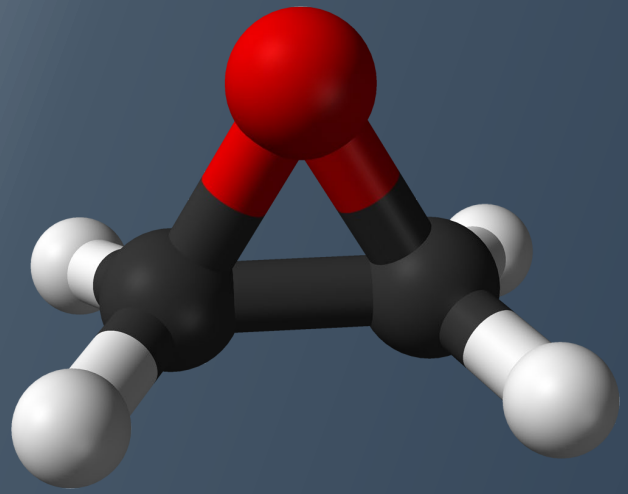
Working Group Meeting #8



Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions from Sterilization and Related Operations

October 4, 2023
3:00 PM

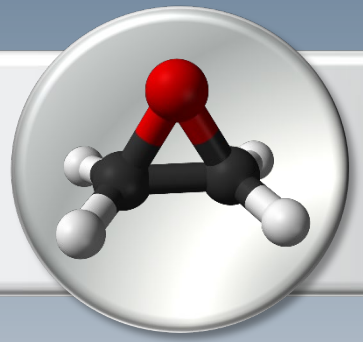
Zoom Meeting Link:
https://scaqmd.zoom.us/j/97580880732

Dial In: (669) 900 6833

Meeting ID: 975 8088 0732

Agenda

- Health Effects of Ethylene Oxide
- PAR 1405 Rulemaking Process
- 2nd Revised Preliminary Draft Rule Language
- Public Process



Health Effects of Ethylene Oxide (EtO)

Long-Term Health Effects

- Associated with blood cancers (non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia) and, in women, breast cancer
- Also linked with reproductive harm to men and women
- U.S. EPA's revised inhalation cancer risk is 30 to 50 times higher than previously known

Children May be More Susceptible

- EtO is mutagenic, meaning it damages DNA
- Children are expected to be more susceptible to EtO's toxic effects because their bodies are growing and duplicating DNA

Overview of PAR 1405 Key Requirements (July 2023 Version)

	Key Requirements
Stack Emission Requirements	
Control Efficiency	99.99% for Large Facilities, 99.9% for others
Concentration Alternative	0.01 ppm, rolling 30-day average*
Mass Emission Rate	0.015 lb/hr, rolling 30-day average*
CEMS/SCEMS	Required for Large Facilities
Fugitive Emission Requirements	
Permanent Total Enclosure (PTE)	Required for Large Facilities and certain areas of Medium Facilities
Leak Detection and Repair (LDAR)	Audio/visual checks every day, leak checks every 60 days
Fenceline Monitoring	Interim requirement for Large Facilities, subject to curtailment
Warehouses	Pallet tracking and reporting with emission study or fenceline monitoring

**Averaging period only applicable to CEMS/SCEMS performance standard*

Summary of PAR 1405 Rulemaking Process

- **Initial Rule Language**
  - Released 2/10/23
- **Preliminary Draft Rule Language**
  - Released 3/23/23
- **Revised Preliminary Draft Rule Language**
  - Released 7/21/23
- **2nd Revised Preliminary Draft Rule Language**
  - Released 9/28/23
- **Draft Rule Language**
  - To be released November 1, 2023 (tentatively)

Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions
from Sterilization and Related Operations

