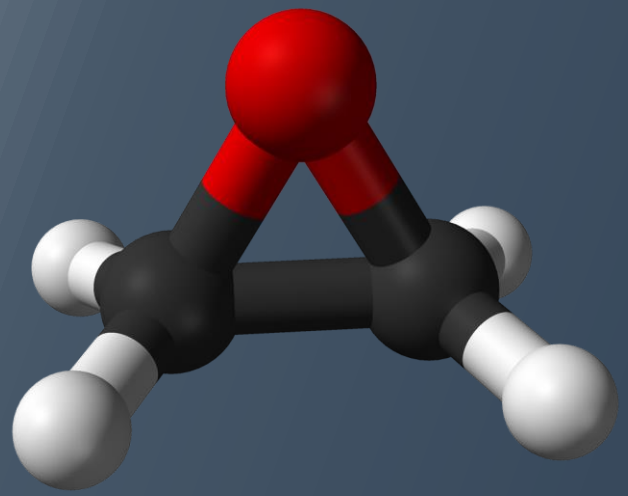
Working Group Meeting #5



Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions from Sterilization Processes

February 16, 2023
10:00 AM

Zoom Meeting Link:
https://scaqmd.zoom.us/j/91293613357

Dial In: (669) 900 6833

Meeting ID: 912 9361 3357

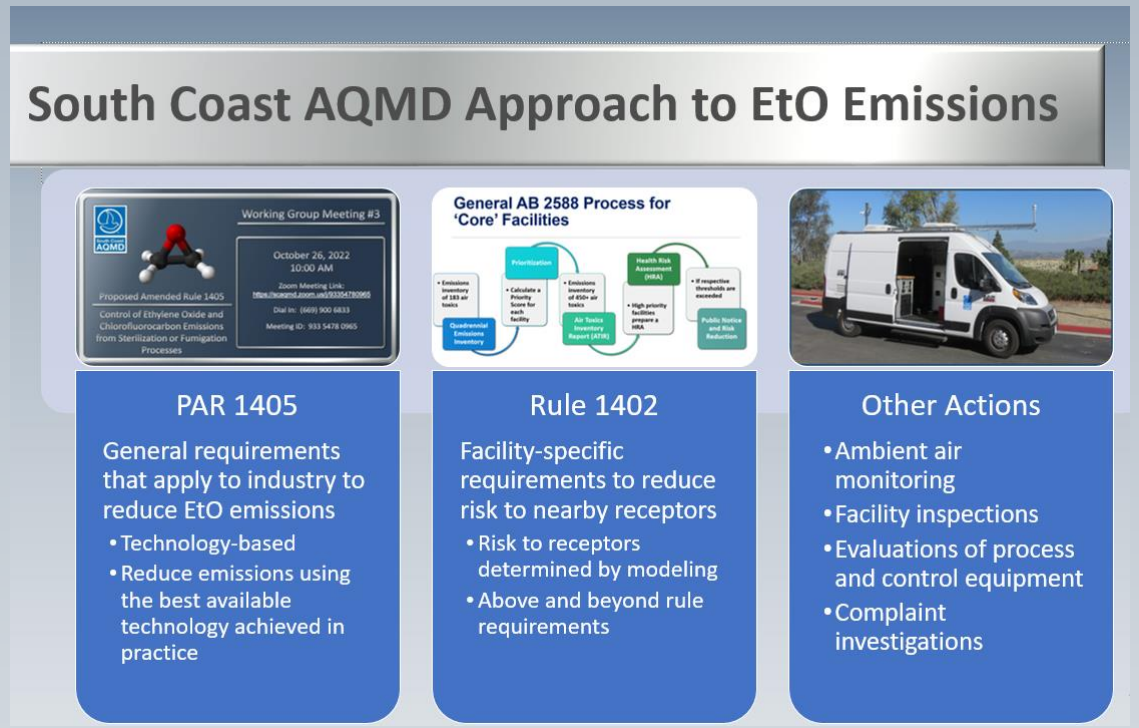
South Coast AQMD Staff Outreach

- After Working Group Meeting #4, met with stakeholders to solicit feedback for the proposed rule concepts
  - Concerns about fugitive emissions
- Continued discussion with vendors
- Staff welcomes conversations with any stakeholder who would like to discuss PAR 1405

