AIR POLLUTION CONTROL DISTRICT
COUNTY OF SAN DIEGO

NOTICE OF WORKSHOP

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

The San Diego County Air Pollution Control District (District) will hold a public meeting to consider comments concerning proposed amendments to District rules for control of ethylene oxide emissions from sterilizers and aerators. Comments concerning this proposal may be submitted in writing before, or made at, the workshop which is scheduled as follows:

DATE: **March 21, 2000**

TIME: **1:00 p.m. to 3:00 p.m.**

PLACE: **San Diego Air Pollution Control District**
9150 Chesapeake Drive
San Diego, CA 92123
Conference Room 139

Rule 1203 controls emissions of ethylene oxide from sterilization and aeration operations. The rule, adopted in 1990, is based on a statewide Airborne Toxic Control Measure (ATCM). The state recently amended the ATCM by adding a section specifically applicable to commercial ethylene oxide sterilizers. The requirements are contained in two parts. Part 1 of the ATCM applies to sterilizers and aerators at medical facilities, such as hospitals, clinics, and doctors' offices and at "small commercial" facilities (using less than 2,000 pounds per year of ethylene oxide).

Part 2 of the ATCM was developed to implement the requirements of a new federal National Emission Standard for Hazardous Air Pollutants (NESHAP) regulation. It applies to sterilizers and aerators in use at commercial facilities, including all facilities that are not direct providers of medical services, that use 2,000 pounds per year or more of ethylene oxide. Operators of commercial sterilizers and aerators are subject to emission control

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requirements which are at least as stringent as those of Rule 1203, and more stringent for sources with large ethylene oxide usage. In addition, commercial operations are subject to more comprehensive monitoring, reporting and recordkeeping requirements.

The District is proposing to incorporate Part 1 of the ATCM into amended Rule 1203. Concurrently, the District will include in Appendix A of the District's Rules and Regulations Part 2 of the state ATCM that applies to commercial sterilizing facilities using 2,000 pounds or more of ethylene oxide annually. The District will implement and enforce Part 2 of the ATCM directly, as allowed by state law.

Specifically, amended Rule 1203 will:

- Clarify the required emission control efficiency (99.7%) for units which vent sterilizer and aerator exhaust streams simultaneously.
- Clarify the definition of sterilizer cycle to include steam or other washes.
- Exclude large commercial sterilization facilities (using 2, 000 pounds or more of ethylene oxide annually) from requirements which are superseded by Part 2 of the ATCM.
- Extend from three years to five years the amount of time records must be kept to comply with new federal requirements.

If you would like a copy of the proposed amended Rule 1203, or summary and full text of the state ATCM, please contact Juanita Ogata at (858) 694-8851, or access the District's Web Site at www.sdapcd.co.san-diego.ca.us under Rules and Regulations, Workshop Notices.

For questions regarding these requirements, please call Archi dela Cruz at (858) 694-3399 or Debbie Ryan at (858) 694-3838.

Richard J. Smith

RICHARD J. SMITH
Assistant Director

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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 stream~~s~~ 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.~~

SAN DIEGO AIR POLLUTION CONTROL DISTRICT

INFORMATIONAL VERSION

17 CCR, Section 93108.5. Ethylene Oxide Airborne Toxic Control Measure -- Sterilizers and Aerators.

PART 2

COMMERCIAL STERILIZERS AND AERATORS USING 2,000 POUNDS OR MORE OF ETHYLENE OXIDE PER 12 CONSECUTIVE MONTHS

Explanation of Relationship to District Rule 1203:

The Air Resources Board has amended Section 93108, Title 17, California Code of Regulations (CCR) and added Section 93108.5, Title 17, California Code of Regulations (Part 2). These changes are intended to simplify and clarify the Airborne Toxic Control Measure and emission test methods to reflect implementation experience practices and, for large commercial ethylene oxide sterilizers, to integrate the state requirements with the U.S. Environmental Protection Agency's promulgation of the National Emission Standards for Ethylene Oxide Commercial Sterilization and Fumigation Operations.

San Diego Air Pollution Control District will implement the requirements of 17 CCR 93108 under District Rule 1203. The requirements of 17 CCR 93108.5 will be incorporated into the District's appendices without change. However, within the text of 17 CCR 93108.5 which follows, the District has provided some additional explanatory information, identified within brackets [ ] to:

- Redirect reference to Part 1 of the regulation (17 CCR 93108) to Rule 1203, through which the District will implement 17 CCR 93108 requirements;
- Address identified errors and omissions in 17 CCR 93108.5 which will be corrected through administrative process by the Air Resources Board; and
- Provide additional definitions, background and interpretive information, as well as clarifications to enhance understanding.

