(Adopted December 21, 1990)(Amended January 4, 1991)(TBD)

PROPOSED AMENDED RULE 1405. CONTROL OF ETHYLENE OXIDE ~~AND CHLOROFLUOROCARBON~~ EMISSIONS FROM STERILIZATION ~~OR FUMIGATION~~ PROCESSES

(a) Purpose

The purpose of this rule is to protect public health by reducing ~~e~~Ethylene ~~o~~Oxide emissions from ~~s~~Sterilization ~~or fumigation~~ operations and associated processes ~~in the South Coast Air Basin~~ and to assess potential Ethylene Oxide emissions from Warehouses~~and to fulfill state requirements~~. ~~Pursuant to the requirements of Health and Safety Code Section 39650 (AB 1807 Tanner), the Air Resources Board (ARB) adopted an Air Toxic Control Measure for Ethylene Oxide Emissions from Sterilizers and Aerators in May, 1990. The District is required to enact equivalent or more stringent requirements than this measure. This rule requires recovery or reclamation of chlorofluorocarbons at certain commercial facilities and eliminates the use of certain chlorofluorocarbons as diluents in sterilization processes by 1997.~~

(b) Applicability

This rule shall apply to the owner or operator of any facility performing ~~is applicable to persons that use e~~Ethylene ~~o~~Oxide ~~for s~~Sterilization ~~or fumigation~~, any Post-Aeration Storage Facility, or Warehouse storing materials Sterilized with Ethylene Oxide. ~~aerate products sterilized with ethylene oxide at another facility.~~

(c) Definitions

For purposes of this rule the following definitions shall apply:

(1) AERATION is the process during which residual ~~ethylene oxide~~ Ethylene Oxide dissipates by forced air flow, or through natural or mechanically assisted convection, or other means, from ~~previously sterilized~~ Sterilized materials after the ~~sterilization cycle~~ Sterilization Cycle is completed. Aeration is completed when Products achieve predetermined allowable residual levels of Ethylene Oxide under U.S. Food and Drug Administration (FDA) recognized consensus standards. ~~Aeration is completed when materials that have previously undergone ethylene oxide~~

~~sterilization can be handled, stored, and transported in the same manner as similar materials that have not been sterilized with ethylene oxide.~~

~~(2) AERATION-ONLY FACILITY is any facility which performs aeration on materials which have been sterilized with ethylene oxide at another facility.~~

~~(3)~~ (2) AERATOR is any equipment (excluding a Sterilizer or a Combined Sterilizer/Aerator), area~~space~~, or room ~~in which air is~~ used to perform Aeration.~~remove residual ethylene oxide from sterilized materials.~~

~~(4)~~ (3) BACK-DRAFT VALVE is a valve, hood, or rear chamber exhaust system for removal of ~~ethylene oxide~~ Ethylene Oxide during unloading of ~~sterilized~~ Sterilized materials ~~prior to Aeration~~.

~~(5)~~ (4) CHLOROFLUOROCARBON (CFC) DILUENT is any of the five chlorinated fluorinated carbon compounds (CFC-11, CFC-12, CFC-113, CFC-114, or CFC-115), or combinations of these compounds, used in ~~sterilant gas~~ Sterilant Gas mixtures.

(5) COMPONENT is any part of a Sterilizer, Sterilizer Exhaust Vacuum Pump, Combined Sterilizer/Aerator, Aerator, or Control System that may have a Leak of Ethylene Oxide.

(6) CONTINUOUS EMISSION MONITORING is a monitoring technique in which a minimum of one measurement (e.g. concentration, mass emission, flow rate) is taken and recorded every one (1) minute.

(7) CONTINUOUS EMISSION MONITORING SYSTEM (CEMS) is the total combined equipment and systems required to continuously determine air contaminants and diluent gas concentrations and/or mass emission rate of a source effluent (as applicable). The CEMS consists of three major subsystems: sampling interface, analyzer and data acquisition system.

(8) COMBINED STERILIZER/AERATOR is any chamber or related piece of equipment that performs the functions of a Sterilizer and an Aerator and where Aeration is completed within the chamber.

(9) CONTROL SYSTEM is equipment and ducting installed for the purposes of collecting Exhaust Streams and one or more adjoining air pollution control devices that reduces emissions of Ethylene Oxide.

(10) ELEMENT is any drum, container, bin, or other vessel used to store Sterilant Gas or any Ethylene Oxide-contaminated liquids or solids.

~~(6)~~ (11) ETHYLENE OXIDE (C_2H_4O) is a colorless, flammable gas that has been identified as a suspected human carcinogen and a toxic air contaminant by the California Air Resources Board (CARB).

~~(7)~~ (12) EXHAUST STREAM is ~~the ethylene oxide~~ Ethylene Oxide-contaminated effluent. ~~emitted from a sterilizer or aerator.~~

(13) LARGE FACILITY is any facility performing Sterilization that is permitted to use more than or equal to 2,000 pounds (lbs) of Ethylene Oxide per calendar year.

