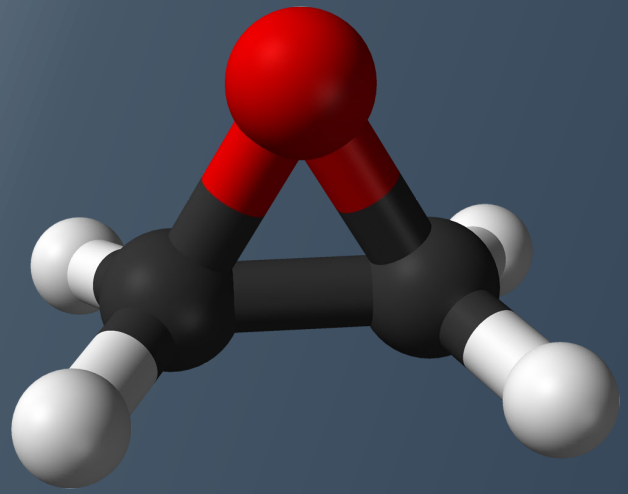
PUBLIC CONSULTATION MEETING



Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions from Sterilization and Related Operations

July 26, 2023
3:00 PM

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

Dial In: (669) 900 6833

Meeting ID: 981 7127 1952

Agenda

- Recent Rulemaking Activity for PAR 1405
- Revised Preliminary Draft Rule Language
- Public Process

Summary of Activities Since Public Workshop

- Initial rule language released 2/10/23
- Preliminary Draft Rule Language released 3/23/23
  - Fugitive emissions
    - Permanent Total Enclosures (PTE)
    - Continuous monitoring for PTE
    - Enhanced Leak Detection and Repair (LDAR)
  - Stack emissions
    - Enhanced performance standards for control equipment
    - Facility-wide emission limit
    - Continuous or Semi-continuous Monitoring (CEMS/SCEMS)
    - Enhanced recordkeeping and reporting requirements
- Revised Preliminary Draft Rule Language released 7/21/23
  - Fenceline monitoring
  - Curtailment of sterilization operations
  - **Comments due August 9, 2023**

Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions
from Sterilization and Related Operations

Revised Preliminary Draft Rule Language

PAR 1405 Structure

PAR 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 Requirements
- (i) Interim Requirements
- (j) SCEMS or CEMS Requirements for Stack Emissions
- (k) Permanent Total Enclosure Requirements
- (l) Source Test Requirements
- (m) Leak Detection and Repair (LDAR) Program Requirements
- (n) Prohibitions
- (o) Facility performing Sterilization Exceeding Applicable Ethylene Oxide Usage
- New (p) Interim Fenceline Air Monitoring Requirements
- New (q) Curtailment of Sterilization Operations
- New (r) Plan Administration
- (s) Recordkeeping
- (t) Reporting Requirements for a Facility Performing Sterilization
- (u) Exemptions

Appendices

- Appendix 1 – Mobile Monitoring Fee — New
- Appendix 2 – PTE Inward Face Air Velocity Measurement Procedures
- Appendix 3 –Emission Study Plan — New
- Appendix 4 – Fenceline Air Monitoring Plan — New
- Appendix 5 – Semi-Annual Summary Reports
- Appendix 6 – Semi-Annual Excess Emission Reports

NOTE: Several subdivisions and appendices have been relabeled, reordered, and/or renumbered since Preliminary Draft 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 collect information from warehouses receiving materials Sterilized with Ethylene Oxide.

(b) Applicability

This rule shall apply to the owner or operator of any Facility performing Ethylene Oxide Sterilization, any Post-Aeration Storage Facility, any Tier I Warehouse, and any Tier II Warehouse.

- Purpose updated for clarity
- Applicability updated to include only Tier I Warehouses and Tier II Warehouses, defined in subdivision (c)

NOTE: Text presented is without underline or strikeout for clarity

Subdivision (c)
DEFINITIONS

Definitions

(4) BASELINE OPERATION is the daily average pounds (lbs) of Ethylene Oxide used in the seven (7) Sterilizer or Combined Sterilizer/Aerator operating days including and prior to the date of the monitoring result or sampling day completion.

(9) CONTROL SYSTEM is equipment and ducting installed for the purposes of collecting Exhaust Streams and reducing Ethylene Oxide emissions consisting of one (1) or more adjoining air pollution control devices in series or parallel and exhausts to one (1) or more stacks.

(14) FIRST DESTINATION is a location that receives Sterilized Palletized Units shipped from a Facility performing Sterilization.

- Baseline Operation added for use in subdivision (q) to calculate daily curtailment amount
- Control System updated to include multiple exhaust stacks for equipment in series or in parallel
- First Destination added for tracking and reporting

Definitions cont.

(15) LARGE FACILITY means a Facility performing Sterilization permitted to use more than or equal to 2,000 lbs of Ethylene Oxide per calendar year, either expressed as a facility-wide permit limit or calculated as the sum of permit limits for equipment that perform Sterilization at the Facility.