FINAL REGULATION ORDER

17 CCR, Section 93108.5. Ethylene Oxide Airborne Toxic Control Measure -- Sterilizers and Aerators.

PART 2

COMMERCIAL STERILIZERS AND AERATORS USING 2,000 POUNDS OR MORE OF ETHYLENE OXIDE PER 12 CONSECUTIVE MONTHS

(a) DEFINITIONS

For the purposes of this section, the definitions set forth in Section 93108 (a) [District Rule 1203 Section (b)] shall apply unless otherwise specified below:

(1) **Administrator** means the Administrator of the United States Environmental Protection Agency (or the implementing agency in accordance with any delegation of authority to approve alternatives from the U. S. Environmental Protection Agency).

(2) **Back-draft valve chamber exhaust stream** is the air stream which results from collection of ethylene oxide-contaminated air which may be removed from the sterilizer through a back-draft valve or rear chamber exhaust system during unloading of the sterilized materials.

(3) **Baseline temperature** means the range of temperatures at the outlet point of a catalytic oxidation control device or at the exhaust point from the combustion chamber for a thermal oxidation control device established during the performance test at which the unit achieves at least 99 percent control of ethylene oxide emissions.

[**Continuous emission monitoring systems (CEMS)** means those monitoring systems which provide direct, continuous information related to emission rates, such as in-stack emission monitors.]

[**Continuous monitoring system (CMS)** means those monitoring systems, including continuous emission monitoring systems and parametric monitoring systems, which can be used to demonstrate system performance.]

(4) **Manifolding emissions** means combining ethylene oxide emissions from two or more vent types for the purpose of controlling these emissions with a single control device.

(5) **Maximum ethylene glycol concentration** means the concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device established during a performance test when the scrubber achieves at least 99 percent control of ethylene oxide emissions.

(6) **Maximum liquor tank level** means the level of scrubber liquor in the acid-water scrubber liquor recirculation tank established during a performance test when the scrubber achieves at least 99 percent control of ethylene oxide emissions.

(7) **Modification** means either:

(A) any physical change in, method of operation of, or addition to, an existing permit unit that requires an application for a permit to construct and/or operate. Routine maintenance and/or repair shall not be considered a physical change. A change in the method of operation of equipment, unless previously limited by an enforceable permit condition, shall not include:

(i) an increase in the production rate, unless such increases will cause the maximum design capacity of the equipment to be exceeded; or

(ii) an increase in the hours of operation; or,

(iii) a change in ownership of a source; or,

(B) the addition of any new permit unit at an existing source; or,

(C) the replacement of components if the fixed capital cost of the components exceeds 50 percent of the fixed capital cost that would be required to construct a comparable new source.

(8) **Oxidation temperature** means the temperature at the outlet point of a catalytic oxidation device or at the exhaust point from the combustion chamber for a thermal oxidation device.

(9) **Parametric monitoring** means monitoring of a specific operating parameter or parameters of a control device established to demonstrate that the control device is operating under conditions that meet a performance standard.

(b) **APPLICABILITY**

Any person who owns or operates a commercial sterilizer or an aerator using 2,000 pounds or more of ethylene oxide in any 12 consecutive month period after December 6, 1996 must comply with Part 2 of this regulation, Section 93108.5, effective the date that the National Emission Standard For Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization And Fumigation Operations (Code of Federal Regulation 40, Part 63, Subpart O) becomes effective [December 8, 1997]. Until that time the requirements in Part I, Section 93108 [District Rule 1203], are applicable to all sterilizer and aerators.

[This subpart does not apply to ethylene oxide sterilization operations at stationary sources whose primary purpose is to conduct research and development into new processes and products, where such source is operated under the close supervision of technically-trained

personnel and is not engaged in the manufacture of products for commercial sale in commerce, except in a de minimis manner. These sources are subject to District Rule 1203.]

[This subpart does not apply to ethylene oxide sterilization operations at stationary sources such as hospitals, doctors offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals. These sources are subject to District Rule 1203.]

(c) **INITIAL NOTIFICATION**

Any person subject to this regulation must provide the District with the following information, in writing, within 30 days after the source becomes subject to the regulation. Facilities must also provide the information to the Administrator unless the Administrator has waived this requirement.

(1) The name(s) and address of the owner and operator of the facility;

(2) The location of the facility;

(3) The number of sterilizers and aerators at the facility;

(4) An estimate of the facility-wide pounds of ethylene oxide used per year;

(5) A brief description of the nature, size, design, design operating capacity, expected control efficiency, and method of operation of the source, and control equipment, including operating design capacity, bypass valves, and an identification of each point of emission;

(6) Facilities complying with this regulation with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers must provide information describing the design and operation of the air pollution control system including recommendations for the operating parameters to be monitored that will indicate proper operation and maintenance. The site specific operating, reporting and monitoring parameters will be determined during the performance test.

(7) A statement of whether the source is a major or area source to the Administrator. If the source is a new major source or a major source undergoing modification, it must receive written approval in advance from the Administrator. The source may use the Application for Construction or Modification in Appendix 2 to satisfy the initial notification requirements; and

(8) An identification of the relevant standard, or other requirement, that is the basis of the notification and the source's compliance date.