(14) LARGE WAREHOUSE is any Warehouse greater than or equal to 100,000 square feet of indoor floor area in a single building and reporting to U.S. FDA as a Wholesale Distributor or a Third-Party Logistics Provider as required by the Drug Supply Chain Security Act as it exists on [Date of Amendment].

(15) LEAK is the detection of a concentration of Total Organic Compound (TOC) above background, determined according to CARB Test Method 21.

(16) LEEWARD WALL means the furthest exterior wall of a Permanent Total Enclosure that is opposite the Windward Wall.

(17) MEDIUM FACILITY is any facility performing Sterilization that is permitted to use more than 400 lbs and less than 2,000 lbs of Ethylene Oxide per calendar year.

(18) NEW LARGE WAREHOUSE is any Warehouse that is a Large Warehouse after [Date of Amendment].

(19) PALLETIZED UNIT is any pallet, skid, or other container with a collection of Products packaged in paper cartons, corrugated cardboard, or other packaging, often secured with strapping, stretch wrap, shrink wrap, or other binding.

(20) PERMANENT TOTAL ENCLOSURE means any permanent building or containment structure, enclosed with a floor, walls, and a roof to prevent exposure to the elements, (e.g., precipitation, wind, run-off) that has limited openings to allow access for people and vehicles, that is free of breaks or deterioration that could cause or result in fugitive emissions, and has been evaluated to meet the design requirements set forth in U.S. Environmental Protection Agency (EPA) Method 204.

(21) POST-AERATION is the process during which residual Ethylene Oxide off-gasses from Sterilized materials after Aeration is complete until the Sterilized materials leave the facility.

(22) POST-AERATOR is any equipment, area, or room where Post-Aeration occurs including but not limited to areas where Sterilized materials are stored, transferred, loaded, or unloaded.

(23) POST-AERATION STORAGE ~~AERATION ONLY~~ FACILITY is any facility where Post-Aeration occurs on materials which have been Sterilized at another facility.

(24) PRODUCT is any material intended to be Sterilized by Ethylene Oxide, and may include primary packaging.

(25) SEMI-CONTINUOUS EMISSION MONITORING is a monitoring technique in which a minimum of one measurement (e.g. concentration, mass emission, flow rate) is taken and recorded every fifteen (15) minutes.

(26) SEMI-CONTINUOUS EMISSION MONITORING SYSTEM (SCEMS) is the total combined equipment and systems to semi-continuously determine air contaminant and diluent gas concentrations and/or the mass emission rate in a source effluent (as applicable). The system consists of three major subsystems: sampling interface, analyzer and data acquisition system. This class of monitoring includes but is not limited to gas chromatography, integrated sensitized tape analyzer, other sample integration based technologies, and time-shared CEMS.

(27) SMALL FACILITY is any facility performing Sterilization that is permitted to use more than four (4) lbs and less than or equal to 400 lbs of Ethylene Oxide per calendar year.

(28) STERILANT GAS is Ethylene Oxide, or any combination of Ethylene Oxide and other gases, used to perform Sterilization.

(29) STERILANT GAS STORAGE AREA is any cabinet, area, or room used to store Sterilant Gas not in current use by a Sterilizer or Combined Sterilizer/Aerator.

~~(11)~~ STERILIZATION~~/FUMIGATION~~ is the process where Sterilant Gas

(30) ~~ethylene oxide or any combination of ethylene oxide and other gases are~~ is used to destroy bacteria, viruses, fungi, and other unwanted organisms on materials. This includes fumigation processes using Sterilant Gas. ~~These materials include, by way of illustration and not limitation, medical products, cosmetics, and foodstuffs.~~

(31) STERILIZATION CYCLE is the process where Products and other incidental materials are exposed to Sterilant Gas in a Sterilizer or a Combined Sterilizer/Aerator.

(32) STERILIZED is having undergone a Sterilization Cycle in a Sterilizer or a Combined Sterilizer/Aerator.

~~(12)~~ STERILIZER is any chamber or related piece of equipment (excluding a

(33) Combined Sterilizer/Aerator) that uses Sterilant Gas ~~ethylene oxide or an ethylene oxide mixture~~ in ~~any sterilization~~ Sterilization~~or fumigation process~~.

~~(13)~~ STERILIZER EXHAUST VACUUM PUMP is a device (including any

(34) associated heat exchanger) used to evacuate ~~sterilant gas~~ Sterilant Gas during the ~~sterilizer cycle~~ Sterilization Cycle, but is not a device used solely to evacuate a Sterilizer or Combined Sterilizer/Aerator ~~sterilizer~~ prior to the introduction of Sterilant Gas ~~ethylene oxide~~.

(36) WAREHOUSE is any building with the primary purpose of storing materials for later distribution to intermediaries or users of stored materials.