2nd Revised Preliminary Draft Rule Language

PAR 1405 Structure

PAR 1405

Key Updates

- (a) Purpose
- (b) Applicability
- (c) Definitions
- (d) Large Facility Requirements — Key Updates
- (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 — Key Updates
- (k) Permanent Total Enclosure Requirements — Key Update
- (l) Source Test Requirements
- (m) Leak Detection and Repair (LDAR) Program Requirements
- (n) Prohibitions
- (o) Facility performing Sterilization Exceeding Applicable Ethylene Oxide Usage
- (p) Interim Fenceline Air Monitoring Requirements
- (q) Curtailment of Sterilization Operations
- (r) Plan Administration
- (s) Recordkeeping
- (t) Reporting — Key Update
- (u) Exemptions — Key Updates

Appendices

- Appendix 1 – Calculations — New
- Key Update — Appendix 2 - Mobile Monitoring Fee and Program Fund
- Appendix 3 – Emission Study Plan
- Appendix 4 – PTE Inward Face Air Velocity Measurement Procedures
- Key Update — Appendix 5 – Fenceline Air Monitoring Plan
- Appendix 6 – Semi-Annual Summary Reports
- Appendix 7 – Semi-Annual Excess Emission Reports

Various subdivisions THROUGHOUT

THROUGHOUT – Compliance Dates

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)	Dat
	(d)(3)	

July 2023 version

Example of Key Update

Table 1 – Implementation Schedu

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

September 2023 version

NOTE: Text presented is without underline or strikeout for clarity

Updated Compliance Dates:

- Compliance dates developed based on expected Public Hearing in October
- Several compliance dates for Large Facilities have been extended by approximately 60 days to reflect a Governing Board Public Hearing in December 2023

THROUGHOUT – Simplified Requirement

(1) Stack Emission Requirements

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

July 2023 version

Key Update

(1) Stack Emission Requirements

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

September 2023 version

Updated Requirement Language:

- Rule language has been simplified with uniform "shall" language throughout, consistent with rest of PAR 1405
- Compliance with rule still required and a facility would still be subject to enforcement action if in violation

Subdivision (d)
LARGE FACILITY REQUIREMENTS

Mass Emission Rate Limit

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

July 2023 version

Mass emission rate limit:

- 0.015 lb/hr determined based on 99.99% control efficiency of the highest throughout facility in South Coast AQMD
- Based on rounding, a source test demonstrating 99.985% control efficiency would also satisfy the 99.99% requirement

Alternative Mass Emission Rate Limit

(B) Demonstrate by a SCEMS or CEMS that the facility-wide mass emission rate of Ethylene Oxide from all exhaust stacks for all Control Systems at the Facility does not exceed either:

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

Key Update

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

September 2023 version

New alternative mass emission rate limit:

- Added alternative calculated rate based on a compliant 99.99% control efficiency and permitted throughput
- Procedures with example calculation detailed in Appendix 1 – Calculations

Packaging Area

(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.

July 2023 version

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

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

July 2023 version

Packaging Area:

- Post-Aerator must be under PTE
  - Packaging area is not a Post-Aerator if certain conditions were met (July 2023 version)
- Draft NESHAP allows certain warehousing areas to be excluded from PTE requirements if advanced sterilization cycle design are used

Alternative PTE Pathway – Post-Aerator

Key Update

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

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

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

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

September 2023 version

Updated alternative PTE pathway for post-aeration materials:

- Certain existing Large Facilities may exclude some areas from the need for PTE if certain conditions are met
- PTE is required for the first 7 days after aeration (more protective than draft NESHAP)
- One (1) additional fenceline air monitoring location is required

Alternative PTE Pathway – Sterilant Gas Storage

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

July 2023 version

Key Update

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

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

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

(iii) Measure and record the ambient Ethylene Oxide concentration using an established methodology approved by the Executive Officer that has a method detection limit of 1.0 ppb or lower every one (1) minute;

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

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

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

September 2023 version

Alternative PTE pathway for sterilant gas storage areas:

Instead of storing all sterilant gas under PTE, a Large Facility may choose to install a real-time EtO monitor sensitive to 1.0 ppb or lower, monitor the area under LDAR, and maintain an emergency enclosure venting to a Control System

