(Adopted December 21, 1990)(Amended January 4, 1991)(Amended December 1, 2023)

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

(a) Purpose

The purpose of this rule is to protect public health by reducing ~~e~~Ethylene ~~o~~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 ~~o~~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.~~

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

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

~~(3)~~(4) 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 by Sterilizers or Combined Sterilizer/Aerators in the seven (7) operating days including and prior to the date of the real-time 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 air pollution control devices in series or parallel and exhausts to one (1) or more stacks as identified by the Facility in a permit to operate, a Title V permit, a Control System Implementation Plan, or a Facility Implementation Plan.

(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.

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

(12)~~(7)~~ EXHAUST STREAM is ~~the ethylene oxide~~ Ethylene Oxide-contaminated 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 is 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 is the furthest exterior wall of a Permanent Total Enclosure that is opposite the Windward Wall.

(18) MEDIUM FACILITY is a Facility performing Sterilization 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 performs Sterilization at the Facility.

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

(20) PERMANENT TOTAL ENCLOSURE (PTE) is 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 – Definition 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.~~

(c) (21) 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.

(22) POST-AERATION STORAGE FACILITY is any Facility not performing Sterilization that stores Sterilized materials and has installed a Control System.

(23) PRECONDITIONER is any equipment, area, or room used to treat Products prior to a Sterilization Cycle to attain a specific temperature and relative humidity.

(24) 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.~~

(25) 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.

(26) SMALL FACILITY is a Facility performing Sterilization 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.

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

(c) (28) STERILANT GAS DISPENSING AREA is any area used to dispense Sterilant Gas used by a Sterilizer or a Combined Sterilizer/Aerator.

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

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

(31) STERILIZATION CYCLE is the process where Products and other 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.

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

(33)~~(12)~~ STERILIZER is any chamber or related piece of equipment (excluding a Combined Sterilizer/Aerator) that uses Sterilant Gas ~~ethylene oxide or an ethylene oxide mixture~~ in ~~any sterilization~~ Sterilization~~or fumigation process~~.

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

(35) TIER I WAREHOUSE is a Facility that 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] with an indoor floor area used for Warehousing Activities of at least 250,000 square feet.

(36) TIER II WAREHOUSE is a Facility that reports to U.S. FDA as a Wholesale Distributor or a Third-Party Logistics Provider as of [Date of Rule Amendment] with an indoor floor area used for Warehousing Activities of at least 100,000 square feet and less than 250,000 square feet.

(37) 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 collected by the owner or operator, U.S. EPA, California Air Resources Board, or the Executive Officer.

(c) (38) WAREHOUSING ACTIVITIES are 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.

(39) 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.

(40) WINDWARD WALL is 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:

(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 (l); or

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

(D) Demonstrate by a source test meeting the requirements in subdivision (l) that the facility-wide mass emission rate from all exhaust stacks for all Control Systems at the facility does not exceed either:

(i) 0.015 pounds per hour (lbs/hr) of Ethylene Oxide; or

(ii) A calculated facility-wide mass emission rate of Ethylene Oxide, based on permitted Ethylene Oxide usage and the required control

efficiency of 99.99% or greater, by weight, determined pursuant to Appendix 1 – Calculations; and

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

(i) No later than September 1, 2025 for a Control System installed or modified on or before July 3, 2025;

(ii) Within 60 days after initial operation of a Control System installed or modified after July 3, 2025;

(iii) No later than 12 calendar months from the date of the most recent source test for any Control System used to demonstrate a control efficiency of 99.99% or greater, by weight; and

(iv) No later than 12 calendar months from the date of the most recent source test of the Control System used to demonstrate the Ethylene Oxide concentration requirement in clause (d)(1)(C)(ii) or the facility-wide mass emission rate requirement in subparagraph (d)(1)(D), unless the owner or operator of the Large Facility monitors the Control System by operating a SCEMS or CEMS that is certified by the Executive Officer and conducts an annual Relative Accuracy Test Audit (RATA) for the SCEMS or CEMS monitoring the Control System.

(2) Stack Emission Monitoring Requirements

Beginning on the date specified in Table 1 – Implementation Schedule, the owner or operator of a Large Facility shall:

(A) Monitor the Ethylene Oxide emissions from each exhaust stack of a Control System 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 facility-wide mass emission rate of Ethylene Oxide from all exhaust stacks for all Control Systems at the Facility does not exceed either:

(i) 0.015 lbs/hr on a rolling 30-day period, determined pursuant to Appendix 1 – Calculations; or

(ii) The calculated facility-wide mass emission rate on a rolling 30-day period, based on permitted Ethylene Oxide usage and the required control efficiency of 99.99% or greater, by weight, determined pursuant to Appendix 1 – Calculations; and

(d) (2) (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, by volume at stack conditions, at each exhaust stack in the Control System on a rolling 30-day period, determined pursuant to Appendix 1 – Calculations.

