d)(5), including, but not limited to, temperatures, flow rates and pressures.

(5) Inspection and ongoing maintenance schedules for the emission control equipment.

These records shall be maintained on-site for ~~three~~ five years and made available to the District ~~immediately~~ upon request.

~~(f) COMPLIANCE SCHEDULE~~

~~(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 Subsections (d)(1)(i) and (d)(2) no later than July 23, 1993.~~

~~(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 Subsections (d)(1)(i) and (d)(3) no later than January 23, 1993.~~

~~(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 Subsections (d)(1)(i) and (d)(4) no later than July 23, 1992..~~

~~(4) Any person operating an existing aeration only facility shall comply with the requirements of Subsection (d)(5) no later than January 23, 1993.~~

~~(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.~~

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

(g) **TEST METHODS**

To determine compliance with Section (d) of this rule, measurement of ethylene oxide concentrations shall be conducted in accordance with:

(1) California Air Resources Board (ARB) Test Method 21 for detection of leaks using an ethylene oxide-specific, metal-oxide detector or alternative test equipment previously approved in writing by the Air Pollution Control Officer; and

(2)~~(1) Measurements of sterilant gas emissions subject to Section (d) of this rule shall be conducted in accordance with~~ ARB Test Method 431 ~~(Title 17, CCR 60, Section 94143) as it exists on July 23, 1991.~~for determination of control efficiency during the initial performance test, or an acceptable source test method approved in writing by the Air Pollution Control Officer with the concurrence of ~~the Executive Officer of~~ ARB. These tests shall be conducted in accordance with the following requirements:

(i) Tests ~~on~~ of the emission control equipment efficiency shall be run with a maximum ethylene oxide charge in the sterilizer and maximum load in the aerator, as applicable.

(ii) The inlet concentration may be measured or calculated in accordance with ARB Test Method 431. If the emission reduction efficiency is determined by

inlet and outlet sampling, the ~~The~~ inlet and outlet of the emission control equipment shall be sampled simultaneously during testing to measure the emission reduction ~~control~~ efficiency.

(iii) To measure the control efficiency of the emission 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 emission 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 emission control ~~device~~ 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.

(iv) There shall be no dilution of either the aerator ~~and~~ or 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 equipment is below 0.2. parts per million.~~