

Proposed Amended Rule 1405

Control of Ethylene Oxide
Emissions from Sterilization
and Related Operations

Working Group Meeting #6

June 8, 2023
1:00 PM

Zoom Meeting Link:

<https://scaqmd.zoom.us/j/98171271952>

Dial In: (669) 900 6833

Meeting ID: 981 7127 1952



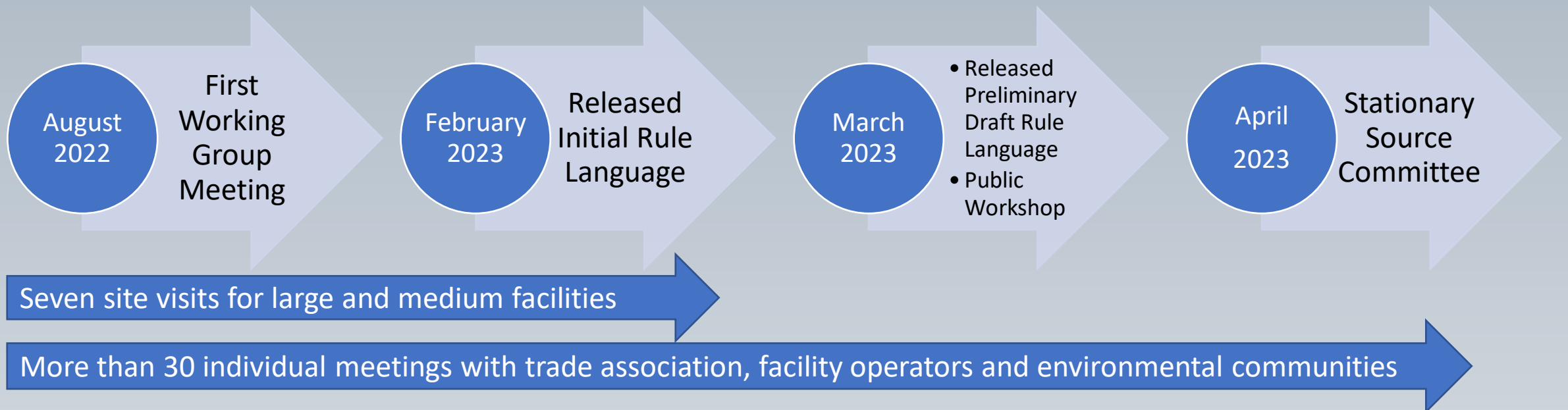
Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions
from Sterilization and Related Operations

Rule Development Updates

Updates to PAR 1405 Public Process

- PAR 1405 has gone through an extensive public process



- Stakeholders provided comments in writing or at public meetings
 - Staff responses to key comments are included in the next section

Regulatory Development in Other Agencies

- Other regulatory agencies have recently released draft publications
- U.S. EPA
 - Draft National Emission Standards for Hazardous Air Pollutants (NESHAP): Ethylene Oxide Emission Standards for Sterilization Facilities Residual Risk and Technology Review (April 2023)
 - Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA): Draft Human Health Draft Risk Assessment Addendum (April 2023)
- California Office of Environmental Health Hazard Assessment (OEHHA)
 - Draft Ethylene Oxide Cancer Inhalation Unit Risk Factor (April 2023)





Agenda

- Responses to Key Public Comments
- Overview – Fenceline Monitoring
- Technical Assessment of EtO Fenceline Monitoring
- Rule Concept – Fenceline Monitoring at Sterilization Facilities
- Rule Concept – Fenceline Monitoring at Warehouses



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Responses to Key Public Comments



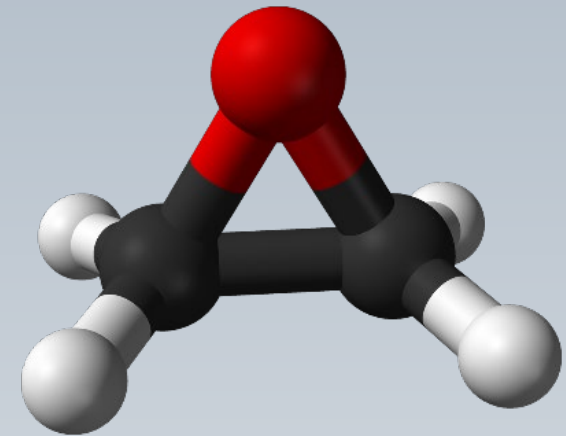
Key Comment #1 – EtO Alternatives/Phase-out

Stakeholder comments

- South Coast AQMD should require switching to safer alternatives of sterilization
- Sterilization facilities may move to other areas

Staff responses

- EtO is used to sterilize 50% of medical devices in the U.S., about 20 billion medical devices annually
- EtO, with its lower heat and lower humidity, sterilizes some devices no other technology can do at this time
- Some sterilization facilities use both EtO and radiation
- A mandatory phase-out would cause disruptions to the worldwide medical device supply chain and potential shortage of life saving medical devices
- U.S. FDA leads initiatives to 1) encourage alternatives and 2) reduce EtO usage





Key Comment #2 – Updated Risk Values

Stakeholder comments

- U.S. EPA and OEHHA risk values show EtO is more toxic than previously published
- Pause rulemaking for OEHHA risk factors update
- Concern whether facilities are able to meet the risk requirements in Rule 1402 - *Control of Toxic Air Contaminants from Existing Sources*

Staff responses

- PAR 1405 is technology-based and establishes the most stringent performance standards independent of risk factors
 - Will reduce EtO emissions and the associated risks from all regulated sources
- Rule 1402 (AB 2588) is risk-based and will use the updated OEHHA risk factors once adopted
- Updated risk value **may** require some facilities to install multi-stage controls, implement process changes, and possibly curtail operations





Key Comment #3 - Delay PAR 1405

Stakeholder comments

- Pause PAR 1405 until U.S. EPA rulemaking on NESHAP/FIFRA (National Emission Standards for Hazardous Air Pollutants/Federal Insecticide, Fungicide, and Rodenticide Act) is complete