(18) MEDIUM FACILITY is any Facility performing Sterilization that is permitted to use more than 400 lbs and less than 2,000 lbs of Ethylene Oxide per calendar year, either expressed as a facility-wide permit limit or calculated as the sum of permit limits for equipment that perform Sterilization at the Facility.

(27) SMALL FACILITY is any Facility performing Sterilization that is permitted to use more than four (4) lbs and less than or equal to 400 lbs of Ethylene Oxide per calendar year, either expressed as a facility-wide permit limit or calculated as the sum of permit limits for equipment that perform Sterilization at the Facility.

- Large Facility, Medium Facility, and Small Facility updated to include facility-wide permit limit or sum of equipment limits

Definitions cont.

(19) PACKAGING AREA is any area used to perform packaging or re-packaging of Sterilized materials that have completed Aeration and biological indicator sterility testing. A Packaging Area excludes areas used for handling or storage of Sterilized Palletized Units.

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

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

(B) Equipment, area, or room that is an Aerator or a Combined Sterilizer/Aerator; and

(C) Packaging Areas at a Large Facility permitted to use less than 20,000 lbs of Ethylene Oxide per calendar year.

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

- Packaging Area added for clarity
- Post-Aerator updated to clearly exclude certain Packaging Areas
- Preconditioner added for clarity

Definitions cont.

(36) TIER I WAREHOUSE is a Facility that has at least one building with at least 250,000 square feet of indoor floor area used for Warehousing Activities and reports to U.S. Food and Drug Administration (FDA) as a Wholesale Distributor or a Third-Party Logistics Provider as of [Date of Rule Amendment].

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

(38) TRIGGER RESULT is the 24-hour average Ethylene Oxide concentration obtained via a canister sample or other approved methodology in the Fenceline Air Monitoring Plan that is at or above the applicable trigger threshold specified in Table 5 – Trigger Threshold for Sterilization Facilities.

(39) WAREHOUSING ACTIVITIES is operations at a warehouse related to the storage and distribution of goods, including but not limited to the storage, labelling, sorting, consolidation and deconsolidation of Products into different size packages. Supporting office administration, maintenance, manufacturing areas, or retail sales areas open to the general public, within the same warehouse building, that are physically separate from the warehouse area, are not considered Warehousing Activities for the purpose of this rule.

- Tier I Warehouse added for Fenceline Air Monitoring Plan and tracking and reporting purposes
- Tier II Warehouse added for tracking and reporting purposes
- Trigger Result added for clarity for curtailment requirements
- Warehousing Activities added for clarity

Subdivision (d)
LARGE FACILITY REQUIREMENTS

LARGE – Stack Emissions (d)(1)

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

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

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

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

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

Updated stack emission control requirements:

- New compliance date specified in Table 1
- Lower facility-wide mass emission rate of 0.015 lbs/hr
- New compliance dates for source tests

LARGE – Stack Emission Monitoring (d)(2)

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

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

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

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

Updated stack emission monitoring requirements:

- New compliance date specified in Table 1
- Lower mass emission rate of 0.015 lbs/hr
- Performance standards on a rolling 30-day period basis

LARGE – Fugitive Emissions (d)(3)

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

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

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

Updated fugitive emission control requirements:

- New compliance date specified in Table 1

LARGE – Permit Application Schedule (d)(5)

(5) Submittal of Permit and SCEMS/CEMS Applications

The owner or operator of a Large Facility shall:

(A) No later than March 1, 2024, submit complete South Coast AQMD permit application(s) to meet stack emission requirements pursuant to paragraph (d)(1) and fugitive emissions requirements pursuant to paragraph (d)(3); and

(B) No later than March 1, 2025, submit to the Executive Officer applications for new SCEMS or CEMS to meet stack emission monitoring requirements pursuant to paragraph (d)(2).

Increments of progress:

- Updated compliance schedules

LARGE – Interim Mobile Monitoring (d)(7)

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

(i) The Executive Officer to conduct mobile monitoring; or

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

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

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

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

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

Interim (Phase I) Mobile Monitoring:

- Within 30 days of rule amendment, mobile monitoring of EtO near property boundaries
- Performed by third-party contractors or South Coast AQMD on contract basis

LARGE – Interim Mobile Monitoring (d)(7) cont.

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

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

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

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

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

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

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

Interim (Phase I) Mobile Monitoring (cont.):

- Mobile monitoring required once per calendar month
- If using a contractor with indirect measurement of EtO, grab canister sample collection required if above a threshold value

LARGE – Interim Fenceline Monitoring (d)(8) & Submittal of Plans (d)(9)

(8) Interim Fenceline Monitoring

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

(9) Submittal of Plans

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

Interim (Phase II) Fenceline Monitoring

- Will be discussed in detail in subdivision (p)

Submittal of Plans:

- Compliance alternative

LARGE – Implementation Schedule (d)(10)

(10) Implementation Schedule

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

Table 1 – Implementation Schedule

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

Table 1

- Establishes compliance timeline schedule for an existing Large Facility and a new Large Facility

Subdivision (e)
MEDIUM FACILITY REQUIREMENTS

MEDIUM – Stack Emissions (e)(1)

Beginning January 1, 2026:

(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, 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.