Subdivision (j)
SCEMS OR CEMS REQUIREMENTS FOR STACK EMISSIONS

SCEMS/CEMS – Measurement Parameters

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;

July 2023 version

Key Updates

The owner or operator of a Facility required to monitor the emissions from a Control System shall install, operate, and maintain a SCEMS or CEMS complying with the following requirements:

(A) Measures the following parameters:

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

(ii) Oxygen concentration, if required by the SCEMS or CEMS certification; and

(iii) Exhaust stack flow rate;

September 2023 version

Updated EtO concentration requirement:

- Removed specific minimum detection limit
- Minimum detection limit would need to be low enough to demonstrate compliance with performance standard

Updated oxygen concentration requirement:

- Only if required by the SCEMS or CEMS certification

SCEMS/CEMS – Backup Battery

(3) The owner or operator of a Facility required to operate a SCEMS or CEMS shall provide an uninterruptible power supply, including the installation and operation of a backup battery, to ensure operation of the SCEMS or CEMS.

July 2023 version

Key Update

(3) The owner or operator of a Facility required to operate a SCEMS or CEMS shall provide an uninterruptible power supply, including the installation and operation of a backup battery, to ensure operation of the SCEMS or CEMS for a minimum of 60 consecutive minutes.

September 2023 version

Updated backup battery requirement:

- Provides clarity at the request of stakeholders
- Ensures at least one (1) hour of uninterruptible power in the event of a power outage

Subdivision (k)
PERMANENT TOTAL ENCLOSURE REQUIREMENTS

PTE – Averaging Time

(k) Permanent Total Enclosure Requirements

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

(1) Maintain any Permanent Total Enclosure at a negative pressure of at least 0.007 inches of water column averaged over one (1) minute;

July 2023 version

Key Update

(k) Permanent Total Enclosure Requirements

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

(1) Maintain any Permanent Total Enclosure at a negative pressure of at least 0.007 inches of water column averaged over 15 minutes;

September 2023 version

Background on Permanent Total Enclosure (PTE):

- PTE ensures fugitive emissions are captured
- Negative pressure is required to be continuously monitored

Updated PTE negative pressure averaging time:

- The averaging period has been updated from one (1) minute to 15 minutes, consistent with other toxic rules

Subdivision (t)
REPORTING

REPORTING – Operational Noncompliance

Key Update

(11) Operational Noncompliance Reporting

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

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

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

September 2023 version

New reporting requirement: Facilities must report to South Coast AQMD noncompliant source tests or when leaks are detected under the LDAR program

Subdivision (u)
EXEMPTIONS

Curtailment Exemption

(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

July 2023 version

Curtailment exemption:

- PAR 1405 includes curtailment provisions in response to elevated fenceline EtO levels
- To address concerns about potential impacts on supply chain, the July 2023 version contained an exemption from curtailment events for Products that were in reduced supply

Curtailment Exemption (cont.)

Key Update

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

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

(i) Product name;

(ii) Product code;

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

(iv) Either the communication dated within 90 days that identifies the Product, the date of determination, and estimated duration of the status from the public health agency or California hospital or medical center that made the determination or, for non-public communication prohibited by law, a statement certifying non-public communication from the public health agency or California hospital or medical center;

(B) Maintain daily records of the amount of Sterilant Gas (measured or calculated, in lbs per day) used to sterilize Products, including Palletized Units containing Products, reported pursuant to subparagraph (u)(12)(A) for each operating day during the curtailment event; and

(C) For each Palletized Unit containing the Product reasonably likely to experience a reduced supply and is critical to public health, affix on a vertical surface on the Palletized Unit at least one (1) yellow label, size 8.5 inches by 11 inches, with black letters of sufficient size and contrast as to be readily visible and legible, with the following prior to entering a Sterilizer or Combined Sterilizer/Aerator:

(i) Product name;