Staff responses

- U.S. EPA's Proposed Rule will go through its public process, and final adoption is uncertain (expected summer 2024 or later)
 - Staff evaluated draft and PAR 1405 is more stringent
- PAR 1405 would require facilities to install additional EtO controls as expeditiously as feasible and addresses operations outside the scope of NESHAP (i.e., warehouses)
- Rule 1405 can be amended as necessary based on the final adopted NESHAP/FIFRA





Key Comment #4 – Implementation Timeline

Stakeholder comments

- Implementation timeline for large facilities is insufficiently short
- Implementation timeline is too long

Staff responses

- Staff agrees with the concerns on supply chain issues, potential long lead time to get building construction permits for PTE installation, and surge of demand for control and monitoring equipment with U.S. EPA's rulemaking
- Proposed changes allow for additional implementation time:
 - Large and Medium facility stack emission requirements and fugitive emission requirements to be extended by 6 months (e.g., December 31, 2024 → July 1, 2025)
 - Large facility stack emission monitoring requirements: December 31, 2025 → 18 months after receiving initial certification from the Executive Officer for SCEMS or CEMS
 - Post-Aeration Storage Facility requirements: 3 months after date of amendment → July 1, 2025 to allow for potential PTE installation



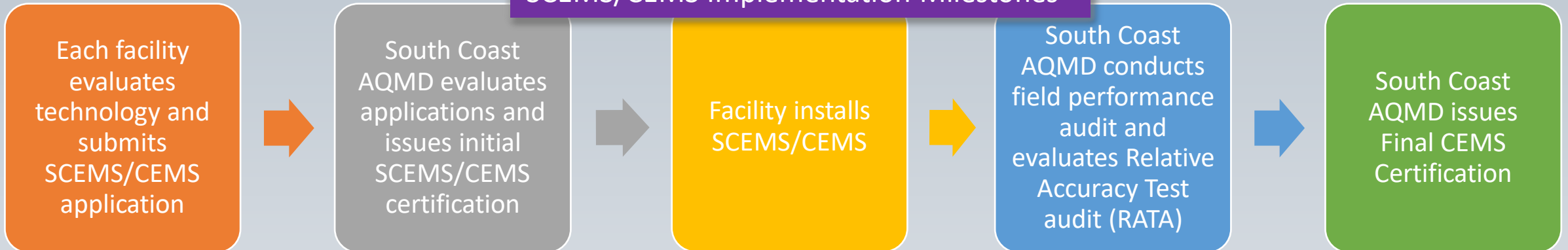


Implementation Milestones

Control System Implementation Milestones



SCEMS/CEMS Implementation Milestones*



*Currently no EtO SCEMS/CEMS certified by South Coast AQMD; certification expected to take 1-2 years



Key Comment #5 – Feasibility and Concerns on Performance Standards

Stakeholder comments

- Performance standards are not feasible to achieve and should be less stringent, and that facility-wide mass emission limit is based on a mid-size facility in Illinois with lower usage
- Performance standards should be more stringent
- Permanent Total Enclosure (PTE) could increase onsite worker exposure

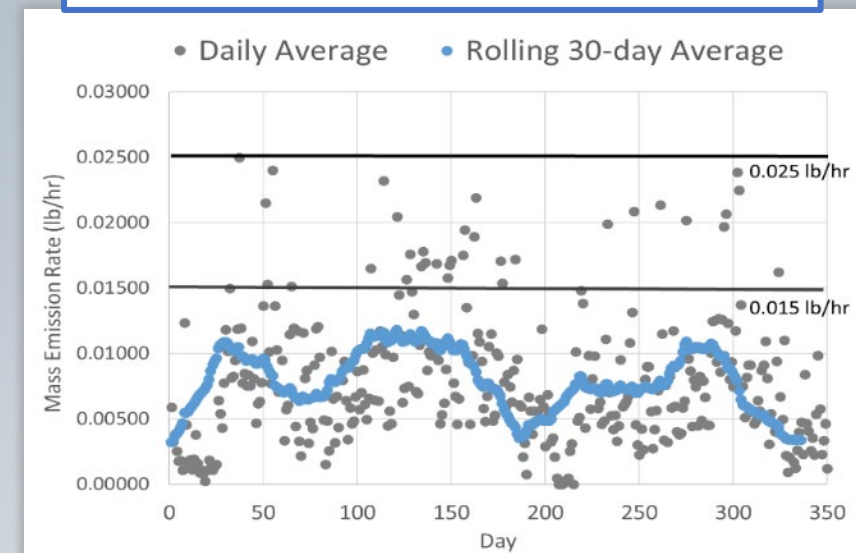
Staff responses

- Performance standards based on source test data and monitoring data from facilities that have recently upgraded their controls
 - Rule would be updated to reflect facility throughput for facility-wide mass limit
 - Facilities in South Coast AQMD may need to install additional layers of control to meet proposed performance standards
- Proposed requirements are the most stringent based on levels achieved-in-practice
- A properly designed PTE would provide adequate ventilation within the enclosure

Mass Emission Rate Data Analysis

- Proposed mass emission rate (daily mass emission rate of 0.025 lb/hr) based on the case study facility at Medline Waukegan
 - Stakeholders commented that it was inappropriate to use Medline's data to represent the performance of facilities larger than Medline
- Revised proposal is a **rolling 30-day average mass emission rate of 0.015 lb/hr** :
 - Performance standard based on highest permitted throughput in South Coast AQMD assuming the facility would meet PAR 1405 control efficiency requirement of 99.99%
 - Medline's data indicated that 0.015 lb/hr mass emission rate is feasible on a rolling 30-day average basis (see graph)
 - U.S. EPA's proposed NESHAP also uses rolling 30-day averaging

Medline Waukegan Mass Emission Rates



Outlet Concentration Data Analysis

- Proposed concentration limit (daily average of 0.01 ppm) to address low inlet scenarios such as emissions from aeration rooms
 - An alternative compliance option to 99.99% control efficiency
 - Based on source test data from non-sterilizer EtO sources at South Coast AQMD (see table)
 - Stakeholders commented that a daily 0.01 ppm alternative performance standard is not feasible on a continuous basis
- Revised proposal is **rolling 30-day average concentration limit of 0.01 ppm**
 - A rolling 30-day average accounts for periodic fluctuations observed in continuous data
 - CEMS data from the Medline Waukegan facility shows emissions fluctuate from day to day but source test data corresponds well to 30-day averaging
 - U.S. EPA's proposed NESHAP also uses rolling 30-day averaging