(3) Fugitive Emission Requirements

Beginning on the date specified in Table 1 – Implementation Schedule, the owner or operator of a Large Facility shall:

(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);

(B) In lieu of maintaining all Post-Aerators within a Permanent Total Enclosure pursuant to subparagraph (d)(3)(A), maintain at least one (1) Post-Aerator within a Permanent Total Enclosure that meets the requirements in subdivision (k) where any materials Sterilized at the Facility are loaded and stored for at least seven (7) calendar days after completing Aeration, provided:

(i) The existing Large Facility was permitted as such as of [Date of Amendment];

(ii) The Large Facility is permitted to use less than or equal to 40,000 lbs of Ethylene Oxide per calendar year; and

(iii) The owner or operator proposes at least two (2) monitoring locations in a Fenceline Air Monitoring Plan;

(C) In lieu of maintaining all Elements in a Sterilant Gas Storage Area within a Permanent Total Enclosure pursuant to subparagraph (d)(3)(A) at a Large Facility permitted as such as of [Date of Amendment]:

(i) Monitor all Elements in a Sterilant Gas Storage Area by implementing a Leak Detection and Repair Program that meets the requirements in subdivision (m);

(ii) Install, calibrate, operate, and maintain a real-time monitor that measures ambient Ethylene Oxide concentrations at a minimum of three (3) locations in the Sterilant Gas Storage Area;

(iii) Measure and record ambient Ethylene Oxide concentration using an established methodology approved by the Executive Officer that

has a method detection limit of 1.0 ppb or lower every one (1) minute;

(d) (3) (C) (iv) Install and maintain an emergency enclosure that vents to a Control System in the Sterilant Gas Storage Area;

(v) Conduct a Leak inspection of all Elements in the Sterilant Gas Storage Area immediately upon measurement of an ambient Ethylene Oxide concentration exceeding 3.0 ppb in the Sterilant Gas Storage Area; and

(vi) Store any Element in the emergency enclosure that vents to a Control System upon discovery the Element is a contributing source of the Ethylene Oxide concentration exceeding 3.0 ppb in the Sterilant Gas Storage Area; and

(D) For each Control System, either 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) or operate the Control System within a Permanent Total Enclosure that meets the requirements in subdivision (k).

Table 1 – Implementation Schedule

Facility Category	Rule Requirement	Effective Date
Large Facility existing as of [Date of Rule Amendment]	(d)(1)	September 1, 2025 or 60 days after final SCEMS or CEMS certification is issued by the Executive Officer for each Control System at the Facility, whichever is earlier
	(d)(2)	18 months after receiving approval for an application for SCEMS or CEMS
	(d)(3)	September 1, 2025 or 60 days after final SCEMS or CEMS certification is issued by the Executive Officer for each Control System at the Facility, whichever is earlier
Large Facility existing after [Date of Rule Amendment]	(d)(1)	[Date of Rule Amendment]
	(d)(2)	Date of Permit to Operate issuance
	(d)(3)	[Date of Rule Amendment]

(d) (4) Labeling and Facility Diagram Requirements

Beginning [90 Days After Date of Amendment], the owner or operator of a Large Facility shall:

(A) Prior to a Sterilized Palletized Unit leaving a Post-Aerator, affix 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:

TREATED 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, Sterilant Gas Storage Area, Sterilant Gas Dispensing Area, and Waste Storage Area with:

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

(d) (4) (B) (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, "TREATED 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, Sterilizer Exhaust Vacuum Pump, Sterilant Gas Storage Area, Sterilant Gas Dispensing Area, and Waste Storage Area.

(5) Submittal of Permit and SCEMS or CEMS Applications

The owner or operator of a Large Facility shall:

(A) No later than May 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 May 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 ±5.6 degrees Celsius (±10 degrees Fahrenheit); and

(d) (6) (B) (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; and

(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 February 1, 2024 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 or a third-party contracted with the Executive Officer to conduct mobile monitoring; or

(ii) An independent third-party operator to conduct mobile monitoring capable of:

(I) Measuring Ethylene Oxide using an Ethylene Oxide specific instrument, or other method approved by the Executive Officer, with a method detection limit of 1.0 ppb or lower, and a measurement frequency of at least once every five (5) seconds; and

(II) A measurement protocol approved by the Executive Officer, capable of collecting concurrent grab canister samples for subsequent analysis per subparagraph (d)(7)(E).

(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:

(i) Pay fees pursuant to Appendix 2 – Mobile Monitoring Fee and Program Fund; and

(d) (7) (C) (ii) No later than 30 days prior to no longer electing to have the Executive Officer or a third-party contracted with the Executive Officer conduct mobile monitoring, report to the Executive Officer in writing by electronic mail to Rule1405notifications@aqmd.gov.

(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:

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

(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; and

(iii) Pursuant to a measurement protocol approved by the Executive Officer.

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

(i) Collect a grab canister sample at locations with three (3) consecutive readings of Ethylene Oxide that measure above the Level 2 concentration specified in Table 5 – Trigger Threshold for Sterilization Facilities, unless three (3) canister-based grab samples were previously collected during the mobile monitoring calendar day; and

(ii) Analyze grab 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) with a method detection limit of 0.2 ppb or lower.

(8) Interim Fenceline Air 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.