(d) **REQUIREMENTS**

No person subjected to these standards shall operate a sterilizer or aerator, unless all of the following requirements are satisfied:

(1) all ethylene oxide released from the sterilizer and aerator shall be controlled to meet the requirements shown in Table 1 for the applicable control category;

Table 1
Emissions Standards [and Test Requirements] for Commercial Facilities

Control Category [Ethylene Oxide usage] (facility-wide Pounds of Total Ethylene Oxide used per 12 consecutive months)	Requirements for Ethylene Oxide Sterilizer [and Aeration] Facilities		
	(a) Emission Streams to be Controlled	(b) Emission Streams to be Tested	(c) Control Efficiency (%) [by weight] or Outlet Concentration [ppm by volume]
Equal to or greater than 2,000 & less than 5,000	Sterilizer Aerator Back-draft Valve	Sterilizer Aerator [*]	99.9 95.0 *
	Aeration Only	[Aerator]	95.0
Equal to or greater than 5,000 & less than 20,000	Sterilizer Aerator Sterilizer Door Hood & Back-draft Valve	Sterilizer Aerator [*]	99.9 99.0 *
	Aeration Only	[Aerator]	95.0
Equal to or more than 20,000	Sterilizer Aerator Sterilizer Door Hood Back-draft Valve	Sterilizer Aerator [*] [*]	99.9 99.0 or 1 ppm max [*] 99.0*
	Aeration Only	[Aerator]	99.0

* Sources may show compliance by manifolding emissions to control device used to comply with sterilizer or aerator requirement.

(2) the exhaust systems and EtO [ethylene oxide] supply including, but not limited to, any piping, ducting, fittings, valves, or flanges, through which ethylene oxide is conveyed to and from the sterilizer, aerator and the control device shall be leak-free; and

(3) Facilities must obtain a Title V permit from the Administrator.[1]

(e) COMPLIANCE PROCEDURES

[1] [The schedule for submittal of Title V permit applications for this source category has been deferred by the U.S. Environmental Protection Agency to December 9, 2005, and will ultimately be determined considering applicable Federal requirements promulgated pursuant to Subpart O and subsequent amendments related to that subpart at that time.]

(1) Compliance Testing Notification

The facility shall notify the Administrator 60 days before the date and time of any performance tests and monitoring system evaluations. In the event the source is unable to conduct the test on the date specified in the notification, the source shall notify the Administrator within 5 days prior to the scheduled performance test date.

(2) Compliance Testing

(A) Source testing conducted for the purpose of demonstrating compliance must be according to ARB [California Air Resources Board] Test Method 431 (Title 17, CCR, Section 94143) and the method evaluations cited therein or an acceptable source test method approved by the District with the concurrence of the Executive Officer of the Air Resources Board, and the Administrator. Before conducting a required source test, the source shall develop a site-specific test program summary, the test schedule, data quality objectives, and both an internal and external quality assurance program.

(B) The following procedures shall be used to determine the monitored parameters for acid-water scrubbers:

(i) For determining the ethylene glycol concentration, the facility owner or operator shall establish the maximum ethylene glycol concentration as the ethylene glycol concentration averaged over three test runs; the sampling and analysis procedures in ASTM [American Society for Testing and Materials] D 3695-88, Standard Test Method for Volatile Alcohols in Water by Direct Aqueous-Injection Gas Chromatography (1988).

(ii) For determining the scrubber liquor tank level, the sterilization facility owner or operator shall establish the maximum liquor tank level based on a single measurement of the liquor tank level during one test run.

(C) The following procedures shall be used to demonstrate the baseline temperature for catalytic oxidation units or thermal oxidation units and to continuously monitor the oxidation temperature as required by this measure.

(i) The baseline temperature for the sterilization chamber vent shall be the temperature for the catalytic oxidation unit or oxidation temperature at the exhaust point from the thermal oxidation unit averaged over three test runs using the procedures in Test Method 431, and Subsection (f)(2)(A).

(ii) The baseline temperature for the aeration room vent shall be the temperature for the catalytic oxidation unit or the oxidation temperature at the exhaust point from the thermal oxidation unit

averaged over three test runs using the procedures in Test Method 431, and Subsection (f)(2)(B).

(iii) The baseline temperature for the chamber exhaust vent shall be the temperature for the catalytic oxidation unit or oxidation temperature at the exhaust point from the thermal oxidation unit averaged over three test runs using the procedures in Test Method 431, and Subsection (f)(2)(C).