(37) WASTE STORAGE AREA is any cabinet, area, or room used to store any Ethylene Oxide-contaminated liquids and solids produced as a consequence of Sterilization and associated processes.

(38) WINDWARD WALL means the exterior wall of a Permanent Total Enclosure which is most impacted by the wind in its most prevailing direction determined by a wind rose using data from the nearest meteorological station.

(d) Large Facility Requirements

(1) Stack Emission Requirements

Beginning December 31, 2024, the owner or operator of a Large Facility shall:

(A) Install and maintain a Back-Draft Valve for each Sterilizer and operate the Back-Draft Valve when unloading the Sterilizer;

(B) Vent the Exhaust Stream of any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, and Permanent Total Enclosure to a Control System;

(C) Within 60 days after the initial operations of a Control System and no later than 12 months from the day of the most recent source test

that demonstrates compliance with all applicable requirement thereafter, conduct a source test that meets the requirements in subdivision (m) for each Control System;

(D) Monitor the emissions from the exhaust stack(s) of each Control System by operating a SCEMS or CEMS, pursuant to subdivision (j);

(E) Demonstrate a facility-wide mass emission rate of 0.025 pounds per hour (lbs/hr) or less of Ethylene Oxide from all Control Systems by a source test pursuant to subdivision (m) and, averaged over each calendar day in operation, by a SCEMS or CEMS pursuant to subdivision (j); and

(F) For each Control System:

(i) Demonstrate control of Ethylene Oxide emissions with 99.99% efficiency or greater, by weight, by a source test pursuant to subdivision (m); or

(ii) Demonstrate emissions of Ethylene Oxide at a concentration of 0.01 parts per million (ppm) or less, by volume, by a source test pursuant to subdivision (m) and by a SCEMS or CEMS pursuant to subdivision (j).

(2) Fugitive Emissions Requirements

Beginning December 31, 2024, the owner or operator of a Large Facility shall:

(A) Operate any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, Sterilant Gas Storage Area, and Waste Storage Area within a Permanent Total Enclosure that meets the requirements in subdivision (k); and

(B) Operate a Control System within a Permanent Total Enclosure that meets the requirements in subdivision (k) or monitor all Components up to the exhaust stack of Control System by implementing a Leak Detection and Repair Program that meets the requirements in subdivision (n).

(3) Other Requirements

Beginning [3 Months After Date of Adoption], the owner or operator of a Large Facility shall:

(A) Record the destinations of Sterilized Palletized Units shipped;

(B) Place on a vertical surface on each Sterilized Palletized Unit at least one label, size 8.5 inches by 11 inches, with letters of sufficient size and contrast as to be readily visible and legible, reading:

STERILIZED WITH ETHYLENE OXIDE (EtO/EO) ON {Date of Sterilization}

(C) Clearly label each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, ~~and~~ Aerator, and Permanent Total Enclosure with:

(i) Type of equipment, area, or room;

(ii) Unit number or other identifier, if applicable; and

(iii) South Coast AQMD permit number, if applicable; and

(D) Label or write on each bill of lading, "STERILIZED WITH ETHYLENE OXIDE (EtO/EO)"; and

(E) Prepare and maintain onsite a facility diagram that identifies each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, and Aerator, and Permanent Total Enclosure.

(e) Medium Facility Requirements

(1) Stack Emission Requirements

Beginning July 1, 2025, the owner or operator of a Medium Facility shall:

(A) Vent the Exhaust Stream of any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator that immediately follow an Aerator or Combined Sterilizer/Aerator, and Permanent Total Enclosure to a Control System; and

(B) Within 60 days after the initial operations of a Control System and no later than 12 months from the day of the most recent source test that demonstrates compliance with all applicable requirement thereafter, conduct a source test that meets the requirements in subdivision (m) for each Control System that demonstrates either:

(i) Control of Ethylene Oxide emissions with 99.9% efficiency or greater, by weight; or

(ii) Does not emit Ethylene Oxide at a concentration greater than 0.01 ppm, by volume.

(2) Fugitive Emissions Requirements

Beginning July 1, 2025, the owner or operator of a Medium Facility shall:

(A) Operate each of the following within a Permanent Total Enclosure that meets the requirements in subdivision (k):

(i) Sterilizer, if applicable;

(ii) Aerator, if applicable; and

(iii) Post-Aerator that immediately follows~~ing~~ an Aerator or Combined Sterilizer/Aerator; and

(B) Operate each of the following either within a Permanent Total Enclosure that meets the requirements in subdivision (k) or monitor each of the following by implementing a Leak Detection and Repair Program that meets the requirements in subdivision (n):

(i) Combined Sterilizer/Aerator, if applicable;

(ii) Back-Draft Valve, if applicable;

(iii) All Components up to the exhaust stack of the Control System;

(iv) Sterilant Gas Storage Area; and

(v) Waste Storage Area, if applicable.

