

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

*[Rule index to be added after Amendment]*

(a) Purpose

The purpose of this rule is to protect public health by reducing ~~e~~Ethylene ~~e~~Oxide emissions from ~~s~~Sterilization ~~and related operations~~ ~~or fumigation operations in the South Coast Air Basin~~ and to collect information from warehouses receiving ~~materials Sterilized with Ethylene Oxide~~ 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 ~~e~~Oxide ~~for s~~Sterilization ~~or fumigation, any Post-Aeration Storage Facility, any Tier I Warehouse, and any Tier II Warehouse.~~ ~~or 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 ~~Sterilized~~ ~~previously sterilized~~ materials ~~in an Aerator or a Combined Sterilizer/Aerator~~ after the ~~Sterilization Cycle~~ ~~sterilization cycle~~ is completed. ~~Aeration is completed when Products have been aerated for the minimum time specified in protocols, work orders, validation documents, or manufacturer's instructions, and have been removed from the Aerator or the Combined Sterilizer/Aerator.~~ ~~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.~~

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

- ~~(2)~~ AERATOR is any equipment (excluding a Sterilizer or a Combined Sterilizer/Aerator), ~~areospace,~~ or room in which air is used to perform Aeration, ~~remove residual ethylene oxide from sterilized materials.~~
- ~~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.
- ~~(4)~~ BASELINE OPERATION is the daily average pounds (lbs) of Ethylene Oxide used in the seven (7) Sterilizer or Combined Sterilizer/Aerator operating days including and prior to the date of the monitoring result or sampling day completion.
- ~~(5)~~ 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.
- ~~(6)~~ COMPONENT is any seal, gasket, or connection in Ethylene Oxide service at a Sterilizer, Sterilizer Exhaust Vacuum Pump, Combined Sterilizer/Aerator, Aerator, or Control System.
- ~~(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 (3) major subsystems: sampling interface, analyzer, and data acquisition system. The CEMS is able to take and record a minimum of one (1) measurement (e.g., concentration, mass emission, flow rate) every one (1) minute.
- ~~(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 reducing Ethylene Oxide emissions consisting of one (1) or more adjoining air pollution control devices in series or parallel and exhausts to one (1) or more stacks.

- (10) ELEMENT is any bulk cylinder, ampule, cartridge, drum, container, bin, or other vessel used to store Sterilant Gas or any Ethylene Oxide-contaminated liquids or solids. Elements exclude Sterilized materials and shipping containers.
- (11) ETHYLENE OXIDE (C<sub>2</sub>H<sub>4</sub>O) is a colorless, flammable gas that has been  
(6) identified as a suspected human carcinogen and a toxic air contaminant by the California Air Resources Board (CARB).
- (12) EXHAUST STREAM is the ethylene oxide Ethylene Oxide-contaminated  
(7) effluent, emitted from a sterilizer or aerator.
- (13) FACILITY is any source or group of sources or other air contaminant-emitting activities which are located on one (1) or more contiguous properties within South Coast AQMD, in actual physical contact or separated solely by a public roadway or other public right-of-way, and are owned or operated by the same person (or by persons under common control), or an outer continental shelf (OCS) source as determined in 40 CFR Section 55.2. Such above-described groups, if noncontiguous, but connected only by land carrying a pipeline, shall not be considered one (1) Facility.
- (14) FIRST DESTINATION is a location that receives Sterilized Palletized Units shipped from a Facility performing Sterilization.
- (15) LARGE FACILITY means a Facility performing Sterilization permitted to use more than or equal to 2,000 lbs of Ethylene Oxide per calendar year, either expressed as a facility-wide permit limit or calculated as the sum of permit limits for equipment that perform Sterilization at the Facility.
- (16) LEAK is the detection of a concentration of Total Organic Compounds (TOC) above background, determined according to CARB Test Method 21.
- (17) LEEWARD WALL means the furthest exterior wall of a Permanent Total Enclosure that is opposite the Windward Wall.
- (18) 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, either expressed as a facility-wide permit limit or calculated as the sum of permit limits for equipment that perform Sterilization at the Facility.
- (19) PACKAGING AREA is any area used to perform packaging or re-packaging of Sterilized materials that have completed Aeration and

biological indicator sterility testing. A Packaging Area excludes areas used for handling or storage of Sterilized Palletized Units.

- (20) 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.
- (21) PERMANENT TOTAL ENCLOSURE (PTE) 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 except the term “Administrator” in provision 5.1 is revised to mean Executive Officer, as defined in Rule 102 – Definitions of Terms.
- (8) ~~PERSON is any firm, business establishment, association, partnership, corporation or individual, whether acting as principal, agent, employee or other capacity, including any governmental entity or charitable organization.~~
- (22) POST-AERATOR is any equipment, area, or room where Sterilized materials are stored, transferred, loaded, or unloaded after completing Aeration. Post-Aerator excludes:
- (A) Motor vehicles used during loading, unloading, and transport;
- (B) Equipment, area, or room that is an Aerator or a Combined Sterilizer/Aerator; and
- (C) Packaging Areas at a Large Facility permitted to use less than 20,000 lbs of Ethylene Oxide per calendar year.
- (23) POST-AERATION STORAGE FACILITY is any Facility not performing Sterilization that stores Sterilized materials and has installed a Control System.
- (24) PRECONDITIONER is any equipment, area, or room used to treat Products prior to a Sterilization Cycle to attain a specific temperature and relative humidity.
- (25) PRODUCT is any material intended to be Sterilized by Ethylene Oxide and may include primary packaging.

- (9) ~~RECOVER is to remove refrigerant in any condition from a system and store it in an external container, without necessarily testing or processing it in any way.~~
- (10) ~~RECLAIM is to process refrigerant to new product specifications.~~
- (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 SCEMS consists of three (3) 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. The SCEMS is able to take and record a minimum of one (1) measurement (e.g., concentration, mass emission, flow rate) every fifteen (15) minutes.
- (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, either expressed as a facility-wide permit limit or calculated as the sum of permit limits for equipment that perform Sterilization at the Facility.
- (28) STERILANT GAS is Ethylene Oxide, or any combination of Ethylene Oxide and other gases, used to perform Sterilization.
- (29) STERILANT GAS DISPENSING AREA is any area used to dispense Sterilant Gas used by a Sterilizer or a Combined Sterilizer/Aerator.
- (30) STERILANT GAS STORAGE AREA is any area used to store Sterilant Gas not in use by a Sterilizer or a Combined Sterilizer/Aerator.
- (31) ~~STERILIZATION/FUMIGATION is the process where Sterilant Gas~~  
(11) ~~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.~~
- (32) STERILIZATION CYCLE is the process where Products and other materials are exposed to Sterilant Gas in a Sterilizer or a Combined Sterilizer/Aerator. A Sterilization Cycle is completed when Products are removed from the Sterilizer or the Combined Sterilizer/Aerator.

- (33) STERILIZED is having undergone a Sterilization Cycle in a Sterilizer or a Combined Sterilizer/Aerator.
- (34) STERILIZER is any chamber or related piece of equipment (excluding a  
(12) Combined Sterilizer/Aerator) that uses Sterilant Gas ethylene oxide or an ethylene oxide mixture in any sterilization Sterilization or fumigation process.
- (35) STERILIZER EXHAUST VACUUM PUMP is a device (including any  
(13) 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 a Combined Sterilizer/Aerator sterilizer prior to the introduction of Sterilant Gas ethylene oxide.
- (36) TIER I WAREHOUSE is a Facility that has at least one building with at least 250,000 square feet of indoor floor area used for Warehousing Activities and reports to U.S. Food and Drug Administration (FDA) as a Wholesale Distributor or a Third-Party Logistics Provider as of [Date of Rule Amendment].
- (37) TIER II WAREHOUSE is a Facility that has at least one building with at least 100,000 square feet and less than 250,000 square feet of indoor floor area used for Warehousing Activities, reports to U.S. FDA as a Wholesale Distributor or a Third-Party Logistics Provider as of [Date of Rule Amendment].
- (38) TRIGGER RESULT is the 24-hour average Ethylene Oxide concentration obtained via a canister sample or other approved methodology in the Fenceline Air Monitoring Plan that is at or above the applicable trigger threshold specified in Table 5 – Trigger Threshold for Sterilization Facilities.
- (39) WAREHOUSING ACTIVITIES is operations at a warehouse related to the storage and distribution of goods, including but not limited to the storage, labelling, sorting, consolidation and deconsolidation of Products into different size packages. Supporting office administration, maintenance, manufacturing areas, or retail sales areas open to the general public, within the same warehouse building, that are physically separate from the warehouse area, are not considered Warehousing Activities for the purpose of this rule.

(40) WASTE STORAGE AREA is any area used to store any Ethylene Oxide-contaminated liquids and solids produced as a byproduct of Sterilization and associated processes.

(41) 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 on the date specified in Table 1 – Implementation Schedule, the owner or operator of a Large Facility shall not initiate a new Sterilization Cycle unless the following requirements are met:

(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) For each Control System either:

(i) Meet a control efficiency of 99.99% or greater, by weight, of Ethylene Oxide emissions, demonstrated by a source test that meets the requirements in subdivision (1); or

(ii) Not exceed an Ethylene Oxide concentration of 0.01 parts per million (ppm), by volume, demonstrated by a source test that meets the requirements in subdivision (1);

(D) Not exceed a total mass emission rate of 0.015 pounds per hour (lbs/hr) of Ethylene Oxide from all exhaust stacks at the Facility demonstrated by a source test that meets the requirements in subdivision (1); and

(E) Conduct a source test that demonstrates compliance with requirements in subparagraphs (d)(1)(C) and (d)(1)(D):

(i) No later than July 1, 2025 for a Control System installed or modified on or before May 2, 2025;

(ii) Within 60 days after initial operation of a Control System installed or modified after May 2, 2025; and

(iii) Either no later than 12 calendar months from the date of the most recent source test of the Control System or no later than 36 calendar months from the date of the most recent source test of the Control System that is monitored by a SCEMS or CEMS certified by the Executive Officer that meets the requirements in subdivision (j) to demonstrate compliance with clause (d)(1)(C)(ii).