(e) Medium Facility Requirements

(1) Stack Emission Requirements

Beginning January 1, 2026, the owner or operator of a Medium Facility shall:

(e) (1) (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 (l); or

(ii) Not exceed an Ethylene Oxide concentration of 0.01 ppm, by volume at stack conditions, demonstrated by a source test that meets the requirements in subdivision (l); 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:

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

(e) (2) (B) (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 [90 Days 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) Prior to a Sterilized Palletized Unit leaving the first Post-Aerator, affix 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:

TREATED WITH ETHYLENE OXIDE (EtO/EO)
AERATION COMPLETED ON {Date of Completion}

; and

(D) Label or write on each bill of lading listing Sterilized Products, "TREATED 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:

(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 at stack conditions, 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:

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

applicable to the Small Facility, within a Permanent Total Enclosure that meets the requirements in subdivision (k):

(f) (2) (B) (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 [90 Days 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 September 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 (l);

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

(A) No later than September 1, 2025 for a Control System installed or modified on or before July 3, 2025;

(g) (2) (B) Within 60 days after initial operation of a Control System installed or modified after July 3, 2025; and

(C) No later than 12 calendar months from the date of the most recent source test of the Control System;

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

(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

Type of Warehouse	**Start Date to Record Number of Sterilized Palletized Units**	**End Date to Record Number of Sterilized Palletized Units**
Tier I Warehouse or Tier II Warehouse	April 1, 2024	March 31, 2025

(2) No later than June 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 in writing by electronic mail to Rule1405notifications@aqmd.gov 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;

(h) (2) (E) Total number of Sterilized Palletized Units received from any entity performing Sterilization each month during the consecutive 12-month period specified in Table 2 – Warehouse Recording Period;

(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 [180 days After Date of Rule Amendment], fund and participate in a real-time fenceline air monitoring 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 2 – Mobile Monitoring Fee and Program Fund for funding a real-time fenceline air monitoring demonstration program;

(ii) Provide access for South Coast AQMD personnel and its contractors; and

(iii) Provide for each real-time monitor an appropriate location to operate and the infrastructure to operate; or

(D) Not receive Sterilized Palletized Units between April 1, 2024 to March 31, 2025 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 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:

(h) (5) (A) (i) Emission factors approved by U.S. EPA, CARB, or South Coast AQMD; 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;

(B) No later than [180 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 or 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 greater~~more~~, by weight.

(B) If ~~e~~Ethylene ~~o~~Oxide emissions from ~~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 greater~~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 greater~~more~~, by weight.

(2) ~~The following requirements shall be met by June 21, 1992 by t~~The owner or 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 ~~e~~Ethylene

~~o~~Oxide per calendar year until the date specified in Table 8 – Interim Requirements under subdivision (u):

(i) (2) (A) Sterilizer(s) and Combined Sterilizer/Aerator(s) shall be vented to control equipment with an efficiency of 99.9 ~~percent~~% or greater~~more~~, by weight.

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

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

(3) ~~The following requirements shall be met by December 21, 1991 by t~~The owner or operator of a Facility performing Sterilization ~~all persons~~ who uses a total of more than 4,000 ~~pounds~~ lbs of ~~e~~Ethylene ~~o~~Oxide per calendar year 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~~to control equipment with an efficiency of 99.9 ~~percent~~% or greater~~more~~, by weight.

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

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

(D) If the ~~e~~Exhaust ~~s~~Streams 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 greater~~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 greater, by weight.

(i) (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 ppm by volume 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 (i)(7)~~(f), 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~~

(i) (7)~~(1)~~ Source tests shall be conducted according to CARB Test Method 431 or an acceptable source test method approved by ~~the~~ CARB and the ~~District~~Executive Officer. Unless otherwise specified in a source test protocol approved by the Executive Officer~~In addition~~, the following requirements shall be met:

(A) Tests on control equipment shall be run with a typical load in the ~~sterilizer~~ Sterilizer, Combined Sterilizer/Aerator, or ~~aerator~~Aerator.

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

(C) The efficiency of control equipment shall be determined under normal operating conditions. To measure the control efficiency on the ~~sterilizer~~ Sterilization Cycle ~~exhaust~~ Exhaust ~~stream~~Stream, 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)~~(2)~~ ~~Leak t~~Tests pursuant to paragraph to (i)(5) shall be conducted by CARB Test Method 21 using a portable flame ionization detector or a non-dispersive infrared analyzer calibrated with methane, or an acceptable alternative method or analytical instrument approved by the Executive Officer~~ 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 the following requirements:

(A) Measures the following parameters:

(i) Ethylene Oxide concentration, with a resolution of at least 0.001 ppm, by volume;

(ii) Oxygen concentration, if required by the SCEMS or CEMS certification; 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 the Executive Officer; 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 facility-wide mass emission rate in lbs/hr from all exhaust stacks of each Control System at the Facility, determined pursuant to Appendix 1 – Calculations.

(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 for a minimum of 60 consecutive minutes.

(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 and applicable requirements in Rule 218 through Rule 218.3, including conduct:

(A) A calibration error test for every 24 hours with a two (2) hour grace period;

(B) A cylinder gas audit for every calendar quarter when relative accuracy test audit is not conducted, but in no more than three quarters in succession; and

(C) A relative accuracy test audit performed annually no later than the end of the calendar quarter of the previous relative accuracy test, in the as-found unit operating condition.

(j) (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 a rolling one (1) hour period;

(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;

(k) (2) (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;

(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

(H) Record the differential pressure reading at a minimum of every one (1) minute for each differential pressure monitor; 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 4 – PTE Inward Face Air Velocity Measurement Procedures.

