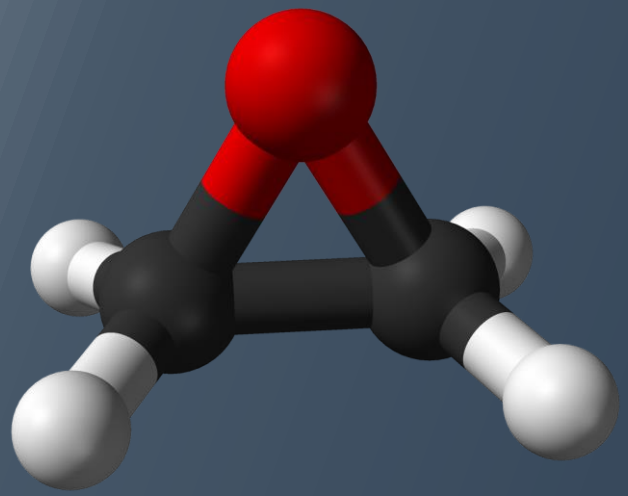


PUBLIC WORKSHOP

Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions from Sterilization and Related Operations

March 23, 2023
2:00 PM

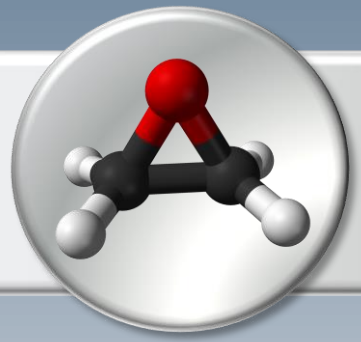
Zoom Meeting Link:
https://scaqmd.zoom.us/j/98171271952

Dial In: (669) 900 6833

Meeting ID: 981 7127 1952

Proposed Amended Rule 1405 (PAR 1405)

- Rule 1405 was adopted in 1990 and last amended in 1991
- PAR 1405 will address ethylene oxide (EtO) emissions from sterilization facilities and related operations
  - Add information gathering requirement from warehouses that receive EtO-sterilized products
- New and updated requirements for sterilization facilities in PAR 1405
  - Control stack emissions using updated performance standards, annual source tests and, for large facilities, continuous or semi-continuous emission monitoring systems
  - New fugitive emission control strategies using permanent total enclosures (PTE) and leak detection and repair (LDAR)
  - Enhanced reporting and notification requirements to South Coast AQMD
- New requirements for warehouses
  - Tracking inbound EtO-sterilized palletized units and report to South Coast AQMD for one year



Ethylene Oxide

EtO Characteristics

- Flammable and colorless gas at room temperature
- EtO released into the air stays for several months

Key EtO Uses

- Antifreeze, textiles, solvents, detergents, and adhesives production
- Ensure safety by fumigating cosmetics and some foodstuffs like spices
- Sterilize medical devices and equipment

Health effects:

- Known human carcinogen associated: Hematopoietic (blood) cancer, breast cancer in women
- Long-term, chronic effects include reproductive harm
- Immediate, acute effects: eye irritation and skin burns, breathing problems, neurological difficulties

EtO Sterilization Process

Step 1: **Preconditioning**

Medical devices, still wrapped and packaged on pallets, brought up to optimal temperature and humidity

Examples of **medical devices** are gloves, IV needles and catheters, and implantable pacemakers

Step 2: **Sterilization**

Medical devices transferred to heated chambers where EtO is introduced inside then sent to control devices after use

Source: steris-ast.com

Step 3: **Aeration**

Medical devices transferred to aeration room where residual EtO off-gassed and sent to control devices

Step 4: **Post-aeration**

Medical devices await pickup for delivery to distributors or end-users

Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions
from Sterilization and Related Operations

Preliminary Draft Rule Language

PAR 1405 Structure

Proposed Amended Rule 1405

- (a) Purpose
- (b) Applicability
- (c) Definitions
- (d) Large Facility Requirements
- (e) Medium Facility Requirements
- (f) Small Facility Requirements
- (g) Post-Aeration Storage Facility Requirements
- (h) Warehouse Reporting Requirements
- (i) Interim Requirements
- (j) SCEMS, CEMS, or other Monitoring Requirements for Stack Emissions
- (k) Permanent Total Enclosure Requirements
- (l) Recordkeeping
- (m) Source Test Requirements
- (n) Leak Detection and Repair (LDAR) Program Requirements
- (o) Prohibitions
- (p) Reporting
- (q) Sterilization Facilities Exceeding Applicable Ethylene Oxide Usage
- (r) Exemptions
- Appendix 1 – Content of Semi-Annual Summary Reports
- Appendix 2 – Content of Semi-Annual Excess Emission Reports
- Appendix 3 – PTE Inward Face Air Velocity Measurement Procedures

Rule Title Change

New

CONTROL OF ETHYLENE OXIDE EMISSIONS FROM STERILIZATION AND RELATED OPERATIONS

CONTROL OF ETHYLENE OXIDE AND CHLOROFLUOROCARBON EMISSIONS FROM STERILIZATION OR FUMIGATION PROCESSES

- Updated rule title as chlorofluorocarbons can no longer be used
- Kept prohibition in rule language

Subdivisions (a) and (b)
PURPOSE and APPLICABILITY

Purpose & Applicability

(a) Purpose

The purpose of this rule is to protect public health by reducing Ethylene Oxide emissions from Sterilization and related operations and to assess potential Ethylene Oxide emissions from Warehouses.