(3) Other Requirements

Beginning July 1, 2025, the owner or operator of a Medium Facility shall:

(A) Clearly label each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator subject to the requirements of clause (e)(2)(A)(iii), and Permanent Total Enclosure with:

(i) Type of equipment, area, or room;

(ii) Unit number or other identifier, if applicable; and

(iii) South Coast AQMD permit number, if applicable; and

(B) Prepare and maintain onsite a Facility diagram that identifies each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator subject to the requirements of clause (e)(2)(A)(iii), and Permanent Total Enclosure.

(f) Small Facility Requirements

(1) Stack Emission Requirements

Beginning December 31, 2025, the owner or operator of a Small Facility shall:

(A) Vent the Exhaust Stream of any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, and Permanent Total Enclosure to a Control System; and

(B) Within 60 days after the initial operations of a Control System and no later than 12 months from the day of the most recent source test that demonstrates compliance with all applicable requirement thereafter, conduct a source test that meets the requirements in subdivision (m) for each Control System that demonstrates either:

(i) Control of Ethylene Oxide emissions with 99.9% efficiency or greater, by weight; or

(ii) Emits Ethylene Oxide at a concentration of 0.01 ppm or less, by volume.

(2) Fugitive Emission Requirements

Beginning December 31, 2025, the owner or operator of a Small Facility shall:

(A) Operate the following areas and processes within a Permanent Total Enclosure pursuant to subdivision (k):

(i) Sterilizer, if applicable; and

(ii) Aerator, if applicable; and

(B) Operate the following areas and processes within a Permanent Total Enclosure pursuant to subdivision (k) or monitor the following areas and processes by implementing a Leak Detection and Repair Program that meets the requirements in subdivision (n):

(i) Combined Sterilizer/Aerator, if applicable;

(ii) All Components up to the exhaust stack of the Control System;

(iii) Post-Aerator;

(iv) Sterilant Gas Storage Area;

(v) Waste Storage Area, if applicable; and

(vi) Back-Draft Valve, if applicable.

(3) Other Requirements

Beginning December 31, 2025, the owner or operator of a Small Facility shall:

(A) Clearly label each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, and Aerator with:

(i) Type of equipment, area, or room;

(ii) Unit number or other identifier, if applicable; and

(iii) South Coast AQMD permit number, if applicable; and

(B) Prepare and maintain onsite a Facility diagram that identifies each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, and Permanent Total Enclosure.

(g) Post-Aeration Storage Facility Requirements

Beginning [3 Months After Date of Adoption], the owner or operator of a Post-Aeration Storage Facility that vents the Exhaust Stream of a Post-Aerator to a Control System shall:

(1) Within 60 days after the initial operations of a Control System and no later than 12 months from the day of the most recent source test that demonstrates compliance with all applicable requirement thereafter, conduct a source test that meets the requirements in subdivision (m) for each Control System that demonstrates each Control System controls Ethylene Oxide emissions with 95% efficiency or greater, by weight;

(2) Operate a Control System within a Permanent Total Enclosure that meets the requirements in subdivision (k) or monitor all Components up to the exhaust stack of Control System by implementing a Leak Detection and Repair Program that meets the requirements in subdivision (n);

(3) Record the number of Sterilized Palletized Units received;

(4) Clearly label each Post-Aerator and Permanent Total Enclosure with:

(A) Type of equipment, area, or room, if applicable;

(B) Unit number or other identifier, if applicable; and

(C) South Coast AQMD permit number, if applicable; and

(5) Prepare and maintain onsite a facility diagram that identifies each Post-Aerator and Permanent Total Enclosure.

(h) Warehouse Reporting Requirements

(1) The owner or operator of an Large Warehouse, New Large Warehouse, or a Warehouse designated pursuant to paragraph (h)(5) shall record the number of Sterilized Palletized Units received each month pursuant to the schedule specified in Table 1 – Warehouse Recording Schedule.

Table 1 – Warehouse Recording Schedule

Type of Warehouse	Start Date to Record Number of Sterilized Palletized Units	End Date to Record Number of Sterilized Palletized Units
Large Warehouse	July 1, 2023	June 30, 2024
New Large Warehouse	30 days after starting operation	395 days after starting operation
Designated Warehouse	30 days after being designated	Per notification by Executive Officer

(2) The owner or operator of an Large Warehouse, New Large Warehouse, or a Warehouse designated pursuant to paragraph (h)(3) shall submit an initial summary report to the Executive Officer to document the number of Sterilized Palletized Units received in the preceding twelve months pursuant to the schedule specified in Table 2 – Warehouse Initial Report Schedule that includes the following:

(A) Name of Warehouse;

(B) South Coast AQMD facility ID, if applicable;

(C) Address of Warehouse;

(D) Contact information for Warehouse;

(E) Total number of Sterilized Palletized Units received each month for the preceeding 12-month period; and

(F) Addresses of where Sterilized Palletized Units shipped from.