Updated stack emission control requirements:

- New compliance date of January 1, 2026

MEDIUM – Fugitive Emissions (e)(2)

Beginning January 1, 2026:

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

(i) Sterilizer;

(ii) Aerator;

(iii) Back-Draft Valve;

(iv) Sterilizer Exhaust Vacuum Pump;

(v) All Elements in a Sterilant Gas Dispensing Area;

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

(vii) First Post-Aerator used to store Sterilized materials removed from an Aerator or a Combined Sterilizer/Aerator; and

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

(i) Combined Sterilizer/Aerator;

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

(iii) All Elements in a Waste Storage Area.

Updated fugitive emission control requirements:

- New compliance date of January 1, 2026
- Requires additional key equipment under PTE
  - Sterilizer exhaust vacuum pump & Elements in dispensing areas
  - Two previously listed under LDAR

MEDIUM – Other Requirements (e)(3)

Beginning 3 Months After Date of Amendment:

(C) Place on a vertical surface on each Sterilized Palletized Unit at least one (1) label, size 8.5 inches by 11 inches, with letters of sufficient size and contrast as to be readily visible and legible, reading:

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

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

Added other requirements:

- Pallet labeling requirements consistent with Large Facilities

25

MEDIUM – Submittal of Permit Applications (e)(4) & Submittal of Plans (e)(5)

(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.

Increments of progress:

- Updated compliance schedules

Submittal of Plans:

- Compliance alternative

Subdivision (f)
SMALL FACILITY REQUIREMENTS

SMALL – Stack Emissions (f)(1)

Beginning January 1, 2026:

(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.

Updated stack emission control requirements:

- New compliance date of January 1, 2026
- Source tests compliance date updated to be consistent with new compliance date

SMALL – Fugitive Emissions (f)(2)

Beginning January 1, 2026:

(A) Operate the following areas and processes, if applicable to the Small Facility, within a Permanent Total Enclosure that meets the requirements of subdivision (k) if Aeration is not exclusively performed in a Combined Sterilizer/Aerator:

- (i) Sterilizer;
- (ii) Aerator;
- (iii) Back-Draft Valve;
- (iv) Sterilizer Exhaust Vacuum Pump; and
- (v) All Elements in a Sterilant Gas Dispensing Area; and

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

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

Updated fugitive emission control requirements:

- New compliance date of January 1, 2026
- Requires additional key equipment under PTE
  - Sterilizer exhaust vacuum pump & Elements in dispensing areas
  - One previously listed under LDAR

SMALL – Labeling and Facility Diagram Requirements (f)(3)

Beginning 3 Months After Date of Amendment:

(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;

- Renamed to Labeling and Facility Diagram Requirements
- Included two storage areas for labeling requirements

SMALL – Submittal of Permit Applications (f)(4) & Submittal of Plans (f)(5)

(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.

Increments of progress:

- Updated compliance schedules

Submittal of Plans:

- Compliance alternative

Subdivision (g)
POST-AERATION STORAGE FACILITY REQUIREMENTS

Post-Aeration Storage Facility Requirements (g)

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

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

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

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

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

- New compliance schedule of July 1, 2025
- Source testing dates updated to be consistent

Subdivision (h)
WAREHOUSE REQUIREMENTS

Tier I Warehouse & Tier II Warehouse Tracking (h)(1) & Reporting (h)(2)

(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	January 1, 2024	December 31, 2024

(2) No later than March 1, 2025, the owner or operator of a Tier I Warehouse or Tier II Warehouse subject to the requirements in paragraph (h)(1) shall submit to the Executive Officer a summary report that includes the following:

(A) Name of warehouse;
(B) South Coast AQMD Facility ID, if applicable;
(C) Address of warehouse;
(D) Contact information for owner or operator of warehouse;
(E) Total number of Sterilized Palletized Units received each month during the consecutive 12-month period specified in Table 2;
(F) Addresses of entities performing Sterilization where Sterilized Palletized Units shipped from; and
(G) Diagram identifying receiving and storage areas for Sterilized Palletized Units and locations of Ethylene Oxide monitors, if any.