(b) Applicability

This rule shall apply to the owner or operator of any Facility performing Ethylene Oxide Sterilization, any Post-Aeration Storage Facility, or any Warehouse storing materials Sterilized with Ethylene Oxide.

- Purpose expanded to include assessing potential EtO emissions from warehouses
- Applicability expanded to include warehouses that store materials sterilized with EtO

NOTE: Text presented is without underline or strikeout for clarity

Subdivision (c)
DEFINITIONS

Definitions

(1) AERATION is the process during which residual Ethylene Oxide dissipates by forced air flow, or through natural or mechanically assisted convection, or other means, from Sterilized materials after the 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 Combined Sterilizer/Aerator.

(2) AERATOR is any equipment (excluding a Sterilizer or a Combined Sterilizer/Aerator), area, or room used to perform Aeration.

(3) BACK-DRAFT VALVE is a valve, hood, or rear chamber exhaust system for removal of Ethylene Oxide during unloading of Sterilized materials.

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

- Aeration updated to reflect a minimum aeration times from a variety of documents
- Aerator clarified to distinguish from Sterilizer or Combined Sterilizer/Aerator (new term)

Definitions cont.

(5) 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.

(6) CONTINUOUS EMISSION MONITORING SYSTEM (CEMS) is the total combined equipment and systems required to continuously determine air contaminants and diluent gas concentrations and/or mass emission rate of a source effluent (as applicable). The CEMS consists of three major subsystems: sampling interface, analyzer, and data acquisition system. The CEMS is able to take and record a minimum of one measurement (e.g., concentration, mass emission, flow rate) every one (1) minute.

(7) 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.

(8) CONTROL SYSTEM is equipment and ducting installed for the purposes of collecting Exhaust Streams consisting of one or more adjoining air pollution control devices that reduces emissions of Ethylene Oxide and exhausts to a single stack.

- CEMS consistent with other South Coast AQMD rules
- Combined Sterilizer/Aerator defined to differentiate from a stand-alone Sterilizer
- Control System can include multiple devices

Definitions cont.

(9) DESIGNATED WAREHOUSE is any Warehouse, excluding a Large Warehouse or New Large Warehouse, that the Executive Officer has determined to be a potential source of Ethylene Oxide emissions and notified in writing of the determination by the Executive Officer.

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

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

(12) EXHAUST STREAM is Ethylene Oxide-contaminated effluent.

(13) FACILITY is any source or group of sources or other air contaminant emitting activities which are located on one or more contiguous properties within the 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 Facility.

- Designated Warehouse defined for tracking and reporting purposes
- Facility defined to update rule language from referencing "persons"

Definitions cont.

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

(15) LARGE WAREHOUSE is any Warehouse greater than or equal to 100,000 square feet of indoor floor area in a single building and reporting to U.S. FDA as a Wholesale Distributor or a Third-Party Logistics Provider.

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

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

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

(19) NEW LARGE WAREHOUSE is a Large Warehouse starting operations after [Date of Amendment].

- Large Facility threshold lowered to 2,000 pounds (lbs)
- Large Warehouse & New Large Warehouse defined for tracking and reporting purposes
- Medium Facility threshold aligned with Large Facility

Definitions cont.

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

(21) PERMANENT TOTAL ENCLOSURE (PTE) means any permanent building or containment structure, enclosed with a floor, walls, and a roof to prevent exposure to the elements, (e.g., precipitation, wind, run-off) that has limited openings to allow access for people and vehicles, that is free of breaks or deterioration that could cause or result in fugitive emissions, and has been evaluated to meet the design requirements set forth in U.S. Environmental Protection Agency (EPA) Method 204 except the term "Administrator" in provision 5.1 is revised to mean Executive Officer, as defined in Rule 102.

(22) POST-AERATOR is any equipment, area, or room where Sterilized materials are stored, transferred, loaded, or unloaded after completing Aeration. Post-Aerator excludes:

(A) Motor vehicles used during loading, unloading, and transport; or

(B) Equipment, area, or room that is an Aerator or Combined Sterilizer/Aerator.

- Palletized Unit defined for tracking and reporting purposes
- Permanent Total Enclosure (PTE) definition is consistent with other South Coast AQMD rules with clarity regarding U.S. EPA Method 204
- Post-Aerator new term defined, identified as source of fugitive emissions

Definitions cont.

(23) POST-AERATION STORAGE FACILITY is any Facility not performing Sterilization and used for the storage of Sterilized materials which have been Sterilized at another Facility.

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

(25) SEMI-CONTINUOUS EMISSION MONITORING 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 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 measurement (e.g., concentration, mass emission, flow rate) every fifteen (15) minutes.

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

- Post-Aeration Storage Facility a new term replacing Aeration-Only Facility
- SCEMS definition consistent with other South Coast AQMD rules
- Small Facility threshold not changed

Definitions cont.

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

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

(29) STERILIZATION is the process where Sterilant Gas is used to destroy bacteria, viruses, fungi, and other unwanted organisms on materials. This includes fumigation processes using Sterilant Gas.

(30) 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 Combined Sterilizer/Aerator.

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

(32) STERILIZER is any chamber or related piece of equipment (excluding a Combined Sterilizer/Aerator) that uses Sterilant Gas in Sterilization.

- Sterilant Gas Storage Area previously unregulated area that would be subject to new fugitive emission requirements
- Sterilization incorporate fumigation into term

Definitions cont.