Source Test of Non-Sterilizer EtO Sources	Outlet Concentration (ppm)	Control Efficiency (%)
A	< 0.01	99.57%
B	< 0.01	99.87%
C	< 0.01	99.96%
D	< 0.01	99.97%
E	< 0.01	99.97%



Key Comment #6 – Warehouses

Stakeholder comments

- PAR 1405 should be delayed for evaluation on warehouses
- PAR 1405 should include emission limits for warehouses

Staff responses

- Staff acknowledged the potential emissions from storing EtO sterilized products in warehouses, however, there is limited data available to assess the potential of emissions and recommended control
- Key factors include:
 - Volume of products stored
 - Type of products stored
 - Duration of storage
 - Time since completion of aeration
- Some warehouse operators are not aware whether the products they receive have been sterilized, or the method of sterilization





Key Comment #6 – Warehouses (cont'd)

Staff responses (cont'd)

- To understand the volume of products warehouses receive, PAR 1405 requires
 - Sterilization facilities to track and report the first destination receiving sterilized products
 - Large warehouses to track and report the volume of EtO sterilized products received
- To understand the time since aeration, PAR 1405 requires
 - Sterilization facilities to label each pallet with completion date
- To understand the rate of off-gas
 - A pallet testing study is being conducted for different sterilized materials
- Initiate rulemaking for warehouses if data establishes a need to control EtO emissions at those facilities
- Working Group #6 introduces proposed concepts for fenceline monitoring to collect more information at certain large warehouses





Key Comment #7 - Lack of Fenceline Monitoring Requirement

Stakeholder comments

- PAR 1405 should require fenceline monitoring

Board members' comments at Stationary Source Committee:

- Address issues raised and include measures to protect the community until PAR 1405 requirements are effective

Staff responses

- Fenceline monitoring currently conducted at two large facilities via AB2588
 - These two facilities accounted for 79% of permitted EtO throughput
- PAR 1405 includes enhanced monitoring requirements:
 - Minute-by-minute data ensuring PTE is capturing (and not releasing) 100% fugitive emissions
 - Continuous monitoring at stack every minute/15-minute to ensure meeting emission limits
- Working Group #6 will discuss proposed concepts for fenceline monitoring for large sterilization facilities until PAR 1405 requirements are effective





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Control of Ethylene Oxide Emissions
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Overview – Fenceline Monitoring

What is Fenceline Monitoring?

- **Fenceline monitoring** is the systematic assessment of pollutant levels by measuring the quantity and types of certain pollutants in outdoor air near property boundaries
 - Assess the extent of air pollution impact with actual measurements to evaluate exposure and/or levels in community
 - Evaluate the effectiveness of emissions control strategies
 - May include sample collection or signal-detection methodologies
 - May include survey measurements



Time-Integrated versus Real-Time

Key Term: **TIME-INTEGRATED**

- **Time-integrated** methods include sample collection over a fixed time interval, typically 24 hours, then laboratory analysis after the sampling event. Data is produced days after sampling.



Key Term: **REAL-TIME**

- **Real-time** data analysis is a process whereby data is produced at the time of sampling or signal detection, usually in seconds, minutes, or hours.



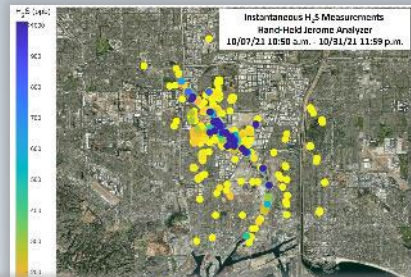
Air Quality Assessments and Investigations Conducted by South Coast AQMD

- South Coast AQMD has used fenceline and other ambient air measurement methods to assess pollutant levels as part of an air quality assessment or investigation



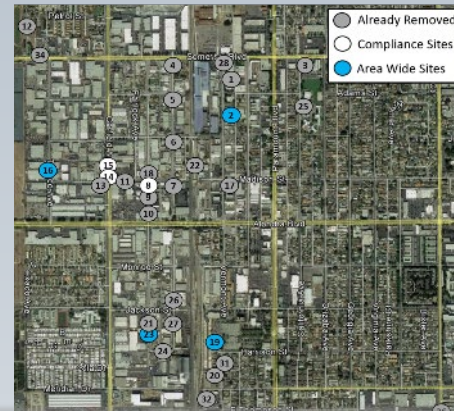
Large lead-acid battery recyclers in Vernon and City of Industry

- Lead and arsenic (metals)



Dominguez Channel Odor Event in Carson area

- Hydrogen sulfide
- VOC



Various metal working facilities in Paramount area

- Hexavalent chromium (metal)



Aliso Canyon gas storage facility in Porter Ranch

- Methane (VOC)



Refinery monitoring program

- Assorted VOCs and toxics, hydrogen sulfide, black carbon

Current EtO Monitoring Efforts



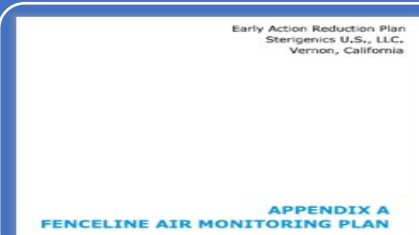
Mobile Platform (South Coast AQMD)

- Performed at multiple sites with EtO emission potentials
- Real-time detection VOC & EtO signals
- Initial screening using Proton Transfer Reaction – Mass Spectrometer



Canister Samples (South Coast AQMD)

- Performed at multiple sites around 3 sterilization facilities
- 24-hour time-integrated sampling and analysis using U.S. EPA Method TO-15



Canister Samples under Rule 1402/AB2588

- Performed at two facilities by facility operators
- 24-hour time-integrated sampling and analysis using U.S. EPA Method TO-15
- Collected and analyzed by independent third-parties

Fenceline Monitoring Regulations

- Some recent South Coast AQMD rules include fenceline monitoring requirements
- The purpose of fenceline monitoring varies
 - Demonstrate compliance with an air quality standard or rule limit
 - Rule 1420 series (lead)
 - Rule 1466 (toxic soil)
 - Provide real-time air quality information of various pollutants
 - Rule 1180 (refinery)
 - Provide information as the facility implements risk reduction measures required under Rule 1402
 - Rule 1480 (metal toxics)