(l) 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 and performance standard;

(l) (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 (l)(1)(A) through (C) if there are any changes in the conditions, numbers, or parameters referenced by subparagraphs (l)(1)(A) through (C) in the most recently-approved source test protocol or if the Executive Officer requests an updated or new 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 or verbally by telephone to 1-800-CUT-SMOG;

(4) Report any changes to the source test schedule in writing by electronic mail to Rule1405notifications@aqmd.gov or verbally by telephone to 1-800-CUT-SMOG 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 most recent source test protocol approved by the Executive Officer;

(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 emissions 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.

(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 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, by volume, 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, by volume, 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 reading 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 ~~s~~Sterilizer ~~e~~Exhaust ~~v~~Vacuum ~~p~~Pump working fluid to the wastewater stream.

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

(3) The owner or operator of a Facility performing Sterilization shall not allow the release of uncontrolled emissions of Ethylene Oxide to atmosphere from any Permanent Total Enclosure at any time.

(n) (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).

(6) The owner or operator of a Large Facility not maintaining all Elements in a Sterilant Gas Storage Area within a Permanent Total Enclosure that meets the requirements in subdivision (k) shall not allow any materials that contain Ethylene Oxide, other than Sterilant Gas, in the Sterilant Gas Storage Area.

(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) through (d)(4)(D); 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 – Applicable Ethylene Oxide Usage, 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 5 – 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

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

(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 24-hour canister sample collection shall:

(p) (2) (B) (i) Collect a 24-hour canister 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 24-hour canister 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) Determine Ethylene Oxide concentration of the sample with a method of detection limit 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

(p) (2) (D) (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) 24-hour canister sample at each monitoring location concurrently;

(III) Collect and analyze the 24-hour canister sample pursuant to clause (p)(2)(B)(ii) and (p)(2)(B)(iii); and

(IV) Submit the 24-hour canister sample collected for analysis within one (1) calendar day of collection.

Table 4 – Concentration Threshold

Applicable Date	Average Concentration
[Date of Amendment] – October 31, 2025	> 17.5 ppb
On or after November 1, 2025	> 3.0 ppb

(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 calibration, maintenance, malfunction, or other occurrence beyond the control of the Facility:

(I) More than one valid 24-hour canister sample; and

(II) More than 96 hours of valid real-time data; and

(ii) Due to any other reason:

(p) (2) (F) (ii) (I) Any valid 24-hour canister sample; and

(II) Any valid real-time data.

(3) Fenceline Air Monitoring End Date

(A) Beginning 60 days after final SCEMS or CEMS certification is issued by the Executive Officer for each Control System at the Facility, 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).

(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 24-hour canister 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 not use more than the applicable Ethylene Oxide daily limit specified in Table 6 – Curtailment Daily Usage Limit.

Table 5 – Trigger Threshold for Sterilization Facilities

Trigger Type	Trigger Threshold	Facility Type	Applicability Start Date	Applicability End Date
Level 1	> 17.5 ppb and ≤ 25.0 ppb	Large Facility	[Date of Amendment]	October 31, 2025
		Medium Facility or Small Facility	[Date of Amendment]	March 1, 2026
Level 2	> 25.0 ppb	Large Facility	[Date of Amendment]	October 31, 2025
		Medium Facility or Small Facility	[Date of Amendment]	March 1, 2026
Level 3	> 3.0 ppb	Large Facility	November 1, 2025	None
		Medium Facility or Small Facility	March 2, 2026	None

Table 6 – Curtailment Daily Usage Limit

Trigger Type	First Result	Second Result	Third Result
Level 1	80% of Baseline Operation	50% of Baseline Operation	0% of Baseline Operation*
Level 2	50% of Baseline Operation	0% of Baseline Operation*	Not Applicable
Level 3	50% of Baseline Operation	0% of Baseline Operation*	Not Applicable

**Subsequent sample results exceeding a trigger threshold would maintain a daily usage limit of 0% of Baseline Operation*

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

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

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

(q) (3) (A) (i) Subsequent result(s) of a 24-hour period obtained via a 24-hour 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 – Trigger Threshold for Sterilization Facilities; 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 – Trigger Threshold for Sterilization Facilities; or

(B) If not 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 24-hour 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 – Trigger Threshold for Sterilization Facilities; 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 24-hour 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 Results that are 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:

(s) (1) (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, 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; and

(iv) Document source of minimum required time of Aeration specified in clause (s)(1)(L)(iii).

(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, 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.

(s) (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

(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.

(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 6 – Semi-Annual Summary Reports; and

(B) Semi-Annual Excess Emission Report pursuant to Appendix 7 – Semi-Annual Excess Emission Reports, if the duration of excess emissions or parameter monitoring exceedances for the reporting period exceeds 1% of the reporting period or the total monitored downtime for the reporting period exceeds 5% 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.