(33) STERILIZER EXHAUST VACUUM PUMP is a device (including any associated heat exchanger) used to evacuate Sterilant Gas during the Sterilization Cycle, but is not a device used solely to evacuate a Sterilizer or Combined Sterilizer/Aerator prior to the introduction of Sterilant Gas.

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

(35) 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.

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

- Warehouse defined for tracking and reporting purposes
- Waste Storage Area previously unregulated area that would be subject to new fugitive emission requirements

Subdivision (d)
LARGE FACILITY REQUIREMENTS

LARGE – Stack Emissions (d)(1)

Beginning December 31, 2024:

(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) Demonstrate control of Ethylene Oxide emissions with 99.99% efficiency or greater, by weight, by a source test that meets the requirements in subdivision (m); or

(ii) Demonstrate emissions of Ethylene Oxide at a concentration of 0.01 parts per million (ppm) or less, by volume, by a source test that meets the requirements in subdivision (m);

(D) Demonstrate the sum of mass emission rates measured at each exhaust stack is 0.025 pounds per hour (lbs/hr) or less of Ethylene Oxide from all Control Systems by a source test that meets the requirements in subdivision (m); and

Enhanced stack emission control requirements:

- Clearly mandates back-draft valves
- Requires individual control systems to meet <u>either</u> a control efficiency <u>or</u> concentration limit
  - Addresses high and low concentration sources
- Establishes a facility-wide limit on EtO mass emission rate

LARGE – Stack Emissions (d)(1) cont.

Beginning December 31, 2024:

(E) Conduct a source test that meets the requirements in subparagraphs (d)(1)(C) and (d)(1)(D) and pursuant to subdivision (m) for each Control System:

(i) No later than February 28, 2025 for an existing Control System installed or modified on or before December 31, 2024;

(ii) Within 60 days after initial operation of a Control System installed or modified after December 31, 2024; and

(iii) No later than 12 calendar months from the day of the most recent source test of the Control System.

Additional enhanced stack emission control requirements:

- Requires initial and subsequent annual source tests for all control systems

LARGE – Stack Emission Monitoring (d)(2)

Beginning December 31, 2025 or within 12 months of approval of a South Coast AQMD-certified SCEMS or CEMS, whichever is sooner:

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

(B) Demonstrate the sum of mass emission rates, averaged over a calendar day and measured at each exhaust stack, is 0.025 pounds per hour (lbs/hr) or less of Ethylene Oxide from all Control Systems averaged over each calendar day in operation, by a SCEMS or CEMS that meets the requirements in subdivision (j); and

(C) For each Control System complying with clause (d)(1)(C)(ii), demonstrate emissions of Ethylene Oxide at a concentration of 0.01 parts per million (ppm) or less, by volume, averaged over each calendar day in operation, by a SCEMS or CEMS that meets the requirements in subdivision (j).

Stack emission monitoring requirements:

- Requires stack emission monitoring (SCEMS or CEMS) and data logging

LARGE – Fugitive Emissions (d)(3)

Beginning December 31, 2024:

(A) Maintain all Sterilizers, Combined Sterilizer/Aerators, Back-Draft Valves, Aerators, Post-Aerators, Elements in a Sterilant Gas Storage Area, and Elements in a Waste Storage Area within a Permanent Total Enclosure that meets the requirements in subdivision (k); and

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

Enhanced fugitive emission control requirements:

- Requires Permanent Total Enclosure (PTE) for potential fugitive emission sources
- Requires Controls Systems to either be in PTE or use LDAR program to prevent fugitive emissions

LARGE – Other Requirements (d)(4)

Beginning 3 Months After Date of Amendment:

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

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

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

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

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

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

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

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

(E) Prepare and maintain onsite a Facility diagram that identifies each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, Permanent Total Enclosure, Sterilant Gas Storage Area, and Waste Storage Area;

Other enhanced requirements:

- Track where EtO-sterilized pallets sent
- Labeling requirements for pallet and bill of lading so warehouses know they are receiving EtO sterilized products
- Requires plot plan to identify key areas

LARGE – Other Req. (d)(4) cont.

Beginning 3 Months After Date of Amendment:

(F) Prepare and submit an annual report in writing by electronic mail to Rule1405notifications@aqmd.gov each calendar year on or before January 30 regarding the preceding calendar year. The annual report shall contain at a minimum either:

(i) The number of Sterilization Cycles and the pounds of Sterilant Gas (measured or calculated) used per Sterilization Cycle for each Sterilizer and each Combined Sterilizer/Aerator each operating day; or

(ii) The total pounds of Sterilant Gas purchased and the total pounds of Sterilant Gas used per calendar month and calendar year, respectively; and

(G) Prepare and submit a semi-annual report in writing by electronic mail to Rule1405notifications@aqmd.gov on or before January 30 of each calendar year for the preceding July-December semi-annual reporting period and on or before July 30 of each calendar year for the preceding January-June semi-annual reporting period. The semi-annual report shall contain at a minimum:

(i) Semi-Annual Summary Report pursuant to Appendix 1; and

(ii) Semi-Annual Excess Emission Report pursuant to Appendix 2, if the duration of excess emissions or parameter monitoring exceedances for the reporting period exceeds 1 percent of the reporting period or the total monitored downtime for the reporting period exceeds 5 percent of the reporting period.

Other enhanced requirements:

- CARB Air Toxic Control Measure (ATCM) reporting requirements for Large Facilities incorporated into PAR 1405

LARGE – Permit Application Schedule (d)(5)

(5) No later than December 31, 2023, the owner or operator of a Large Facility operating prior to [Date of Amendment] shall submit complete South Coast AQMD permit application(s) to modify existing permit conditions, modifying existing equipment, or install new equipment to meet the requirements specified in paragraphs (d)(1) and (d)(3).