Summary of Fenceline Monitoring

- South Coast AQMD uses fenceline monitoring and other ambient measurement methods during initial assessment and as part of the rule requirements
- Existing rules may include fenceline monitoring requirements for a variety of purposes
- Current EtO monitoring efforts use real time data analysis or 24-hour time-integrated sample collection
- Elevated levels are investigated



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Technical Assessment of EtO Fenceline Monitoring

PAR 1405 Fenceline Monitoring - Criteria

Purposes

- Serve as interim monitoring measures until stack monitoring is in place (estimated 2026/2027)
- Collect information to assess EtO levels near fenceline

For ambient monitoring of EtO, the following criteria are critical:

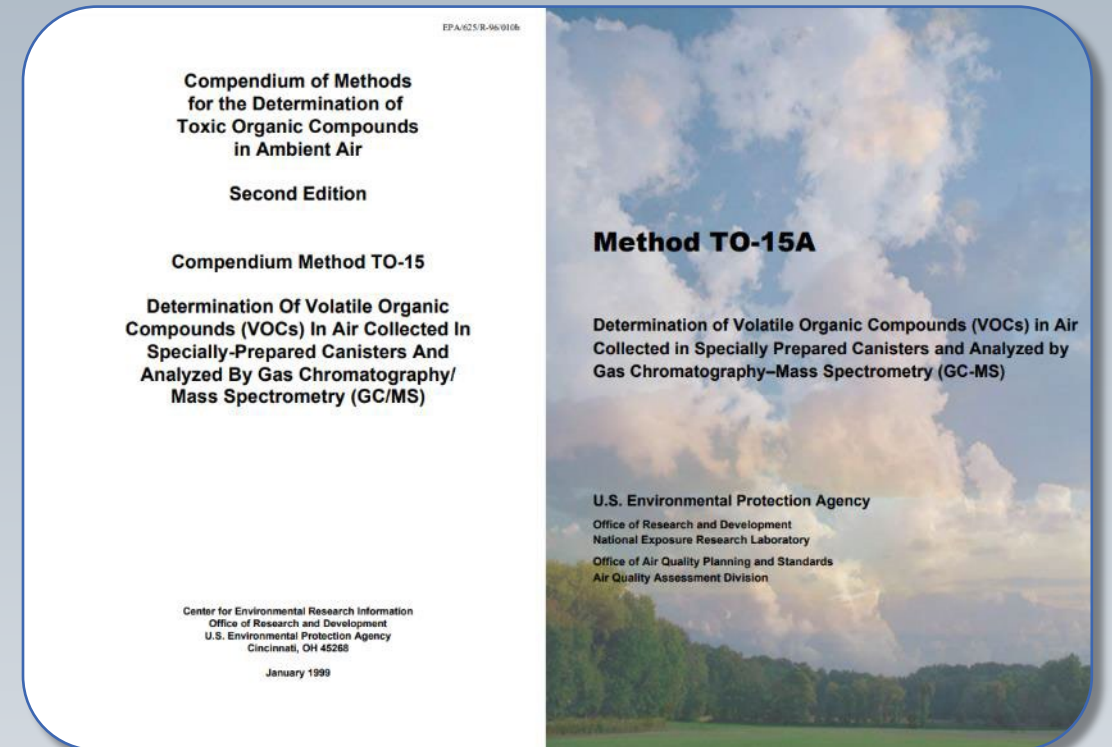
1. Established Method
2. Low Detection Limit
3. Availability and Capacity



To identify technologies that meet the criteria

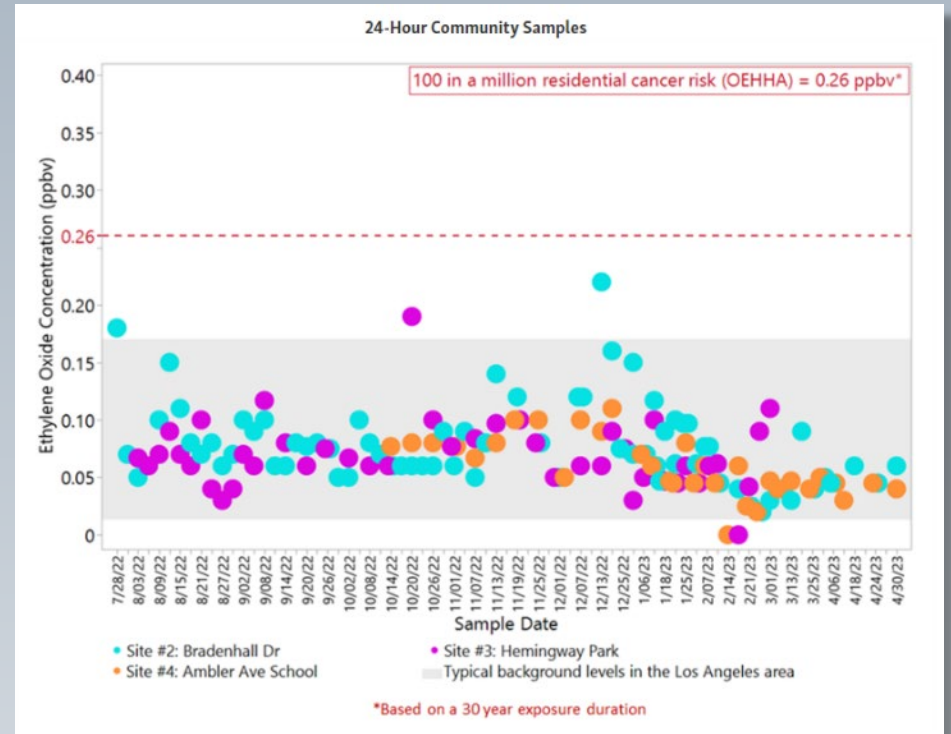
First Criterion – Established Method

- An established method for fenceline monitoring would be:
 - Approved by a regulatory agency to quantify EtO levels
 - EtO specific – differentiates EtO from other volatile organic compounds
 - Quality Assurance and Quality Checked - ensures data integrity
- Ensures that the data collected is valid and defensible