Table 2 – Warehouse Initial Report Schedule

Type of Warehouse	Submittal of Initial Summary Report
Large Warehouse	No later than August 1, 2024
New Large Warehouse	No later 425 days after starting operation
Designated Warehouse	No later than 425 days after being designated by Executive Officer

(3) The Executive Officer may designate any Warehouse to comply with paragraphs (h)(1) and (h)(2) if the Executive Officer has information that the Warehouse is a potential source of Ethylene Oxide emissions. The Executive Officer will notify the owner or operator in writing if a Warehouse is designated.

(i) Interim Requirements

(1) ~~The following requirements shall be met by December 21, 1992 by t~~The owner of operator of a facility performing Sterilization ~~all persons~~ who uses a total of 400 ~~pounds~~lbs or less of ~~e~~Ethylene ~~o~~Oxide per calendar year:

(A) Sterilizer(s) and Combined Sterilizer/Aerator(s) shall be vented to a ~~e~~Control System~~equipment~~ with an efficiency of 99 ~~percent~~ % or more, by weight.

(B) If ~~e~~Ethylene ~~o~~Oxide emissions from ~~a~~Aeration are greater than four pounds per calendar year, the ~~a~~Aerator(s) shall be vented to a ~~e~~Control System~~equipment~~ with an efficiency of 95 ~~percent~~% or more, by weight.

(C) If the ~~e~~Exhaust ~~s~~Streams from the equipment identified in subparagraphs (h)(1)(A) and (h)(1)(B) are vented to the same ~~e~~Control System~~equipment~~, the combined efficiency must be 98.8 ~~percent~~% or more, by weight.

(2) ~~The following requirements shall be met by June 21, 1992 by t~~The owner of operator of a facility performing ~~s~~Sterilization ~~all persons~~ who uses a total of more than 400 ~~pounds~~lbs and less than or equal to 4,000 ~~pounds~~ lbs of ~~e~~Ethylene ~~o~~Oxide per calendar year:

(A) Sterilizer(s) and Combined Sterilizer/Aerator(s) shall be vented to a ~~e~~Control System~~equipment~~ with an efficiency of 99.9 ~~percent~~% or more, by weight.

(B) Aerator(s) shall be vented to a ~~e~~Control System~~equipment~~ with an efficiency of 95 ~~percent~~% or more, by weight.

(C) Back-~~d~~Draft ~~exhaust~~ ~~v~~Valve(s) shall be vented to a ~~e~~Control System~~equipment~~ with an efficiency of 95 percent or more, by weight.

(D) If the ~~e~~Exhaust ~~s~~Streams from the equipment identified in subparagraphs (h)(2)(A), (h)(2)(B), and (h)(2)(C) are vented to the same ~~e~~Control System~~equipment~~, the combined efficiency must be 99.6 ~~percent~~% or more, by weight.

(3) ~~The following requirements shall be met by December 21, 1991 by t~~The owner of operator of a facility performing Sterilization ~~all persons~~ who uses a total of more than 4,000 ~~pounds~~ lbs of ~~e~~Ethylene ~~o~~Oxide per calendar year:

(A) Sterilizer(s) and Combined Sterilizer/Aerator(s) shall be vented to a ~~e~~Control Systems~~equipment~~ with an efficiency of 99.9 ~~percent~~% or more, by weight.

(B) Aerator(s) and ~~s~~Sterilizer door hood ~~e~~Exhaust ~~s~~Stream(s) shall be vented to control equipment with an efficiency of 99 ~~percent~~% or more, by weight.

(C) Back-~~d~~Draft ~~exhaust v~~Valve(s) shall be vented to control equipment with an efficiency of 99 ~~percent~~% or more, by weight.

(D) If the ~~e~~Exhaust ~~s~~Streams from the equipment identified in subparagraphs (h)(3)(A), (h)(3) (B), and (h)(3) (C) are vented to the same control equipment, the combined efficiency must be 99.8 percent or more, by weight.

(4) The owner or operator of a facility that performs Aeration or Post-Aeration of materials that are Sterilized with Sterilant Gas at another facility and have permit to operate issued by South Coast AQMD prior to [Date of Adoption] to control Ethylene Oxide emissions ~~Persons owning or operating aeration only facilities~~ where more than four ~~pounds~~ lbs of ~~e~~Ethylene ~~o~~Oxide are emitted per calendar year shall install a ~~e~~Control System ~~equipment~~ with an efficiency of 95 ~~percent~~% or more, by weight ~~by June 21, 1992~~.