Increments of progress:

- Establishes a permit application submission schedule as increments of progress towards full compliance with PAR 1405

Subdivision (e)
MEDIUM FACILITY REQUIREMENTS

MEDIUM – Stack Emissions (e)(1)

Beginning July 1, 2025:

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

(B) For each Control System either:

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

(ii) Demonstrate emissions of Ethylene Oxide at a concentration of 0.01 parts per million (ppm) or less, by volume, by a source test that meets the requirements in subdivision (m); and

(C) Conduct a source test that meets the requirements in subparagraph (e)(1)(B) and pursuant to subdivision (m) for each Control System:

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

(ii) Within 60 days after initial operation of a Control System installed or modified after July 1, 2025; and

(iii) No later than 12 calendar months from the day of the most recent source test of the Control System.

Enhanced stack emission control requirements:

- Requires individual control systems to meet either a control efficiency or concentration limit
- Requires initial and subsequent annual source tests to ensure emission limits are being met

MEDIUM – Fugitive Emissions (e)(2)

Beginning July 1, 2025:

(2) Fugitive Emissions Requirements

Beginning July 1, 2025, the owner or operator of a Medium Facility shall not perform Sterilization unless all the following requirements are met:

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

(i) Sterilizer, if applicable;

(ii) Aerator, if applicable; and

(iii) Post-Aerator used to store Sterilized materials directly from an Aerator or Combined Sterilizer/Aerator; and

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

(i) Combined Sterilizer/Aerator, if applicable;

(ii) Back-Draft Valve, if applicable;

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

(iv) All Elements in a Sterilant Gas Storage Area; and

(v) All Elements in a Waste Storage Area.

Enhanced fugitive emission control requirements:

- Requires PTE for key EtO sources
  - If aeration is performed outside chamber
  - For the immediate post-aerator storage area following aeration
- Requires other key equipment to either be in PTE or use LDAR program to prevent fugitive emissions

MEDIUM – Other Requirements (e)(3)

Beginning 3 Months After Date of Amendment:

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

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

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

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

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

Other enhanced requirements:

- Requires labels on key EtO sources and PTE for ease of identification
- Requires plot plan to identify key areas

MEDIUM – Permit Application Schedule (e)(4)

(4) No later than July 1, 2024, the owner or operator of a Medium Facility operating prior to [Date of Amendment] 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 (e)(1) and (e)(2).

Increments of progress:

- Establishes a permit application submission schedule as increments of progress towards full compliance with PAR 1405

Subdivision (f)
SMALL FACILITY REQUIREMENTS

SMALL – Stack Emissions (f)(1)

Beginning December 31, 2025:

(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) Demonstrate control of Ethylene Oxide emissions with 99.9% efficiency or greater, by weight, by a source test that meets the requirements in subdivision (m); or

(ii) Demonstrate emissions of Ethylene Oxide at a concentration of 0.01 parts per million (ppm) or less, by volume, by a source test that meets the requirements in subdivision (m); and

(C) Conduct a source test that meets the requirements in subparagraph (f)(1)(B) and pursuant to subdivision (m) for each Control System:

(i) No later than February 28, 2026 for an existing Control System installed or modified on or before December 31, 2025;

(ii) Within 60 days after initial operation of a Control System installed or modified after December 31, 2025; and

(iii) No later than 12 calendar months from the day of the most recent source test of the Control System.

Enhanced stack emission control requirements:

- Requires individual control systems to meet either a control efficiency or concentration limit
- Requires initial and subsequent annual source tests to ensure emission limits are being met

SMALL – Fugitive Emissions (f)(2)

Beginning December 31, 2025:

(A) Operate the following areas and processes within a Permanent Total Enclosure that meets the requirements of subdivision (k):

(i) Sterilizer, if applicable; and

(ii) Aerator, if applicable; and

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

(i) Combined Sterilizer/Aerator, if applicable;

(ii) Back-Draft Valve, if applicable.

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

(iv) All Elements in a Sterilant Gas Storage Area; and

(v) All Elements in a Waste Storage Area.

Enhanced fugitive emission control requirements:

- Requires PTE for key EtO sources to prevent fugitive emissions
  - If aeration is performed outside chamber
- Requires other key equipment to either be in PTE or use LDAR program to prevent fugitive emissions

SMALL – Other Requirements (f)(3)

Beginning 3 Months After Date of Amendment:

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

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

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

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

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

Other enhanced requirements:

- Requires labels on key EtO sources for ease of identification
- Requires plot plan to identify key areas

SMALL – Permit Application Schedule (e)(4)

(4) No later than December 31, 2024, the owner or operator of a Small Facility operating prior to [Date of Amendment] 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 (f)(1) and (f)(2).