Agenda

- Summary of Working Group #4
- Initial Rule Language
- Next Steps

Recap from Working Group Meeting #4



- South Coast AQMD Approach to EtO Emissions
- PAR 1405 Overall Approach
- Rule concepts
  - Introduction
  - Stack Emissions
  - Fugitive Emissions
  - Other Requirements

Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions from Sterilization Processes

Initial Rule Language

PAR 1405 Structure

Proposed Amended Rule 1405

- (a) Purpose
- (b) Applicability
- (c) Definitions
- (d) Large Facility Requirements
- (e) Medium Facility Requirements
- (f) Small Facility Requirements
- (g) Post-Aeration Storage Facility Requirements
- (h) Warehouse Reporting Requirements
- (i) Interim Requirements
- (j) SCEMS or CEMS
- (k) Permanent Total Enclosure
- (l) Recordkeeping
- (m) Source Testing
- (n) LDAR
- (o) Prohibitions
- (p) Exemptions

Rule Title Change

New

CONTROL OF ETHYLENE OXIDE EMISSIONS FROM STERILIZATION PROCESSES

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

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

Subdivisions (a) and (b)
PURPOSE and APPLICABILITY

Purpose/Applicability

(a) Purpose

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

(b) Applicability

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

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

Subdivision (c)
DEFINITIONS

Definitions

(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 after the Sterilization Cycle is completed. Aeration is completed when Products achieve predetermined allowable residual levels of Ethylene Oxide under U.S. Food and Drug Administration (FDA) recognized consensus standards.

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

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

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

- Aeration updated to reflect U.S. FDA allowable residual levels
- Aerator clarified to distinguish from Sterilizer or Combined Sterilizer/Aerator (new term)

Definitions – continued

(5) COMPONENT is any part of a Sterilizer, Sterilizer Exhaust Vacuum Pump, Combined Sterilizer/Aerator, Aerator, or Control System that may have a Leak of Ethylene Oxide.

(6) CONTINUOUS EMISSION MONITORING is a monitoring technique in which a minimum of one measurement (e.g. concentration, mass emission, flow rate) is taken and recorded every one (1) minute.

(7) CONTINUOUS EMISSION MONITORING SYSTEM (CEMS) is the total combined equipment and systems required to continuously determine air contaminants and diluent gas concentrations and/or mass emission rate of a source effluent (as applicable). The CEMS consists of three major subsystems: sampling interface, analyzer and data acquisition system.

(8) COMBINED STERILIZER/AERATOR is any chamber or related piece of equipment that performs the functions of a Sterilizer and an Aerator and where Aeration is completed within the chamber.

(9) CONTROL SYSTEM is equipment and ducting installed for the purposes of collecting Exhaust Streams and one or more adjoining air pollution control devices that reduces emissions of Ethylene Oxide.

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

Definitions – continued

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

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

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

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

(14) LARGE WAREHOUSE is any Warehouse greater than or equal to 100,000 square feet of indoor floor area in a single building and reporting to U.S. FDA as a Wholesale Distributor or a Third-Party Logistics Provider as required by the Drug Supply Chain Security Act as it exists on [Date of Amendment].

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

- Large Facility threshold lowered to 2,000 pounds (lbs)
- Large Warehouse defined for tracking and reporting purposes
- Leak incorporated CARB Test Method 21

Definitions – continued

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

(17) 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.

(18) NEW LARGE WAREHOUSE is any Warehouse that is a Large Warehouse after [Date of Amendment].

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

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

- Medium Facility threshold aligned with Large Facility
- Palletized Unit defined for tracking and reporting purposes
- Permanent Total Enclosure (PTE) definition is consistent with other South Coast AQMD rules

Definitions – continued

(21) POST-AERATION is the process during which residual Ethylene Oxide off-gasses from Sterilized materials after Aeration is complete until the Sterilized material leaves the facility.