(2) Stack Emission Monitoring Requirements

Beginning on the date specified in Table 1 – Implementation Schedule, the owner or operator of a Large Facility shall not initiate a new Sterilization Cycle unless the following requirements are met:

(A) Monitor the Ethylene Oxide emissions from each exhaust stack at the Facility by operating a SCEMS or CEMS that meets the requirements in subdivision (j);

(B) Demonstrate by a SCEMS or CEMS that the total mass emission rate of Ethylene Oxide from all exhaust stacks at the Facility does not exceed 0.015 lbs/hr on a rolling 30-day period basis, where the total mass emission rate is the sum of the daily average mass emission rates for each exhaust stack for each calendar day determined from the average of valid hourly averages as calculated from all valid data points acquired during an hour from the SCEMS or CEMS and expressed in lbs/hr; and the rolling 30-day average is determined from the average of valid daily averages over 30 consecutive calendar days; and

(C) For each Control System complying with clause (d)(1)(C)(ii), demonstrate by a SCEMS or CEMS that emissions of Ethylene Oxide do not exceed a concentration of 0.01 ppm or less, by volume, on a rolling 30-day period basis, where the daily average for each calendar day is determined from the average of valid hourly averages as calculated from all valid data points acquired during an hour from the SCEMS or CEMS; and the rolling 30-day average is determined from the average of valid daily averages over 30 consecutive calendar days.

(3) Fugitive Emission Requirements



Beginning on the date specified in Table 1 – Implementation Schedule, the owner or operator of a Large Facility shall not initiate a new Sterilization Cycle unless the following requirements are met:

- (A) Maintain all Sterilizers, Combined Sterilizer/Aerators, Back-Draft Valves, Sterilizer Exhaust Vacuum Pumps, Aerators, Post-Aerators, Elements in a Sterilant Gas Storage Area, Elements in a Sterilant Gas Dispensing Area, and Elements in a Waste Storage Area within a Permanent Total Enclosure that meets the requirements in subdivision (k); and
- (B) Either 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 the Control System by implementing a Leak Detection and Repair Program that meets the requirements in subdivision (m).

(4) Labeling and Facility Diagram Requirements

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

- (A) Place on a vertical surface on each Sterilized Palletized Unit at least one (1) 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)  
AERATION COMPLETED ON {Date of Completion}
- (B) Clearly label each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, Permanent Total Enclosure, Packaging Area, Sterilant Gas Storage Area, Sterilant Gas Dispensing Area, and Waste Storage Area 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;
- (C) Label or write on each bill of lading listing Sterilized Products, “STERILIZED WITH ETHYLENE OXIDE (EtO/EO)”; and
- (D) Maintain a Facility diagram onsite that identifies the location of each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, Permanent Total Enclosure, Packaging Area, Sterilizer Exhaust Vacuum Pump, Sterilant Gas Storage Area, Sterilant Gas Dispensing Area, and Waste Storage Area.

(5) Submittal of Permit and SCEMS/CEMS Applications

The owner or operator of a Large Facility shall:

- (A) No later than March 1, 2024, submit complete South Coast AQMD permit application(s) to meet stack emission requirements pursuant to paragraph (d)(1) and fugitive emissions requirements pursuant to paragraph (d)(3); and
- (B) No later than March 1, 2025, submit to the Executive Officer applications for new SCEMS or CEMS to meet stack emission monitoring requirements pursuant to paragraph (d)(2).

(6) Control System Implementation Requirements

The owner or operator of a Large Facility shall:

- (A) If operating a Control System containing an acid-water scrubber, either:
  - (i) Sample the scrubber liquor at least once per calendar week and analyze and record the ethylene glycol concentration using American Society for Testing and Materials (ASTM) D 3695-88, Standard Test Method for Volatile Alcohols in Water by Direct Aqueous-Injection Gas Chromatography (1988); or
  - (ii) Measure and record at least once per calendar week the level of the scrubber liquor in the recirculation tank and install, maintain, calibrate, and use a liquid level indicator to measure the scrubber liquor tank level.
- (B) If operating a Control System containing a catalytic oxidation unit or thermal oxidation unit, 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:
  - (i) Installed, calibrated, operated, and maintained to an accuracy within  $\pm 5.6$  degrees Celsius ( $\pm 10$  degrees Fahrenheit); and
  - (ii) Verified for accuracy twice each calendar year with a reference temperature monitor traceable to National Institute of Standards and Technology (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.

(C) If operating a Control System containing an air pollution control device other than an acid-water scrubber, catalytic oxidation unit, or thermal oxidation unit, monitor specific parameters of the device as approved by the Executive Officer.

(7) Interim Mobile Monitoring Requirements

(A) Beginning [30 Days After Date of Amendment] and ending when implementation of a Fenceline Air Monitoring Plan pursuant to subparagraph (p)(1)(A) begins, the owner or operator of a Large Facility shall utilize either:

- (i) The Executive Officer to conduct mobile monitoring; or
- (ii) An independent third-party operator to conduct mobile monitoring capable of either:

(I) Measuring Ethylene Oxide with a method detection limit of 1.0 ppb or lower with measurement at least once every ten (10) seconds; or

(II) Measuring signals associated with Ethylene Oxide with a method detection limit of [TBD] ppb or lower with measurement at least once every [TBD] seconds.

(B) The owner or operator of a Large Facility shall report no later than [14 Days After Date of Amendment] to the Executive Officer in writing by electronic mail to Rule1405notifications@aqmd.gov of the mobile monitoring option selected pursuant to subparagraph (d)(7)(A).

(C) The owner or operator of a Large Facility electing to conduct mobile monitoring pursuant to clause (d)(7)(A)(i) shall pay fees pursuant to Appendix 1 – Mobile Monitoring Fee and Program Fund.

(D) The owner or operator of a Large Facility electing to conduct mobile monitoring pursuant to clause (d)(7)(A)(ii) shall measure the concentration of Ethylene Oxide or the indirect concentrations associated with Ethylene Oxide:

- (i) At least once per calendar month during a single calendar day; and

(ii) For at least two (2) hours along a drivable and accessible route that is closest to all property boundaries of the Facility and surrounding area.

(E) The owner or operator of a Large Facility electing to conduct mobile monitoring pursuant to subclause (d)(7)(A)(ii)(II) shall:

(i) Collect a grab canister sample at locations where one (1) minute average concentration associated with Ethylene Oxide measure above the Level 2 concentration specified in Table 5 – Trigger Threshold for Sterilization Facilities, unless three (3) canister samples were previously collected during the calendar day;

(ii) Analyze all canister samples collected pursuant to clause (d)(7)(E)(i) using a method specified in either subclause (p)(2)(B)(ii)(I) or (p)(2)(B)(ii)(II); and

(iii) Quantify Ethylene Oxide results of the sample by a method of detection of 0.2 ppb or lower.

(8) Interim Fenceline Monitoring

The owner or operator of a Large Facility shall implement a Fenceline Air Monitoring Plan pursuant to subdivision (p).

(9) Submittal of Plans

The owner or operator of a Large Facility may elect to submit permit applications for a Control System Implementation Plan and/or a Facility Implementation Plan.

(10) Implementation Schedule

The owner or operator of a Large Facility shall comply with the applicable requirements and schedule pursuant to Table 1 – Implementation Schedule.

**Table 1 – Implementation Schedule**

<u>Facility Category</u>	<u>Rule Requirement</u>	<u>Effective Date</u>
<u>Large Facility existing as of [Date of Rule Amendment]</u>	<u>(d)(1)</u>	<u>July 1, 2025</u>
	<u>(d)(2)</u>	<u>18 months after receiving approval for an application for SCEMS or CEMS</u>
	<u>(d)(3)</u>	<u>July 1, 2025</u>
<u>Large Facility permitted after [Date of Rule Amendment]</u>	<u>(d)(1)</u>	<u>[Date of Rule Amendment]</u>
	<u>(d)(2)</u>	<u>Date of Permit to Operate issuance</u>
	<u>(d)(3)</u>	<u>[Date of Rule Amendment]</u>

(e) Medium Facility Requirements

(1) Stack Emission Requirements

Beginning January 1, 2026, the owner or operator of a Medium Facility shall not initiate a new Sterilization Cycle unless the following requirements are met:

(A) Vent the Exhaust Stream of any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, first Post-Aerator used to store Sterilized materials removed from an Aerator or a Combined Sterilized/Aerator, and Permanent Total Enclosure to a Control System;

(B) For each Control System either:

(i) Meet a control efficiency of 99.9% or greater, by weight, of Ethylene Oxide emissions, demonstrated by a source test that meets the requirements in subdivision (1); or

(ii) Not exceed an Ethylene Oxide concentration of 0.01 ppm, by volume, demonstrated by a source test that meets the requirements in subdivision (1); and

(C) Conduct a source test that demonstrates compliance with the requirements in subparagraph (e)(1)(B):

(i) No later than January 1, 2026 for a Control System installed or modified on or before November 2, 2025;

- (ii) Within 60 days after initial operation of a Control System installed or modified after November 2, 2025; and
- (iii) No later than 12 calendar months from the date of the most recent source test of the Control System.

(2) Fugitive Emission Requirements

Beginning January 1, 2026, the owner or operator of a Medium Facility shall not initiate a new Sterilization Cycle unless the following requirements are met:

(A) Operate each of the following, if applicable to the Medium Facility, within a Permanent Total Enclosure that meets the requirements in subdivision (k):

- (i) Sterilizer;
- (ii) Aerator;
- (iii) Back-Draft Valve;
- (iv) Sterilizer Exhaust Vacuum Pump;
- (v) All Elements in a Sterilant Gas Dispensing Area;
- (vi) All Elements in a Sterilant Gas Storage Area; and
- (vii) First Post-Aerator used to store Sterilized materials removed from an Aerator or a Combined Sterilizer/Aerator; and

(B) Either maintain each of the following, if applicable to the Medium Facility, within a Permanent Total Enclosure that meets the requirements in subdivision (k) or monitor each of the following, if applicable to the Medium Facility, by implementing a Leak Detection and Repair Program that meets the requirements in subdivision (m):

- (i) Combined Sterilizer/Aerator;
- (ii) All Components up to the exhaust stack of the Control System; and
- (iii) All Elements in a Waste Storage Area.