- Update compliance schedule
- Use of new defined terms
  - Tier I Warehouse
  - Tier II Warehouse
- Streamlined to collect set 2024-year warehouse data
  - Warehouses registered with U.S. FDA with 100,000 square feet and up to record Sterilized Palletized Units received each month
  - Submit a summary report to the Executive Officer

Tier I Warehouse Fenceline Monitoring (h)(3) & (h)(4)

(3) The owner or operator of a Tier I Warehouse shall either:

(A) Implement a Fenceline Air Monitoring Plan pursuant to subdivision (p);

(B) Conduct an emission study pursuant to paragraph (h)(5) and the approved Emission Study Plan;

(C) No later than [6 Months After Date of Rule Amendment], fund and participate in a real-time fenceline monitoring system demonstration program by the South Coast AQMD to monitor in real-time ambient Ethylene Oxide concentrations near Tier I Warehouse property boundaries and meet the following requirements:

(i) Submit payment to the South Coast AQMD pursuant to the payment schedule in Appendix 1 for funding a real-time fenceline monitoring system demonstration program;

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

(iii) Provide for each real-time Fenceline Air Monitoring system an appropriate location to operate and the infrastructure to operate; or

(D) Not receive Sterilized Palletized Units between January 1, 2024 to December 31, 2024 from any entity performing Sterilization.

- Assess Tier I Warehouse EtO emissions either by:
  - Monitoring fenceline EtO levels for one year
  - Perform an EtO emission study
  - Fund a real-time fenceline monitoring demonstration program
  - Not receive Sterilized Palletized Units in 2024

Tier I Warehouse Fenceline Monitoring (h)(4)

(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).

- Notify South Coast AQMD of choice within 60 days of rule amendment

Emission Study (h)(5)

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

(A) Determine the annual Ethylene Oxide emissions from the warehouse with a methodology approved in the Emission Study Plan by using:

(i) Emission factors approved by U.S. EPA, CARB, South Coast AQMD, or other regulatory agency; or

(ii) Emissions rates from source tests or other sample testing consisting of at least duplicate runs or samples unless otherwise specified in the Emission Study Plan; and

(B) No later than [120 days After Date of Rule Amendment], submit an Emission Study Plan that contains the information specified in Appendix 3 – Emission Study Plan to the Executive Officer;

(C) Within 30 calendar days after disapproval of the Emission Study Plan, resubmit the revised plan to the Executive Officer that includes any information necessary to address deficiencies;

(D) If the resubmitted Emission Study Plan is denied, meet the requirements of the Emission Study Plan modified and approved by the Executive Officer;

(E) Within 180 calendar days of approval of the Emission Study Plan, submit the results of the Emission Study to the Executive Officer; and

(F) If the results of Emission Study indicate that more than four (4) lbs of Ethylene Oxide is emitted per year by the Tier I Warehouse, meet the requirements of subdivision (p).

- Purpose is to demonstrate warehouse has less than four pounds of EtO emission per year
- Study to be conducted in accordance with an approved Emission Study Plan
  - Additional details in Appendix 3
- If Tier I Warehouse emits more than 4 lbs EtO per year, fenceline monitoring is required

Subdivision (j)
SCEMS OR CEMS REQUIREMENTS FOR STACK EMISSIONS

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

(A) Measures the following parameters:

(i) Ethylene Oxide concentration, with minimum detection limit of 0.01 ppm or less and a resolution of at least 0.001 ppm, by volume;

(ii) Oxygen concentration; and

(iii) Exhaust stack flow rate;

(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.

Updated SCEMS or CEMS requirements:

- Clarified minimum detection limit of 0.01 ppm (10 ppb) and resolution of 0.001 ppm (1 ppb)
- Limit of 96 hours of missing or invalid data per rolling 30-day period

Subdivision (k)
PERMANENT TOTAL ENCLOSURE REQUIREMENTS

Permanent Total Enclosure Requirements

(2)	Install, operate, and maintain a digital differential pressure monitoring system for each Permanent Total Enclosure to demonstrate compliance with paragraph (k)(1):	
	(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

Updated PTE requirements:

- Audible alarm to alert when insufficient negative pressure

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

Leak Detection and Repair Program

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

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

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

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

(4) Conduct audio-visual checks once per operating day for all applicable Components and Elements; and

(5) No later than 60 calendar days of being required to implement an LDAR program and no later than every 60 calendar days thereafter, conduct leak inspections of all applicable Components and Elements pursuant to CARB Test Method 21, or an approved alternative method, using a portable photoionization detector, or an approved alternative analytical instrument, calibrated with Ethylene Oxide, or an appropriate calibrating gas provided:

(A) All alternatives used are capable of determining or detecting Leaks great than 2 ppm above background and approved by the Executive Officer in writing; and

(B) If an appropriate calibrating gas is used, the correction factor is recorded and the measured readings is correlated to and also expressed as Ethylene Oxide.

Updated LDAR requirements:

- Leak inspections required at least every 60 days

Subdivision (n)
PROHIBITIONS

Prohibitions

(n) 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 emissions of Ethylene Oxide to atmosphere from any Permanent Total Enclosure at any time.

(4) The owner or operator of a Facility performing Sterilization shall not remove Sterilized materials from the Facility before completing Aeration, except for testing with no further distribution.