Second Criterion – Low Detection Limit

- Ambient levels of EtO are in the range of 0.02 ppb to 0.17 ppb in the Los Angeles area (2021 data from 24-hour samples)
- Fenceline EtO levels could range from sub-ppb to ppb
- A large sterilization facility which recently installed controls and PTE shows fenceline levels near background (see graph)
- Detection limits must be low to identify elevated levels above background



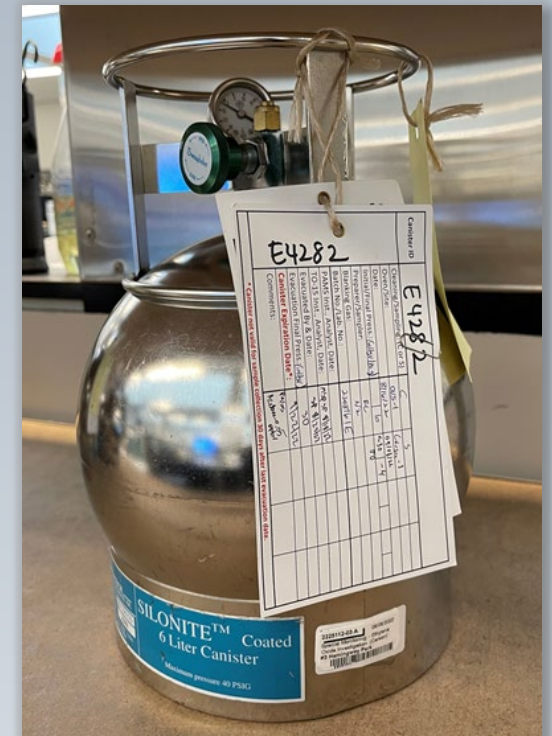
Third Criterion – Availability and Capacity

- Technology’s availability is critical for successful implementation of a monitoring program
- Factors that would limit availability include:
 - Availability of equipment (e.g. supply chain issues, time between order and arrival)
 - Installation time
 - Capacity of laboratories or vendors to provide key services (e.g., analyze samples, collect samples)



Measurement Method - Canister Collection

- Characteristics:
 - Time-integrated method
 - Reusable silica-lined canisters used for EtO
 - Used for high concentration and low concentration samples
 - Holding time for up to 30 days
 - Long lag time between sample collection and data reporting (1-2 weeks)
- Established Method for EtO:
 - U.S. EPA TO-15 or TO-15A (established method for ambient air)
- Detection Limit:
 - Vendors: 0.5 ppb to 0.05 ppb or lower
 - South Coast AQMD laboratory: 0.5 ppb to 0.02 ppb
- Availability/Capacity:
 - Canisters are available for purchase and use
 - Multiple laboratories inside and outside California capable of analysis
 - Requires several months to respond to potential uptake in demand



Measurement Method - Tedlar Bag



- Characteristics:
 - Time-integrated method
 - Disposable plastic collection bag
 - Typical used during source testing with higher concentration samples
 - Samples must be analyzed within 8 hours of sample collection
- Established Method for EtO:
 - CARB Method 431 (not referenced for ambient air)
- Detection Limit:
 - Data in ppm to sub-ppm range
- Availability/Capacity :
 - Tedlar bags are available for purchase and use
 - Multiple laboratories inside and outside California capable of analysis

Measurement Method - Infrared (IR) detector

- Characteristics:
 - Real-time data analysis
 - Typically used for worker protection as fire/explosion safety monitors
 - Currently deployed for indoor environments
- Established Method for EtO:
 - Not aware of any approvals by air quality agencies for ambient monitoring
- Detection limit:
 - 1 ppm to 0.1 ppm (100 ppb)
- Availability/Capacity :
 - Readily available technology already widely in use in indoors environments



Measurement Method - Gas chromatography-photoionization detector (GC-PID)



- Characteristics:
 - Real-time data analysis
 - Widely used for indoor EtO worker protection monitoring
 - Also used in EtO source testing
 - Implemented in semi-continuous stack emission monitoring of VOCs
- Established Method for EtO:
 - CARB Method 431 (not referenced for ambient air)
 - U.S. EPA Method 18 (not referenced for ambient air)
 - U.S. EPA Performance Specifications (PS) 8 and 9 (not referenced for ambient air)
- Detection Limit:
 - As low as 0.01 ppm (10 ppb)
- Availability/Capacity :
 - Multiple vendors capable of delivery in short timeframes
 - Not aware of any implementations for outdoor ambient EtO monitoring

Measurement Method - Proton Transfer Reaction – Mass Spectrometer (PTR-MS) Mobile Platform

- Characteristics:
 - Detects Volatile Organic Compound (VOC) signals, including signals associated with EtO
 - Currently deployed for outdoor VOC and EtO detection
 - Validation/analysis takes a few days to complete
 - Other emerging technologies may be available for mobile monitoring
- Established Method for EtO:
 - Not aware of any approvals by certification organizations (e.g., U.S. EPA, CARB)
 - Separate canister sample typically collected and analyzed using U.S. EPA Method TO-15/TO-15A
- Detection Limit:
 - EtO signal in ppb to sub-ppb range
- Availability/Capacity :
 - Aware of only a few contractors
 - Aware of only a few PTR-MS mobile platforms



Measurement Method - Fourier Transform Infrared (FTIR)



- Characteristics:
 - Real-time data analysis
 - Currently used for EtO stack emission monitoring (CEMS)
 - Approved for CEMS by U.S. EPA Performance Specification 15
- Established Method for EtO:
 - U.S. EPA Method 320 (not referenced for ambient air)
 - U.S. EPA Performance Specification (PS) 15 (not referenced for ambient air)
 - Proposed U.S. EPA PS-19 for real-time continuous EtO stack monitoring expected (ambient air not expected to be referenced)
- Detection limit:
 - Level of detection to sub-ppb
- Availability/Capacity :
 - Procurement would take a few months to 1 year
 - Testing and assessment expected to take additional time
 - Not aware of any implementations for outdoor ambient EtO monitoring

Measurement Method - Cavity Ring-down Spectroscopy (CRDS)