Increments of progress:

- Establishes a permit application submission schedule as increments of progress towards full compliance with PAR 1405

Subdivision (g)
POST-AERATION STORAGE FACILITY REQUIREMENTS

Post-Aeration Storage Facility Requirements

Beginning 3 Months After Date of Amendment:

(1) For each Control System, demonstrate control of Ethylene Oxide emissions with 95% efficiency or greater, by weight, by a source test that meets the requirements in subdivision (m);

(2) Conduct a source test that meets the requirements in paragraph (g)(1) and pursuant to subdivision (m) for each Control System:

- (A) No later than [5 Months After Date of Amendment] for an existing Control System installed or modified on or before [3 Months After Date of Amendment];
- (B) Within 60 days after initial operation of a Control System installed or modified after [3 Months After Date of Amendment]; and
- (C) No later than 12 calendar months from the day of the most recent source test of the Control System;

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

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

- (A) Type of equipment, area, or room, if applicable;
- (B) Unit number or other identifier, if applicable; and
- (C) South Coast AQMD permit number, if applicable; and

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

Applies to facilities already equipped with control systems:

- Requires initial and subsequent annual source tests to ensure emission limits are being met
- Requires control systems to meet a control efficiency of 95%
- Requires other key equipment to either be in PTE or use LDAR program to prevent fugitive emissions
- Requires labels on key EtO sources for ease of identification
- Requires plot plan to identify key areas

Subdivision (h)
WAREHOUSE REPORTING REQUIREMENTS

Warehouse Reporting Requirements

(h) Warehouse Reporting Requirements

(1) The owner or operator of a Large Warehouse, New Large Warehouse, or Designated Warehouse shall record the number of Sterilized Palletized Units, excluding Sterilized Palletized Units received from other Warehouses, received each month according to the schedule specified in Table 1 – Warehouse Recording Schedule.

Table 1 – Warehouse Recording Schedule

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

Applies to large and designated warehouses:

- Includes provisions for data collection to better understand potentials of fugitive emissions
- Requires one year tracking of EtO sterilized products received
- Specifies schedule for:
  - Existing Warehouses
  - New Warehouses
  - Designated Warehouses

Warehouse Reporting Req. cont.

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

(A) Name of Warehouse;

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

(C) Address of Warehouse;

(D) Contact information for Warehouse;

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

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

Table 2 – Warehouse Initial Report Schedule

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

- Submit <u>one-time</u> report by schedule specified for:
  - Existing warehouses
  - New warehouses
  - Designated warehouses

Subdivision (i)
INTERIM REQUIREMENTS

Interim Requirements

(i) Interim Requirements

(1) The owner of operator of a Facility performing Sterilization that uses a total of 400 lbs or less of Ethylene Oxide per calendar year:

(A) Sterilizer(s) and Combined Sterilizer/Aerator(s) shall be vented to control equipment with an efficiency of 99% or more, by weight.

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

(C) If the Exhaust 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% or more, by weight.

(2) The owner of operator of a Facility performing Sterilization who uses a total of more than 400 lbs and less than or equal to 4,000 lbs of Ethylene Oxide per calendar year:

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

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

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

(D) If the Exhaust 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% or more, by weight.

(3) The owner of operator of a Facility performing Sterilization who uses a total of more than 4,000 lbs of Ethylene Oxide per calendar year:

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

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

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

(D) If the Exhaust 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 more, by weight.

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

(5) The owner or operator of a Facility subject to either paragraph (i)(1), (i)(2), (i)(3), or (i)(4) operating Sterilizers, Combined Sterilizer/Aerators, Aerators, control equipment, and emissions collection systems shall meet the following:

(A) The maximum Sterilant Gas mass flow shall be less than 10 parts per million Ethylene Oxide, as measured one (1) centimeter away from any portion of a Sterilizer, Combined Sterilizer/Aerator, Aerator, or Control System that could have an Ethylene Oxide leak;

(B) Test during conditions of maximum Sterilant Gas mass flow; and

(C) Test at least once every six months, as specified in paragraph (i)(8).

(6) The owner or operator of a Facility subject to either paragraph (i)(1), (i)(2), (i)(3), or (i)(4) 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). Thereafter, source tests shall be conducted on control equipment at least once per calendar year.

- Existing requirements from Rule 1405 were moved to this subdivision
- Interim requirements would sunset when new stack or fugitive emission requirements are in effect (see Exemptions)

Interim Requirements cont.

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

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

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

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

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

- Prior test methods for source testing and leak detection were incorporated
  - Would sunset when new requirements for stack and fugitive emissions are in effect

Subdivision (j)
SCEMS, CEMS, OR OTHER MONITORING REQUIREMENTS FOR STACK EMISSIONS

SCEMS, CEMS, and Other Monitoring Requirements

(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 for each Control System complying with applicable requirements in Rule 218 through Rule 218.3 and the following requirements:

(A) Measures the following parameters:

(i) Ethylene Oxide concentration, with a resolution of at least 0.01 ppm, by volume;

(ii) Oxygen concentration; and

(iii) Exhaust stack flow rate;

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

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

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

(2) The owner or operator of a Facility required to operate a SCEMS or CEMS shall calculate and record the sum of mass emission rates for all exhaust stacks, averaged over a calendar day and expressed in lbs/hr, no later than the next calendar day.

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

(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.

- SCEMS or CEMS consist of a monitoring system that are required for each stack at a large facility, a data recording system, and backup battery to ensure that emissions are continuously monitored
- Applicable SCEMS or CEMS requirements in Rule 218 through 218.3 apply
- SCEMS requires a measurement of parameters every 15 minutes
- CEMS requires a measurement of parameters every 1 minute

SCEMS, CEMS, and Other Monitoring Req. cont.

(5) The owner or operator of a Large Facility operating a Control System containing an acid-water scrubber shall either:

(A) 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

(B) 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.

(6) The owner or operator of a Large Facility operating a Control System containing a catalytic oxidation unit or thermal oxidation unit shall continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion chamber using a temperature monitor:

(A) Installed, calibrated, operated, and maintained to an accuracy within ±5.6 degrees Celsius (±10 degrees Fahrenheit); and

(B) 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.