(D) A facility seeking to demonstrate compliance with the standards with a control device other than an acid-water scrubber or catalytic or thermal oxidation unit shall submit: a description of the device; tests results collected in accordance with the test method cited within or an approved method verifying the performance of the device for controlling ethylene oxide emissions to the levels required by the applicable standards; the appropriate operating parameters that will be monitored; and the frequency of measuring and recording to establish continuous compliance with the standards. The monitoring plan is subject to the Administrator's approval. The owner or operator of the sterilization facility shall install, calibrate, operate, and maintain the monitor(s) approved by the Administrator based on the information submitted by the owner or operator. The owner or operator shall include in the information submitted to the Administrator proposed performance specifications and quality assurance procedures for their monitors.

(E) A facility seeking to demonstrate compliance with the standards with a monitoring device or procedure other than a gas chromatograph shall provide to the Administrator information describing the operation of the monitoring device or procedure and the parameter(s) that would indicate proper operation and maintenance of the device or procedure.

(3) Compliance Testing Report

(A) The facility shall send the District and the Administrator an initial statement of compliance and test results within 60 days following the performance test.

(B) The facility shall submit (before a Title V permit is issued) to the Administrator;

(i) The methods that were used to determine compliance;

(ii) The results of any performance tests, [continuous monitoring system (CMS)] performance evaluations, and/or other monitoring procedures or methods that were conducted;

(iii) The methods that will be used for determining continuing compliance, including a description of monitoring and reporting requirements and test methods.

(iv) A statement by the owner or operator of the affected existing, new, or modified source as to whether the source has complied with the relevant standard or other requirements.

(f) **MONITORING REQUIREMENTS**

The owner or operator of a sterilizer or aerator shall monitor the parameters of the control system specified in this Section to show compliance with the provisions of this regulation. If continuous monitoring systems are required, Appendix 1 should be consulted for their application. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters which affect emissions from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include, at a minimum, completion of the manufacturer's written specifications or recommendations for installation, operation, maintenance, and calibration of the system.

(1) For sterilization facilities complying with the emissions standard through the use of an acid-water scrubber, the owner or operator shall either:

(A) Sample the scrubber liquor and analyze and record once per week the ethylene glycol concentration using the test procedures in Subsection (e)(2)(B)(i). Monitoring is required only if the scrubber unit has been operated during that week; or

(B) Measure and record once per week the level of the scrubber liquor in the recirculation tank. The owner or operator shall install, maintain, calibrate, and use a liquid level indicator to measure the scrubber liquor tank level (i.e., a visible depth gauge, a dipstick, a magnetic indicator, etc.).

(C) Operation of the facility with an ethylene glycol concentration in the scrubber liquor in excess of the maximum [ethylene glycol concentration or liquor tank level in excess of the maximum] liquor tank level shall constitute a violation of the [applicable sterilizer/aerator or backdraft/] chamber exhaust vent standard for sources using [2,000] ~~20,000~~ pounds or more of ethylene oxide per 12 consecutive months.[2]

(2) For sterilization facilities complying with the emissions standards through the use of catalytic oxidation or thermal oxidation, the owner or operator shall continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion chamber using a temperature monitor. The temperature monitor shall be installed, calibrated, operated, and maintained to an accuracy within ± 5.6 °C (± 10 °F). The owner or operator shall verify the accuracy of the temperature monitor twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology

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[2] [Corrections provided by the California Air Resources Board.]

(NIST) standard, or with an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested.

[Operation] ~~For sources using 20,000 pounds or more of ethylene oxide per 12 consecutive months,~~ of the facility with the oxidation temperature, averaged over the cycle, more than 5.6 °C (10 °F) below the baseline temperature shall constitute a violation of the [applicable sterilizer/aerator or backdraft/] chamber exhaust vent standard.[3]

(A) For the sterilization chamber vent, a data acquisition system for the temperature monitor shall compute and record an average oxidation temperature over the length of the cycle (based on the length of the cycle used during the performance test) and a three-cycle block average every third cycle.

(B) For the aeration room vent, a data acquisition system for the temperature monitor shall compute and record an average oxidation temperature each hour and a 3-hour block average every third hour.

(C) For the back draft valve (chamber exhaust vent), a data acquisition system for the temperature monitor shall compute and record an average oxidation temperature over the length of the cycle (based on the length of the cycle used during the performance test).

(3) For sterilization facilities complying with the emission standards with the use of a control device other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator shall monitor the parameters as approved by the Administrator.

(4) For facilities continuously measuring the ethylene oxide concentration from the aeration room (after a control device) or in the sterilization chamber immediately prior to the operation of the chamber exhaust, the owner or operator shall follow either paragraph (A) or (B) of this Subsection:

(A) Measure and record once per hour the ethylene oxide concentration at the outlet to the atmosphere from the aeration room vent after any control device. The owner or operator shall compute and record a 3-hour average every third hour. The owner or operator will install, calibrate, operate, and maintain a gas chromatograph to measure ethylene oxide. The daily calibration requirements are required only on days when ethylene oxide emissions are vented to the control device from the aeration room vent.