(ii) Product code; and

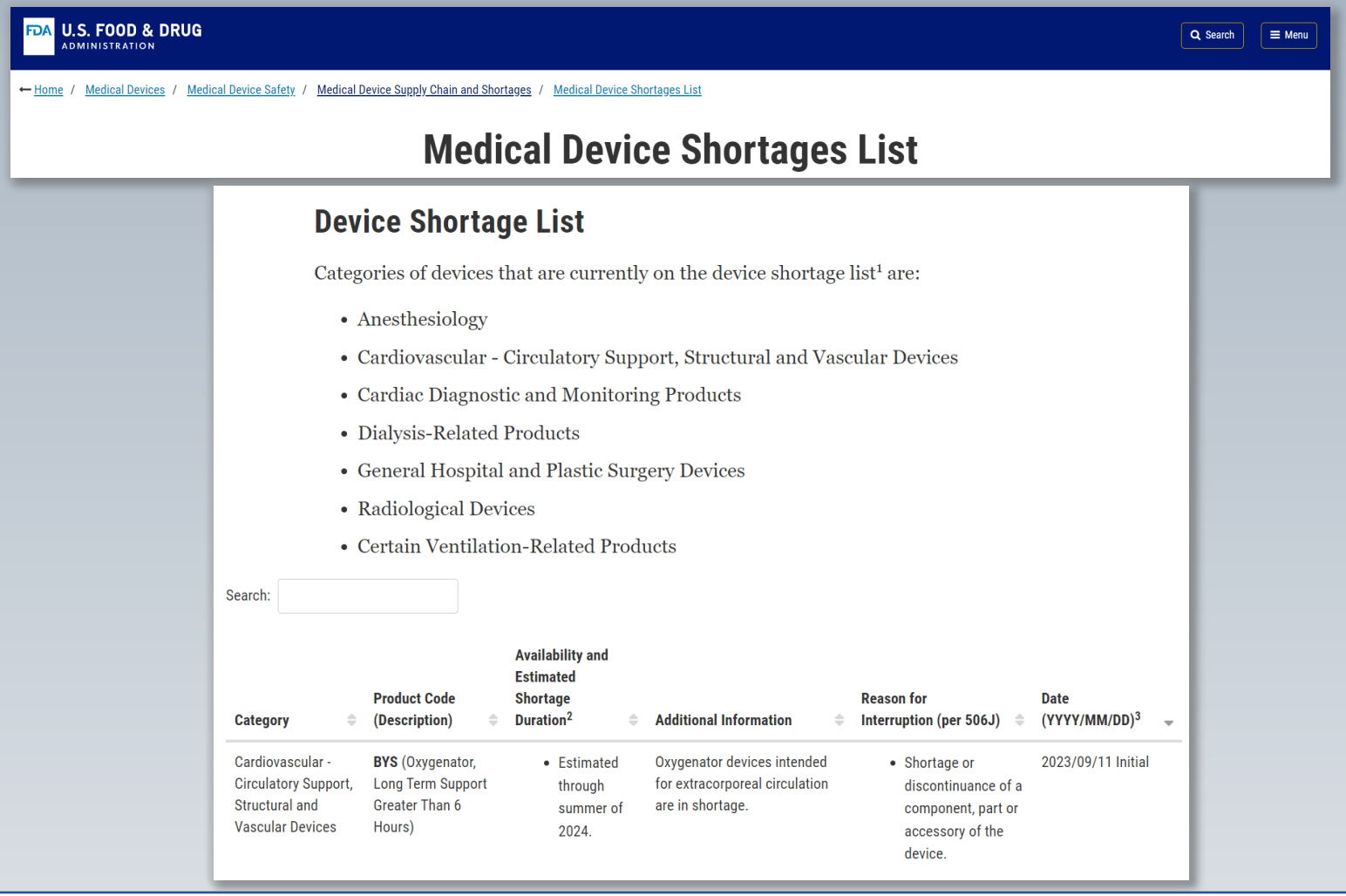
(iii) Name of public health agency or California hospital or medical center that made the determination.