(22) POST-AERATOR is any equipment, area, or room where Post-Aeration occurs including but not limited to areas where Sterilized materials are stored, transferred, loaded, or unloaded.

(23) POST-AERATION STORAGE FACILITY is any Facility where Post-Aeration occurs on materials which have been Sterilized at another Facility.

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

(25) SEMI-CONTINUOUS EMISSION MONITORING is a monitoring technique in which a minimum of one measurement (e.g. concentration, mass emission, flow rate) is taken and recorded every fifteen (15) minutes.

(26) SEMI-CONTINUOUS EMISSION MONITORING SYSTEM (SCEMS) is the total combined equipment and systems to semi-continuously determine air contaminant and diluent gas concentrations

- Post-Aeration Storage Facility a new term replacing Aeration-Only Facility
- SCEMS definition consistent with other South Coast AQMD rules

Definitions – continued

(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.

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

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

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

(31) STERILIZATION CYCLE is the process where Products and other incidental materials are exposed to Sterilant Gas in a Sterilizer or a Combined Sterilizer/Aerator.

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

- Small Facility threshold not changed
- Sterilant Gas Storage Area previously unregulated area that would be subject to new fugitive emission requirements
- Sterilization incorporate fumigation into term

Definitions – continued

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

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

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

(37) WASTE STORAGE AREA is any cabinet, area, or room used to store any Ethylene Oxide-contaminated liquids and solids produced as a consequence of Sterilization and associated processes.

(38) WINDWARD WALL means the exterior wall of a Permanent Total Enclosure which is most impacted by the wind in its most prevailing

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

Subdivision (d)
LARGE FACILITY REQUIREMENTS

LARGE – Stack Emissions (d)(1)

Beginning December 31, 2024:

(A) Install and maintain a Back-Draft Valve for each Sterilizer and operate the Back-Draft Valve when unloading the Sterilizer;

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

(C) Within 60 days after the initial operations of a Control System and no later than 12 months from the day of the most recent source test that demonstrates compliance with all applicable requirement thereafter, conduct a source test that meets the requirements in subdivision (m) for each Control System;

(D) Monitor the emissions from the exhaust stack(s) of each Control System by operating a SCEMS or CEMS, pursuant to subdivision (j);

Enhanced stack emission control requirements:

- Clearly mandates back-draft valves
- Requires initial and annual source tests for all control devices, regardless of type
- Requires stack emission monitoring (SCEMS or CEMS) and data logging

LARGE – Stack Emissions (d)(1) cont.

Beginning December 31, 2024:

(E) Demonstrate a Facility-wide mass emission rate of 0.025 pounds per hour (lbs/hr) or less of Ethylene Oxide from all Control Systems by a source test pursuant to subdivision (m) and, averaged over each calendar day in operation, by a SCEMS or CEMS pursuant to subdivision (j); and

(F) For each Control System:

(i) Demonstrate control of Ethylene Oxide emissions with 99.99% efficiency or greater, by weight, by a source test pursuant to subdivision (m); or

(ii) Demonstrate emissions of Ethylene Oxide at a concentration of 0.01 parts per million (ppm) or less, by volume, by a source test pursuant to subdivision (m) and by a SCEMS or CEMS pursuant to subdivision (j).

Additional enhanced stack emission control requirements:

- Establishes a facility-wide limit on EtO mass emission rate for large facilities
- Requires individual control systems to meet <u>either</u> a control efficiency <u>or</u> concentration limit
  - Addresses high and low concentration sources

LARGE – Fugitive Emissions (d)(2)

Beginning December 31, 2024:

(A) Operate any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, Sterilant Gas Storage Area, and Waste Storage Area within a Permanent Total Enclosure that meets the requirements in subdivision (k); and

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

Enhanced fugitive emission control requirements:

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

LARGE – Other Requirements (d)(3)

Beginning 3 Months After Date of Adoption:

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

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

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

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

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

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

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

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

(E) Prepare and maintain onsite a Facility diagram that identifies each Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, and Aerator, and Permanent Total Enclosure.