(3) Labeling and Facility Diagram Requirements

Beginning [3 Months After Date of Amendment], 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)(vii), Permanent Total Enclosure, Sterilant Gas Storage Area, and Waste Storage Area 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;
- (B) Maintain a Facility diagram onsite that identifies the location of each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator subject to the requirements of clause (e)(2)(A)(vii), Permanent Total Enclosure, Sterilant Gas Storage Area, and Waste Storage Area;
- (C) Place on a vertical surface on each Sterilized Palletized Unit at least one (1) 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)  
AERATION COMPLETED ON {Date of Completion}
- (D) Label or write on each bill of lading listing Sterilized Products, “STERILIZED WITH ETHYLENE OXIDE (EtO/EO)”.

(4) Submittal of Permit Applications

No later than January 1, 2025, the owner or operator of a Medium Facility operating prior to [Date of Amendment] shall submit complete South Coast AQMD permit application(s) to meet stack emission requirements pursuant to paragraph (e)(1) and fugitive emission requirements pursuant to paragraph (e)(2).

(5) Submittal of Plans

The owner or operator of a Medium Facility may elect to submit permit applications for a Control System Implementation Plan and/or a Facility Implementation Plan.

(f) Small Facility Requirements

(1) Stack Emission Requirements

Beginning January 1, 2026, the owner or operator of a Small Facility shall not initiate a new Sterilization Cycle unless the following requirements are met:

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

- (B) For each Control System either:
  - (i) Meet a control efficiency of 99.9% or greater, by weight, of Ethylene Oxide emissions, demonstrated by a source test that meets the requirements in subdivision (l); or
  - (ii) Not exceed an Ethylene Oxide concentration of 0.01 ppm, by volume, demonstrated by a source test that meets the requirements in subdivision (l); and
- (C) Conduct a source test that demonstrates compliance with requirements in subparagraph (f)(1)(B):
  - (i) No later than January 1, 2026 for a Control System installed or modified on or before November 2, 2025;
  - (ii) Within 60 days after initial operation of a Control System installed or modified after November 2, 2025; and
  - (iii) No later than 12 calendar months from the date of the most recent source test of the Control System.

(2) Fugitive Emission Requirements

Beginning January 1, 2026, the owner or operator of a Small Facility shall not initiate a new Sterilization Cycle unless the following requirements are met:

- (A) Operate the following areas and processes, if applicable to the Small Facility, within a Permanent Total Enclosure that meets the requirements of subdivision (k) if Aeration is not exclusively performed in a Combined Sterilizer/Aerator:
  - (i) Sterilizer;
  - (ii) Aerator;
  - (iii) Back-Draft Valve;
  - (iv) Sterilizer Exhaust Vacuum Pump; and
  - (v) All Elements in a Sterilant Gas Dispensing Area; and
- (B) Either maintain the following areas and processes, if applicable to the Small Facility, within a Permanent Total Enclosure that meets the requirements in subdivision (k) or monitor the following areas and processes, if applicable to the Small Facility, by implementing a Leak Detection and Repair Program that meets the requirements in subdivision (m):
  - (i) Combined Sterilizer/Aerator;



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

(iii) All Elements in a Waste Storage Area; and

(iv) All Elements in a Sterilant Gas Storage Area.

(3) Labeling and Facility Diagram Requirements

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

(A) Clearly label each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Sterilant Gas Storage Area, and Waste Storage Area 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) Maintain a Facility diagram onsite that identifies the location of each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, Permanent Total Enclosure, Sterilant Gas Storage Area, and Waste Storage Area.

(4) Submittal of Permit Applications

No later than January 1, 2025, the owner or operator of a Small Facility operating prior to [Date of Amendment] shall submit complete South Coast AQMD permit application(s) to meet stack emission requirements pursuant to paragraph (f)(1) and fugitive emission requirements pursuant to (f)(2).

(5) Submittal of Plans

The owner or operator of a Small Facility may elect to submit permit applications for a Control System Implementation Plan and/or a Facility Implementation Plan.

(g) Post-Aeration Storage Facility Requirements

Beginning July 1, 2025, the owner or operator of a Post-Aeration Storage Facility shall not receive Sterilized Products unless the following requirements are met:

(1) For each Control System, meet a control efficiency of 95% or greater, by weight, demonstrated by a source test that meets the requirements in subdivision (1);

(2) Conduct a source test that demonstrates compliance with the requirements in paragraph (g)(1) for each Control System:

- (A) No later than July 1, 2025 for a Control System installed or modified on or before May 2, 2025;
  - (B) Within 60 days after initial operation of a Control System installed or modified after May 2, 2025; and
  - (C) No later than 12 calendar months from the dayte of the most recent source test of the Control System;
  - (3) Either 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 (m);
  - (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) Maintain a Facility diagram onsite that identifies the location of each Post-Aerator and Permanent Total Enclosure.
- (h) Warehouse Requirements
- (1) The owner or operator of a Tier I Warehouse or Tier II Warehouse shall record each month according to the dates specified in Table 2 – Warehouse Recording Period, the number of Sterilized Palletized Units received from any entity performing Sterilization.

**Table 2 – Warehouse Recording Period**

<u>Type of Warehouse</u>	<u>Start Date to Record Number of Sterilized Palletized Units</u>	<u>End Date to Record Number of Sterilized Palletized Units</u>
<u>Tier I Warehouse or Tier II Warehouse</u>	<u>January 1, 2024</u>	<u>December 31, 2024</u>

- (2) No later than March 1, 2025, the owner or operator of a Tier I Warehouse or Tier II Warehouse subject to the -requirements in paragraph (h)(1) shall submit to the Executive Officer a summary report that includes the following:
  - (A) Name of warehouse;
  - (B) South Coast AQMD Facility ID, if applicable;

- (C) Address of warehouse;
  - (D) Contact information for owner or operator of warehouse;
  - (E) Total number of Sterilized Palletized Units received each month during the consecutive 12-month period specified in Table 2;
  - (F) Addresses of entities performing Sterilization where Sterilized Palletized Units shipped from; and
  - (G) Diagram identifying receiving and storage areas for Sterilized Palletized Units and locations of Ethylene Oxide monitors, if any.
- (3) The owner or operator of a Tier I Warehouse shall either:
- (A) Implement a Fenceline Air Monitoring Plan pursuant to subdivision (p);
  - (B) Conduct an emission study pursuant to paragraph (h)(5) and the approved Emission Study Plan;
  - (C) No later than [6 Months After Date of Rule Amendment], fund and participate in a real-time fenceline monitoring system demonstration program by the South Coast AQMD to monitor in real-time ambient Ethylene Oxide concentrations near Tier I Warehouse property boundaries and meet the following requirements:
    - (i) Submit payment to the South Coast AQMD pursuant to the payment schedule in Appendix 1 for funding a real-time fenceline monitoring system demonstration program;
    - (ii) Provide access for South Coast AQMD personnel and its contractors; and
    - (iii) Provide for each real-time Fenceline Air Monitoring system an appropriate location to operate and the infrastructure to operate; or
  - (D) Not receive Sterilized Palletized Units between January 1, 2024 to December 31, 2024 from any entity performing Sterilization.
- (4) No later than [60 days after Rule Amendment], the owner or operator of a Tier I Warehouse operating prior to [Date of Rule Amendment] shall report to the Executive Officer in writing by electronic mail to [Rule1405notifications@aqmd.gov](mailto:Rule1405notifications@aqmd.gov) of the compliance option selected pursuant to paragraph (h)(3).
- (5) Emission Study

The owner or operator of a Tier I Warehouse electing to implement an emission study to meet the requirements of subparagraph (h)(3)(B) shall:

- (A) Determine the annual Ethylene Oxide emissions from the warehouse with a methodology approved in the Emission Study Plan by using:
  - (i) Emission factors approved by U.S. EPA, CARB, South Coast AQMD, or other regulatory agency; or
  - (ii) Emissions rates from source tests or other sample testing consisting of at least duplicate runs or samples unless otherwise specified in the Emission Study Plan; and
- (B) No later than [120 days After Date of Rule Amendment], submit an Emission Study Plan that contains the information specified in Appendix 3 – Emission Study Plan to the Executive Officer;
- (C) Within 30 calendar days after disapproval of the Emission Study Plan, resubmit the revised plan to the Executive Officer that includes any information necessary to address deficiencies;
- (D) If the resubmitted Emission Study Plan is denied, meet the requirements of the Emission Study Plan modified and approved by the Executive Officer;
- (E) Within 180 calendar days of approval of the Emission Study Plan, submit the results of the Emission Study to the Executive Officer; and
- (F) If the results of Emission Study indicate that more than four (4) lbs of Ethylene Oxide is emitted per year by the Tier I Warehouse, meet the requirements of subdivision (p).

(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 that uses a total of 400 ~~pounds~~lbs or less of ~~e~~Ethylene ~~o~~Oxide per calendar year shall meet the following requirements until the date specified in Table 8 – Interim Requirements under subdivision (u):
  - (A) Sterilizer(s) and Combined Sterilizer/Aerator(s) shall be vented to control equipment with an efficiency of 99~~-percent~~% or more, by weight.

- (B) If ~~e~~Ethylene ~~o~~Oxide emissions from a ~~a~~Aeration are greater than four ~~(4) lbs pounds~~-per calendar year, the ~~a~~Aerator(s) shall be vented to control equipment with an efficiency of 95-~~percent~~% or more, by weight.
  - (C) If the ~~e~~Exhaust ~~s~~Streams from the equipment identified in subparagraphs (i)(1)(A) and (i)(1)(B) are vented to the same control 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~~ The owner of operator of a Facility performing Sterilization all persons who uses a total of more than 400 ~~pounds~~lbs and less than or equal to 4,000 ~~pounds~~ lbs of eEthylene oOxide per calendar year until the date specified in Table 8 under subdivision (u):
- (A) Sterilizer(s) and Combined Sterilizer/Aerator(s) shall be vented to control equipment with an efficiency of 99.9-~~percent~~% or more, by weight.
  - (B) Aerator(s) shall be vented to control equipment with an efficiency of 95-~~percent~~% or more, by weight.
  - (C) ~~Back-d~~Draft-~~exhaust~~ ~~v~~Valve(s) shall be vented to control equipment with an efficiency of 95 percent or more, by weight.
  - (D) If the ~~e~~Exhaust ~~s~~Streams from the equipment identified in subparagraphs (i)(2)(A), (i)(2)(B), and (i)(2)(C) are vented to the same control 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~~ The owner of operator of a Facility performing Sterilization all persons who uses a total of more than 4,000 ~~pounds~~-~~lbs~~ of eEthylene oOxide per calendar year shall meet the following requirements until the date specified in Table 8 under subdivision (u):
- (A) Sterilizer(s) and Combined Sterilizer/Aerator(s) shall be vented to control equipment with an efficiency of 99.9-~~percent~~% or more, by weight.
  - (B) Aerator(s) and sSterilizer door hood eExhaust sStream(s) shall be vented to control equipment with an efficiency of 99-~~percent~~% or more, by weight.