(t) (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

Facility Type	**Ethylene Oxide Usage per Calendar Year**
Medium Facility	2,000 lbs
Small Facility	400 lbs
Other*	4 lbs

**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 April 1, 2024 until March 31, 2025, record either:

(i) The First Destination of Sterilized Palletized Units shipped and the number of Sterilized Palletized Units shipped each month to each First Destination; or

(ii) The customer who ordered the Sterilization of the Sterilized Palletized Units and the number of Sterilized Palletized Units ordered by the customer each month; and

(B) No later than June 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 500 Sterilized Palletized Units or customers that order more than 500 Sterilized Palletized Units over the reporting period pursuant to subparagraph (t)(5)(A) that includes the following:

(I) Name of First Destination or customer;

(II) Mailing address of First Destination or customer; and

(III) Contact information of responsible party; and

(t) (5) (B) (ii) Total number of Sterilized Palletized Units shipped to each First Destination or ordered by each customer identified in clause (t)(5)(B)(i) over the reporting period; and

(iii) Electronic copy of records maintained pursuant to subparagraph (t)(5)(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 as soon as reasonably possible, but no later than 9:00 a.m. of the next operating day after receiving the results of a grab 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:

(t) (7) (A) If meeting the requirements of subparagraph (p)(2)(A) by 24-hour canister sample collection;

(i) No later than 14 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-hour canister 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 air monitor, date of occurrence, and reason of occurrence;

(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) As soon as reasonably possible, but no later than 48 hours after exceeding 24 hours of valid data not recorded over a consecutive 30-day period at a monitoring location, 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 air monitor, date of occurrence, and reason of occurrence; and

(iii) No later than two (2) hours after starting to collect a 24-hour canister sample, the location and the start time of collecting the 24-hour canister sample to the Executive Officer by calling 1-800-CUT-SMOG or by electronic mail to Rule1405notifications@aqmd.gov; and

(C) No later than 14th 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 as soon as reasonably possible, but no later than 9:00 a.m. of the next operating day after

receiving the results of a 24-hour sample that is at or above the applicable concentration specified in Table 4 – Concentration Threshold either:

(t) (8) (A) Results of the 24-hour 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) SCEMS or CEMS Exceedance Reporting

The owner or operator of a Facility required to monitor the emissions from a Control System by SCEMS or 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 facility-wide 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).

(11) Operational Noncompliance Reporting

The owner or operator of a Facility 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 knowing of the following occurrences:

(A) A source test conducted pursuant to subdivision (l) indicating noncompliance with an applicable performance standard; or

(t) (11) (B) A Component or Element subject to the LDAR program pursuant to subdivision (m) is not maintained free of Leaks greater than 2 ppm, by volume, above background.

(u)~~(g)~~ Exemptions

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

(1) The following requirements do not apply to an owner or operator of a Facility that uses four (4) lbs or less of Ethylene Oxide per calendar year:

(A) Subdivisions (i) and (n); and

(B) Subparagraph (s)(1)(L).

(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

Applicable Subdivision	Beginning Date of Exemption
(d)	September 1, 2025 or 60 days after final SCEMS or CEMS certification is issued by the Executive Officer for each Control System at the Facility, whichever is earlier
(e)	January 1, 2026
(f)	January 1, 2026
(g)	September 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;

(u) (3) (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 the 1st day of the month following the 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 the 1st day of the month following the 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 air monitoring at a sampling frequency at least 1-in-6 days; or

(u) (5) (B) The owner or operator of the Large Facility conducts fenceline air monitoring for Ethylene Oxide pursuant to a plan approved by the Executive Officer.

(6) The requirements of subparagraph (d)(2)(B) do not apply to an owner or operator of a Large Facility that is unable to demonstrate compliance with the applicable performance standard specified in (d)(2)(B) during the present rolling 30-day period, provided the owner or operator:

(A) Does not perform Sterilization for at least 48 consecutive hours after being unable to demonstrate compliance with the applicable performance standard;

(B) After resuming operations, demonstrates by a SCEMS or CEMS that the sum of mass emission rates, averaged over a calendar day and measured at each exhaust stack, meets the performance standard specified in either clause (d)(2)(B)(i) or (d)(2)(B)(ii); 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 with a Control System that is unable to demonstrate compliance with the performance standard specified in subparagraph (d)(2)(C) during the present rolling 30-day period, provided the owner or operator:

(A) Does not perform Sterilization with Sterilizers and Combined Sterilizer/Aerators controlled by the Control System for at least 48 consecutive hours after being unable to demonstrate compliance with the performance standard;

(B) After resuming operations, demonstrates by a SCEMS or CEMS that emissions of Ethylene Oxide do not exceed a concentration of 0.01 ppm, by volume at stack conditions, at each exhaust stack in a Control System averaged over each calendar day in operation after resuming Sterilization with Sterilizers and Combined Sterilizer/Aerators controlled by the Control System; and

(C) Reports to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov 24 hours prior to initiating a new Sterilization Cycle with Sterilizers and Combined Sterilizer/Aerators controlled by the Control System.

(u) (8) The requirements of paragraph (j)(5) do not apply to an owner or operator that exceeded 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, provided the owner or operator:

(A) Does not perform Sterilization for at least 48 consecutive hours after exceeding 96 hours of missing or invalid data per SCEMS or CEMS the present rolling 30-day period;

(B) After resuming operation, does not exceed more than one (1) hour of missing or invalid data during a calendar day when a Sterilization Cycle is performed; and

(C) Reports to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov 24 hours prior to initiating a new Sterilization Cycle.

(9) 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 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 approves the real-time monitoring method to be exclusively used; 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 (q).

(10) The following requirements do not apply to a new or modified Large Facility, not permitted as a Large Facility on [Date of Rule Amendment] and permitted as a Large Facility 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).

(11) The requirements of subdivision (q) to 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 that are 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.