Other enhanced requirements:

- Track where EtO-sterilized pallets sent
- Pallet labeling required so warehouses know they are receiving EtO sterilized products
- Requires plot plan to identify key areas

Subdivision (e)
MEDIUM FACILITY REQUIREMENTS

MEDIUM – Stack Emissions (e)(1)

Beginning July 1, 2025:

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

(B) Within 60 days after the initial operations of a Control System and no later than 12 months from the day of the most recent source test that demonstrates compliance with all applicable requirement thereafter, conduct a source test that meets the requirements in subdivision (m) for each Control System that demonstrates either:

(i) Control of Ethylene Oxide emissions with 99.9% efficiency or greater, by weight; or

(ii) Does not emit Ethylene Oxide at a concentration greater than 0.01 ppm, by volume.

Enhanced stack emission control requirements:

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

MEDIUM – Fugitive Emissions (e)(2)

Beginning July 1, 2025:

(A) Operate each of the following within a Permanent Total Enclosure that meets the requirements in subdivision (k):
- (i) Sterilizer, if applicable;
- (ii) Aerator, if applicable; and
- (iii) Post-Aerator that immediately follows an Aerator or Combined Sterilizer/Aerator; and

(B) Operate each of the following either within a Permanent Total Enclosure that meets the requirements in subdivision (k) or monitor each of the following by implementing a Leak Detection and Repair Program that meets the requirements in subdivision (n):
- (i) Combined Sterilizer/Aerator, if applicable;
- (ii) Back-Draft Valve, if applicable;
- (iii) All Components up to the exhaust stack of the Control System;
- (iv) Sterilant Gas Storage Area; and
- (v) Waste Storage Area, if applicable.

Enhanced fugitive emission control requirements:

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

MEDIUM – Other Requirements (e)(3)

Beginning July 1, 2025:

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

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

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

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

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

Other enhanced requirements:

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

Subdivision (f)
SMALL FACILITY REQUIREMENTS

SMALL – Stack Emissions (f)(1)

Beginning December 31, 2025:

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

(B) Within 60 days after the initial operations of a Control System and no later than 12 months from the day of the most recent source test that demonstrates compliance with all applicable requirement thereafter, conduct a source test that meets the requirements in subdivision (m) for each Control System that demonstrates either:

(i) Control of Ethylene Oxide emissions with 99.9% efficiency or greater, by weight; or

(ii) Emits Ethylene Oxide at a concentration of 0.01 ppm or less, by volume.

Enhanced stack emission control requirements:

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

SMALL – Fugitive Emissions (f)(2)

Beginning December 31, 2025:

(A) Operate the following areas and processes within a Permanent Total Enclosure pursuant to subdivision (k):
  (i) Sterilizer, if applicable; and
  (ii) Aerator, if applicable; and

(B) Operate the following areas and processes within a Permanent Total Enclosure pursuant to subdivision (k) or monitor the following areas and processes by implementing a Leak Detection and Repair Program that meets the requirements in subdivision (n):
  (i) Combined Sterilizer/Aerator, if applicable;
  (ii) All Components up to the exhaust stack of the Control System;
  (iii) Post-Aerator;
  (iv) Sterilant Gas Storage Area;
  (v) Waste Storage Area, if applicable; and
  (vi) Back-Draft Valve, if applicable.