(B) Measure and record the ethylene oxide concentration in the sterilization chamber immediately before the chamber exhaust is activated. The owner or operator shall install, calibrate, operate, and maintain a gas chromato-

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[3] [Corrections provided by the California Air Resources Board.]

graph to measure ethylene oxide concentration. The daily calibration requirements are required only on days when the chamber exhaust is activated.

(5) At facilities using 20,000 pounds or more of ethylene oxide per consecutive 12 months, seeking to comply with the standard by manifolding emissions from the chamber exhaust vent to a control device controlling emissions from another vent type (sterilization chamber vent and/or aeration room vent), shall monitor the control device to which emissions from the chamber exhaust vent are manifolded.

(g) **RECORDKEEPING**

(1) The owner or operator of a sterilizer or aerator subject to the emissions standards in Subsection (d) Table 1 shall maintain records of all reports and notifications (including compliance notifications) in a form suitable and readily available for expeditious inspection and review. The files shall be retained for at least 5 years following the date of each occurrence, measurement, maintenance, corrective action, report or record. At a minimum the most recent 2 years of data shall be retained on-site. The files shall contain:

(A) The occurrence and duration of each malfunction of the air pollution control equipment;

(B) All required measurements needed to demonstrate compliance with the standard (including, but not limited to, 15-minute averages of CMS data, raw performance testing measurements, and raw performance evaluation measurements, that support data that the source is required to report);

(C) All measurements as may be necessary to determine the conditions of performance tests and performance evaluations;

(D) Any information demonstrating whether a source is meeting the requirements for a waiver of recordkeeping or reporting requirements.

(2) The source may apply for a waiver of recordkeeping or reporting requirements by submitting a written application to the Administrator. Until the waiver is granted, the source remains subject to the requirements of this Section. The application must contain at a minimum:

(A) A request for an extension of compliance (if applicable);

(B) All required compliance progress reports or compliance status reports;

(C) Any excess emissions and CMS performance report;

(D) Information to convince the administrator that a waiver of recordkeeping or reporting is warranted.

(h) **REPORTING**

Any person who owns or operates a sterilizer shall furnish the following written report to the Administrator and to the District within thirty days after the date specified by the District.

(1) An annual report that demonstrates that the facility is a major or area source. The report shall contain at a minimum;

(A) the number of sterilizer cycles and the pounds of ethylene oxide used per cycle for each sterilizer during the consecutive 12-month reporting period from the District permit; or

(B) the total pounds of sterilant gas and the total pounds of ethylene oxide purchased, used, and returned in the consecutive 12-months from the date of the permit.

(2) Facilities shall provide semi-annual compliance reports to the Administrator that contain information on the compliance status of the source. This report should also contain the summary report in Appendix 1, [Subsection] (i). The report shall be signed by the responsible official who shall certify its accuracy.

(i) **CONSTRUCTION OR MODIFICATION**

The requirements of this Section apply to sources subject to the emission standards in Table 1. No person may construct or modify a source, without obtaining written approval, in advance, from the District and from the Administrator. For major sources, the application for approval of construction or modification may be used to fulfill the notification requirements. For specific requirements, see Appendix 2. In lieu of complying with requirements in Appendix 2, a facility may fulfill these requirements by complying with the permitting agency's new source review rule or policy, provided similar information is obtained.

NOTE: Authority cited: Sections 39600, 39650, 39610, and 39666, Health and Safety Code. Reference: Sections 39650, 39665, and 39666, Health and Safety Code, and 40 CFR, Part 63 Subpart O.

APPENDIX 1
REQUIREMENTS FOR CONTINUOUS MONITORING SYSTEMS (CMS)

(a) GENERAL REQUIREMENTS

(1) When the effluent from a single source, or when two or more sources are combined before being released to the atmosphere, the owner or operator shall install an applicable CMS on each effluent.

(2) When the effluent from one source is released to the atmosphere through more than one point, the owner or operator shall install an applicable CMS at each emission point unless the installation of fewer systems is approved by the Administrator.

(3) If more than one CEMS [continuous emission monitoring system] is used to measure the emissions from one source, the owner shall report the results as required for each CEMS.

(4) The date and time during which a CMS is malfunctioning or inoperative, except for zero (low-level) and high-level checks. Also records of all required CMS measurements (including monitoring data recorded during unavoidable CMS breakdowns and out-of-control periods) shall be maintained.

(b) RECORDKEEPING

(1) All results of performance tests, and CMS performance evaluations;

(2) All CMS calibration checks;

(3) All adjustments and maintenance performed on CMS (including the nature and cause of any malfunction and the corrective action taken or preventive measures adopted). Records of the total process operating time during the reporting period shall be maintained as well;

(4) For facilities using 20,000 pounds or more of ethylene oxide per 12 month consecutive period, records shall be maintained for all procedures that are part of a quality control program developed and implemented for CMS.