(5) The owner or operator of a Post-Aeration Storage Facility shall not remove or render inoperable a Control System unless it is replaced by a Control System permitted by South Coast AQMD to meet the applicable Ethylene Oxide performance standard specified in paragraph (g)(1) or (i)(4).

Updated prohibitions:

- Prohibit the removal of products before completion of aeration, unless for testing
- Prohibit the removal of Control Systems at Post-Aeration Storage Facilities unless replaced with ones meeting the rule requirements

Subdivision (p)
INTERIM FENCELINE AIR MONITORING REQUIREMENTS

New

Submittal and Approval of Fenceline Air Monitoring Plan (p)(1)

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

Table 3 – Submission of Fenceline Air Monitoring Plan

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.

Fenceline Air Monitoring Plan (FAMP):

- Applies to:
  1. Large Facility ≥ 2,000 lbs EtO/year
  2. Tier 1 Warehouse ≥ 250,000 square feet receiving EtO sterilized products
- Establishes timeline of FAMP for submission and approval

Implementation of FAMP (p)(2)

(A) Beginning 90 days after approval of the Fenceline Air Monitoring Plan, unless a different date is specified in the approved Fenceline Air Monitoring Plan, the owner or operator of a Facility subject to subparagraph (p)(1)(A) shall implement the approved Fenceline Air Monitoring Plan.

(B) The owner or operator of a Facility implementing a Fenceline Air Monitoring Plan to meet the requirements of subparagraph (p)(2)(A) by canister collection shall:

(i) Collect a 24-hour integrated sample at a frequency of 1-in-6 days, unless a more frequent schedule is specified in the approved Fenceline Air Monitoring Plan, at each location specified in the Fenceline Air Monitoring Plan;

(ii) Collect and analyze the sample pursuant to either:

(I) U.S. EPA Compendium Method TO-15 Second Edition Determination Of Volatile Organic Compounds in Air Collected In Specially-Prepared Canisters And Analyzed By Gas Chromatography/ Mass Spectrometry; or

(II) U.S. EPA Method TO-15A Determination of Volatile Organic Compounds in Air Collected in Specially Prepared Canisters and Analyzed by Gas Chromatography–Mass Spectrometry; and

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

FAMP implementation:

- Must begin fenceline air monitoring within 90 days of approval of FAMP
- For 24-hour integrated canister collection:
  - 1-in-6 day schedule, unless approved otherwise
  - Must use U.S. EPA Compendium Method TO-15 or Method TO-15A

Implementation of FAMP (p)(2)(C)

(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.

FAMP implementation for real-time monitoring:

- On a schedule approved in FAMP
- Must have method detection limit of 1.0 ppb or lower every 15 minutes

Implementation of FAMP (p)(2)(D)

(D) The owner or operator of a Large Facility implementing a Fenceline Air Monitoring Plan to meet the requirements of subparagraph (p)(2)(A) by real-time monitoring shall:

(i) Calculate and record the average hourly concentration of Ethylene Oxide for each monitoring location using data obtained pursuant to clause (p)(2)(C)(iii); and

Table 4 – Concentration Threshold

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

(ii) If a real-time monitor measures an Ethylene Oxide 3-hour average concentration that exceeds the concentration specified in Table 4 – Concentration Threshold:

(I) No later than one (1) hour after, begin collecting a 24-hour canister sample at the monitoring location, unless currently collecting a 24-hour canister sample at the monitoring location or unless otherwise specified in the Fenceline Air Monitoring Plan;

(II) Collect no more than one (1) canister sample at each monitoring location concurrently;

(III) Meet the requirements specified in clauses (p)(2)(B)(ii) and (p)(2)(B)(iii); and

(IV) Submit canister samples collected for analysis within one (1) calendar day of collection.

FAMP implementation for Large Facility

- Large Facility with real-time monitoring also must:
  - Calculate average hourly EtO concentrations
  - Collect canister sample if hourly concentration above threshold value

Implementation of FAMP (p)(2)(E) – (p)(2)(F)

(E) The owner or operator of a Facility implementing a Fenceline Air Monitoring Plan to meet the requirements of subparagraph (p)(2)(A) shall continuously record wind speed and direction data at all times using equipment capable of meeting the U.S. EPA Performance Criteria for Wind Sensors for both wind speed and wind direction at a location approved in the Fenceline Air Monitoring Plan.

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

- (i) Due to malfunction or other occurrence beyond the control of the Facility:
  - (I) More than one valid 24-hr integrated sample; and
  - (II) More than 48 hours of valid real-time data; and
- (ii) Due to any other reason:
  - (I) Any valid 24-hr integrated sample; and
  - (II) More than 24 hours of valid real-time data.

FAMP implementation (continued):

- Large Facility or Tier I Warehouse required to record wind speed and direction
- Include provisions for missing data

Fenceline Air Monitoring End Date (p)(3)

(3) Fenceline Air Monitoring End Date

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

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

(ii) After August 31, 2025.