Enhanced fugitive emission control requirements:

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

SMALL – Other Requirements (f)(3)

Beginning December 31, 2025:

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

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

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

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

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

Other enhanced requirements:

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

Subdivision (g)
POST-AERATION STORAGE FACILITY REQUIREMENTS

POST-AERATION STORAGE FACILITY

Beginning 3 Months After Date of Adoption:

(1) Within 60 days after the initial operations of a Control System and no later than 12 months from the day of the most recent source test that demonstrates compliance with all applicable requirement thereafter, conduct a source test that meets the requirements in subdivision (m) for each Control System that demonstrates each Control System controls Ethylene Oxide emissions with 95% efficiency or greater, by weight;

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

(3) Record the number of Sterilized Palletized Units received;

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

(A) Type of equipment, area, or room, if applicable;

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

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

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

Applies to facilities with control systems

- Requires initial and annual source tests to ensure emission limits are being met
- Requires control systems to meet a control efficiency of 95%
- Requires other key equipment to either be in PTE or use LDAR program to prevent fugitive emissions
- Track number of shipments received

Subdivision (h)
WAREHOUSE REPORTING REQUIREMENTS

WAREHOUSE REPORTING REQ.

(1) The owner or operator of an Large Warehouse, New Large Warehouse, or a Warehouse designated pursuant to paragraph (h)(3) shall record the number of Sterilized Palletized Units received each month pursuant to the schedule specified in Table 1 – Warehouse Daily Record Schedule.

Table 1 – Warehouse Recording Schedule

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

(3) The Executive Officer may designate any Warehouse to comply with paragraphs (h)(1) and (h)(2) if the Executive Officer has information that the Warehouse is a potential source of Ethylene Oxide emissions. The Executive Officer will notify the owner or operator in writing if a Warehouse is designated.

Applies to large and designated warehouses

- Includes provisions for data collection to better understand industry
- Requires tracking of EtO sterilized products received
- Specifies schedule for
  - Existing warehouses
  - New warehouses
  - Designated warehouses
- Executive Officer would notify a warehouse in writing

WAREHOUSE REPORTING REQ. (cont)

(2) The owner or operator of an Large Warehouse, New Large Warehouse, or a Warehouse designated pursuant to paragraph (h)(3) shall submit an initial summary report to the Executive Officer to document the number of Sterilized Palletized Units received in the preceding twelve months pursuant to the schedule specified in Table 2 – Warehouse Initial Report Schedule that includes the following:

(A) Name of Warehouse;

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

(C) Address of Warehouse;

(D) Contact information for Warehouse;

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

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

Table 2 – Warehouse Initial Report Schedule

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

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

Subdivision (i)
INTERIM REQUIREMENTS

Interim Requirements

(i) Interim Requirements

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

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

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

(C) If the Exhaust Streams from the equipment identified in subparagraphs (h)(1)(A) and (h)(1)(B) are vented to the same Control System, the combined efficiency must be 98.8% or more, by weight.

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

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

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

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

(D) If the Exhaust Streams from the equipment identified in subparagraphs (h)(2)(A), (h)(2)(B), and (h)(2)(C) are vented to the same Control System, the combined efficiency must be 99.6% or more, by weight.

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

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

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

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

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

(4) The owner or operator of a facility that performs Aeration or Post-Aeration of materials that are Sterilized with Sterilant Gas at another facility and have permit to operate issued by South Coast AQMD prior to [Date of Adoption] to control Ethylene Oxide emissions where more than four lbs of Ethylene Oxide are emitted per calendar year shall install a Control System with an efficiency of 95% or more, by weight.

(5) Sterilizers, Combined Sterilizer/Aerators, Aerators, Control Systems, and emissions collection systems shall be leak free. The maximum Sterilant Gas mass flow shall be less than 10 parts per million ethylene oxide, as measured one (1) centimeter away from any portion of a Sterilizer, Combined Sterilizer/Aerator, Aerator, or Control System that could have an Ethylene Oxide leak. Leak tests shall be conducted during conditions of maximum Sterilant Gas mass flow. Leak tests shall be conducted every six months, as specified in paragraph (i)(8).

(6) The owner or operator of a Large Facility, Medium Facility, Small Facility or Post-Aeration Storage Facility shall conduct source tests on Control Systems within 60 days after the initial operation of the equipment to verify compliance with control efficiency requirements, as specified in paragraph (i)(7). Thereafter, source tests shall be conducted on Control Systems at least once per calendar year.