(5) The specific identification (i.e., the date and time of commencement and completion) of each period of excess emissions and parameter monitoring exceedances, as defined in the standard, that occurs during periods other than startups, shutdowns, and malfunctions of the affected source;

(6) The total process operating time during the reporting period.

(c) **ADDITIONAL REPORTING**

The owner or operator shall submit to the Administrator a semiannual summary report. The summary report shall contain, at a minimum, the information in (h) of this Subsection. In addition if the duration of excess emissions or process or control system parameter exceedances for the reporting period exceeds 1 percent or the total CMS downtime exceeds 5 percent of the reporting period, an excess emissions and continuous monitoring system performance report shall be submitted semiannually as well. The performance report shall contain, at a minimum, all information required in (h) of this Subsection.

(d) **OPERATION AND MAINTENANCE OF CONTINUOUS MONITORING SYSTEMS**

Each CMS shall be maintained and operated as specified in this Subsection, and in a manner consistent with good air pollution control practices.

(1) All CMS shall be installed such that representative measurements of emissions or process parameters are obtained.

(2) All CMS shall be installed, operational, and the data verified either prior to or in conjunction with conducting performance tests. Verification of operational status shall, at a minimum, include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.

(e) **QUALITY CONTROL PROGRAM**

(Sources using 20,000 pounds or more EtO per 12 consecutive months)

(1) The owner or operator shall develop and implement a CMS quality control program. As part of the quality control program, the owner or operator shall develop and submit upon request by the Administrator, a site-specific performance evaluation test plan for the CMS performance evaluation. In addition, each quality control program shall include, at a minimum, a written protocol that describes procedures for each of the following operations:

(A) Initial and any subsequent calibration of the CMS;

(B) Determination and adjustment of the calibration drift of the CMS;

(C) Preventive maintenance of the CMS, including spare parts inventory;

(D) Data recording, calculations, and reporting;

(E) Accuracy audit procedures, including sampling and analysis methods; and

(F) Program of corrective action for a malfunctioning CMS.

(2) The owner or operator shall keep these written procedures on record for the life of the affected source or until the affected source is no longer subject to the provisions of this performance evaluation plan is revised, the owner or operator shall keep previous (i.e., superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to the plan.

(f) PERFORMANCE EVALUATION OF CONTINUOUS MONITORING SYSTEMS

(1) If the Administrator requests a performance evaluation, the evaluation shall be conducted according to the applicable specifications and procedures described in this Subsection.

(2) Notification of performance evaluation. The owner or operator shall notify the Administrator in writing of the date of the performance evaluation simultaneously with the notification of the performance test date or at least 60 days prior to the date the performance evaluation is scheduled to begin if no performance test is required.

(3) Submission of site-specific performance evaluation test plan.

(A) Before conducting a required CMS performance evaluation, the owner or operator shall develop and submit a site-specific performance evaluation test plan to the Administrator for approval. The performance evaluation test plan shall include the evaluation program objectives, an evaluation program summary, the performance evaluation schedule data quality objectives, and both an internal and external QA [quality assurance] program. Data quality objectives are the pre-evaluation expectations of precision, accuracy, and completeness of data.

(B) The internal QA program shall include, at a minimum, the activities planned by routine operators and analysts to provide an assessment of CMS performance. The external QA program shall include, at a minimum, systems audits that include the opportunity for on-site evaluation by the Administrator of instrument calibration, data validation, sample logging, and documentation of quality control data and field maintenance activities.

(C) The owner or operator shall submit the site-specific performance evaluation test plan to the Administrator (if requested) at least 60 days before the performance test or performance evaluation is scheduled to begin, or on a mutually agreed upon date, and review and approval of the performance evaluation test plan by the Administrator will occur with the review and approval of the site-specific test plan (if review of the site-specific test plan is requested).

(D) In the event that the Administrator fails to approve or disapprove the site-specific performance evaluation test plan within the specified time period, the following conditions shall apply;

(i) If the owner or operator intends to demonstrate compliance by using an alternative to a monitoring method specified in this measure, the owner or operator shall refrain from conducting the performance evaluation until the Administrator approves the use of the alternative method.

[(ii)] If the Administrator does not approve the use of the alternative method within 30 days before the performance evaluation is scheduled to begin, the performance evaluation deadlines may be extended such that the owner or operator shall conduct the performance evaluation within 60 calendar days after the Administrator approves the use of the alternative method.

[(iii)] Notwithstanding the requirements in the preceding two sentences, the owner or operator may proceed to conduct the performance evaluation as required in this Section (without the Administrator's prior approval of the site-specific performance evaluation test plan) if he/she subsequently chooses to use the specified monitoring method(s) instead of an alternative.