(u) (12) The requirements of subdivision (q) to curtail Sterilization do not apply to a Product (including medical devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery or Palletized Units containing the Product) determined by a local, state, or federal public health agency, such as the U.S. FDA, or a California hospital or medical center, to be reasonably likely to experience a reduced supply and is critical to public health, as certified by the owner or operator or reported to the Executive Officer, provided:

(A) For owner or operator certification, the owner or operator no later than 12 hours prior to initiating the first Sterilization Cycle each operating day during the curtailment event, reports to the Executive Officer in writing by electronic mail to Rule1405notifications@aqmd.gov for each Product reasonably likely to experience a reduced supply and is critical to public health the following:

(i) Product name;

(ii) Product code assigned by the U.S. FDA; and

(iii) Name of public health agency, or California hospital, or medical center that made the determination;

(B) Where applicable and as soon as reasonably possible, the owner or operator provides the Executive Officer with either:

(i) A communication written by the public health agency or California hospital or medical center that made the determination, dated within 90 days of certification that identifies the Product, the date of determination, and estimated duration of the status; or

(ii) A statement from the owner or operator certifying that the communication from the public health agency or California hospital or medical center is non-public if prohibited by law;

(C) The owner or operator maintains daily records of the amount of Sterilant Gas (measured or calculated, in lbs per day) used to sterilize Products, including Palletized Units containing Products, reported pursuant to paragraph (u)(12) for each operating day during the curtailment event; and

(D) For each Palletized Unit containing the Product reasonably likely to experience a reduced supply and is critical to public health, the owner or operator affixes on a vertical surface on the Palletized Unit at least one (1)

yellow label, size 8.5 inches by 11 inches, with black letters of sufficient size and contrast as to be readily visible and legible, with the following prior to entering a Sterilizer or Combined Sterilizer/Aerator:

(u) (12) (D) (i) Product name;

(ii) Product code assigned by the U.S. FDA; and

(iii) Name of public health agency or California hospital or medical center that made the determination.

(13) The requirements of paragraphs (h)(1) and (h)(2) do not apply to the owner or operator of a Tier I Warehouse provided:

(A) No later than [60 Days After Date of Rule Amendment], reports to the Executive Officer in writing by electronic mail to Rule1405notifications@aqmd.gov that the Tier I Warehouse would not receive Sterilized Palletized Units between April 1, 2024 to March 31, 2025 from any entity performing Sterilization; and

(B) The owner or operator does not receive Sterilized Palletized Units between April 1, 2024 to March 31, 2025 from any entity performing Sterilization.

(14) The requirements of paragraph (k)(1) do not apply to an owner or operator of a Facility for any one (1) hour period when wind speed is greater than 20 miles per hour, averaged over a minute, at the Facility provided the owner or operator:

(A) Has an approved Fenceline Air Monitoring Plan that is being implemented pursuant to subdivision (p) or an approved Facility Implementation Plan, which includes the location and operation of a wind sensor;

(B) Records wind speed and direction data at a minimum of once per minute at all times using equipment capable of meeting the U.S. EPA Performance Criteria for Wind Sensors pursuant to the approved Fenceline Air Monitoring Plan or Facility Implementation Plan;

(C) Records the one (1) hour period when differential pressure data is excluded from determining compliance with paragraph (k)(1) and the corresponding wind speed and direction, averaged over a minute; and

(D) For each operating day with a one (1) hour period recorded pursuant to subparagraph (u)(14)(C), no later than 9:00 a.m. of the next operating day, submit to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov the information recorded pursuant to subparagraph (u)(14)(C).

Appendix 1 – Calculations

1. Applicability

   This appendix specifies the methodology for calculating performance standards specified in the rule.

2. Facility-Wide Mass Emission Rate

   Subparagraph (d)(2)(B) requires a demonstration by SCEMS or CEMS that the facility-wide mass emission rate from all exhaust stacks at the Facility does not exceed 0.015 lbs/hr on a rolling 30-day period. The 30-day rolling facility-wide mass emission rate shall be determined as follow.

   A. Determine Hourly Average for each Exhaust Stack

      i. An hourly average covers the 60-minute period commencing on the hour. For each exhaust stack, compute the hourly average utilizing all valid data points with at least one valid data point in each 15-minute quadrant of the hour.

      ii. For any hour in which required maintenance or quality assurance activities are performed, a minimum of two (2) valid data points, separated by at least 15 minutes, is required to calculate the hourly average, if the unit operates in two (2) or more quadrants of the hour. If the unit operates in only one (1) quadrant of the hour, at least one (1) valid data point is required to calculate the hourly average.

      iii. A valid data point for quantification is any data point recorded and reported from the SCEMS or CEMS meeting the quality assurance and quality control program requirements as specified in the applicable requirements of Rules 218 through 218.3.

      iv. If the conditions specified in A.i. or A.ii. are not met, then the hourly average is not valid.

   B. Determine Daily Average for each Exhaust Stack

      i. For each exhaust stack, compute the daily average by averaging all valid hourly averages in the calendar day.

      ii. At least one (1) valid hourly average is required to compute the daily average for the exhaust stack.

      iii. If the conditions specified by B.ii. are not met, then the daily average for the exhaust stack is not valid.

   C. Determine Daily Facility-Wide Mass Emission Rate

      i. Compute the daily facility-wide mass emission rate by adding all valid daily averages for each exhaust stack in the calendar day.