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

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

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

Fenceline Air Monitoring Off-ramp:

- For a Large Facility, off-ramp is:
  - 60 days after final SCEMS or CEMS certification issued
  - No earlier than August 31, 2025
- For a Tier I Warehouse, off-ramp is 1 year of valid data:
  - 60 valid canister samples
  - 8,760 hours of valid real-time data

Subdivision (q)
CURTAILMENT OF STERILIZATION OPERATIONS

New

Curtailment Trigger Thresholds (q)(1)

(1) Within 24 hours of the owner or operator of a Large Facility, Medium Facility, or Small Facility receiving the Trigger Result that is at or above the applicable trigger threshold specified in Table 5 – Trigger Threshold for Sterilization Facilities, the owner or operator shall curtail daily Ethylene Oxide usage by the applicable amount specified in Table 6 – Curtailment Schedule from Baseline Operation.

Table 5 – Trigger Threshold for Sterilization Facilities

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]	August 31, 2025
		Medium Facility or Small Facility	[Date of Amendment]	March 1, 2026
Level 2	> 25.0 ppb	Large Facility	[Date of Amendment]	August 31, 2025
		Medium Facility or Small Facility	[Date of Amendment]	March 1, 2026
Level 3	≥ 3.0 ppb	Large Facility	September 1, 2025	None
		Medium Facility or Small Facility	March 2, 2026	None

New curtailment provisions added for Large, Medium or Small Facility:

- Curtailment based on fenceline EtO levels collected over a 24-hour period by third-party contractor or South Coast AQMD
- Level 1 or Level 2 triggers applicable from rule amendment until:
  - August 31, 2025 for a Large Facility
  - March 1, 2026 otherwise
- Lower Level 3 trigger in effect thereafter

Curtailment Schedule (q)(1)

Table 6 – Curtailment Schedule

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

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

Curtailment Procedures:

- Within 24 hours of receiving sample result, reduce Ethylene Oxide daily usage by:
  - By 20% of if Level 1 concentration exceeded
  - By 50% if Level 2 concentration exceeded or if second Level 1
  - By 100% if second Level 2 or third Level 1
- After phase-in date, reduce Baseline Operations:
  - By 50% if Level 3 concentration exceeded
  - By 100% if second Level 3 exceeded

Curtailment Procedures (q)(2)-(q)(4)

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

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

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

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

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

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

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

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

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

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

Curtailment Procedures :

- Curtailment lifted when sample collected below trigger threshold
- Number of trigger samples resets to zero after 30 consecutive calendar days without trigger exceedance

Subdivision (r)
PLAN ADMINISTRATION

New

Plan Administration

(r) Plan Administration

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

- Various plans referenced in PAR 1405 subject to fees specified in Rule 306 – Plan Fees

Subdivision (s)
RECORDKEEPING

Recordkeeping – Sterilization Facilities

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

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

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

(C) Data collected from the SCEMS or CEMS pursuant to paragraphs (j)(1) through (j)(2);

(D) Source test reports pursuant to paragraph (l)(6);

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

(F) Data collected from the digital differential pressure monitoring system in Permanent Total Enclosures pursuant to paragraph (k)(2);

(G) Plot-plan reports, audio-visual checks, and leak inspections for LDAR programs pursuant to subdivision (n);

(H) The number of Sterilized Palletized Units shipped, grouped by First Destination, pursuant to paragraph (d)(7);

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

(J) Annual reports pursuant to paragraph (t)(1);

(K) Semi-annual reports pursuant to paragraph (t)(2); and

(L) For each Sterilization Cycle, a log entry with the following:

(i) Cycle number, product identifier or batch number;

(ii) Starting and ending time of Aeration in local time;

(iii) Minimum required time of Aeration;

(iv) Document source of minimum required time of Aeration specified in clause (d)(4)(E)(iii); and

(v) For a Large Facility maintaining a Packaging Area outside a Permanent Total Enclosure pursuant to paragraph (d)(3), status of completion of biological indicator sterility testing.

Update in recordkeeping

- Sterilization Cycle log including:
  - Cycle ID
  - Starting and ending Aeration clock time
  - Minimum Aeration time
  - Source of minimum Aeration time
  - BI sterility testing status under certain circumstances

Subdivision (t)
REPORTING REQUIREMENTS FOR A FACILITY PERFORMING STERILIZATION

Mobile Monitoring Reporting (t)(6)

(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 the results of all mobile monitoring within seven (7) days of measurement that includes a concentration map showing the mobile monitoring route along with measurements of Ethylene Oxide concentration (or indirect concentration) at all locations.

(C) The owner or operator of a Large Facility electing to conduct mobile monitoring pursuant to subclause (d)(7)(A)(ii)(II) shall report no later than two (2) hours after receiving the results of a canister sample collected pursuant to clause (d)(7)(E)(ii):

(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.

