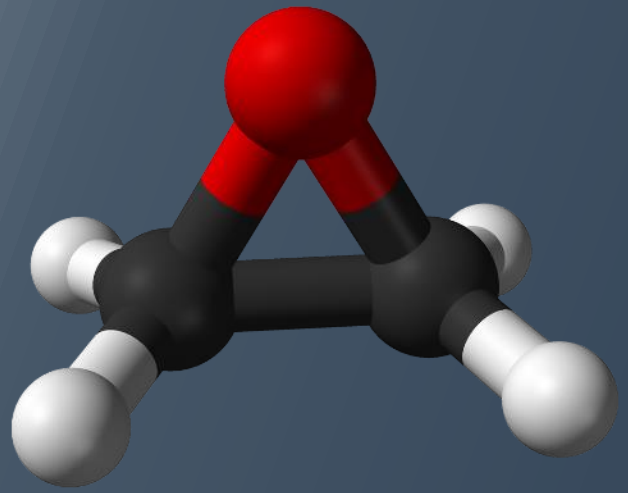
Working Group Meeting #7



Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions from Sterilization and Related Operations

July 6, 2023
10:00 AM

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

Dial In: (669) 900 6833

Meeting ID: 981 7127 1952

Agenda

- Response to Public Comments
- Overview – PAR 1405 Structure
- Overview – Curtailment
- Rule Concept – Curtailment of EtO Sterilization Facilities

Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions
from Sterilization and Related Operations

Response to Public Comments

Comment #1 – OP-FTIR Consideration

Stakeholder comment:

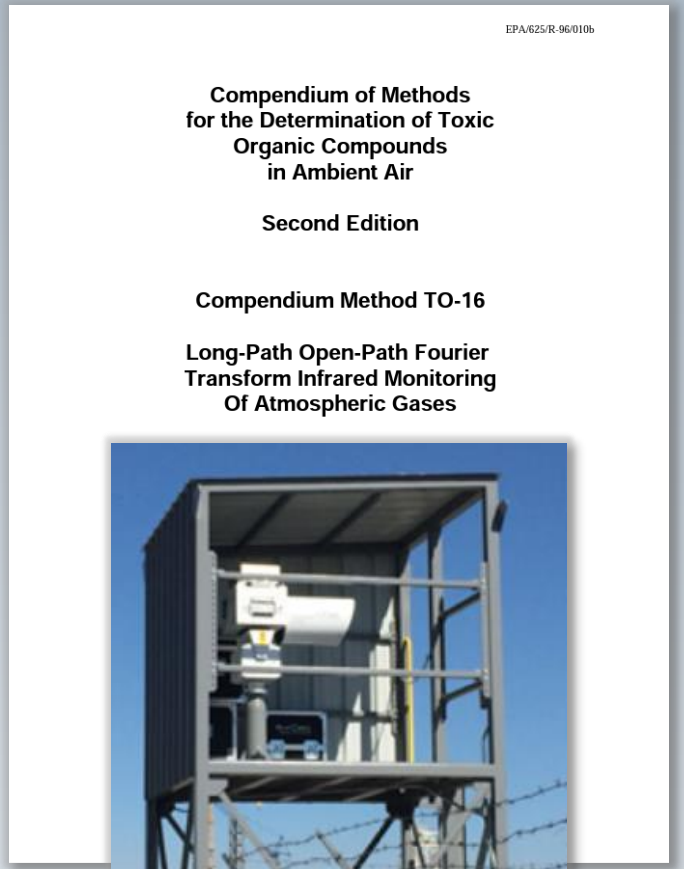
- South Coast AQMD should consider OP-FTIR (Open Path-Fourier Transform Infrared) for interim EtO fenceline monitoring

Staff responses:

- Staff is unaware of any published studies on the use OP-FTIR to measure fenceline concentrations of EtO at the present time
- Upcoming slides will discuss:
  - Updated assessment of monitoring technology (OP-FTIR and TILDAS)
  - Criteria to be considered for technologies used to perform monitoring

Update to Technology Assessment – Open Path-Fourier Transform Infrared (OP-FTIR)