(C) ~~Back-draft exhaust v~~Valve(s) shall be vented to control equipment with an efficiency of ~~99-percent~~90 or more, by weight.

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

~~(4) Persons owning or operating aeration only facilities where more than four pounds of ethylene oxide are emitted per calendar year shall install control equipment with an efficiency of 95 percent or more, by weight, by June 21, 1992.~~

(4) The owner or operator of a Facility that stores materials that are Sterilized with Sterilant Gas at another Facility, where more than four (4) lbs of Ethylene Oxide are emitted, and has as a permit to operate to control Ethylene Oxide emissions issued by South Coast AQMD prior to [Date of Amendment] shall vent to control equipment with an efficiency of 95% or more, by weight.

(5) The owner or operator of a Facility subject to either paragraph (i)(1), (i)(2), (i)(3), or (i)(4) shall not exceed a maximum concentration of 10 parts per million of Ethylene Oxide. This measurement shall be taken one (1) centimeter away from any portion of a Sterilizer, Combined Sterilizer/Aerator, Aerator, control equipment, or emissions collection system that could emit Ethylene Oxide and during conditions of maximum Sterilant Gas flow, at least once every six (6) months, and meeting the requirement as specified in paragraph (i)(8).

~~Sterilizers, aerators, control equipment, and emissions collection systems shall be leak free effective December 21, 1990. The maximum sterilant gas mass flow shall be less than 30 parts per million ethylene oxide for sterilant gas composed of 12 percent ethylene oxide/88 percent chlorofluorocarbon12, 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 sterilizer, aerator, or control equipment that could have an ethylene oxide leak. Leak tests shall be conducted during conditions of maximum sterilant gas mass flow. Leak tests shall be conducted every six months, as specified in paragraph (f), Test Methods.~~

- (6) The owner or operator of a Facility subject to either paragraph (i)(1), (i)(2), (i)(3), or (i)(4) All persons subject to this rule shall conduct source tests on control equipment within 60 days after the initial operation of the equipment to verify compliance with control efficiency requirements, as specified in paragraph ~~(f)(7)~~, Test Methods. Thereafter, annual source tests shall be conducted on catalytic oxidation, carbon, or solid bed control 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.~~
  
- (e) Record Keeping  
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.~~
  
- (f) Test Methods
  - ~~(7)~~ Source tests shall be conducted according to CARB Test Method 431 or
  - ~~(4)~~ an acceptable source test method approved by ~~the~~ CARB and the District 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~~—Sterilizer, Combined Sterilizer/Aerator, or aeratorAerator.
- (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~~—Sterilization Cycle exhaust—Exhaust streamStream, sampling shall be done during the entire duration of the first ~~sterilizer~~—Sterilization Cycle evacuation and subsequent air washes after ~~ethylene oxide~~Ethylene Oxide has been introduced. To measure the control efficiency on an ~~aerator~~—Aeration exhaust Exhaust stream-Stream with a constant air flow, sampling shall be done during a period of at least 60 minutes and during normal operations. To measure the control efficiency of the control equipment on an ~~aerator~~—Aeration exhaust—Exhaust stream-Stream with a non-constant air flow, sampling shall be done during the entire duration of the first ~~aerator~~—Aeration evacuation after ~~aeration~~—Aeration begins.

~~(8)~~ ~~Leak~~ Tests pursuant to paragraph to ~~(i)~~(5) shall be conducted by CARB  
~~2)~~ 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-District. ~~A chlorofluorocarbon-12 detector with an audible signal 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 chlorofluorocarbon-12.~~

(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, operate, and maintain a SCEMS or CEMS complying with applicable requirements in Rule 218 through Rule 218.3 for each Control System and the following requirements:
  - (A) Measures the following parameters:



- (i) Ethylene Oxide concentration, with minimum detection limit of 0.01 ppm or less and a resolution of at least 0.001 ppm, by volume;
      - (ii) Oxygen concentration; and
      - (iii) Exhaust stack flow rate;
    - (B) Measures at a location reviewed and approved by the Executive Officer during the SCEMS or CEMS certification process;
    - (C) Meets the performance specifications 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 in local standard time, and applicable Ethylene Oxide performance standard.
  - (2) No later than the next calendar day, the owner or operator of a Facility required to operate a SCEMS or CEMS shall calculate and record the total mass emission rate in lbs/hr from all exhaust stacks at the Facility. The mass emission rate for each exhaust stack for each calendar day is determined from the average of valid hourly averages as calculated from all valid data points acquired during an hour from the SCEMS or CEMS and expressed in lbs/hr, excluding hours of maintenance and repair for the SCEMS or CEMS.
  - (3) The owner or operator of a Facility required to operate a SCEMS or CEMS shall provide an uninterruptible power supply, including the installation and operation of a backup battery, to ensure operation of the SCEMS or CEMS.
  - (4) The owner or operator of a Facility required to operate a SCEMS or CEMS shall maintain and calibrate each SCEMS or CEMS pursuant to manufacturer specification.
  - (5) Beginning 30 months after receiving approval from the Executive Officer for an application for SCEMS or CEMS, the owner or operator of a Facility required to operate a SCEMS or CEMS pursuant to paragraph (d)(2) shall not exceed 96 hours of missing or invalid data per SCEMS or CEMS over a rolling 30-day period for days when a Sterilization Cycle is performed.
- (k) Permanent Total Enclosure Requirements

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

- (1) Maintain any Permanent Total Enclosure at a negative pressure of at least 0.007 inches of water column averaged over one (1) minute;
- (2) Install, operate, and maintain a digital differential pressure monitoring system for each Permanent Total Enclosure to demonstrate compliance with paragraph (k)(1):
  - (A) A minimum of one (1) digital differential pressure monitor at each of the following three (3) 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; and
    - (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 (2) other monitors specified in clauses (k)(2)(A)(i) and (k)(2)(A)(ii); and
      - (III) Is not located on the same wall as either of the other two (2) monitors described in clauses (k)(2)(A)(i) or (k)(2)(A)(ii);
  - (B) A minimum of one (1) 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 to 0.110 inches of water column with a minimum increment of measurement of plus or minus 0.001 inches of water column;
  - (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;

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

(G) Equipped with an audible alarm that alerts when the negative pressure of the Permanent Total Enclosure is not maintained at least at the value specified in paragraph (k)(1); and

(3) Demonstrate an inward air velocity of at least 200 feet per minute (fpm) at each natural draft opening at least once per calendar quarter and pursuant to Appendix 2 – PTE Inward Face Air Velocity Measurement Procedures.

(1) Source Test Requirements

The owner or operator of a Facility required to conduct source test pursuant to either subdivision (d), (e), (f), or (g) shall:

(1) Prior to conducting the initial source test to demonstrate compliance with subdivision (d), (e), (f), or (g) for the Control System, 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) Prior to conducting any subsequent source test to demonstrate compliance with subdivision (d), (e), (f), or (g) for the Control System, submit a source test protocol that includes the conditions, numbers, and parameters

referenced by subparagraphs (1)(1)(A) through (C) if there are any changes in the conditions, numbers, or parameters referenced by subparagraphs (1)(1)(A) through (C) in the most recently-approved source test protocol;

- (3) Report the source test schedule to the Executive Officer at least 10 days prior to the start of any source test in writing by electronic mail to [Rule1405notifications@aqmd.gov](mailto:Rule1405notifications@aqmd.gov) or verbally by telephone to 1-800-CUT-SMOG;
- (4) 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;
- (5) Conduct a source test:
  - (A) Pursuant to the source test protocol approved by the Executive Officer within the last three (3) years of the source testing date;
  - (B) With triplicate runs at either typical operating conditions or at maximum operating parameters, as specified in the source test protocol;
  - (C) With each run being a minimum of 60 minutes;
  - (D) 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; and
  - (E) When assessing the efficiency of controlling Ethylene Oxide emissions:
    - (i) Measure or determine the total inlet mass emission in lbs 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; and
    - (ii) Measure or determine the total outlet mass emissions in lbs of Ethylene Oxide exhausted from the Control System; and
- (6) Submit the source test report to the Executive Officer within 60 days of completing all sampling for the source test.
  - ~~(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.~~

(m) 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 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) Maintain all Components and Elements subject to the LDAR program free of Leaks greater than 2 ppm above background;
- (4) Conduct audio-visual checks once per operating day for all applicable Components and Elements; and
- (5) No later than 60 calendar days of being required to implement an LDAR program and no later than every 60 calendar days thereafter, conduct leak inspections of all applicable Components and Elements pursuant to CARB Test Method 21, or an approved alternative method, using a portable photoionization detector, or an approved alternative analytical instrument, calibrated with Ethylene Oxide, or an appropriate calibrating gas provided:
  - (A) All alternatives used are capable of determining or detecting Leaks great than 2 ppm above background and approved by the Executive Officer in writing; and
  - (B) If an appropriate calibrating gas is used, the correction factor is recorded and the measured readings is correlated to and also expressed as Ethylene Oxide.