Mobile Monitoring (Phase I) reporting required for:

- Exceeding the Level 2 concentration (25 ppb) during mobile monitoring
- Results of mobile monitoring within 7 days
- Results of any canister samples collected within 2 hours

FAMP Reporting (t)(7)

(7) Fenceline Air Monitoring Plan Reporting

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

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

(i) No later than 10 days after the date of sampling, report the Ethylene Oxide concentration to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov;

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

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

(i) No later than the 14th of each calendar month, report the daily average concentrations of Ethylene Oxide for the prior calendar month to the Executive Officer by electronic mail to Rule1405notifications@aqmd.gov;

(ii) No later than two (2) hours after more than 24 hours of valid data over a consecutive 30-day period at a monitoring location was not recorded, report to the Executive Officer by calling 1-800-CUT-SMOG or by electronic mail to Rule1405notifications@aqmd.gov and provide Facility name, name of fenceline monitor, date of occurrence, and reason of occurrence;

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

(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.

FAMP reporting required for:

- Canister collection:
  - Report results no later than 10 days after sampling via email
  - Report if valid sample not collected within 2 hours
  - A sample may not be valid if it is collected or analyzed improperly
- Real-time monitoring:
  - Report results monthly no later than 14th day of following month
  - Report if more than 24 hours of valid data not collected within 2 hours
  - Report canister collection within 2 hours
- Report wind speed and direction monthly

Trigger Level Reporting (t)(8)

(8) Trigger Level Reporting

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

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

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

(i) The daily average concentration;

(ii) Date when exceeded the applicable daily average concentration; and

(iii) Location of monitor.

Curtailment reporting:

- Within 2 hours after receiving results that exceed a trigger level, report by telephone and email
- Additional data for real-time monitoring data

SCEMS or CEMS Reporting (t)(9) and PTE Reporting (t)(10)

(9) CEMS/SCEMS Exceedance Reporting

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

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

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

(10) Permanent Total Enclosure Monitor Reporting

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

(A) The negative pressure in any Permanent Total Enclosure does not meet the requirement in paragraph (k)(1); or

(B) There are more than 24 consecutive hours of missing data for data used to demonstrate compliance with paragraph (k)(1).

SCEMS or CEMS reporting:

- Within 2 hours, report via email or telephone:
  - Exceeding total mass emission rate for any rolling 30-day period
  - If complying with outlet concentration limit, exceeding limit for any rolling 30-day period

PTE reporting:

- Moved from subdivision (k)
- Within 24 hours, report via email or telephone:
  - Insufficient negative pressure
  - More than 24 hours of missing continuous data

Subdivision (u)
EXEMPTIONS

Exemptions (u)(2)

(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 6 – Interim Requirements:

Table 6 – Interim Requirements

Applicable Subdivision	Beginning Date of Exemption
(d)	July 1, 2025
(e)	January 1, 2026
(f)	January 1, 2026
(g)	July 1, 2025

Interim Requirement Phase-out

- Interim requirement dates of exemption updated
- Consistent with effective dates of corresponding subdivisions

Exemptions (u)(3)

(3) The requirements of paragraph (k)(1) and (n)(3) do not apply to an owner or operator of a Facility during the loss of power or other unplanned event outside of the control of the owner or operator provided, as applicable:

(A) No Products or other materials are added or removed from Sterilizers, Combined Sterilizer/Aerators, Aerators, Post-Aerators, or Permanent Total Enclosures;

(B) All natural draft openings (NDOs) are closed except for the purposes of exiting a Permanent Total Enclosure or restarting a Control System;

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

(i) All alternatives used are capable of determining or detecting Leaks great than 2 ppm above background and approved by the Executive Officer in writing; and

(ii) If an appropriate calibrating gas is used, the correction factor is recorded and the measured readings is correlated to and also expressed as Ethylene Oxide; and

(D) Event reported pursuant to paragraph (k)(4).

PTE Procedures during Power Outages

- Exemption updated regarding leak detection equipment with reporting requirement

Exemptions (u)(4) – (u)(5)

(4) The requirements of subdivision (d) do not apply to an owner or operator of a Large Facility provided:

(A) The owner or operator submits to the Executive Officer a complete permit application or a Facility Implementation Plan to limit the facility-wide use of Ethylene Oxide to be less than 2,000 lbs per calendar year;

(B) The complete permit application or the Facility Implementation Plan submitted to meet the requirements of subparagraph (u)(4)(A) is not cancelled; and

(C) The owner or operator uses less than 167 lbs of Ethylene Oxide facility-wide per calendar month, either:

(i) Beginning date of the complete permit application submittal and until the date the permit associated with the permit application submitted pursuant to subparagraph (v)(4)(A) has been issued; or

(ii) Beginning date of the Facility Implementation Plan submittal and until the date the Facility Implementation Plan has been approved.