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

Interim Requirements

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

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

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

(C) The efficiency of control equipment shall be determined under normal operating conditions. To measure the control efficiency on the sterilizer exhaust stream, sampling shall be done during the entire duration of the first sterilizer evacuation and subsequent air washes after ethylene oxide has been introduced. To measure the control efficiency on an aerator exhaust stream with a constant air flow, sampling shall be done during a period of at least 60 minutes, starting 15 minutes after aeration begins. To measure the control efficiency of the control equipment on an aerator exhaust stream with a non-constant air flow, sampling shall be done during the entire duration of the first aerator evacuation after aeration begins.

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

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

Subdivision (j)
SCEMS OR CEMS
REQUIREMENTS FOR STACK EMISSIONS

SCEMS or CEMS Requirements

(j) SCEMS or CEMS Requirements for Stack Emissions

(1) The owner or operator of a facility required to monitor the emissions from a Control System shall install and operate a SCEMS or CEMS for each Control System that:

(A) Measures the following parameters:

(i) Ethylene Oxide concentration, in increments no greater than 0.01 ppm, by volume;

(ii) Oxygen concentration; and

(iii) Exhaust stack flow rate; and

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

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

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

(2) The owner or operator of a facility required to operate a SCEMS or CEMS shall install and operate a system capable of calculating the mass emission rate, expressed in lbs/hr, averaged over a calendar day from all Control Systems.

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

(4) The owner or operator of a facility required to operate a SCEMS or CEMS shall maintain and calibrate each SCEMS or CEMS pursuant to manufacturer specification.

- SCEMS or CEMS consist of a monitoring system that are required for each stack at a large facility, a data recording system, and backup battery to ensure that emissions are continuously monitored
- SCEMS requires a measurement of parameters every 15 minutes
- CEMS requires a measurement of parameters every 1 minute
- SCEMS is being considered as CEMS certifications for EtO monitoring are still being developed

Subdivision (k)
PERMANENT TOTAL ENCLOSURE REQUIREMENTS

Permanent Total Enclosure

(k) Permanent Total Enclosure Requirements

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

(1) Demonstrate the Permanent Total Enclosure is maintained at a negative pressure of at least 0.007 inches H2O at least once per minute;

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

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

(i) The Leeward Wall;

(ii) The Windward Wall;

(iii) An exterior wall that:

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

(II) Intersects within plus or minus ten (+/-10) meters of the midpoint of a straight line between the two other monitors specified in clauses (k)(3)(A)(i) and (k)(3)(A)(ii); and

(III) Is not located on the same wall as either of the other two monitors described in clauses (k)(3)(A)(i) or (k)(3)(A)(ii);

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

Permanent Total Enclosure (cont.)

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

(C) Certified by the manufacturer to be capable of measuring and displaying negative pressure in the range of 0.005 inches to 0.110 inches H2O with a minimum increment of measurement of plus or minus 0.0005 inches H2O;

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

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

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

(3) Demonstrate pursuant to U.S. EPA Method 204 at least once per calendar month an inward air velocity of at least 200 feet per minute (fpm) at each natural draft opening.

- Additional periodic measurements of inward air velocity to verify the performance of the Permanent Total Enclosure

Subdivision (l)
RECORDKEEPING

Recordkeeping – Sterilization Facilities

(l) Recordkeeping

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

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

(B) The total pounds of Sterilant Gas purchased and the total pounds of Sterilant Gas used per calendar month and calendar year, respectively, provided that monthly totals are also kept.;

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

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

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

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

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

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

(I) The facility diagram pursuant to subparagraph (d)(3)(D).

- New proposed recordkeeping requirements support new proposed requirements for stack and fugitive emissions

Recordkeeping – Other

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

- (A) Source test reports pursuant to subdivision (m);
- (B) Measurements of inward face velocity pursuant to subdivision (k);
- (C) Data collected from the digital differential pressure monitoring system in Permanent Total Enclosures pursuant to subdivision (k);
- (D) Plot-plan reports, daily check, and monthly inspections for LDAR programs pursuant to subdivision (n);
- (E) The number of Sterilized Palletized Units received pursuant to paragraph (g)(4); and
- (F) The facility diagram pursuant to paragraph (g)(6).