(n) Prohibitions

- (1) The owner or operator of a Facility performing Sterilization ~~A person shall not discharge any sSterilizer eExhaust vVacuum pPump working fluid to the wastewater stream.~~
  - (2) The owner or operator of a Facility performing Sterilization ~~A person shall not use eChlorofluorocarbon dDiluents in-ethylene-oxide sSterilization; effective January 1, 1997.~~
  - (3) The owner or operator of a Facility performing Sterilization shall not allow the release of uncontrolled emissions of Ethylene Oxide to atmosphere from any Permanent Total Enclosure at any time.
  - (4) The owner or operator of a Facility performing Sterilization shall not remove Sterilized materials from the Facility before completing Aeration, except for testing with no further distribution.
  - (5) The owner or operator of a Post-Aeration Storage Facility shall not remove or render inoperable a Control System unless it is replaced by a Control System permitted by South Coast AQMD to meet the applicable Ethylene Oxide performance standard specified in paragraph (g)(1) or (i)(4).
- (o) Facility performing Sterilization Exceeding Applicable Ethylene Oxide Usage
- (1) No later than 24 months from the date of using 2,000 lbs or more of Ethylene Oxide within in a calendar year, the owner or operator of a Facility performing Sterilization, excluding a Large Facility, that uses 2,000 lbs or more of Ethylene Oxide in a calendar year shall meet the requirements in subparagraphs (d)(1)(A) through (d)(1)(E); (d)(2)(A) through (d)(2)(C); (d)(3)(A) and (d)(3)(B); and (d)(4)(A) through (d)(4)(D).
  - (2) No later than 24 months from the date of using more than 400 lbs of Ethylene Oxide within in a calendar year, the owner or operator of a Facility performing Sterilization, excluding a Large Facility or Medium Facility, that uses more than 400 lbs of Ethylene Oxide in a calendar year shall meet the requirements specified in subparagraphs (e)(1)(A) through (e)(1)(C), (e)(2)(A) and (e)(2)(B), and (e)(3)(A) through (e)(3)(D).
  - (3) No later than 24 months from the date of using more than 4 lbs of Ethylene Oxide within in a calendar year, the owner or operator of a Facility performing Sterilization, excluding a Large Facility, Medium Facility, or Small Facility, that uses more than 4 lbs of Ethylene Oxide in a calendar

year shall meet the requirements specified in subparagraphs (f)(1)(A) through (f)(1)(C), (f)(2)(A) and (f)(2)(B), and (f)(3)(A) through (f)(3)(B).

(4) No later than 12 months from the date of exceeding the applicable Ethylene Oxide usage limit in Table 7, the owner or operator of a Facility performing Sterilization subject to the requirements of paragraphs (o)(1), (o)(2), or (o)(3) shall submit complete South Coast AQMD permit application(s) to modify existing permit conditions, modify existing equipment, or install new equipment to meet the requirements specified in paragraphs (o)(1), (o)(2), or (o)(3).

(p) Interim Fenceline Air Monitoring Requirements

(1) Submittal and Approval of a Facility Air Monitoring Plan

(A) The owner or operator of a Large Facility or a Tier I Warehouse shall submit a Fenceline Air Monitoring Plan that includes the information listed in Appendix 4 – Fenceline Air Monitoring Plan pursuant to the schedule specified in Table 3 – Submission of Fenceline Air Monitoring Plan:

**Table 3 – Submission of Fenceline Air Monitoring Plan**

<b><u>Facility Type</u></b>	<b><u>Applicability</u></b>	<b><u>Submission Due Date</u></b>
<u>Large Facility</u>	<u>Pursuant to the requirements of paragraph (d)(8)</u>	<u>[60 Days After Date of Rule Amendment]</u>
<u>Tier I Warehouse</u>	<u>Pursuant to the requirements of subparagraph (h)(3)(A)</u>	<u>[180 Days After Date of Rule Amendment]</u>
	<u>Pursuant to the requirements of subparagraph (h)(5)(F)</u>	<u>60 calendar days after submission of results of Emission Study</u>

(B) Within 30 calendar days after disapproval of the Fenceline Air Monitoring Plan, the owner or operator of a Facility subject to subparagraph (p)(1)(A) shall resubmit a revised plan to the Executive Officer that includes any information necessary to address deficiencies.

(C) If the resubmitted Fenceline Air Monitoring Plan is denied, the owner or operator of a Facility subject to subparagraph (p)(1)(A) shall implement the Fenceline Air Monitoring Plan as modified and approved by the Executive Officer.

- (2) Implementation of a Facility Air Monitoring Plan
- (A) Beginning 90 days after approval of the Fenceline Air Monitoring Plan, unless a different date is specified in the approved Fenceline Air Monitoring Plan, the owner or operator of a Facility subject to subparagraph (p)(1)(A) shall implement the approved Fenceline Air Monitoring Plan.
- (B) The owner or operator of a Facility implementing a Fenceline Air Monitoring Plan to meet the requirements of subparagraph (p)(2)(A) by canister collection shall:
- (i) Collect a 24-hour integrated sample at a frequency of 1-in-6 days, unless a more frequent schedule is specified in the approved Fenceline Air Monitoring Plan, at each location specified in the Fenceline Air Monitoring Plan;
- (ii) Collect and analyze the sample pursuant to either:
- (I) U.S. EPA Compendium Method TO-15 Second Edition Determination Of Volatile Organic Compounds in Air Collected In Specially-Prepared Canisters And Analyzed By Gas Chromatography/Mass Spectrometry; or
- (II) U.S. EPA Method TO-15A Determination of Volatile Organic Compounds in Air Collected in Specially Prepared Canisters and Analyzed by Gas Chromatography–Mass Spectrometry; and
- (iii) Quantify Ethylene Oxide results of the sample by a method of detection of 0.2 ppb or lower.
- (C) The owner or operator of a Facility implementing a Fenceline Air Monitoring Plan to meet the requirements of subparagraph (p)(2)(A) by real-time monitoring shall:
- (i) Conduct real-time monitoring at each monitoring location approved in the Fenceline Air Monitoring Plan;
- (ii) Operate equipment pursuant to manufacturer specifications and instructions; and
- (iii) Measure and record the concentration of Ethylene Oxide for each monitoring location using an established methodology that:



- (I) Has a method detection limit of 1.0 ppb or lower every 15 minutes; and
- (II) Generates a minimum of one (1) measurement every 15 minutes.
- (D) The owner or operator of a Large Facility implementing a Fenceline Air Monitoring Plan to meet the requirements of subparagraph (p)(2)(A) by real-time monitoring shall:
  - (i) Calculate and record the average hourly concentration of Ethylene Oxide for each monitoring location using data obtained pursuant to clause (p)(2)(C)(iii); and

**Table 4 – Concentration Threshold**

<b><u>Applicable Date</u></b>	<b><u>Average Concentration</u></b>
<u>[Date of Amendment] – August 31, 2025</u>	<u>≥17.5 ppb</u>
<u>On or after September 1, 2025</u>	<u>≥3.0 ppb</u>

- (ii) If a real-time monitor measures an Ethylene Oxide 3-hour average concentration that exceeds the concentration specified in Table 4 – Concentration Threshold:
  - (I) No later than one (1) hour after, begin collecting a 24-hour canister sample at the monitoring location, unless currently collecting a 24-hour canister sample at the monitoring location or unless otherwise specified in the Fenceline Air Monitoring Plan;
  - (II) Collect no more than one (1) canister sample at each monitoring location concurrently;
  - (III) Meet the requirements specified in clauses (p)(2)(B)(ii) and (p)(2)(B)(iii); and
  - (IV) Submit canister samples collected for analysis within one (1) calendar day of collection.
- (E) The owner or operator of a Facility implementing a Fenceline Air Monitoring Plan to meet the requirements of subparagraph (p)(2)(A) shall continuously record wind speed and direction data at all times using equipment capable of meeting the U.S. EPA Performance Criteria for Wind Sensors for both wind speed and

wind direction at a location approved in the Fenceline Air Monitoring Plan.

(F) For each monitoring location, the owner or operator of a Facility implementing a Fenceline Air Monitoring Plan to meet the requirements of subparagraph (p)(2)(A) shall not miss collecting over a consecutive 30-day period:

(i) Due to malfunction or other occurrence beyond the control of the Facility:

(I) More than one valid 24-hr integrated sample; and

(II) More than 48 hours of valid real-time data; and

(ii) Due to any other reason:

(I) Any valid 24-hr integrated sample; and

(II) More than 24 hours of valid real-time data.

(3) Fenceline Air Monitoring End Date

(A) The owner or operator of a Large Facility shall no longer be required to implement a fenceline air monitoring program pursuant to paragraph (d)(8):

(i) 60 days after final SCEMS or CEMS certification is issued by the Executive Officer for each Control System at the Facility; and

(ii) After August 31, 2025.

(B) The owner or operator of a Tier I Warehouse shall no longer be required to implement a Fenceline Air Monitoring Plan pursuant to subparagraph (h)(3)(A) or (h)(5)(F), provided the owner or operator either:

(i) Collected 60 valid samples for each monitoring location during a period of at least 365 calendar days; or

(ii) Collected 8,760 hours of valid real-time data for each monitoring location.

(q) Curtailment of Sterilization Operations

(1) Within 24 hours of the owner or operator of a Large Facility, Medium Facility, or Small Facility receiving the Trigger Result that is at or above the applicable trigger threshold specified in Table 5 – Trigger Threshold for Sterilization Facilities, the owner or operator shall curtail daily

Ethylene Oxide usage by the applicable amount specified in Table 6 – Curtailment Schedule from Baseline Operation.

**Table 5 – Trigger Threshold for Sterilization Facilities**

<u>Trigger Type</u>	<u>Trigger Threshold</u>	<u>Facility Type</u>	<u>Applicability Start Date</u>	<u>Applicability End Date</u>
<u>Level 1</u>	<u>≥ 17.5 ppb and ≤ 25.0 ppb</u>	<u>Large Facility</u>	<u>[Date of Amendment]</u>	<u>August 31, 2025</u>
		<u>Medium Facility or Small Facility</u>	<u>[Date of Amendment]</u>	<u>March 1, 2026</u>
<u>Level 2</u>	<u>&gt; 25.0 ppb</u>	<u>Large Facility</u>	<u>[Date of Amendment]</u>	<u>August 31, 2025</u>
		<u>Medium Facility or Small Facility</u>	<u>[Date of Amendment]</u>	<u>March 1, 2026</u>
<u>Level 3</u>	<u>≥ 3.0 ppb</u>	<u>Large Facility</u>	<u>September 1, 2025</u>	<u>None</u>
		<u>Medium Facility or Small Facility</u>	<u>March 2, 2026</u>	<u>None</u>

**Table 6 – Curtailment Schedule**

<u>Trigger Type</u>	<u>First Result</u>	<u>Second Result</u>	<u>Third Result</u>
<u>Level 1</u>	<u>20% of Baseline Operation</u>	<u>50% of Baseline Operation</u>	<u>100% of Baseline Operation*</u>
<u>Level 2</u>	<u>50% of Baseline Operation</u>	<u>100% of Baseline Operation*</u>	<u>Not Applicable</u>
<u>Level 3</u>	<u>50% of Baseline Operation</u>	<u>100% of Baseline Operation*</u>	<u>Not Applicable</u>

\*Subsequent sample results exceeding the trigger threshold would maintain a curtailment by 100% of Baseline Operation

- (2) If required to curtail operations by 100 percent, the owner or operator may complete any Sterilization Cycles in progress at the start of the curtailment.