2. C. ii. If any exhaust stack has a daily average that is not valid for the calendar day, the facility-wide mass emission rate for that calendar day is not valid.

iii. Example below represents a facility with two exhaust stacks.

	Stack A	Stack B	Daily Facility-Wide Mass Emission Rate
Day 1	0.002 lbs/hr	0.005 lbs/hr	0.007 lbs/hr
Day 2	0.002 lbs/hr	INVALID	INVALID

The facility-wide mass emission rate for Day 2 is not valid and would not be considered in the 30-day rolling facility-wide mass emission rate.

D. Determine 30-Day Rolling Facility-Wide Mass Emission Rate

i. Compute the 30-day rolling facility-wide mass emission rate by adding the facility-wide mass emission rate for that day with the previous 29 daily facility-wide mass emission rates and divide by 30.

ii. Example

	Emission Rate (lb/hr)		
Day	Stack A	Stack B	Facility-Wide
Day 1	0.006	0.000	0.006
Day 2	0.001	0.005	0.006
Day 3	0.005	0.006	0.011
Day 4	0.004	0.006	0.010
Day 5	0.017	0.006	0.023
Day 6	0.015	0.005	0.020
Day 7	0.014	0.001	0.015
Day 8	0.013	0.007	0.019
Day 9	0.002	0.004	0.005
Day 10	0.007	0.002	0.008
Day 11	0.001	0.007	0.009
Day 12	0.008	0.007	0.016
Day 13	0.014	0.004	0.018
Day 14	0.002	0.003	0.006
Day 15	0.011	0.009	0.020
Day 16	INVALID	0.010	INVALID
Day 17	0.012	0.008	0.021

	Emission Rate (lb/hr)		
Day	Stack A	Stack B	Facility-Wide
Day 18	0.011	0.001	0.011
Day 19	0.005	0.001	0.005
Day 20	0.018	0.005	0.023
Day 21	0.019	0.003	0.022
Day 22	0.016	0.005	0.021
Day 23	0.010	0.009	0.019
Day 24	0.012	0.008	0.020
Day 25	0.005	INVALID	INVALID
Day 26	0.019	0.003	0.022
Day 27	0.006	0.009	0.014
Day 28	0.008	0.008	0.016
Day 29	0.008	0.002	0.010
Day 30	0.001	0.006	0.007
Day 31	0.011	0.004	0.014
Day 32	0.012	0.002	0.014

Add the most recent 30 valid daily facility-wide mass emission rates at the Facility and divide by 30. Day 16 and Day 25 would not be considered as part of the calculation. Day 31 and Day 32 would be considered as part of the calculation.

30-day rolling average = (0.006 + 0.006 + 0.011 + 0.010 + 0.023 + 0.020 + 0.015 + 0.019 + 0.005 + 0.008 + 0.009 + 0.016 + 0.018 + 0.006 + 0.020 + 0.021 + 0.011 + 0.005 + 0.023 + 0.022 + 0.021 + 0.019 + 0.020 + 0.022 + 0.014 + 0.016 + 0.010 + 0.007 + 0.014 + 0.014)/30 = **0.014 lbs/hr**

3. Concentration

For each Control System complying with the concentration limit specified in clause (d)(1)(C)(ii), subparagraph (d)(2)(C) requires a demonstration by SCEMS or CEMS that the emissions of Ethylene Oxide do not exceed a concentration of 0.01 ppm, by volume at stack conditions, on a rolling 30-day period. The 30-day rolling concentration shall be determined as follow.

A. Determine Hourly Average for the Exhaust Stack

i. An hourly average covers the 60-minute period commencing on the hour. For each exhaust stack, compute the hourly average utilizing all valid data points with at least one valid data point in each 15-minute quadrant of the hour.

ii. For any hour in which required maintenance or quality assurance activities are performed, a minimum of two (2) valid data points, separated by at least 15 minutes, is required to calculate the hourly average, if the unit operates in two (2) or more quadrants of the hour. If the unit operates in only one (1) quadrant

of the hour, at least one (1) valid data point is required to calculate the hourly average.

3. A. iii. A valid data point for quantification is any data point recorded and reported from the SCEMS or CEMS meeting the quality assurance and quality control program requirements as specified in the applicable requirements of Rules 218 through 218.3.

iv. If the conditions specified in A.i. or A.ii. are not met, then the hourly average is not valid.

B. Determine Daily Average Concentration for the Exhaust Stack

i. For each exhaust stack, compute the daily average by averaging all valid hourly averages in the calendar day.

ii. At least one (1) valid hourly average is required to compute the daily average concentration for the exhaust stack.

iii. If the conditions specified B.ii. are not met, then the daily average concentration for the exhaust stack is not valid.