September 2023 version

Updated Curtailment Exemption:

- The September 2023 version, after consultation with U.S. FDA and other stakeholders, contains updated refinements including recordkeeping, reporting, and labeling requirements
- In addition to public health agencies, a hospital or medical center in California could also make a determination

EXAMPLE – Curtailment exemption (cont.)



U.S. FOOD & DRUG ADMINISTRATION

Search | Menu

Home / Medical Devices / Medical Device Safety / Medical Device Supply Chain and Shortages / Medical Device Shortages List

Medical Device Shortages List

Device Shortage List

Categories of devices that are currently on the device shortage list[1] are:

- Anesthesiology
- Cardiovascular - Circulatory Support, Structural and Vascular Devices
- Cardiac Diagnostic and Monitoring Products
- Dialysis-Related Products
- General Hospital and Plastic Surgery Devices
- Radiological Devices
- Certain Ventilation-Related Products

Search:

Category	Product Code (Description)	Availability and Estimated Shortage Duration[2]	Additional Information	Reason for Interruption (per 506J)	Date (YYYY/MM/DD)[3]
Cardiovascular - Circulatory Support, Structural and Vascular Devices	**BYS** (Oxygenator, Long Term Support Greater Than 6 Hours)	• Estimated through summer of 2024.	Oxygenator devices intended for extracorporeal circulation are in shortage.	• Shortage or discontinuance of a component, part or accessory of the device.	2023/09/11 Initial

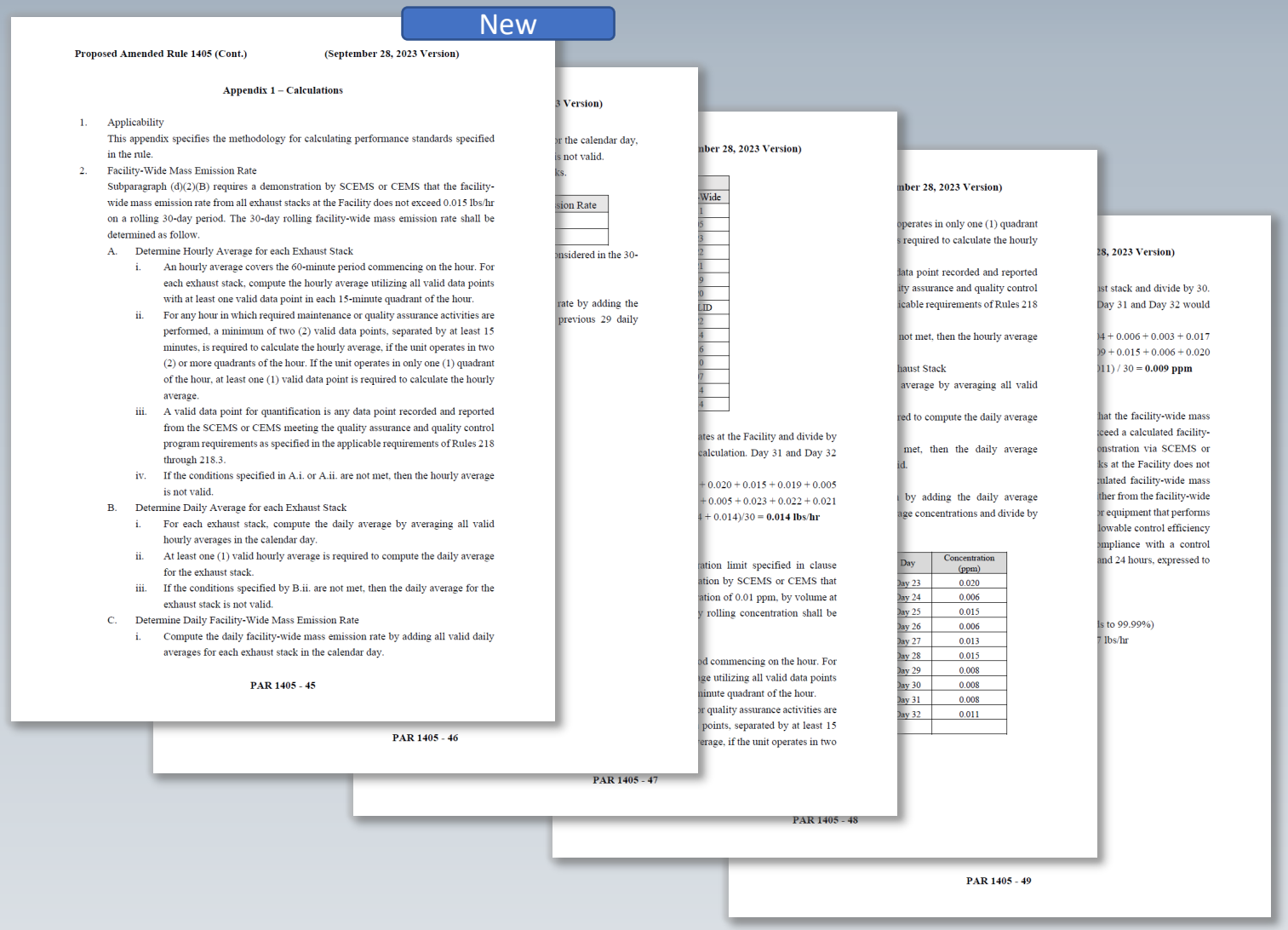
Source: https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/medical-device-shortages-list