(5) Sterilizers, Combined Sterilizer/Aerators, ~~a~~Aerators, ~~e~~Control Systems~~equipment~~, and emissions collection systems shall be leak free ~~effective December 21, 1990.~~. ~~-~~ The maximum ~~s~~Sterilant ~~g~~Gas mass flow shall be ~~less than 30 parts per million ethylene oxide for sterilant gas composed of 12 percent ethylene oxide/88 percent chlorofluorocarbon-12, by weight, and~~ less than 10 parts per million ethylene oxide ~~for other compositions of sterilant gas~~, as measured one (1) centimeter away from any portion of a ~~s~~Sterilizer, Combined Sterilizer/Aerator, ~~a~~Aerator, or ~~e~~Control Systems~~equipment~~ that could have an ~~e~~Ethylene ~~o~~Oxide leak. Leak tests shall be conducted during conditions of maximum ~~s~~Sterilant ~~g~~Gas mass flow. Leak tests shall be conducted every six months, as specified in paragraph (~~f~~i)(8).~~, Test Methods.~~

(6) The owner or operator of a Large Facility, Medium Facility, Small Facility or Post-Aeration Storage Facility ~~All persons subject to this rule~~ shall conduct source tests on ~~e~~Control Systems~~equipment~~ within 60 days after the initial operation of the equipment to verify compliance with control

efficiency requirements, as specified in paragraph (~~f~~i)(7)~~, Test Methods~~. Thereafter, ~~annual~~ source tests shall be conducted on ~~catalytic oxidation, carbon, or solid bed c~~Control Systems~~equipment~~ at least once per calendar year. ~~More frequent source tests, or source tests on other control equipment, may be required at the District's discretion.~~

~~(7) A person shall not discharge any sterilizer exhaust vacuum pump working fluid to the wastewater stream.~~

~~(8) By July 1, 1992, all persons who use more than 30,000 pounds of chlorofluorocarbons per calendar year for ethylene oxide sterilization, except at hospitals, shall vent the sterilizer exhaust to recovery or reclamation equipment with an efficiency of 70 percent or more, by weight.~~

~~(9) A person shall not use chlorofluorocarbon diluents in ethylene oxide sterilization, effective January 1, 1997.~~

(7) Source tests shall be conducted according to CARB Test Method 431 or an acceptable source test method approved by the CARB and the Executive Officer. In addition, the following requirements shall be met:

(A) Tests on control equipment shall be run with a typical load in the sterilizer or aerator.

(B) The inlet and outlet of the control equipment shall be sampled simultaneously during testing to measure the control efficiency.

(C) The efficiency of control equipment shall be determined under normal operating conditions. To measure the control efficiency on the sterilizer exhaust stream, sampling shall be done during the entire duration of the first sterilizer evacuation and subsequent air washes after ethylene oxide has been introduced. To measure the control efficiency on an aerator exhaust stream with a constant air flow, sampling shall be done during a period of at least 60 minutes, starting 15 minutes after aeration begins. To measure the control efficiency of the control equipment on an aerator exhaust stream with a non-constant air flow, sampling shall be done during the entire duration of the first aerator evacuation after aeration begins.

(8) Leak tests shall be conducted by CARB Test Method 21 using a portable flame ionization detector or a non-dispersive infrared analyzer calibrated with methane, or an acceptable alternative method or analytical instrument approved by the Executive Officer.

(j) SCEMS or CEMS Requirements for Stack Emissions

(1) The owner or operator of a facility required to monitor the emissions from a Control System shall install and operate a SCEMS or CEMS for each Control System that:

(A) Measures the following parameters:

(i) Ethylene Oxide concentration, in increments no greater than 0.01 ppm, by volume;

(ii) Oxygen concentration; and

(iii) Exhaust stack flow rate; and

(B) Measures at a location reviewed and approved by the Executive Officer during the SCEMS or CEMS certification process;

(C) Meets the performance requirements for certification and quality assurance of the SCEMS or CEMS established by South Coast AQMD; and

(D) Is equipped with a data acquisition system (DAS) that is capable of logging direct measurements and providing the date, time, and applicable Ethylene Oxide performance standard.

(2) The owner or operator of a facility required to operate a SCEMS or CEMS shall install and operate a system capable of calculating the mass emission rate, expressed in lbs/hr, averaged over a calendar day from all Control Systems.

(3) The owner or operator of a facility required to operate a SCEMS or CEMS shall install and operate a backup battery that provides uninterruptible power supply to ensure operation of the SCEMS or CEMS during a power outage.

(4) The owner or operator of a facility required to operate a~~n~~ SCEMS or CEMS shall maintain and calibrate each SCEMS or CEMS pursuant to manufacturer specification.