- Characteristics:
 - Real-time data analysis
 - Currently in use for indoor EtO monitoring at sterilization facility in Puerto Rico
 - State regulators in Washington used CRDS technology in a pilot study of ambient EtO levels in 2021
- Established Method for EtO:
 - CRDS contractor has submitted a CRDS-based method (OTM-47) to U.S. EPA
 - OTM methods may be used for data collection; other uses require additional U.S. EPA approval
 - U.S. EPA Office of Research and Development testing and assessment of CRDS is ongoing
 - Proposed NESHAP includes PS 19 as a method for real-time EtO detection
- Detection Limit:
 - Level of detection to sub-ppb
- Availability/Capacity :
 - Procurement would take a few months to 1 year
 - Testing and assessment expected to take additional time
 - Long-term feasibility unclear after limited ambient pilot studies



EtO Monitoring Technologies Summary



	Time-Integrated Methods		Real-Time Detection and Analysis				
	Canister	Tedlar Bag	Infrared	GC-PID	PTR-MS	FTIR	CRDS
Established Method	✓	✓	No	✓	No	✓	Pending
Low Detection Limit	✓	No	No	No	✓	✓	✓
Availability/Capacity	✓	✓	✓	✓	Varies	Varies	Varies

- Canister collection meets all the necessary criteria
 - Capacity could increase in a few months but still limited given potential surge in demand
 - Based on discussion with commercial laboratories, a detection limit of 0.2 ppb (vs. 0.05 ppb) would increase the availability of canisters and increase capacity
- PAR 1405 would allow emerging technologies with an established method to detect EtO
 - A detection limit of 1 ppb would promote the use of emerging continuous monitoring technology



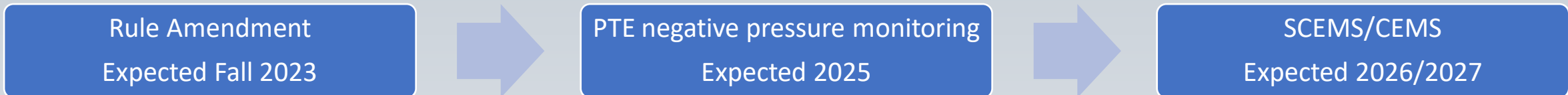
Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions
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Rule Concept –
Fenceline Monitoring at
Sterilization Facilities

Background

- Preliminary draft rule* requires continuous monitoring for large facilities:
 1. Stack emissions
 - Semi Continuous Emission Monitoring System (SCEMS) or Continuous Emission Monitoring System (CEMS)
 2. Fugitive emissions
 - PTE negative pressure monitoring
- Proposed continuous monitoring requirements
 - Verify performance of controls (e.g., inward air flow at all openings at the facility)
 - Quantify emissions from stacks without contributions from ambient air or local meteorology
- Regulatory Gap: Long lead time between rule amendment and when monitoring requirements are in place

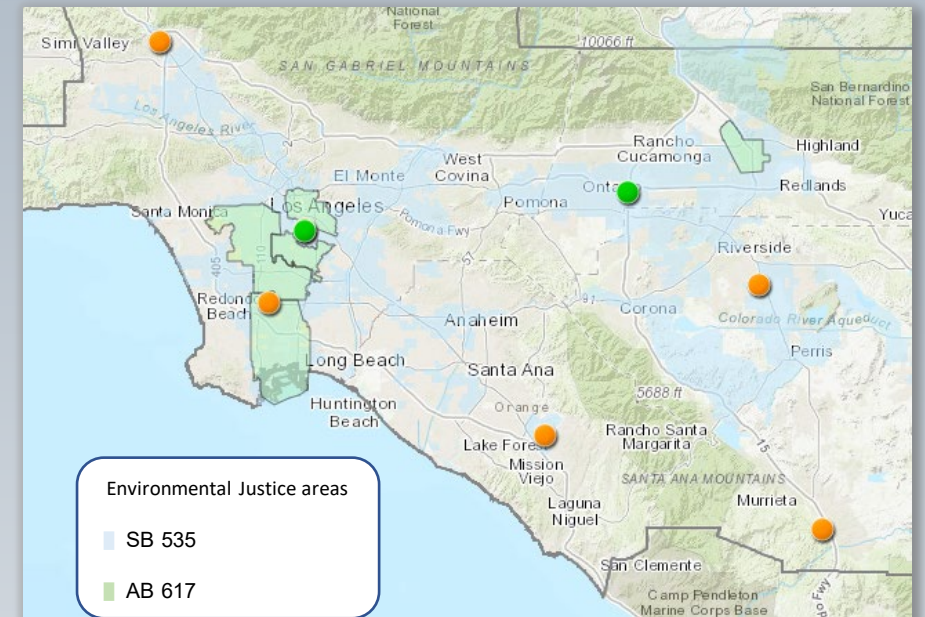


- Revised Proposal: To add interim monitoring measures to address regulatory gap

* http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_pdr1_031723_draftfinal.pdf?sfvrsn=14

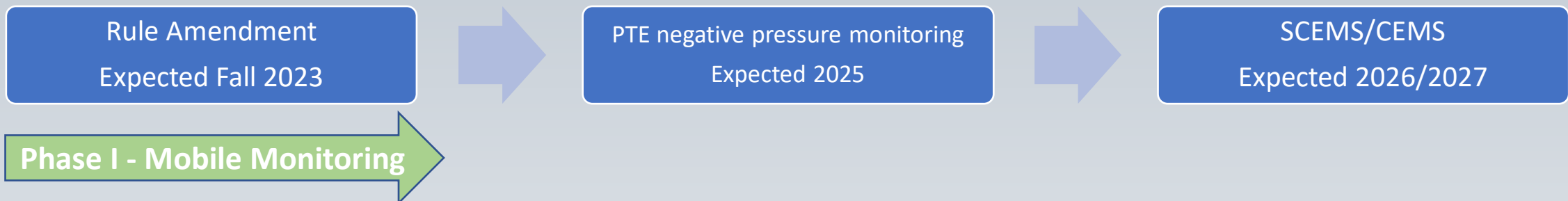
Fenceline Monitoring – Purpose and Applicability for Sterilization Facilities