Example:

- Upon a curtailment event declared and prior to operating sterilizers, a facility emails South Coast AQMD each product likely to experience shortage with communication regarding the products
- Communications can include recent letters or webpage printout (see example from U.S. FDA website)

Appendix 1
CALCULATIONS

APPENDIX 1 – Calculations



New Calculation Appendix:

- Five (5) pages with multiple examples on how to perform calculations including hourly averages, daily averages, 30-day rolling averages, and the calculated facility-wide mass emission rate

APPENDIX 1 – Calculations (cont.)

New

4. Calculated Facility-Wide Mass Emission Rate

Clause (d)(1)(D)(ii) requires a demonstration via a source test that the facility-wide mass emission rate from all exhaust stacks at the Facility does not exceed a calculated facility-wide mass emission rate. Clause (d)(3)(B)(ii) requires a demonstration via SCEMS or CEMS that the facility-wide emission rate from all exhaust stacks at the Facility does not exceed a calculated facility-wide mass emission rate. The calculated facility-wide mass emission rate is calculated from permitted usage (lbs), which is either from the facility-wide permit limit for a calendar year or from the sum of permit limits for equipment that performs Sterilization at the Facility for a calendar year, and the lowest allowable control efficiency expressed to the thousandths of a percent to demonstrate compliance with a control efficiency of 99.99% or greater, by weight, divided by 365 days and 24 hours, expressed to the nearest thousandths lbs/hr.