(k) Permanent Total Enclosure Requirements

The owner or operator of a facility required to operate within a Permanent Total Enclosure shall:

(1) Demonstrate the Permanent Total Enclosure is maintained at a negative pressure of at least 0.007 inches H2O at least once per minute;

(2) Install, operate, and maintain a digital differential pressure monitoring system for each Permanent Total Enclosure as follows:

(A) A minimum of one digital differential pressure monitor at each of the following three walls in each Permanent Total Enclosure having a total ground surface area of 10,000 square feet or more:

(i) The Leeward Wall;

(ii) The Windward Wall;

(iii) An exterior wall that:

(I) Connects the Leeward and Windward wall at a location defined by the intersection of a perpendicular line between a point on the connecting wall and a point on its furthest opposite exterior wall;

(II) Intersects within plus or minus ten (+/-10) meters of the midpoint of a straight line between the two other monitors specified in clauses (k)(3)(A)(i) and (k)(3)(A)(ii); and

(III) Is not located on the same wall as either of the other two monitors described in clauses (k)(3)(A)(i) or (k)(3)(A)(ii);

(B) A minimum of one building digital differential pressure monitor at the Leeward Wall of each Permanent Total Enclosure that has a total ground surface area of less than 10,000 square feet.

(C) Certified by the manufacturer to be capable of measuring and displaying negative pressure in the range of 0.005 inches to 0.110 inches H2O with a minimum increment of measurement of plus or minus 0.0005 inches H2O;

(D) Equipped with a continuous strip chart recorder or electronic recorder approved by the Executive Officer. If an electronic recorder is used, the recorder shall be capable of writing data on a medium that is secure and tamper-proof. The recorded data shall be readily accessible upon request by the Executive Officer. If software is required to access the recorded data that is not readily available to the Executive Officer, a copy of the software, and all subsequent revisions, shall be provided to the Executive Officer at no cost. If a device is required to retrieve and provide a copy of such

recorded data, the device shall be maintained and operated at the facility;

(E) Calibrated pursuant to manufacturer's specifications at least once every 12 calendar months or more frequently if recommended by the manufacturer; and

(F) Equipped with a backup, uninterruptible power supply to ensure operation of the monitoring system during a power outage.

(3) Demonstrate pursuant to U.S. EPA Method 204 at least once per calendar month an inward air velocity of at least 200 feet per minute (fpm) at each natural draft opening.

(4) Notify the Executive Officer in the event of failing to meet the negative pressure performance standard specified in paragraph (k)(1) or if there are more than 24 consecutive hours of missing data in writing by electronic mail to Rule1405notifications@aqmd.gov or verbally by telephone to 1-800-CUT-SMOG.

(l) Record ~~K~~keeping

(1) The owner or operator of any facility performing Sterilization shall maintain records of, as applicable:

(A) The number of ~~s~~Sterilization~~er~~ ~~c~~Cycles and the pounds of Sterilant Gas ~~ethylene oxide~~ (measured or calculated) used per Sterilization ~~c~~Cycle for each ~~s~~Sterilizer and each Combined Sterilizer/Aerator each operating day; ~~or~~

(B) The total pounds of Sterilant Gas ~~ethylene oxide~~ purchased and the total pounds of Sterilant Gas used per calendar month and calendar year, respectively, provided that monthly totals are also kept.;

(C) Data collected from the SCEMS or CEMS pursuant to subdivision (j);

(D) Source test reports pursuant to subdivision (m);

(E) Measurements of inward face velocity pursuant to subdivision (k);

(F) Data collected from the digital differential pressure monitoring system in Permanent Total Enclosures pursuant to subdivision (k);

(G) Plot-plan reports, daily check, and monthly inspections for LDAR programs pursuant to subdivision (n)~~Documentation and results of leak tests; and either~~;

(H) The number~~s~~ of Sterilized Palletized Units shipped, grouped by destination, pursuant to subparagraph (d)(3)(A); and

(I) The facility diagram pursuant to subparagraph (d)(3)(D).

(2) The owner or operator of a Post-Aeration Storage Facility subject to subdivision (g) shall maintain records of, as applicable:

(A) Source test reports pursuant to subdivision (m);

(B) Measurements of inward face velocity pursuant to subdivision (k);

(C) Data collected from the digital differential pressure monitoring system in Permanent Total Enclosures pursuant to subdivision (k);

(D) Plot-plan reports, daily check, and monthly inspections for LDAR programs pursuant to subdivision (n);

(E) The number of Sterilized Palletized Units received pursuant to paragraph (g)(4); and

(F) The facility diagram pursuant to paragraph (g)(6).

(3) The owner or operator of any facility~~Any person~~ subject to this rule shall ~~maintain~~ retain all applicable ~~written~~ records specified in paragraphs (l)(1) and (l)(2) for at ~~minimum of~~least five years with two years of records maintained onsite ~~and~~. ~~Records shall include:~~

(4) The owner or operator of any facility subject to this rule shall provide all onsite records available to the Executive Officer upon request.