- Characteristics:
  - Real-time data analysis
  - OP-FTIR units optically transmit IR energy along a fenceline to reflectors and returning spectra are analyzed for ambient gases
- Established Method* for EtO:
  - U.S. EPA Compendium Method TO-16 for determination of toxic organic compounds in ambient air, including possibility of EtO
  - Not aware of any published studies for ambient EtO
- Detection Limit:
  - Level of detection sub-ppm to ppb for various compounds
  - Not aware of any published documentations in sub-ppb range for EtO
- Availability/Capacity:
  - Aware of at least one vendor implementing OP-FTIR for fenceline EtO monitoring



**Established Method*, *as used in WGM #6, means approved by a regulatory agency to specifically quantify EtO with QA/QC to ensure data integrity for valid and defensible data.*

Update to Technology Assessment – Tunable Infrared Laser Direct Absorption Spectroscopy (TILDAS)

- Characteristics:
  - Real-time data analysis
  - Available in different configurations and for various compounds
- Established Method for EtO:
  - Currently in use for outdoor mobile or fixed monitoring of EtO
  - Part of U.S. EPA EtO Small Business Innovation Research program
  - Implementation report published in peer-reviewed journal* on months-long study in Massachusetts in 2022
- Detection Limit:
  - Level of detection to sub-ppb
- Availability/Capacity:
  - Available on contract basis from vendor in short timeframe

*Yacovitch, T. I., Dyroff, C., Roscioli, J. R., Daube, C., McManus, J. B., Herndon, S. C. (2023). **Ethylene oxide monitor with part-per-trillion precision for in situ measurements**. *Atmos. Meas. Tech., 16*, 1915–1921. https://doi.org/10.5194/amt-16-1915-2023

Key Requirements of Phase I and Phase II Monitoring

Objectives:
- Immediate monitoring after rule amendment
- Identify placement of Phase II monitoring locations

Phase I – Mobile Monitoring
- Required 30 days from amendment
- Mobile monitoring compliance options
  - Vendors or South Coast AQMD perform mobile monitoring directly measuring EtO or indirectly measuring EtO associated signals

Objectives:
- Intermediate monitoring until in-stack SCEMS/CEMS operational and fully certified

Phase II – Fenceline Monitoring
- Required after approval of Fenceline Monitoring Plan
- Fenceline monitoring compliance options
  - 24-hour canister sampling with method detection limit of 0.2 ppb or lower
  - Real-time monitoring with method detection limit of 1.0 ppb or lower measured every 15-minute using an established method

- OP-FTIR would not be a viable option for Phase I or Phase II Monitoring
- TILDAS would be a viable option for Phase I or Phase II Monitoring

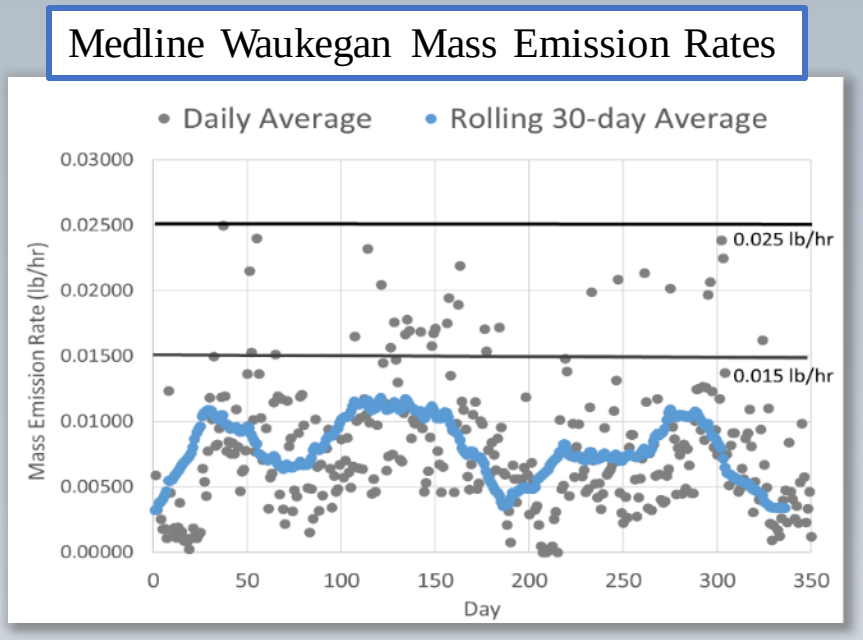
Comment #2 – Facility-wide mass emission rate limit