A. Example

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

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

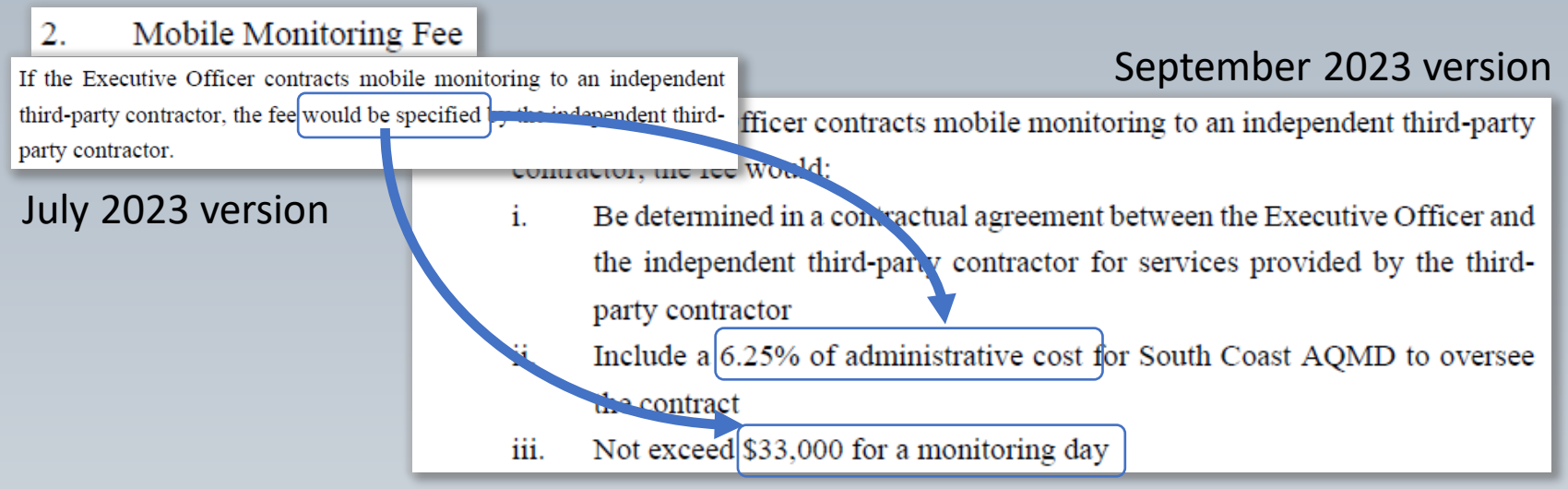
1,000,000 lbs * (1-0.99985) = 150 lbs/365 days/24 hours = 0.017 lbs/hr

Alternative Mass Emission Rate Limit:

- In lieu of the 0.015 lb/hr mass emission rate limit, a facility may request a facility-specific mass emission rate limit
- Calculated from their annual EtO permitted usage and the lowest allowable control efficiency, expressed to the nearest thousandth

Appendix 2
MOBILE MONITORING FEE AND PROGRAM FUND

APPENDIX 2 – Mobile Monitoring Fee



Interim (Phase I) Mobile Monitoring

- Starting February 1, 2024 and until Phase II fenceline air monitoring begins, Large Facilities must either directly contract to third-party or select South Coast AQMD to perform monthly mobile monitoring

Mobile monitoring fee

- Cost recovery based on feedback from contractors
- Provides clarity to existing Large Facilities
- Not to exceed $33,000 per monitoring day for services with an administrative cost

APPENDIX 2 – Program Fee

July 2023 version

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

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

September 2023 version

3. Real-time Fenceline Air Monitoring Demonstration Program Fund

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

Tier I Warehouse Requirements

- Warehouses larger than 250,000 square feet, reporting to U.S. FDA, and receiving EtO-sterilized materials must select either:

1. Emission study
2. Fenceline air monitoring, or
3. Fund a South Coast AQMD-led demo program

Real-Time Monitoring Demonstration Program Fund

- Cost recovery based on quote from a third-party contractor
- 1st installment not to exceed $150,000, due in 6 months
- 2nd installment not to exceed $100,000, due in 18 months