(5) The requirements of paragraph (d)(7) do not apply to an owner or operator of a Large Facility, provided either:

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

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

Voluntary Throughput Reduction

- Large Facility can reduce EtO throughput with an enforceable limit and avoid Large Facility requirements

Mobile Monitoring Exemption

- Large Facility already under fenceline air monitoring

Exemptions (u)(6) – (u)(7)

(6) The requirements of subparagraph (d)(2)(B) do not apply to an owner or operator of a Large Facility that demonstrates the total mass emission rate of Ethylene Oxide from all exhaust stack(s) at the Facility exceeds 0.015 lbs/hr during the present rolling 30-day period, provided:

(A) Facility did not perform Sterilization in the last 48 hours; and

(B) Demonstrate by using the SCEMS or CEMS that the sum of mass emission rates, averaged over a calendar day and measured at each exhaust stack, is 0.015 lbs/hr or less of Ethylene Oxide after resuming Sterilization.

(7) The requirements of subparagraph (d)(2)(C) do not apply to an owner or operator of a Large Facility provided that demonstrates the concentration of Ethylene Oxide from a Control System at the Facility exceeds 0.01 ppm during the present rolling 30-day period, provided:

(A) Facility did not perform Sterilization in the last 48 hours; and

(B) Demonstrate by using the SCEMS or CEMS that emissions of Ethylene Oxide are 0.01 ppm or less, averaged over each calendar day in operation after resuming Sterilization.

Resuming Sterilization with SCEMS or CEMS:

- After exceeding a rolling 30-day average for total mass emission rate or outlet concentration, if applicable, a Large Facility may resume sterilization after a 48-hour shutdown and if next daily average below performance standard on a daily basis

Exemptions (u)(8) - (u)(10)

(8) The requirements of clause (p)(2)(D)(ii) do not apply to owner or operator of a Large Facility implementing a Fenceline Air Monitoring Plan to meet the requirements of paragraph (p)(4) by real-time monitoring, provided:

(A) The real-time monitoring method is approved by the U.S. EPA, CARB or South Coast AQMD; and

(B) In the Fenceline Air Monitoring Plan:

(i) The Executive Officer approved the real-time monitoring method as a legally defensible method; and

(ii) The owner or operator agrees to the stipulation that the results of real-time monitoring are sufficient for curtailment requirements specified in subdivision (s).

(9) The following requirements do not apply to a Large Facility permitted after [Date of Rule Amendment]:

(A) Paragraphs (d)(5), (d)(7), and (d)(8);

(B) Subdivision (i);

(C) Subdivision (p); and

(D) Paragraphs (t)(5), (t)(6), (t)(7), and (t)(8).

(10) The requirements of subdivision (q), (d), (e), and (f) to stop or curtail Sterilization by 100% do not apply to the owner or operator of a Large Facility, Medium Facility, or Small Facility provided, the owner or operator Sterilizes only Products approved by the Executive Officer that either are:

(A) In critical reduced supply to endanger public health, as determined by the U.S. FDA or other local, state, or federal health agency; or

(B) In the Preconditioner at the start of the curtailment and not suitable for use if a Sterilization Cycle is not completed, based on validation documents approved by the U.S. FDA or manufacturer's specification.

FAMP Real-time Monitoring

- Large Facility exempt from collecting canister samples if established real-time monitoring method is approved by U.S. EPA, CARB or South Coast AQMD

New Large Facility

- A Large Facility permitted after date of rule amendment exempt from certain interim requirements

Approved Products to be Sterilized

- Specific allowance for Products to be Sterilized in special circumstances

Summary of New Appendices

- New appendices added to provide additional guidance or clarification on new requirements
  - **Appendix 1** – Mobile Monitoring and Program Fund
    - Fee for cost recovery of mobile monitoring performed by South Coast AQMD
    - One-time payment for Tier I Warehouse to participate in a real-time Fenceline Air Monitoring system demonstration (cost of one-time payment still being evaluated)
  - **Appendix 3** – Emission Study Plan
    - Establishes guidelines for a Tier I Warehouse electing to demonstrate that EtO emissions are below 4 lbs per year
  - **Appendix 4** – Fenceline Air Monitoring Plan
    - Specifies information for a Large Facility or Tier I Warehouse to submit in a Fenceline Air Monitoring Plan
    - Establishes minimum number of monitoring locations
      - 1 monitoring location for a Large Facility permitted to use ≤ 100,000 lbs per year
      - 2 monitoring locations for other Large Facilities or Tier I Warehouses

Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions
from Sterilization and Related Operations

Public Process

Key Dates

Action	Date
Written Comments Due	August 9, 2023
Stationary Source Committee	August 18, 2023
Set Hearing	September 1, 2023
Public Hearing	October 6, 2023

PAR 1405 Staff Contacts

Please contact staff with any questions or comments

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

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

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

Michael Krause
Assistant Deputy Executive Officer
(909) 396-2706
mkrause@aqmd.gov