(3) The owner or operator of any facility subject to this rule shall retain all applicable records specified in paragraphs (l)(1) and (l)(2) for at least five years with two years of records maintained onsite.

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

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

Subdivision (m)
SOURCE TEST REQUIREMENTS

Source Test Requirements

(m) Source Test Requirements

The owner or operator of a facility required to conduct source test shall:

(1) Prior to conducting any source test, submit a source test protocol for approval to the Executive Officer that includes:

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

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

(C) Planned sampling parameters;

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

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

- Requires the submittal of source test protocol and notification to South Coast AQMD when source test would occur and if there are any changes
- South Coast AQMD would evaluate the protocol prior to conducting a source test

Source Test Requirements (cont.)

(4) Conduct a source test:
- (A) Pursuant to the source test protocol approved by the Executive Officer;
- (B) With triplicate runs at typical operating conditions, as specified in the source test protocol;
- (C) With triplicate runs at the permitted maximum operating conditions, if any, in the Sterilizers, Combined Sterilizer/Aerators, Aerators, or Post-Aerators, as applicable;
- (D) With each run being a minimum of 60 minutes;
- (E) Pursuant to CARB Method 431, U.S. EPA Method TO-15 or TO-15A, or an acceptable source testing method approved by the Executive Officer.
- (F) Assessing the efficiency of controlling Ethylene Oxide emissions by:
  - (i) Measuring or determining the total inlet amount of Ethylene Oxide entering the Control System from any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, Post-Aerator, and Permanent Total Enclosure being controlled by the Control System;
  - (ii) Measuring the outlet amount of Ethylene Oxide exhausted from the Control System;

(5) Submit the source testing report to the South Coast AQMD staff and/or department as specified in the source test protocol within 60 days of completing source testing.

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

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

Lead Detection and Repair Program

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

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

(1) Prepare and maintain onsite a plot-plan report that identifies all Components and Elements 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) Demarcate using tape or other means all locations of all Elements subject to the LDAR program;

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

(5) Perform daily audio-visual checks for all applicable Components and Elements; and

(6) Perform monthly leak inspections of all applicable Components and Elements pursuant to CARB Test Method 21 using a portable flame ionization detector or a non-dispersive infrared analyzer calibrated withisobutylene, or an acceptable alternative method or analytical instrument approved by the Executive Officer.

- Expands leak detection requirements by requiring
  - Identification of components
  - More frequent inspections
  - Daily audio/visual checks
  - Lower leak threshold
  - Includes equipment, materials, and containers that may be off-gassing EtO

Subdivision (o)
PROHIBITIONS

Prohibitions

(o) Prohibitions

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

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

(3) The owner or operator of a facility performing Sterilization shall not allow the release of uncontrolled emission of Ethylene Oxide to atmosphere from any Sterilizer, Combined Sterilizer/Aerator, Back-Draft Valve, Aerator, or Permanent Total Enclosure at any time.

- Existing prohibitions retained
- Additional prohibition prevents the uncontrolled release of EtO
  - Emissions are required to be exhausted to a control system