Appendix 5
FENCELINE AIR MONITORING PLAN

APPENDIX 5 – Fenceline Air Monitoring Plan

Table 9 – Minimum Number of Required Monitoring Locations

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

Table 9 – Minimum Number of Required Monitoring Locations

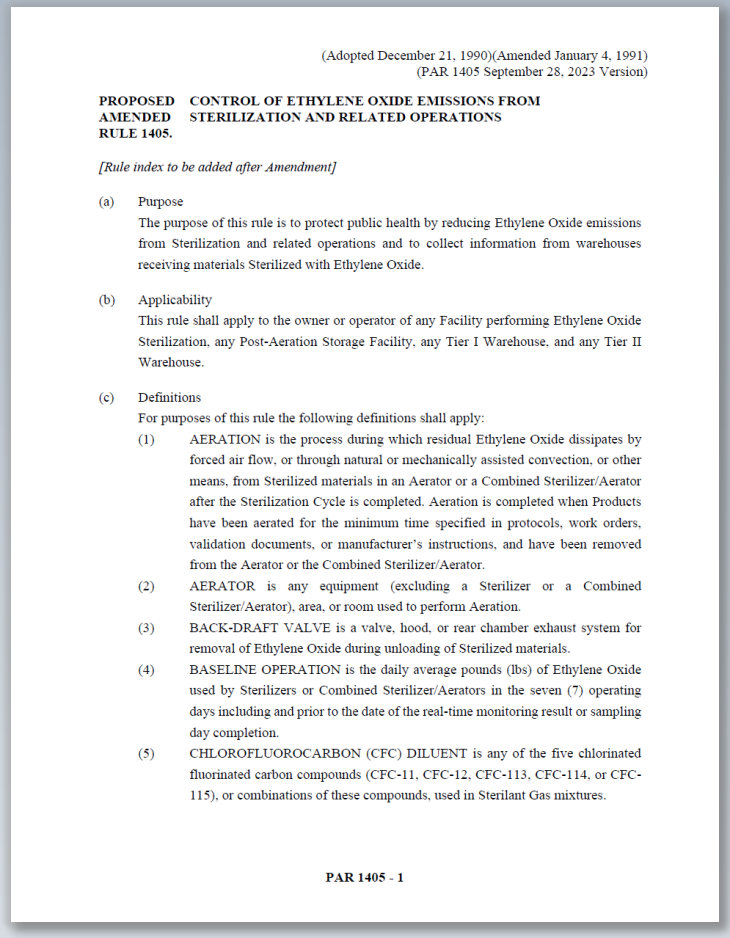
Facility Type	Minimum Number of Required Monitoring Locations
Large Facility permitted to use ≤ 100,000 lbs of Ethylene Oxide per calendar year	1
Large Facility permitted to use ≤ 40,000 lbs of Ethylene Oxide per calendar year and proposing not to maintain all Post-Aerators within a Permanent Total Enclosure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

New

Updated fenceline air monitoring locations:

- For facilities utilizing the alternative PTE pathway for post-aeration materials, an additional monitoring location in the Fenceline Air Monitoring Plan is required
- Identical to the number of monitoring locations as a Tier I Warehouse

Summary of Key Updates



(Adopted December 21, 1990)(Amended January 4, 1991)
(PAR 1405 September 28, 2023 Version)

PROPOSED AMENDED RULE 1405. CONTROL OF ETHYLENE OXIDE EMISSIONS FROM STERILIZATION AND RELATED OPERATIONS

[Rule index to be added after Amendment]

(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.

(c) Definitions

For purposes of this rule the following definitions shall apply:

(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 in an Aerator or a Combined Sterilizer/Aerator 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 the 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) BASELINE OPERATION is the daily average pounds (lbs) of Ethylene Oxide used by Sterilizers or Combined Sterilizer/Aerators in the seven (7) operating days including and prior to the date of the real-time monitoring result or sampling day completion.

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

PAR 1405 - 1

- Compliance dates updated to reflect December 2023 Governing Board Hearing
- Alternative calculated mass emission rate limit
- Alternative PTE requirement for:
  - Post-aerator at certain Large Facilities
  - Sterilant Gas Storage Areas at Large Facilities
- Updated PTE averaging time
- Updated curtailment exemption for Products in shortage
- New Appendix 1 to provide calculation procedures and examples
- Updated Appendix 2 to provide new/updated monitoring fee

Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions
from Sterilization and Related Operations

Public Process

Key Dates

Action	Date
Written Comments Due	October 13, 2023
Stationary Source Committee	October 20, 2023
Stationary Source Committee	November 17, 2023
Public Hearing	December 1, 2023

PAR 1405 Staff Contacts

Please contact staff with any questions or comments

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