(7) The owner or operator of a Large Facility operating a Control System containing an air pollution control device other than an acid-water scrubber, catalytic oxidation unit, or thermal oxidation unit shall monitor specific parameters of the device as approved by the Executive Officer.

- Incorporates CARB ATCM parameter monitoring requirements in PAR 1405

Subdivision (k)
PERMANENT TOTAL ENCLOSURE REQUIREMENTS

Permanent Total Enclosure Requirements

(k) Permanent Total Enclosure Requirements

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

(1) Demonstrate the Permanent Total Enclosure is maintained at a negative pressure of at least 0.007 inches of water column averaged over one (1) minute;

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

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

(i) The Leeward Wall;

(ii) The Windward Wall;

(iii) An exterior wall that:

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

(II) Intersects within plus or minus ten (+/-10) meters of the midpoint of a straight line between the two other monitors specified in clauses (k)(2)(A)(i) and (k)(2)(A)(ii); and

(III) Is not located on the same wall as either of the other two monitors described in clauses (k)(2)(A)(i) or (k)(2)(A)(ii);

- PTE are mandatory requirements for large and medium facilities
- EPA Method 204 establishes the design requirements and performance standards for negative pressure and inward velocity
- PAR 1405 further establishes monitoring requirements for negative pressure and inward velocity
- Differential pressure is measured continuously
- Location of differential pressure monitors is consistent with other toxic rules that require a Permanent Total Enclosure

Permanent Total Enclosure Req. cont.

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

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

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

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

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

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

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

- Additional periodic measurements of inward air velocity to verify the performance of the Permanent Total Enclosure
- Reporting to South Coast AQMD of failures of negative pressure performance or significant missing data required

Subdivision (l)
RECORDKEEPING

Recordkeeping – Sterilization Facilities

(l) Recordkeeping

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

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

(B) The total pounds of Sterilant Gas purchased and the total pounds of Sterilant Gas used per calendar month and calendar year, respectively;

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

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

(E) Measurements of inward face velocity pursuant to Appendix 3;

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

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

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

(I) Facility diagrams pursuant to subparagraph (d)(4)(E), (e)(3)(B), or (f)(3)(B);

(J) Annual reports pursuant to subparagraph (d)(3)(F);

(K) Semi-annual reports pursuant to subparagraph (d)(3)(G); and

(L) Protocols, work orders, validation documents, or manufacturer's instructions that specify the minimum time to complete Aeration for a Sterilization Cycle.

- Recordkeeping is needed to verify compliance with rule requirements
- New proposed recordkeeping requirements support new proposed requirements for stack and fugitive emissions
- Also includes maintaining reports required under CARB ATCM regarding EtO

Recordkeeping – Other

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

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

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

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

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

(E) Facility diagrams pursuant to paragraph (g)(6).

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

(4) The owner or operator of any Facility subject to this rule shall retain all applicable records for at least five years with two years of records maintained onsite.

- New proposed recordkeeping requirements for Post Aeration Storage Facility
- Longer time period of record retention
  - Consistent with Title V and other toxic rules

Subdivision (m)
SOURCE TEST REQUIREMENTS

Source Test Requirements

(m) 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 that demonstrates compliance with subdivision (d), (e), (f), or (g) for the Control System, submit a source test protocol for approval to the Executive Officer that includes:

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

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

(C) Planned sampling parameters;

(2) Prior to conducting any subsequent source test that demonstrates 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 (m)(1)(A) through (C) if there are any changes in the conditions, numbers, or parameters referenced by subparagraphs (m)(1)(A) through (C) in the most recently-approved source test protocol;

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

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

- Annual source test requirements are applicable to a Large Facility, Medium Facility, Small Facility, or Post Aeration Storage Facility equipped with a control system
- Requires the submittal of source test protocol and resubmittal if any changes
- South Coast AQMD would evaluate the protocol prior to conducting a source test
- Also requires notification to South Coast AQMD when source test would occur and any changes to the schedule

Source Test Requirements (cont.)

(5) Conduct a source test:

(A) Pursuant to the 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) Assessing the efficiency of controlling Ethylene Oxide emissions by:

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

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

(6) Submit the source testing report to the South Coast AQMD within 60 days of completing source testing.

- Additional conditions to evaluate typical and potential operating conditions
- Requires the submittal of the source test report

Subdivision (n)
LEAK DETECTION AND REPAIR (LDAR) PROGRAM REQUIREMENTS

Leak Detection and Repair Program

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

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

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

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

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

(4) Conduct daily audio-visual checks for all applicable Components and Elements; and

(5) Conduct monthly leak inspections of all applicable Components and Elements pursuant to CARB Test Method 21 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. If other calibrating gases are used, the correction factor shall also be recorded and the measured readings shall be correlated to and also expressed as Ethylene Oxide.

(6) Record results of daily audio-visual checks or monthly leak inspections at all Components and Elements.

- Applies to Large, Medium, Small, and Post-Aeration Storage Facilities to identify leaks
- Expands leak detection requirements by requiring:
  - Identification of Components
  - Checking certain containers (Elements)
  - More frequent inspections
  - Daily audio/visual checks
  - Lower leak threshold
  - Refers to more commonly-used PIDs

Subdivision (o)
PROHIBITIONS

Prohibitions

(o) Prohibitions

(1) The owner or operator of a Facility performing Sterilization shall not discharge any Sterilizer Exhaust Vacuum Pump working fluid to the wastewater stream.