- Purpose: As an interim measure from rule amendment until SCEMS/CEMS is installed and verified to be reporting accurately
- Applicability: Large sterilization facilities (permitted to use 2,000 lbs or more of EtO per year)
 - 7 large facilities
 - 2 facilities (**green**) are performing fenceline monitoring under Rule 1402
 - 5 additional facilities (**orange**) to perform fenceline monitoring under PAR 1405



Phase I – Mobile Monitoring

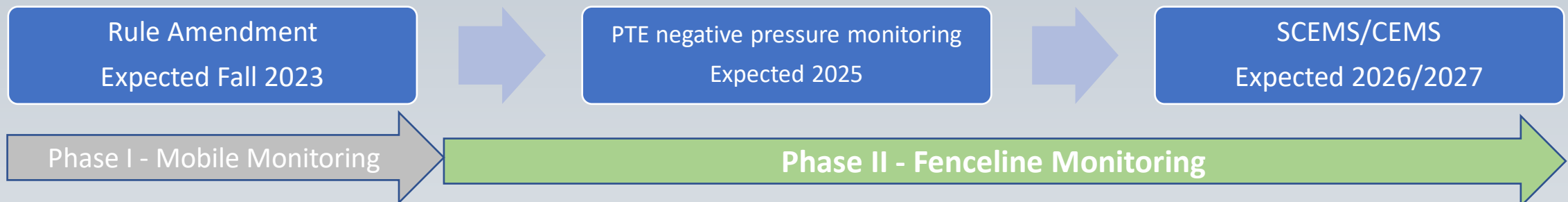
- Purpose:
 - To provide immediate monitoring measure after rule amendment
- Requirements:
 - Within 30 days of rule amendment, begin facility-led monitoring at least once per month using mobile platform with real-time measurements
 - Due to limited contractor availability and the immediate implementation schedule, South Coast AQMD will be available as a service provider
- Offramp:
 - Until fenceline monitoring (Phase II) begins



Note Facilities are recommended to begin planning given the schedule*

Phase II – Fenceline Monitoring

- Purpose:
 - Intermediate monitoring until continuous stack monitoring (SCEMS/CEMS) are implemented
- Compliance Pathways:
 1. Facility-led canister collection with detection limit of 0.2 ppb or better
 2. Facility-led real-time monitoring at 1 ppb or better



Phase II – Fenceline Monitoring (cont'd)

- Requirements:
 - Within 60 days of rule amendment, large facilities to submit a Fenceline Monitoring Plan for review
 - Within 60 days of Fenceline Monitoring Plan approval or according to terms in the Plan, begin fenceline monitoring
 - Within 14 days of sample collection, report data to South Coast AQMD
- Facilities already monitoring may continue monitoring at existing locations

	Facilities permitted to use 2,000 lbs or more of EtO per calendar year	Facilities permitted to use more than 100,000 lbs of EtO per calendar year
Sampling Site	Minimum of one site downwind of facility	Minimum of two sites - one downwind, other to provide facility-specific data (e.g., fugitive emissions from loading docks)
Canister Sampling	At least once every 6 days, 24-hour sample	At least once every 6 days, 24-hour sample

- Offramp:
 - End monitoring 60 days after SCEMS/CEMS final certification has been issued by South Coast AQMD

Contents of Fenceline Monitoring Plan

APPENDIX A FENCELINE AIR MONITORING PLAN

Appendix A

Fenceline Air Monitoring Plan

Sterigenics shall perform periodic ambient air monitoring to measure concentrations of EtO at locations near the perimeter of the adjoining 49th Street and 50th Street facilities ("Fenceline Locations"). Analysis will be by a standard and generally accepted methodology capable of routinely reporting EtO concentrations of less than 1 part-per-billion by volume (ppbv). The District will be allowed access and be able to conduct technical review of the sampling sites, equipment and methods and also be able to conduct side by side testing upon request.

Sampling Locations

Proposed locations near the perimeter are shown on Figure 1. Respondent shall aim to locate a monitor at, or as close as possible to, the existing District sampling location on 49th Street (M2 in Fig. 1) with the understanding that this location has detected the highest levels of ambient EtO concentrations and continued monitoring at this location would promote continuity of monitoring data. Final siting of station locations shall be informed, to the extent practical, by guidelines in Appendix E of 40 CFR Part 58 regarding obstructions, and subject to final District approval. For sampling locations that require off-site access, Respondent shall make best efforts to secure the sampling site location within 14 days of issuance of Order, or shall notify the District (Rule140Snotifications@aamd.gov) within 2 days of becoming aware that an approved site location cannot be secured. Once sampling locations have been finalized, locations may be moved upon the approval of the District to accommodate traffic, access and safety considerations, or any modifications to equipment at the facilities.