C. Determine 30-Day Rolling Concentration

i. Compute the 30-day rolling concentration by adding the daily average concentration with the previous 29 daily average concentrations and divide by 30.

ii. Example

Day	Concentration (ppm)	Day	Concentration (ppm)	Day	Concentration (ppm)
Day 1	0.014	Day 12	INVALID	Day 23	0.020
Day 2	0.012	Day 13	0.002	Day 24	0.006
Day 3	0.007	Day 14	0.000	Day 25	0.015
Day 4	0.006	Day 15	0.019	Day 26	0.006
Day 5	0.002	Day 16	0.003	Day 27	0.013
Day 6	0.004	Day 17	0.016	Day 28	0.015
Day 7	0.006	Day 18	0.005	Day 29	0.008
Day 8	0.003	Day 19	0.016	Day 30	0.008
Day 9	INVALID	Day 20	0.009	Day 31	0.008
Day 10	0.017	Day 21	0.015	Day 32	0.011
Day 11	0.004	Day 22	0.006		

Add the most recent 30 valid daily average concentration for the exhaust stack and divide by 30. Day 9 and Day 12 would not be considered as part of the calculation. Day 31 and Day 32 would be considered as part of the calculation.

30-day rolling average = (0.014 + 0.012 + 0.007 + 0.006 + 0.002 + 0.004 + 0.006 + 0.003 + 0.017 + 0.004 + 0.002 + 0.000 + 0.019 + 0.003 + 0.016 + 0.005 + 0.016 + 0.009 + 0.015 + 0.006 + 0.020 + 0.006 + 0.015 + 0.006 + 0.013 + 0.015 + 0.008 + 0.008 + 0.008 + 0.011) / 30 = **0.009 ppm**

4. Calculated Facility-Wide Mass Emission Rate

Clause (d)(1)(D)(ii) requires a demonstration via a source test that the facility-wide mass emission rate from all exhaust stacks at the Facility does not exceed a calculated facility-wide mass emission rate. Clause (d)(2)(B)(ii) requires a demonstration via SCEMS or CEMS that the facility-wide emission rate from all exhaust stacks at the Facility does not exceed a calculated facility-wide mass emission rate. The calculated facility-wide mass emission rate is calculated from permitted usage (lbs), which is either from the facility-wide permit limit for a calendar year or from the sum of permit limits for equipment that performs Sterilization at the Facility for a calendar year, and the lowest allowable control efficiency expressed to the thousandths of a percent to demonstrate compliance with a control efficiency of 99.99% or greater, by weight, divided by 365 days and 24 hours, expressed to the nearest thousandths lbs/hr.

A. Example

Facility-Wide Permit Limit: 1,000,000 lbs

Lowest allowable control efficiency, by weight: 99.985% (rounds to 99.99%)

1,000,000 lbs * (1-0.99985) = 150 lbs/365 days/24 hours = 0.017 lbs/hr

Appendix 2 – 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 or a third-party contracted by 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 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 A.i. and A.ii. shall not exceed $13,000 for a monitoring day

      Paying the preceding fees is 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:

      i. Be determined in a contractual agreement between the Executive Officer and the independent third-party contractor for services provided by the third-party contractor

      ii. Include a 6.25% of administrative cost for South Coast AQMD to oversee the contract

      iii. Not exceed $33,000 for a monitoring day

   C. The mobile monitoring fee will be billed on a quarterly basis, and payment shall be 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% surcharge shall be imposed.

3. Real-time Fenceline Air Monitoring Demonstration Program Fund

   The owner or operator electing to fund and participate in a real-time Fenceline Air Monitoring demonstration program at a Tier I Warehouse shall pay South Coast AQMD

an initial payment not to exceed $150,000 within 6 months of [Date of Amendment] for South Coast AQMD or its contractors to acquire, assemble, install, maintain, train, test, analyze, administer, and decommission a real-time Fenceline Air Monitoring demonstration program to meet the requirements of subparagraph (h)(3)(C). The owner or operator shall pay South Coast AQMD a second payment, not to exceed $100,000, within 18 months of [Date of Amendment] for the remaining costs for the demonstration program exceeding the initial payment.

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 – 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

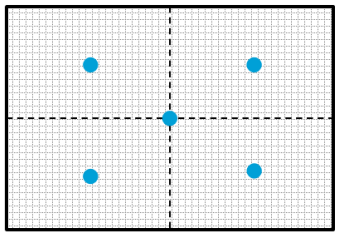
   The inward face air velocity measurement test shall be conducted while the Permanent Total Enclosure is in normal operation and under typical conditions representative of the Facility's operations.

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. The measurement with the anemometer should be performed where a steady reading is obtained and recorded at each measurement point.

5. Recordkeeping

The following information shall be recorded for each inward face air velocity measurement.

Anemometer Make and Model:

Anemometer Calibration Factor:

Anemometer Calibration Date:

Inward Face Air Velocity Measurements:

Natural Draft Opening Location: _____

Upper Left:_____fpm Upper Right:_____fpm

Center:_____fpm

Lower Left:_____fpm Lower Right: _____fpm

Measurements Conducted by:

Measurement Date:

Appendix 5 – 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 are 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

3. D. 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 24-hour 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 – Minimum Number of Required Monitoring Locations.

At least one (1) 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

Facility Type	Minimum Number of Required Monitoring Locations
Large Facility permitted to use ≤ 100,000 lbs of Ethylene Oxide per calendar year	1
Large Facility permitted to use ≤ 40,000 lbs of Ethylene Oxide per calendar year and proposing not to maintain all Post-Aerators within a Permanent Total Enclosure	2
Large Facility permitted to use > 100,000 lbs of Ethylene Oxide per calendar year	2
Tier I Warehouse	2

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 6 – 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 percentage 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 percentage 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

5. 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 percentage 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 7 – 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