(2) The owner or operator of a Facility performing Sterilization shall not use Chlorofluorocarbon Diluents in Sterilization.

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

(4) The owner or operator of a Facility performing Sterilization shall not remove any Sterilized materials from the Facility before completing Aeration.

- Existing prohibitions retained
- Additional prohibition prevents the uncontrolled release of EtO from PTEs
  - Emissions are required to be exhausted to a Control System
- Removal of Sterilized materials from Facility before completing Aeration is prohibited

Subdivision (p)
REPORTING

Reporting

(p) Reporting

(1) The owner or operator of a Sterilization Facility shall notify the Executive Officer in the event of exceeding a limit of permitted use of Ethylene Oxide in writing by electronic mail to Rule1405notifications@aqmd.gov or verbally by telephone to 1-800-CUT-SMOG within 30 days of exceeding the limit of permitted use.

(2) The owner or operator of a Sterilization Facility shall notify the Executive Officer in the event of using more than the applicable amount of Ethylene Oxide in a calendar year as listed in Table 3 in writing by electronic mail to Rule1405notifications@aqmd.gov or verbally by telephone to 1-800-CUT-SMOG within 30 days of exceeding the applicable amount.

Table 3

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

*Any Facility other than a Large Facility, Medium Facility, or Small Facility

- Reporting requirements for when a Sterilization Facility exceeds a permit limit or exceeds a permitted classification threshold
- Reporting Email to dedicated Rule 1405 account or telephone call to 800-CUT-SMOG required if an EtO permit limit is exceeded
- Email or telephone is also required if a Sterilization Facility exceeds the next higher EtO annual usage threshold in Rule 1405

Subdivision (q)
STERILIZATION FACILITIES EXCEEDING APPLICABLE ETHYLENE OXIDE USAGE

Sterilization Facilities Exceeding Applicable Ethylene Oxide Usage

(q) Sterilization Facilities Exceeding Applicable Ethylene Oxide Usage

(1) No later than 24 months from the day of using 2,000 lbs or more of Ethylene Oxide within in a calendar year, the owner or operator of a Sterilization Facility, excluding a Large Facility, that uses more than 2,000 lbs of Ethylene Oxide in a calendar year shall meet the requirements specified in subparagraphs (d)(1)(A) through (d)(1)(E); (d)(2)(A) through (d)(2)(B); (d)(3)(A) through (d)(3)(B); and (d)(4)(C) through (d)(4)(E).

(2) No later than 24 months from the day of using more than 400 lbs of Ethylene Oxide within in a calendar year, the owner or operator of a Sterilization Facility, 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)-(e)(1)(B), (e)(2)(A)-(e)(2)(C), and (e)(3)(A)-(e)(3)(B).

(3) No later than 24 months from the day of using more than 4 lbs of Ethylene Oxide within in a calendar year, the owner or operator of a Sterilization facility, 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)-(f)(1)(B), (f)(2)(A)-(f)(2)(B), and (f)(3)(A)-(f)(3)(B).

(4) No later than 12 months from the day of exceeding the applicable Ethylene Oxide usage limit, the owner or operator of a Sterilization facility subject to the requirements of paragraphs (q)(1), (q)(2), or (q)(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 (q)(1), (q)(2), or (q)(3).

- Requirements on facilities when actual usage exceeds their permitted usage and enters a higher category of throughput (Large, Medium, or Small)
- Within 24 months, facilities must upgrade their stack and fugitive emission controls to meet requirements in that higher tier
- Must submit permit applications within 12 months as increments of progress

Subdivision (r)
EXEMPTIONS

Exemptions

(r) Exemptions

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

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

Table 3 – Interim Requirements

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

(3) The requirements of paragraph (k)(1) do not apply to any owner or operator 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; and

(C) Monitor and record the Ethylene Oxide concentration at all NDOs 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. If other calibrating gases are used, the correction factor shall also be recorded and the measured readings shall be correlated to and also expressed as Ethylene Oxide.

- Existing exemption in Rule 1405 retained in PAR 1405 with additions for interim items and power outages
- Sterilizer facilities permitted to use four pounds or less exempt from interim requirements and prohibitions
- Sunset provisions for interim requirements applicable to Large, Medium, Small and Post-Aeration Storage Facilities
- Procedures to minimize EtO fugitive emissions during loss of power

Appendices 1 & 2
CONTENT OF SEMI-ANNUAL SUMMARY REPORTS
CONTENT OF SEMI-ANNUAL EXCESS EMISSION REPORTS

Content of Semi-Annual Reports

Appendix 1 – Content of Semi-Annual Summary Reports

Semi-annual summary reports shall, at a minimum, contain the following information:

1. The company name and address of the source;
2. The date of the report, and the beginning and ending dates of the reporting period.
3. A brief description of the process units;
4. The emission and operating parameter limitations specified in the standard;
5. The monitoring equipment manufacturer(s) and model number(s);
6. The date of the latest monitoring system certification or audit;
7. The total operating time during the reporting period;
8. An emissions data summary, including the total duration of excess emissions during the reporting period (recorded in hours), the total duration of excess emissions expressed as a percent of the operating time during the reporting period, and a breakdown of the total duration of excess emissions during the reporting period into those that are due to startup/shutdown, control or monitoring equipment problems, process or process equipment problems, quality assurance, quality control calibrations, other known causes, and other unknown causes;
9. A monitoring system performance summary, including the total monitoring system downtime recorded in hours, the total duration of monitoring system downtime expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total monitoring system downtime during the reporting period into periods that are due to monitoring equipment malfunctions, non-monitoring equipment malfunctions, quality assurance, quality control calibrations, other known causes, and other unknown causes;
10. A description of any changes in monitoring system, processes, or controls since the last reporting period; and
11. The name, title, and signature of who is certifying the accuracy of the report.