(3) The owner or operator of a Facility shall not be subject to the curtailment requirements specified in paragraph (q)(1) provided:

(A) If collecting 24-hour canister samples to meet the requirements of subparagraph (p)(2)(A):

(i) Subsequent result(s) of a 24-hour period obtained via a canister sample collected during a scheduled sampling day at the sampling location(s) that triggered the applicable curtailment are below the applicable Level 1 or Level 3 concentration specified in Table 5; and

(ii) Subsequent results of a 24-hour period at all monitoring locations are below the applicable Level 1 or Level 3 concentration specified in Table 5; or

(B) If not collecting canister samples to meet the requirements of subparagraph (p)(2)(A):

(i) Subsequent result(s) of a 24-hour period obtained via a canister sample or other approved methodology in the Fenceline Air Monitoring Plan obtained at the sampling location(s) that triggered the applicable curtailment are below the applicable Level 1 or Level 3 concentration specified in Table 5; and

(ii) Meet requirements specified in clause (q)(3)(A)(ii); or

(C) The Executive Officer determines, based on credible evidence, that the result of a 24-hour period obtained via a canister sample or other approved methodology in the Fenceline Air Monitoring Plan was not due to the contribution of the Facility to ambient air concentration of Ethylene Oxide.

(4) The number of Trigger Result that is at or above the applicable trigger threshold specified in Table 5 – Trigger Threshold for Sterilization Facilities shall reset to zero (0), provided a period of no fewer than 30 consecutive calendar days demonstrated no results exceeded an applicable trigger threshold.

(r) Plan Administration

An Emission Study Plan, Fenceline Air Monitoring Plan, Control System Implementation Plan, or Facility Implementation Plan shall each be subject to fees specified in Rule 306 – Plan Fees.

**(s) Recordkeeping**

- (1) The owner or operator of any Facility performing Sterilization shall maintain records of, as applicable:**
  - (A) The number of Sterilization Cycles and the lbs of Sterilant Gas (measured or calculated) used per Sterilization Cycle for each Sterilizer and each Combined Sterilizer/Aerator each operating day;**
  - (B) The total lbs of Sterilant Gas purchased and the total lbs of Sterilant Gas used per calendar month and calendar year, respectively;**
  - (C) Data collected from the SCEMS or CEMS pursuant to paragraphs (j)(1) through (j)(2);**
  - (D) Source test reports pursuant to paragraph (l)(6);**
  - (E) Measurements of inward face velocity pursuant to paragraph (k)(3);**
  - (F) Data collected from the digital differential pressure monitoring system in Permanent Total Enclosures pursuant to paragraph (k)(2);**
  - (G) Plot-plan reports, audio-visual checks, and leak inspections for LDAR programs pursuant to subdivision (m);**
  - (H) The number of Sterilized Palletized Units shipped, grouped by First Destination, pursuant to paragraph (t)(5);**
  - (I) Facility diagrams pursuant to subparagraphs (d)(4)(D), (e)(3)(B), or (f)(3)(B);**
  - (J) Annual reports pursuant to paragraph (t)(1);**
  - (K) Semi-annual reports pursuant to paragraph (t)(2); and**
  - (L) For each Sterilization Cycle, a log entry with the following:**
    - (i) Cycle number, product identifier or batch number;**
    - (ii) Starting and ending time of Aeration in local time;**
    - (iii) Minimum required time of Aeration;**
    - (iv) Document source of minimum required time of Aeration specified in clause (s)(1)(L)(iii); and**
    - (v) For a Large Facility maintaining a Packaging Area outside a Permanent Total Enclosure pursuant to paragraph (d)(3), status of completion of biological indicator sterility testing.**

- (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 paragraph (l)(6);
    - (B) Measurements of inward face velocity pursuant to paragraph (k)(3);
    - (C) Data collected from the digital differential pressure monitoring system in Permanent Total Enclosures pursuant to paragraph (k)(2);
    - (D) Plot-plan reports, audio-visual checks, and leak for LDAR programs pursuant to subdivision (m); and
    - (E) Facility diagrams pursuant to paragraph (g)(5).
  - (3) The owner or operator of a Facility shall provide all available onsite records to the Executive Officer upon request.
  - (4) The owner or operator of any Facility subject to this rule shall retain all applicable records for at least five (5) years with two (2) years of records maintained onsite.
- (t) Reporting Requirements for a Facility Performing Sterilization
- (1) Annual Reporting

The owner or operator of a Large Facility shall submit an annual report in writing by electronic mail to Rule1405notifications@aqmd.gov each calendar year on or before March 1 for the preceding calendar year. The annual report shall contain at a minimum either:

    - (A) The number of Sterilization Cycles and the lbs of Sterilant Gas (measured or calculated) used per Sterilization Cycle for each Sterilizer and each Combined Sterilizer/Aerator each operating day; or
    - (B) The total lbs of Sterilant Gas purchased and the total lbs of Sterilant Gas used per calendar month and calendar year, respectively; and
  - (2) Semi-Annual Reporting

The owner or operator of a Large Facility shall submit a semi-annual report in writing by electronic mail to Rule1405notifications@aqmd.gov on or before February 28 of each calendar year for the preceding July-December semi-annual reporting period and on or before August 31 of each calendar year for the preceding January-June semi-annual reporting period. The semi-annual report shall contain at a minimum:

- (A) Semi-Annual Summary Report pursuant to Appendix 5 – Contents of Semi-Annual Summary Reports; and
- (B) Semi-Annual Excess Emission Report pursuant to Appendix 6 – Contents of Semi-Annual Excess Emission Reports, if the duration of excess emissions or parameter monitoring exceedances for the reporting period exceeds 1 percent of the reporting period or the total monitored downtime for the reporting period exceeds 5 percent of the reporting period.
- (3) Exceeding Ethylene Oxide Permit Limit Reporting  
The owner or operator of a Facility performing Sterilization that exceeds a limit of Ethylene Oxide, either as a facility-wide permit limit or a permit limit for equipment that performs Sterilization, shall report to the Executive Officer in writing by electronic mail to Rule1405notifications@aqmd.gov or by telephone to 1-800-CUT-SMOG within 30 days of the exceedance.
- (4) Exceeding Ethylene Oxide Threshold Reporting  
The owner or operator of a Facility performing Sterilization that uses more Ethylene Oxide than the amounts shown in Table 7 – Applicable Ethylene Oxide Usage in one (1) calendar year shall report to the Executive Officer in writing by electronic mail to Rule1405notifications@aqmd.gov or by telephone to 1-800-CUT-SMOG within 30 days of the exceedance.

**Table 7 – Applicable Ethylene Oxide Usage**

<b><u>Facility Type</u></b>	<b><u>Ethylene Oxide Usage per Calendar Year</u></b>
<u>Medium Facility</u>	<u>2,000 lbs</u>
<u>Small Facility</u>	<u>400 lbs</u>
<u>Other*</u>	<u>4 lbs</u>

\*Any Facility performing Sterilization other than a Large Facility, Medium Facility, or Small Facility

- (5) First Destination Reporting  
The owner or operator of a Large Facility shall:
  - (A) Beginning January 1, 2024 until December 31, 2024, record the First Destination of Sterilized Palletized Units shipped and the

- number of Sterilized Palletized Units shipped each month to each First Destination; and
- (B) No later than March 1, 2025, submit a summary report to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov that includes the following:
- (i) List of all First Destinations shipped more than 1000 Sterilized Palletized Units over the reporting period pursuant to subparagraph (d)(7)(A);
  - (ii) Total number of Sterilized Palletized Units shipped to each First Destination identified in clause (d)(7)(B)(i) over the reporting period; and
  - (iii) Electronic copy of records maintained pursuant to subparagraph (d)(7)(A).
- (6) Mobile Monitoring Reporting
- (A) The owner or operator of a Large Facility electing to conduct mobile monitoring pursuant to clause (d)(7)(A)(ii) shall, if a one (1) minute average reading obtained via mobile monitoring measures above the Level 2 concentration specified in Table 5 – Trigger Threshold for Sterilization Facilities:
- (i) No later than three (3) hours, report the concentration and the location where the reading occurred to the Executive Officer by calling 1-800-CUT-SMOG; and
  - (ii) No later than 48 hours, submit preliminary monitoring data for the calendar day to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov
- (B) The owner or operator of a Large Facility electing to conduct mobile monitoring pursuant to clause (d)(7)(A)(ii) shall report to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov the results of all mobile monitoring within seven (7) calendar days of measurement that includes a concentration map showing the mobile monitoring route along with measurements of Ethylene Oxide concentration (or indirect concentration) at all locations.
- (C) The owner or operator of a Large Facility electing to conduct mobile monitoring pursuant to subclause (d)(7)(A)(ii)(II) shall



report no later than two (2) hours after receiving the results of a canister sample collected pursuant to clause (d)(7)(E)(i):

- (i) Results to the Executive Officer by calling 1-800-CUT-SMOG; and
- (ii) Laboratory results package to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov.

**(7) Fenceline Air Monitoring Reporting**

The owner or operator of a Facility implementing a Fenceline Air Monitoring Plan shall:

**(A) If meeting the requirements of subparagraph (p)(2)(A) by canister collection:**

- (i) No later than 10 days after the date of sampling, report the Ethylene Oxide concentration to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov; and
- (ii) No later than two (2) hours after knowing that a valid 24-hr integrated sample was not collected, report to the Executive Officer by calling 1-800-CUT-SMOG or by electronic mail to Rule1405notifications@aqmd.gov and provide Facility name, name of fenceline monitor, date of occurrence, and reason of occurrence; and

**(B) If meeting the requirements of subparagraph (p)(2)(A) by real-time monitoring:**

- (i) No later than the 14th of each calendar month, report the daily average concentrations of Ethylene Oxide for the prior calendar month to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov;
- (ii) No later than two (2) hours after more than 24 hours of valid data over a consecutive 30-day period at a monitoring location was not recorded, report to the Executive Officer by calling 1-800-CUT-SMOG or by electronic mail to Rule1405notifications@aqmd.gov and provide Facility name, name of fenceline monitor, date of occurrence, and reason of occurrence; and
- (iii) No later than two (2) hours after starting to collect a 24-hour integrated sample, the location and the start time of collecting the 24-hour integrated sample to the Executive

Officer by calling 1-800-CUT-SMOG or by electronic mail to Rule1405notifications@aqmd.gov; and

(C) No later than 14<sup>th</sup> of each calendar month, report wind speed and direction data for the prior calendar month to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov.