Subdivision (p)
EXEMPTIONS

Exemptions

(p) Exemptions

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

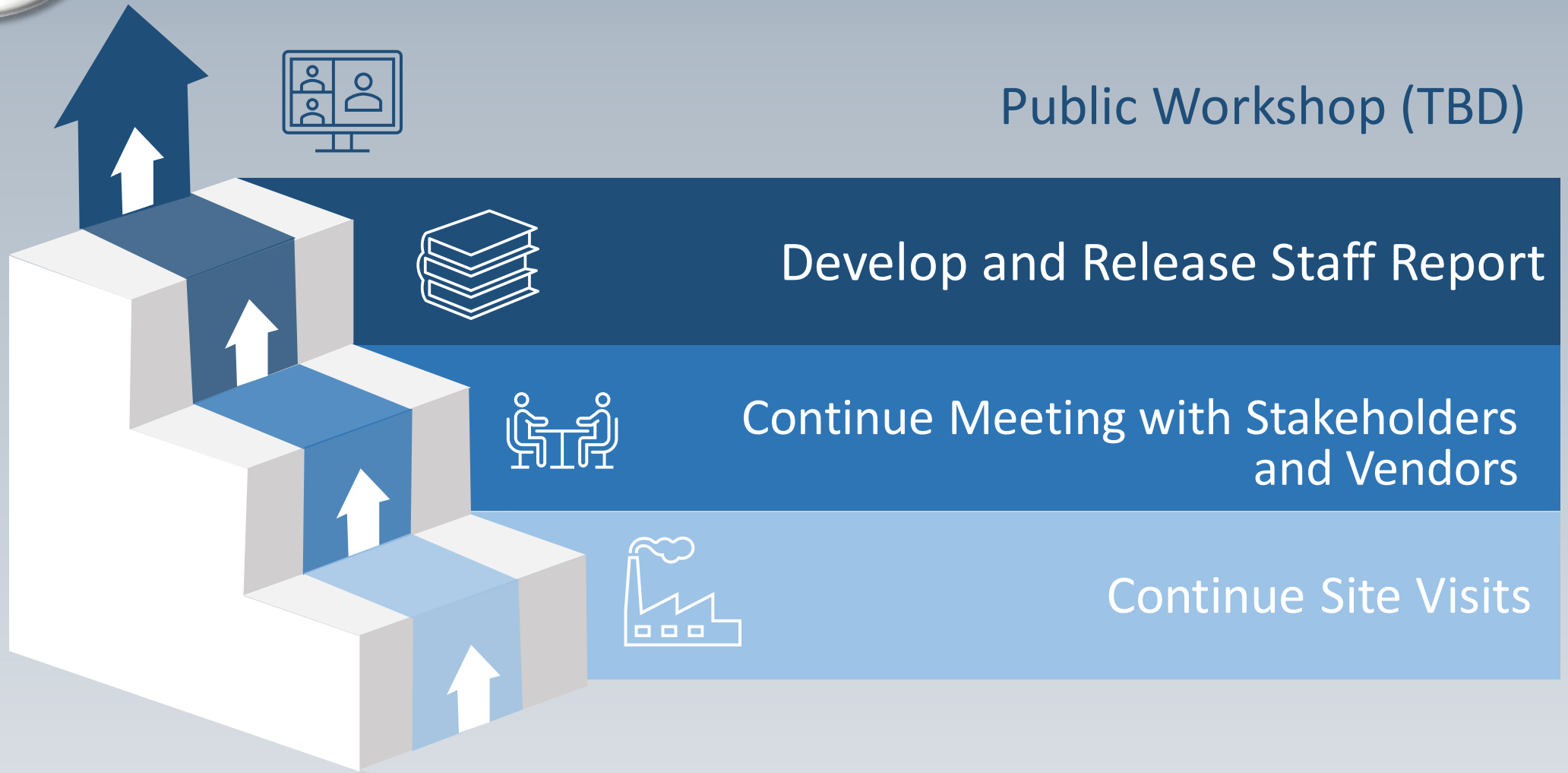
(2) The requirements of subdivision (i) do not apply to any facility subject to requirements of subdivision (d), (e), (f), or (g) pursuant to the schedule specified in Table 3 – Interim Requirements.

Table 3 – Interim Requirements

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

- Sterilizer facilities permitted to use four pounds or less exempt from interim requirements and prohibitions
- Facilities would be exempt from interim requirements when new stack and fugitive emission requirements become effective

Next Steps


Public Workshop (TBD)
Develop and Release Staff Report
Continue Meeting with Stakeholders and Vendors
Continue Site Visits

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