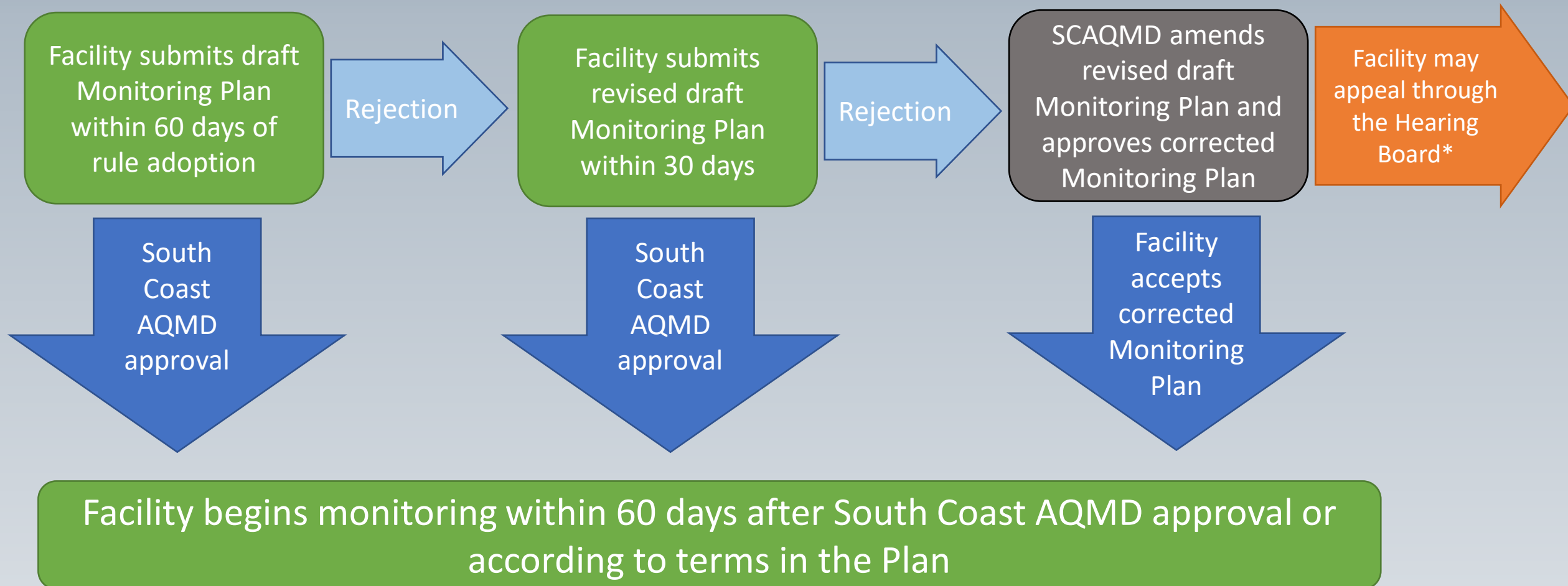
Sampling Methods

Beginning within 14 days of the Effective Date, or, if a sampling location requires securing off-site access, then within 14 days of securing such access, samples will be collected at monitors M1, M3, and M4 on a minimum of 1-in-6 day cycle, while samples will be collected at M2 on a minimum 1-in-3 cycle, both cycles following the calendar established by the USEPA Ambient Monitoring Technology Information Center (<https://www.epa.gov/amtic/sampling-schedule-calendar>). Results for monitors M1, M3 and M4 will be reported to the District within 14 calendar days of sample collection, except as provided below. For monitor M2, Results will be reported to the District within 10 calendar days of sample collection unless Sterigenics provides a reason that results for M2 cannot be reported within 10 days, in which case results for M2 shall be reported as soon as possible thereafter but no later than 14 calendar days after sample collection, except as provided below.

Samples reflective of conditions over an entire day and night ("24-hr Samples") will be collected using standard equipment suitable for collecting ambient air consistently over this duration (e.g., Summa canisters and mass flow controller valves). Sampling duration for individual samples

- Map of facility identifying key locations:
 - Structures, equipment, exhaust stacks, storage areas
 - Property boundaries
 - Publicly-accessible areas
 - Nearest residential/sensitive receptor(s)
- Location(s) of sampling or monitoring equipment and meteorological station
- Equipment and methods used to sample or continuously monitor
- Sampling and data collection information
 - Sampling schedule
 - Quality assurance plan
 - Make-up or missing sample procedures
- Contractor performing fenceline monitoring
- Additional information as needed by South Coast AQMD for approval

Approval Process of Fenceline Monitoring Plan



**Appeals regarding plans may be made pursuant to Rule 221 (e)*



Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions
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Rule Concept –
Fenceline Monitoring at
Warehouses

Background

- Warehouses are potential source of EtO emissions as EtO can continue to off-gas from stored product
 - Limited data from warehouses and storage facility
 - Potential emissions difficult to determine and depend on time since sterilization, volume and type of products stored, and duration of storage
- Preliminary draft rule* included provisions for data collection to better understand industry
 - Requires warehouses registered with U.S. Food and Drug Administration (U.S. FDA) as wholesaler or third-party logistics provider that have a building footprint of at least 100,000 to track and record EtO sterilized products received
- Regulatory Gap: More information is needed to assess emission potentials and EtO levels near fence line, and to evaluate the need for controls
- Revised Proposal: To add monitoring requirements to address potential regulatory gap

* http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1405/par1405_pdr1_031723_draftfinal.pdf?sfvrsn=14

Fenceline Monitoring – Purpose and Applicability for Warehouses

- Purposes: To collect information to assess EtO levels at warehouses with high potential of emissions
- Applicability: Warehouses that
 - 1) are registered with U.S. Food and Drug Administration (U.S. FDA) as wholesaler or third-party logistics provider;
 - 2) receive EtO sterilized products directly from sterilization facilities; and
 - 3) have a building footprint of at least 250,000 square foot
- Among the 71 warehouses registered with U.S. FDA in South Coast AQMD, 16 are 250,000 square foot or larger



Fenceline Monitoring – Rule Concept for Warehouses

Requirements: Within 6 months of rule amendment, applicable warehouses to either

- I. submit a Monitoring Plan or
- II. submit an Emissions Study Plan to demonstrate emissions are no more than 4 lbs per year
 - 4 lbs/year is the existing threshold in Rule 1405 where facilities are exempt from controls
 - Concentration is expected to be too low to control (i.e. below the outlet concentration of existing control technologies)



Monitoring
Pathway



Emissions Study
Pathway

Fenceline Monitoring – Monitoring Plan Pathway for Warehouses

Compliance Pathways:

1. Facility-led canister collection with detection limit of 0.2 ppb or better
 2. Facility-led real-time monitoring at 1 ppb or better
 3. Fund a South Coast AQMD-led real-time fenceline monitoring program
- With 90 days of Monitoring Plan approval, begin monitoring for one year or according to terms in the Plan
 - Within 14 days of sample collection, report data to South Coast AQMD

	Applicable Warehouses
Sampling Site	Minimum of two sites
Sampling Frequency	At least once every 6 days, 24-hour sample

Fenceline Monitoring – Emissions Study Pathway for Warehouses

- South Coast AQMD to evaluate Emissions Study Plan submitted by applicable warehouses
 - Examples including calculations using emissions factors or indoor sampling
- Within 180 days of Emissions Study Plan Approval, complete and submit Emissions Study
- If Emissions Study show emissions are above 4 lbs, submit Monitoring Plan within 60 days and demonstrate compliance through the Monitoring Plan pathway



Emissions Factor Approach

- Based on U.S. EPA emissions factors



Sampling Approach

- Based on indoor EtO concentration and air flow



Next Steps



Public Consultation Meeting
or Public Workshop (TBD)

Develop and Release Updated
Rule Language

Stationary Source Committee
(expected June)

Continue Meeting with
Stakeholders and Vendors



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