~~Any person subject to this rule shall maintain written records for a minimum of two years and shall make them available to the District upon request. Records shall include:~~

~~(1) Documentation and results of leak tests; and either~~

~~(2) The number of sterilizer cycles and the pounds of ethylene oxide (measured or calculated) used per cycle for each sterilizer each day; or~~

~~(3) The total pounds of ethylene oxide purchased and used per calendar year, provided that monthly totals are also kept.~~

(m) Source Test Requirements ~~Test Methods~~

The owner or operator of a facility required to conduct source test shall:

(1) Prior to conducting any source test, submit a source test protocol for approval to the Executive Officer that includes:

(A) Operating conditions of any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, and Permanent Total Enclosure being controlled by the Control System;

(B) Number of Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, and Permanent Total Enclosure being controlled by the Control System; and

(C) Planned sampling parameters;

(2) Report the source test schedule to the Executive Officer at least 10 days prior to the start of source test in writing by electronic mail to Rule1405notifications@aqmd.gov or verbally by telephone to 1-800-CUT-SMOG;

(3) Report any changes to the source test schedule in writing or verbally 24 hours prior to the start of source testing or within one (1) hour of discovery of a change in the source testing schedule;

(4) Conduct a source test:

(A) Pursuant to the source test protocol approved by the Executive Officer;

(B) With triplicate runs at typical operating conditions, as specified in the source test protocol;

(C) With triplicate runs at the permitted maximum operating conditions, if any, in the Sterilizers, Combined Sterilizer/Aerators, Aerators, or Post-Aerators, as applicable;

(D) With each run being a minimum of 60 minutes;

(E) Pursuant to CARB Method 431, U.S. EPA Method TO-15 or TO-15A, or an acceptable source testing method approved by the Executive Officer.

(F) Assessing the efficiency of controlling Ethylene Oxide emissions by:

(i) Measuring or determining the total inlet amount of Ethylene Oxide entering the Control System from any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, and Permanent Total Enclosure being controlled by the Control System;

(ii) Measuring the outlet amount of Ethylene Oxide exhausted from the Control System;

(5) Submit the source testing report to the South Coast AQMD staff and/or department as specified in the source test protocol within 60 days of completing source testing.

~~(B) The inlet and outlet of the control equipment shall be sampled simultaneously during testing to measure the control efficiency.~~

~~(C) The efficiency of control equipment shall be determined under normal operating conditions. To measure the control efficiency on the sterilizer exhaust stream, sampling shall be done during the entire duration of the first sterilizer evacuation and subsequent air washes after ethylene oxide has been introduced. To measure the control efficiency on an aerator exhaust stream with a constant air flow, sampling shall be done during a period of at least 60 minutes, starting 15 minutes after aeration begins. To measure the control efficiency of the control equipment on an aerator exhaust stream with a non-constant air flow, sampling shall be done during the entire duration of the first aerator evacuation after aeration begins.~~

(n) Leak Detection and Repair (LDAR) Program Requirements

The owner or operator of a facility required to implement an LDAR program shall:

(1) Prepare and maintain onsite a plot-plan report that identifies all Components and Elements subject to the LDAR program;

(2) Maintain clear labeling using tags or other means to physically identify all Components subject to the LDAR program;

(3) Demarcate using tape or other means all locations of all Elements subject to the LDAR program;

(4) Maintain all Components and Elements subject to the LDAR program free of Leaks greater than 2 ppm above background;

(5) Perform daily audio-visual checks for all applicable Components and Elements; and

(6) Perform monthly leak inspections of all applicable Components and Elements pursuant to CARB Test Method 21 using a portable flame ionization detector or a non-dispersive infrared analyzer calibrated with isobutylene, or an acceptable alternative method or analytical instrument approved by the Executive Officer.

(o) Prohibitions

(1) The owner or operator of a facility performing Sterilization ~~A person~~ shall not discharge any ~~s~~Sterilizer ~~e~~Exhaust ~~v~~Vacuum ~~p~~Pump working fluid to the wastewater stream.

(2) The owner or operator of a facility performing Sterilization ~~A person~~ shall not use ~~c~~Chlorofluorocarbon ~~d~~Diluents in ~~ethylene oxide~~ ~~s~~Sterilization~~, effective January 1, 1997~~.

(3) The owner or operator of a facility performing Sterilization shall not allow the release of uncontrolled emission of Ethylene Oxide to atmosphere from any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, or Permanent Total Enclosure at any time.

(p) Exemptions

~~The provisions of paragraph (d), "Requirements," of this rule shall not apply to any person who uses less than or equal to four pounds of ethylene oxide per calendar year.~~

(1) The requirements of subdivisions (i) and (o) do not apply to any owner or operator who is permitted to use four (4) pounds or less of Ethylene Oxide per calendar year.

(2) The requirements of subdivision (i) do not apply to any facility subject to requirements of subdivision (d), (e), (f), or (g) pursuant to the schedule specified in Table 3 – Interim Requirements.

Table 3 – Interim Requirements

Applicable Subdivision	Beginning Date of Exemption
(d)	December 31, 2024
(e)	July 1, 2025
(f)	December 31, 2025
(g)	[3 Months After Date of Adoption]