Stakeholder comments:

- Facility-wide mass emission rate limit will be difficult to achieve
- PAR 1405 should instead have an annual EtO emission cap that is facility-specific based on a facility's throughput

Staff responses:

- Staff maintains position that facility-wide emission is achievable
  - Rate limit derived from 99.99% control efficiency (CE) (achieved-in-practice via source testing at multiple sterilization facilities in South Coast AQMD)
  - CEMS data from Medline Waukegan indicates 0.015 lb/hr rolling 30-day average feasible (see graph on right)
- Mass emission rate limits on a rolling 30-day basis allow more rapid assessment of facility operations than an annual cap
- PAR 1405 applies to the industry and the performance standard applies to the applicable category of sterilization facility



Comment #3 – EtO Fenceline Monitoring Concerns

Stakeholder comments:

- Fenceline EtO monitoring is unreliable and cannot distinguish between emissions from sterilizers and other sources of EtO

Staff responses:

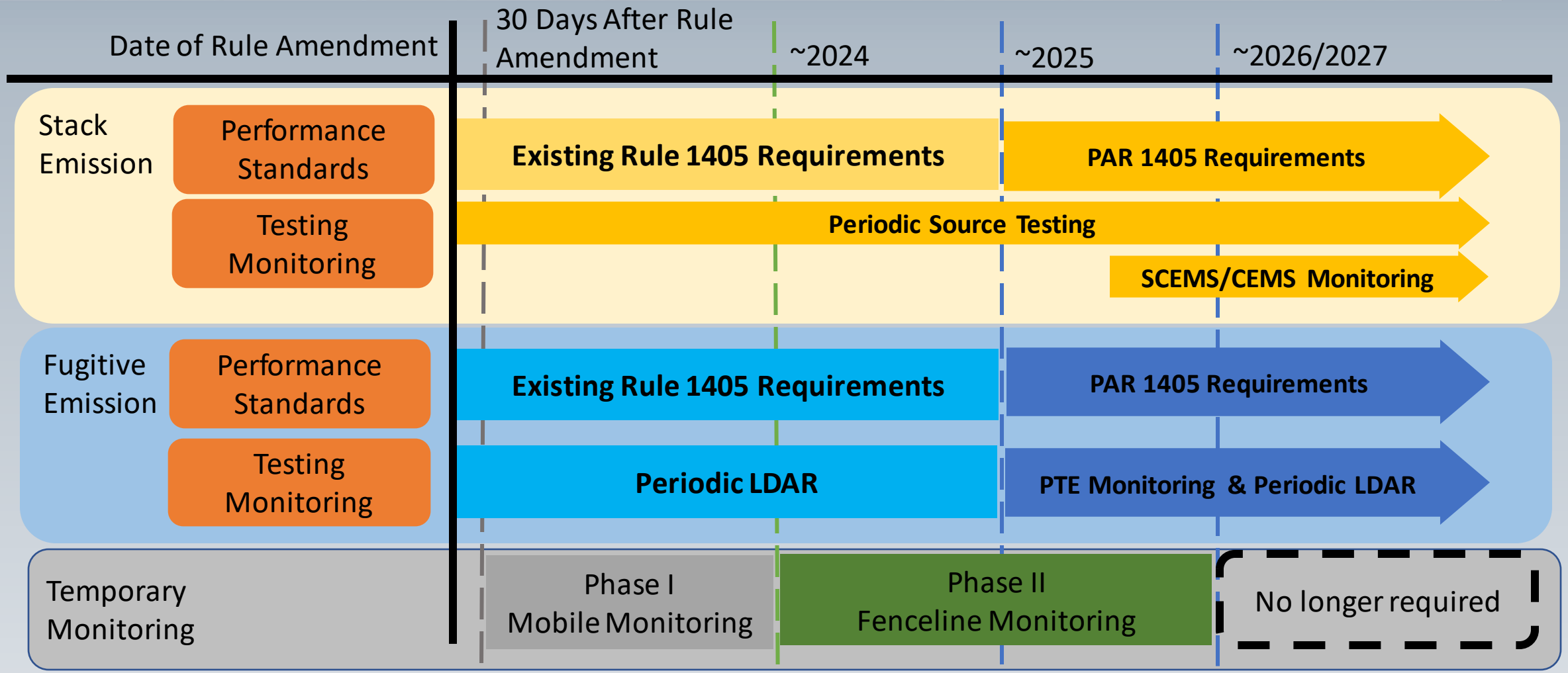
- Mobile and fenceline monitoring have identified enhanced levels (e.g., two orders of magnitude greater than background) downwind near fenceline of sterilization facilities
- Mobile monitoring in the surrounding communities near the sterilization facilities did not identify enhanced levels
- Using upwind and downwind sample collection or continuous mobile monitoring with wind data around entire perimeter of potential sources can assess EtO emissions being emitted from a particular facility

Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions
from Sterilization and Related Operations

Overview –
PAR 1405 Structure

PAR 1405 Regulatory Timeline for Large Facilities*



**Based on revised concepts, rule language to be released publicly*

Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions
from Sterilization and Related Operations

Overview of Curtailment

Background – Curtailment

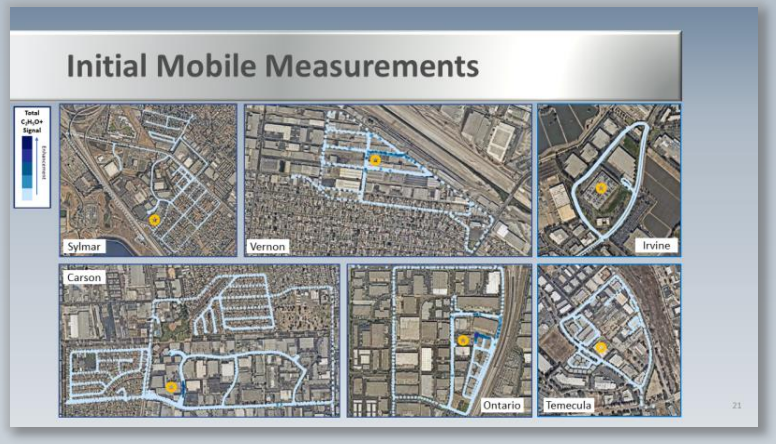
- **Curtailment** is the rapid, temporary limiting of facility operations in response to observed levels of an air contaminant
- Examples of curtailment in South Coast AQMD include
  - Rule 1420.1 for large lead-acid battery recyclers (lead and arsenic)
  - Stipulated Orders for Abatement with aerospace subcontractors (hexavalent chromium)
  - Approved Early Action Reduction Plans for sterilization facilities (EtO)
- Curtailment may be a percentage reduction in feedstock or complete cessation of certain operations believed to be contributing to elevated levels

RULE 1420.1. EMISSION STANDARDS FOR LEAD AND OTHER TOXIC AIR CONTAMINANTS FROM LARGE LEAD-ACID BATTERY RECYCLING FACILITIES

Effective Date	Air Contaminant	Total Facility Mass Emission Rate (lbs/hour)	Reduction in Feedstock Charged to Reverberatory Furnace
On and after September 4, 2015	Lead	>0.003 – 0.0675	15%
		>0.0675 – 0.09	25%
		>0.09 – 0.1125	50%
		>0.1125	75%

Early Action Reduction Plan (EARP)

- Two facilities were designated as a Potentially High Risk Level Facility under Rule 1402 based on monitoring data
  - Sterigenics Vernon – June 2022
  - Sterigenics Ontario – September 2022
- An Early Action Reduction Plan is required, which includes enforceable measures that would occur to reduce emissions and risks quickly, such as:
  - Sealing draft openings and keeping rollup doors closed
  - Operating temporary air pollution control equipment
  - **Curtailing operations/curtailment based on fenceline EtO readings**