(8) Trigger Level Reporting

The owner or operator of a Large Facility implementing a Facility Air Monitoring Plan to meet the requirements of subparagraph (p)(2)(A) shall report no later than two (2) hours after receiving the results of a 24-hour sample that is at or above the applicable concentration specified in Table 4 either:

(A) Results of the canister sample to the Executive Officer by calling 1-800-CUT-SMOG and Laboratory results package of the canister sample to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov; or

(B) If exclusively using real-time monitoring data:

(i) The daily average concentration; and

(ii) Date when exceeded the applicable daily average concentration.

(9) CEMS/SCEMS Exceedance Reporting

The owner or operator of a Facility required to monitor the emissions from a Control System by SCEMS/CEMS shall report to the Executive Officer in writing by electronic mail to Rule1405notifications@aqmd.gov or by telephone to 1-800-CUT-SMOG within two (2) hours of the following occurrences:

(A) Exceeding the total mass emission rate of Ethylene Oxide specified in subparagraph (d)(2)(B) for any rolling 30-day period; or

(B) For each Control System complying with clause (d)(1)(C)(ii), exceeding the outlet concentration specified in subparagraph (d)(2)(C) for any rolling 30-day period.

(10) Permanent Total Enclosure Monitor Reporting

The owner or operator of a Facility required to operate a Permanent Total Enclosure shall report to the Executive Officer in writing by electronic mail to Rule1405notifications@aqmd.gov or by telephone to 1-800-CUT-SMOG within 24 hours of the following occurrences:

- (A) The negative pressure in any Permanent Total Enclosure does not meet the requirement in paragraph (k)(1); or
- (B) There are more than 24 consecutive hours of missing data for data used to demonstrate compliance with paragraph (k)(1).

~~(u)~~ Exemptions  
~~g)~~

~~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 (n) do not apply to an owner or operator of a Facility that uses four (4) lbs or less of Ethylene Oxide per calendar year.
- (2) The requirements of subdivision (i) do not apply to an owner or operator of a Facility subject to requirements of subdivision (d), (e), (f), or (g) pursuant to the schedule specified in Table 8 – Interim Requirements:

**Table 8 – Interim Requirements**

<b><u>Applicable Subdivision</u></b>	<b><u>Beginning Date of Exemption</u></b>
(d)	July 1, 2025
(e)	January 1, 2026
(f)	January 1, 2026
(g)	July 1, 2025

- (3) The requirements of paragraph (k)(1) and (n)(3) do not apply to an owner or operator of a Facility during the loss of power or other unplanned event outside of the control of the owner or operator provided, as applicable:
  - (A) No Products or other materials are added or removed from Sterilizers, Combined Sterilizer/Aerators, Aerators, Post-Aerators, or Permanent Total Enclosures;
  - (B) All natural draft openings (NDOs) are closed except for the purposes of exiting a Permanent Total Enclosure or restarting a Control System;

- (C) The Ethylene Oxide concentration at all NDOs are monitored and recorded at least once every calendar day during the loss of power or other unplanned event outside of the control of the owner or operator using a portable photoionization detector calibrated with Ethylene Oxide or other calibrating gas, or an acceptable alternative method or analytical instrument approved by the Executive Officer provided:

  - (i) All alternatives used are capable of determining or detecting Leaks great than 2 ppm above background and approved by the Executive Officer in writing; and
  - (ii) If an appropriate calibrating gas is used, the correction factor is recorded and the measured readings is correlated to and also expressed as Ethylene Oxide; and
- (D) Event reported pursuant to paragraph (t)(10).
- (4) The requirements of subdivision (d) do not apply to an owner or operator of a Large Facility provided:

  - (A) The owner or operator submits to the Executive Officer a complete permit application or a Facility Implementation Plan to limit the facility-wide use of Ethylene Oxide to be less than 2,000 lbs per calendar year;
  - (B) The complete permit application or the Facility Implementation Plan submitted to meet the requirements of subparagraph (u)(4)(A) is not cancelled; and
  - (C) The owner or operator uses less than 167 lbs of Ethylene Oxide facility-wide per calendar month, either:

    - (i) Beginning date of the complete permit application submittal and until the date the permit associated with the permit application submitted pursuant to subparagraph (v)(4)(A) has been issued; or
    - (ii) Beginning date of the Facility Implementation Plan submittal and until the date the Facility Implementation Plan has been approved.
- (5) The requirements of paragraph (d)(7) do not apply to an owner or operator of a Large Facility, provided either:

  - (A) The Executive Officer conducts fenceline monitoring at a sampling frequency at least 1-in-6 days; or

- (B)     The owner or operator of the Large Facility conducts fenceline monitoring for Ethylene Oxide pursuant to a plan approved by Executive Officer.
- (6)     The requirements of subparagraph (d)(2)(B) do not apply to an owner or operator of a Large Facility that demonstrates the total mass emission rate of Ethylene Oxide from all exhaust stack(s) at the Facility exceeds 0.015 lbs/hr during the present rolling 30-day period, provided the owner or operator:
- (A)     Did not perform Sterilization in the last 48 hours;
- (B)     Demonstrates by using the SCEMS or CEMS that the sum of mass emission rates, averaged over a calendar day and measured at each exhaust stack, is 0.015 lbs/hr or less of Ethylene Oxide after resuming Sterilization; and
- (C)     Reports to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov 24 hours prior to initiating a new Sterilization Cycle.
- (7)     The requirements of subparagraph (d)(2)(C) do not apply to an owner or operator of a Large Facility provided that demonstrates the concentration of Ethylene Oxide from a Control System at the Facility exceeds 0.01 ppm during the present rolling 30-day period, provided:
- (A)     Facility did not perform Sterilization in the last 48 hours; and
- (B)     Demonstrate by using the SCEMS or CEMS that emissions of Ethylene Oxide are 0.01 ppm or less, averaged over each calendar day in operation after resuming Sterilization; and
- (C)     Reports to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov 24 hours prior to initiating a new Sterilization Cycle.
- (8)     The requirements of clause (p)(2)(D)(ii) do not apply to owner or operator of a Large Facility implementing a Fenceline Air Monitoring Plan to meet the requirements of paragraph (p)(4) by real-time monitoring, provided:
- (A)     The real-time monitoring method is approved by the U.S. EPA, CARB or South Coast AQMD; and
- (B)     In the Fenceline Air Monitoring Plan:
- (i)     The Executive Officer approved the real-time monitoring method as a legally defensible method; and

- (ii) The owner or operator agrees to the stipulation that the results of real-time monitoring are sufficient for curtailment requirements specified in subdivision (s).
- (9) The following requirements do not apply to a Large Facility permitted after [Date of Rule Amendment]:
  - (A) Paragraphs (d)(5), (d)(7), and (d)(8);
  - (B) Subdivision (i);
  - (C) Subdivision (p); and
  - (D) Paragraphs (t)(5), (t)(6), (t)(7), and (t)(8).
- (10) The requirements of subdivision (q), (d), (e), and (f) to stop or curtail Sterilization by 100% do not apply to the owner or operator of a Large Facility, Medium Facility, or Small Facility provided, the owner or operator Sterilizes only Products approved by the Executive Officer that either are:
  - (A) In critical reduced supply to endanger public health, as determined by the U.S. FDA or other local, state, or federal health agency; or
  - (B) In the Preconditioner at the start of the curtailment and not suitable for use if a Sterilization Cycle is not completed, based on validation documents approved by the U.S. FDA or manufacturer's specification.

**Appendix 1: Mobile Monitoring Fee and Program Fund**

1. Applicability

The following apply to an owner or operator of a Facility electing to either:

- A. Have the Executive Officer conduct mobile monitoring for a Large Facility pursuant to clause (d)(7)(A)(i); or
- B. Fund a real-time Fenceline Air Monitoring system demonstration program for a Tier I Warehouse pursuant to clause (h)(3)(C)(i).

2. Mobile Monitoring Fee

A. The owner or operator electing to have the Executive Officer conduct mobile monitoring for a Large Facility shall pay:

- i. An hourly staff rate of \$209.31 unless Regulation III - Fees assigns a fee amount associated with the mobile monitoring conducted to meet the requirements of clause (d)(7)(A)(i) that shall be paid in lieu of this rate
- ii. Other fees associated with consumables and analyses
- iii. The total fees assessed in Appendix 1 - (2)(A)(i) and Appendix 1 - (2)(A)(ii) shall not exceed \$13,000 for a monitoring day

Paying the preceding fees are required to meet the requirements of subparagraph (d)(7)(C).

- B. If the Executive Officer contracts mobile monitoring to an independent third-party contractor, the fee would be specified by the independent third-party contractor.
- C. The mobile monitoring fee shall be billed on a quarterly basis with payments due on or before 30 calendar days from the billing date. The mobile monitoring fee shall be based on monitoring conducted during the preceding quarter and include any other unpaid mobile monitoring fees.
- D. If the mobile monitoring fee is not paid in full within 60 calendar days of its due date, a 10 percent surcharge shall be imposed.

3. Real-time Fenceline Air Monitoring System Demonstration Program Fund

The owner or operator electing to fund and participate in a real-time Fenceline Air Monitoring system demonstration program at a Tier I Warehouse shall pay South Coast AQMD a one-time payment of [\$TBD] within 6 months of [Date of Amendment] for South Coast AQMD or its contractors to acquire, assemble, install, maintain, train, test, analyze, and decommission a real-time Fenceline Air

Monitoring system demonstration program to meet the requirements of subparagraph (h)(3)(C).



**Appendix 2 – PTE Inward Face Air Velocity Measurement Procedures**

1. Applicability

This method applies to an owner or operator of a Facility required to measure the inward face air velocity of each natural draft openings (NDO), defined in U.S. EPA Method 204 as “Any permanent opening in the enclosure that remains open during operation of the Facility and is not connected to a duct in which a fan is installed.”