(4) Neither the submission of a site-specific performance evaluation test plan for approval, nor the Administrator's approval or disapproval of a plan, nor the Administrator' failure to approve or disapprove a plan in a timely manner shall;

(A) Relieve an owner or operator of legal responsibility for compliance with any applicable provisions of this part or with any other applicable Federal, State, or local requirement; or

(B) Prevent the Administrator from implementing or enforcing this part or taking any other action under the Act.

(5) Conduct of performance evaluation and performance evaluation dates. The owner or operator of an affected source shall conduct a performance evaluation of a required CMS during any performance test required in accordance with the applicable performance specification as specified in the standard. If a performance test is not required, or the requirement for a performance test has been waived, the owner or operator of an affected source shall conduct the performance evaluation not later than 180 days after the appropriate compliance date, or as otherwise specified in the standard.

(6) Reporting performance evaluation results. The owner or operator shall furnish the Administrator a copy of a written report of the results of the performance evaluation simultaneously with the results of the performance test within 60 days of completion of the performance evaluation if no test is required, unless otherwise

specified in the standard. The Administrator may request that the owner or operator submit the raw data from a performance evaluation in the report of the performance evaluation results.

(g) **USE OF AN ALTERNATIVE MONITORING METHOD**

Until permission to use an alternative monitoring method has been granted by the Administrator under this paragraph, the owner or operator of an source remains subject to the requirements of this Section and the standard.

(1) Request to use alternative monitoring method.

(A) An owner or operator who wishes to use an alternative monitoring method shall submit an application to the Administrator. The application may be submitted at any time provided that the monitoring method is not used to demonstrate compliance with the standard or other requirement. If the alternative monitoring method is to be used to demonstrate compliance with the standard, the application shall be submitted not later than with the site specific test plan (if requested), with the site-specific performance evaluation plan (if requested), or at least 60 days before the performance evaluation is scheduled to begin.

(B) The application shall contain a description of the proposed alternative monitoring system and a performance evaluation test plan, if required. In addition, the application shall include information justifying the owner or operator's request for an alternative monitoring method, such as the technical or economic infeasibility, or the impracticality, of the affected source using the required method.

(C) The owner or operator may submit the information required in this paragraph well in advance of the submittal dates to ensure a timely review by the Administrator in order to meet the compliance demonstration date specified in this Section or the standard.

(2) After receipt and consideration of written application, the Administrator may approve alternatives to any monitoring methods or procedures of this part including, but not limited to, the following:

(A) Alternative monitoring requirements when installation of a CMS specified by the standard would not provide accurate measurements due to liquid water or other interferences caused by substances within the effluent gases;

(B) Alternative monitoring requirements when the affected source is infrequently operated;

(C) Alternative locations for installing CMS when the owner or operator can demonstrate that installation at alternate locations will enable accurate and representative measurements;

(D) Alternate procedures for performing daily checks of zero (low-level) and high-level drift that do not involve use of high-level gases or test cells;

(E) Alternatives to the American Society for Testing and Materials (ASTM) test methods or sampling procedures specified by any relevant standard;

(F) Alternative monitoring requirements when the effluent from a single affected source or the combined effluent from two or more affected sources is released to the atmosphere through more than one point.

(3) Status of request to use alternative monitoring method.

(A) The Administrator will notify the owner or operator of approval or intention to deny approval of the request to use an alternative monitoring method within 30 calendar days after receipt of the original request and within 30 calendar days after receipt of any supplementary information that is submitted. Before disapproving any request to use an alternative monitoring method, the Administrator will notify the applicant of the Administrator's intention to disapprove the request together with:

(i) Notice of the information and findings on which the intended disapproval is based.

(ii) Notice of opportunity for the owner or operator to present additional information to the Administrator before final action on the request. At the time the Administrator notifies the applicant of his or her intention to disapprove the request, the Administrator will specify how much time the owner or operator will have after being notified of the intended disapproval to submit the additional information.

(B) If the Administrator approves the use of an alternative monitoring method for a source, the owner or operator shall continue to use the alternative monitoring method until he or she receives approval from the Administrator to use another monitoring method.

(4) If the Administrator finds reasonable grounds to dispute the results obtained by an alternative monitoring method, requirement, or procedure, the Administrator may require the use of a specific method, requirement, or procedure. If the results of the specified and alternative method, requirement, or procedure do not agree, the results obtained by the specified method, requirement, or procedure shall prevail.

(h) **[MONITORING DATA REDUCTION]**

Monitoring data recorded during periods of unavoidable CMS breakdowns, out-of-control periods, repairs, maintenance periods, calibration checks, and zero (low-level) and high-level adjustments shall not be included in any data average computed.

(1) A CMS is out of control if;

(A) The zero (low-level), mid-level, or high-level calibration drift (CD) exceeds two times the applicable performance specification; or

(B) The CMS fails a performance test audit, relative accuracy test audit, or linearity test audit.