Appendix 2 – Content of Semi-Annual Excess Emission Reports

Semi-annual excess emission reports shall, at a minimum, contain the following information:

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 the 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; and
9. The total process operating time during the reporting period.

- Semi-annual reporting requirements in CARB ATCM are organized as these two appendices for clarity
- Required for Large Facilities under existing CARB ATCM and PAR 1405 paragraph (d)(4)
- Appendix 1 details the Semi-Annual Summary Report, required twice per year
- Appendix 2 lists the Semi-Annual Excess Emission Report, required only if certain excess emissions or missing data occur

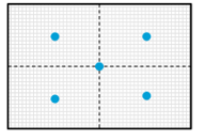
Appendix 3
PTE INWARD FACE AIR VELOCITY MEASUREMENT PROCEDURES

Inward Face Velocity Procedures

Appendix 3 – 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 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.

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 3 is new as Rule 1405 did not require PTE
- PTEs are mandatory for Large and Medium Facilities
- Monthly, facilities must demonstrate 200 feet per minute at each natural draft opening per (k)(3) and U.S. EPA Method 204
- Establishes detailed procedures for measuring the inward face air velocity measurement for PTEs
- Also details recordkeeping for these measurements

Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions
from Sterilization and Related Operations

CEQA and Socioeconomic Impacts

Scope of Socioeconomic Impact Assessment for PAR 1405

Applicable Legal Requirements Related to Socioeconomic Impact Assessment

- California Health and Safety Code Section 40440.8 and 40728.5
  - Requires socioeconomic impact assessment for a proposed rule or rule amendment which "will significantly affect air quality or emissions limitations"
  - Socioeconomic impact assessment shall consider:
    1. Type of affected industries, including small businesses
    2. Impact on employment and regional economy
    3. Range of probable costs, including costs to industry or business and other elements typically included in the staff report

Cost Considerations

- One-time capital costs
  - Purchase, installation, and permitting of required controls and monitoring systems
  - Building modifications for permanent total enclosure
- Recurring costs
  - Operating and maintenance costs
  - Other recurring costs such as annual source tests and media replacement for controls
- Staff is seeking input on these and/or other costs

California Environmental Quality Act for PAR 1405

California Environmental Quality Act (CEQA)

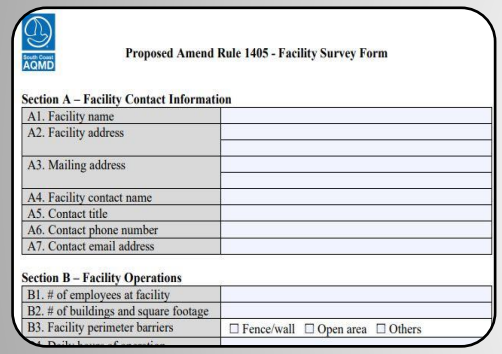
- The South Coast AQMD, as lead agency, is reviewing the proposed project (PAR 1405) to determine if it will result in any potential adverse environmental impacts
- Appropriate CEQA documentation will be prepared based on the analysis

Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions
from Sterilization and Related Operations

Public Process

Stakeholder Involvement in Rulemaking



Proposed Amend Rule 1405 - Facility Survey Form

Section A – Facility Contact Information

A1. Facility name	
A2. Facility address	
A3. Mailing address	
A4. Facility contact name	
A5. Contact title	
A6. Contact phone number	
A7. Contact email address	

Section B – Facility Operations

B1. # of employees at facility	
B2. # of buildings and square footage	
B3. Facility perimeter barriers	☐ Fence/wall ☐ Open area ☐ Others

Distributed survey to sterilization facilities and warehouses to better understand industry and operations

Stakeholders meetings with:

- Facilities
- Vendors
- Consultants
- Trade groups
- Environmental groups

Five Working Group Meetings between August 2022 to February 2023 via Zoom for safety and greater participation from stakeholders

Seven site visits to facilities, conducted in-person or virtually

Key Dates

Action	Date
Written Comments Due	April 6, 2023
Stationary Source Committee	April 21, 2023
Set Hearing	May 5, 2023
Public Hearing	June 2, 2023

PAR 1405 Staff Contacts

Please contact staff with any questions or comments

Rule Development:

Areio Soltani
(909) 396-3318
asoltani@aqmd.gov

Neil Fujiwara
(909) 396-3512
nfujiwara@aqmd.gov

Kalam Cheung, Ph.D.
(909) 396-3281
kcheung@aqmd.gov

Michael Krause
(909) 396-2706
mkrause@aqmd.gov

CEQA:

Barbara Radlein
(909) 396-2716
bradlein@aqmd.gov

Farzaneh Khalaj, Ph.D.
(909) 396-3022
fkhalaj@aqmd.gov

Socioeconomic:

Elaine Shen, Ph.D.
(909) 396-2715
eshen@aqmd.gov

Tony Tian, Ph.D.
(909) 396-2323
ttian@aqmd.gov

James McCreary
(909) 396-2451
jmccreary@aqmd.gov

To receive email notifications, sign up via the:
South Coast AQMD Newsletter Sign Up Website
Additional information is located on the:
South Coast AQMD Proposed Rules and Proposed Rule Amendments Website