2. Equipment – Anemometer

The anemometer shall be capable of measuring the inward face air velocity in feet per minute (fpm) within an appropriate velocity range with an accuracy within +/- 10% of full scale.

The anemometer shall be operated and calibrated per the manufacturer’s recommendations.

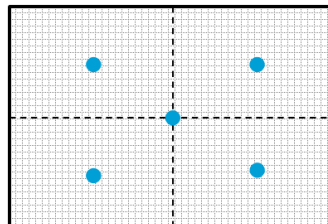
3. Test Conditions

The inward face air velocity measurement test shall be conducted while the Permanent Total Enclosure is in normal operation and under typical conditions representative of the Facility’s operations.

4. Procedure

The inward face velocity air measurements shall be taken at the plane of the NDO. The inward face air velocity measurement shall be conducted over a five-point grid pattern such as shown in the below example. For a NDO one (1) square foot or less, the single center point may be used in lieu of the five-point grid:

Natural Draft Opening  
Using a Five-Point Grid  
Pattern



● = Measurement Point

The inward face velocity air measurements shall be taken at the plane of the NDO.



**Appendix 3: Emission Study Plan**

1. Applicability

The following conditions apply to an owner or operator of a Tier I Warehouse electing to conduct an Emission Study pursuant to paragraph (h)(5). The Emission Study would assess the annual Ethylene Oxide emissions emitted from the Tier I Warehouse.

2. Contents of Emission Study Plan

The following information is required in an Emission Study Plan:

- A. Tier I Warehouse information
- B. Identification of Ethylene Oxide emission sources and emission activity
- C. Diagram of warehouse building(s) identifying:
  - i. The following areas:
    - a. Warehousing Activity (i.e., exclude administrative spaces such as offices)
    - b. Loading docks
    - c. Shipping and Receiving
    - d. Storage of Sterilized Palletized Units
  - ii. Ventilation system(s) with collection and discharge points, if any
- D. If emission factors are proposed to be used, provide the basis or source of each emission factor such as U.S. EPA, CARB, South Coast AQMD or others.
- E. If emission testing or sampling is proposed, provide the following:
  - i. Parameters of the emission testing or sampling including the operation of any ventilation systems during tests or sampling
  - ii. Emission source or emission activity to be tested or sampled
  - iii. If not conducting two runs or collecting two samples:
    - a. Number of runs or samples
    - b. Basis for a different number of runs or samples
  - iv. Equipment to be used for testing or sampling (include recent calibration or certifications for equipment)
  - v. Laboratory to be used for purposes of sample analysis
  - vi. Methods that will be used for sample analysis
  - vii. Procedures for determination of airflow of ventilation system to be used for calculations mass emission rate or concentration

F. Proposed methodology to quantify annual Ethylene Oxide from each emission source and emission activity

3. Disapproval of Emission Study Plan

The Executive Officer may disapprove the Emission Study Plan if the plan is incomplete, incorrect, inaccurate, or proposes inappropriate elements. The Executive Officer would inform the owner or operator of the Facility of the disapproval of the Emission Study Plan.

**Appendix 4: Fenceline Air Monitoring Plan**

1. Purpose

The purpose of implementing a Fenceline Air Monitoring Plan at a Large Facility is to assess concentrations of Ethylene Oxide at the fenceline of the Facility until the requirements of paragraphs (d)(1), (d)(2), and (d)(3) are met. Collected information may result in the Large Facility curtailing operations, if fenceline concentration is at or above certain trigger thresholds.

The purpose of implementing a Fenceline Air Monitoring Plan at a Tier I Warehouse is to collect information regarding fenceline concentrations of Ethylene Oxide at the largest warehouses receiving Sterilized Palletized Units.

2. Applicability

The following apply to an owner or operator of a Facility required to conduct fenceline air monitoring to meet the requirements of subdivision (p). The Fenceline Air Monitoring Plan would identify sources of Ethylene Oxide emissions, equipment to conduct fenceline air monitoring, and methods that would be used to conduct fenceline air monitoring.

3. Contents of Fenceline Air Monitoring Plan

The following information shall be included in a Fenceline Air Monitoring Plan:

- A. Ethylene Oxide monitoring data that was collected in the past year
- B. Nearest South Coast AQMD meteorological station
- C. Meteorological information collected at the Facility
- D. A map of the Facility and surrounding area that identifies the location of the following, as applicable:
  - i. Property boundary of the Facility
  - ii. Areas within the property boundary of the Facility that is inappropriate to site a monitor
  - iii. Each Sterilizer, Combined Sterilizer/Aerator, Aerator, Post-Aerator, Sterilant Gas Storage Area, Sterilant Gas Dispensing Area, Waste Storage Area, Control System, and exhaust stack of a Control System
  - iv. Buildings and associated building openings that contain a Sterilizer, Combined Sterilizer/Aerator, Aerator, Post-Aerator, Sterilant Gas Storage Area, Sterilant Gas Dispensing Areas, Waste Storage Areas, or Control Systems

- v. Nearest sensitive receptor
- vi. Nearest sensitive receptor downwind of the Facility based on meteorological data
- vii. Proposed Ethylene Oxide monitor(s)/sampler(s)
- viii. Proposed Ethylene Oxide sampler, if collecting real-time monitoring data
- ix. Proposed Meteorology station:
- x. Loading dock(s)
- E. A list of all applicable equipment and methods used to:
  - i. Collect a canister sample
  - ii. Collect real-time monitoring data
- F. The company name(s), location, and contact information that will be conducting:
  - i. Sample collection and sample retrieval
  - ii. Sample analysis
  - iii. Maintenance of monitoring infrastructure and equipment
  - iv. Set-up of monitoring equipment
- G. If collecting a canister sample to meet the requirements of paragraph (p)(4):
  - i. Sampling frequency

4. Number and Location of Ethylene Oxide Monitors

The owner or operator shall propose a minimum number of Ethylene Oxide in the Fenceline Air Monitoring Plan based on facility type and operation specified in Table 9.

At least one (1) the monitoring location shall be downwind of the Facility's operation that handles Ethylene Oxide operation at or near the property boundary.

For a Large Facility proposing two (2) monitoring locations, the additional monitoring location shall be located downwind of a location that would be a potential source of fugitive or stack emission.

For a Tier I Warehouse proposing two (2) monitoring locations, the additional monitoring location shall be located downwind of a location that would be potentially a source of fugitive emission.

**Table 9 – Minimum Number of Required Monitoring Locations**

<b><u>Facility Type</u></b>	<b><u>Minimum Number of Required Monitoring Locations</u></b>
<u>Large Facility permitted to use ≤ 100,000 lbs of Ethylene Oxide per calendar year</u>	<u>1</u>
<u>Large Facility permitted to use &gt; 100,000 lbs of Ethylene Oxide per calendar year</u>	<u>2</u>
<u>Tier I Warehouse</u>	<u>2</u>

5. Modification of Monitoring Locations

The Executive Officer may require a Facility to relocate monitoring locations prior to and following the approval of a Fenceline Air Monitoring Plan if information becomes available demonstrating either:

- A. A new or existing source of Ethylene Oxide was not previously identified or fully disclosed.
- B. An increase in Ethylene Oxide emissions from an existing source where existing monitoring location(s) are not capturing the potential Ethylene Oxide concentration.
- C. Existing monitoring location(s) are not capturing fenceline locations or near fenceline locations with the highest Ethylene Oxide concentration based on new information.

If required to relocate existing Fenceline Air Monitoring locations after the implementation of a Fenceline Air Monitoring Plan, within 30 days of receiving written notice from the Executive Officer, the owner or operator of a Facility shall relocate the monitoring location. The written notice would be considered an addendum to the approved Fenceline Air Monitoring Plan.

6. Disapproval of Fenceline Air Monitoring Plan

The Executive Officer may disapprove the Fenceline Air Monitoring Plan if the plan is incomplete, incorrect, inaccurate, or proposes inappropriate elements. The Executive Officer would inform the owner or operator of the Facility of the disapproval of the Fenceline Air Monitoring Plan.

**Appendix 5 –Semi-Annual Summary Reports**

Semi-annual summary reports shall, at a minimum, contain the following information specified in CARB’s Ethylene Oxide Airborne Toxic Control Measure and listed below:

1. The Large Facility name and address
2. The date of the report, and the beginning and ending dates of the reporting period
3. A brief description of each Control System including air pollution control devices and the SCEMS or CEMS
4. For each Control System air pollution control device:
  - A. The operating parameter limitations specified in the Permit to Operate, Control System Implementation Plan, and/or the Facility Implementation Plan
  - B. The monitoring equipment manufacturer and model number for each continuous monitoring system (CMS)
  - C. The date of the latest monitoring system certification or audit for each CMS
  - D. A monitoring system performance summary, including the total monitoring system downtime recorded in hours, the total duration of monitoring system downtime expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total monitoring system 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 for each CMS
  - E. A description of any changes in monitoring system, processes, or controls since the last reporting period for each CMS
5. For each Control System exhaust stack:
  - A. The emission limitations specified in the Permit to Operate, Control System Implementation Plan, and/or the Facility Implementation Plan
  - B. The monitoring equipment manufacturer(s) and model number(s) for each SCEMS or CEMS
  - C. The date of the latest monitoring system certification or audit for each SCEMS or CEMS
  - D. 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 for each SCEMS or CEMS

- E. A monitoring system performance summary, including the total monitoring system downtime recorded in hours, the total duration of monitoring system downtime expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total monitoring system 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 for each SCEMS or CEMS
- F. A description of any changes in monitoring system, processes, or controls since the last reporting period for each SCEMS or CEMS

6. The total operating time during the reporting period

7. The name, title, and signature of who is certifying the accuracy of the report

**Appendix 6 –Semi-Annual Excess Emission Reports**

Semi-annual excess emission reports shall, at a minimum, contain the following information specified in CARB’s Ethylene Oxide Airborne Toxic Control Measure:

1. The name, title, and signature of who is certifying the accuracy of the report
2. The date and time identifying each period during which the monitoring system was inoperative except for zero (low-level) and high-level checks
3. The date and time identifying each period during which the monitoring system 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 monitoring system that was inoperative or out of control
9. The total process operating time during the reporting period