(i) **SUMMARY REPORT - GASEOUS AND CONTINUOUS MONITORING SYSTEM PERFORMANCE**

The summary report shall contain the following information:

(1) The company name and address of the source;

(2) The date of the report, and the beginning and ending dates of the reporting period;

(3) A brief description of the process units;

(4) The emission and operating parameter limitations specified in the standard;

(5) The monitoring equipment manufacturer(s) and model number(s);

(6) The date of the latest CMS certification or audit;

(7) The total operating time during the reporting period;

(8) An emissions data summary, including the total duration of excess emissions during the reporting period (recorded in hours), the total duration of excess emissions expressed as a percent of the operating time during the reporting period, and a breakdown of the total duration of excess emissions during the reporting period into those that are due to startup/shutdown, control or monitoring equipment problems, process or process equipment problems, quality assurance, quality control calibrations, other known causes, and other unknown causes;

(9) A CMS performance summary, including the total CMS downtime recorded in hours, the total duration of CMS downtime expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total CMS downtime during the reporting period into periods that are due to monitoring equipment malfunctions, non-monitoring equipment malfunctions, quality assurance, quality control calibrations, other known causes, and other unknown causes;

(10) A description of any changes in CMS, processes, or controls since the last reporting period.

(11) The name, title, and signature of the responsible official who is certifying the accuracy of the report.

(j) EXCESS EMISSIONS AND CONTINUOUS MONITORING SYSTEM PERFORMANCE REPORT

The excess emission report shall contain the following information:

(1) The name, title, and signature of the responsible official who is certifying the accuracy of the report;

(2) The date and time identifying each period during which the CMS was inoperative except for zero (low-level) and high-level checks;

(3) The date and time the identifying each period during which the CMS was out of control;

(4) The specific identification (i.e. the date and time of commencement and completion) of each period of excess emissions and parameter monitoring exceedances, that occurs during periods other than startups, shutdowns, and malfunctions;

(5) The specific identification (i.e. the date and time of commencement and completion) of each period of excess emissions and parameter monitoring exceedances, that occurs during startups, shutdowns, and malfunctions;

(6) The nature and cause of any malfunction if known;

(7) The corrective action taken or preventive measures adopted;

(8) The nature of the repairs or adjustments to the CMS that was inoperative or out of control;

(9) The total process operating time during the reporting period.

APPENDIX 2
APPLICATION FOR CONSTRUCTION OR MODIFICATION

(a) GENERAL REQUIREMENTS

An owner or operator shall submit to the District and Administrator an application for approval of the construction of a new affected source, or the modification of an existing source. Each application for approval of construction or modification shall include at a minimum:

(1) The applicant's name and address;

(2) A notification of intention to construct a new affected or make any modification as defined in Subsection (a)(7);

(3) The address (i.e., physical location) or proposed address of the source;

(4) An identification of the relevant standard that is the basis of the application;

(5) The expected commencement date of the construction or modification;

(6) The expected completion date of the construction or modification. Facilities undergoing modification shall provide a brief description of the components that are to be replaced;

(7) The anticipated date of (initial) startup of the source,

(8) The mixture (100%, 12/88, 8/92, etc.,) and quantity of ethylene oxide emitted by the source, reported in units and averaging times and in accordance with the test methods specified in the standard, or if actual emissions data are not yet available, an estimate of the type and quantity of ethylene oxide expected to be emitted by the source reported in units and averaging times specified in the standard. The owner or operator may submit percent reduction information. Operating parameters, such as flow rate, shall be included in the submission to the extent that they demonstrate performance and compliance; and

(9) An owner or operator who submits estimates or preliminary information in place of the actual emissions data and analysis shall submit the actual, measured emissions data and other correct information as soon as available but no later than with the notification of compliance status.

(b) APPLICATION FOR CONSTRUCTION

Each application shall include technical information describing the proposed nature, size, design, operating design capacity, and method of operation of the source, including an identification of each point of emission for ethylene oxide and a description of the planned air pollution control system (equipment or method) for each emission point. The description of the

equipment to be used for the control of emissions shall include the estimated control efficiency (percent) for each control device. The description of the method to be used for the control of emissions shall include an estimated control efficiency (percent) for that method. Such technical information shall include calculations of emission estimates in sufficient detail to permit assessment of the validity of the calculations.

(c) **APPLICATION FOR MODIFICATION**

Each application shall include in addition to the information in (a) above of this Section the following;

(1) A brief description of the affected source and the components that are to be replaced;

(2) A description of present and proposed emission control systems (i.e., equipment methods) that will be used to comply with the standard in Table 1. The description of the equipment to be used for the control of emissions shall include the estimated control efficiency (percent) for each control device. The description of the method to be used for the control of emissions shall include an estimated control efficiency (percent) for that method. Such technical information shall include calculations of emission estimates in sufficient detail to permit assessment of the validity of the calculations;

(3) An estimate of the fixed capital cost of the replacements and of constructing a comparable entirely new source;

(4) The estimated life of the affected source after the replacement.