EARP Curtailment Provision Structure

Curtailment Amount

- Incremental percent reduction in allowable daily use of EtO based on the number of readings that exceed a threshold
  - Samples that exceed a higher threshold triggers greater reduction
- Facility potentially subject to a 100% curtailment

Calculation of Baseline

- Based on preceding seven-day period daily average

Removal of Curtailment

- A sample reading below the applicable threshold at the monitoring location

i. Upon first reading at or above 17.5 ppb, but less than 25.0 ppb, Sterigenics shall curtail operations by 20 percent. Upon a first reading at or above 25.0 ppb, Sterigenics shall curtail operations by 50 percent.

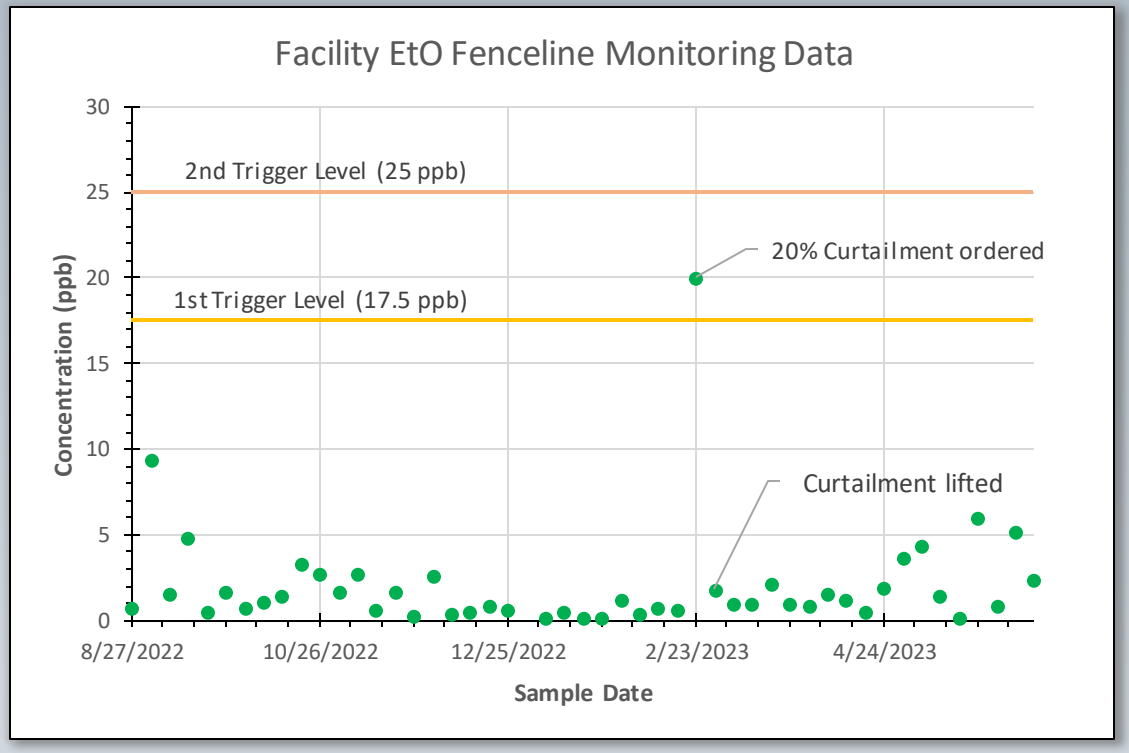
ii. Upon a second reading at or above 17.5 ppb, Sterigenics shall curtail operations by 50 percent or, if the first reading was at or above 25.0 ppb, Sterigenics shall curtail operations by 100 percent.

iii. Upon a third or any subsequent reading at or above 17.5 ppb, Sterigenics shall curtail operations by 100 percent.

iv. Multiple monitors exceeding a threshold on the same day shall not constitute multiple readings for this provision and the highest value shall be used to determine curtailment.

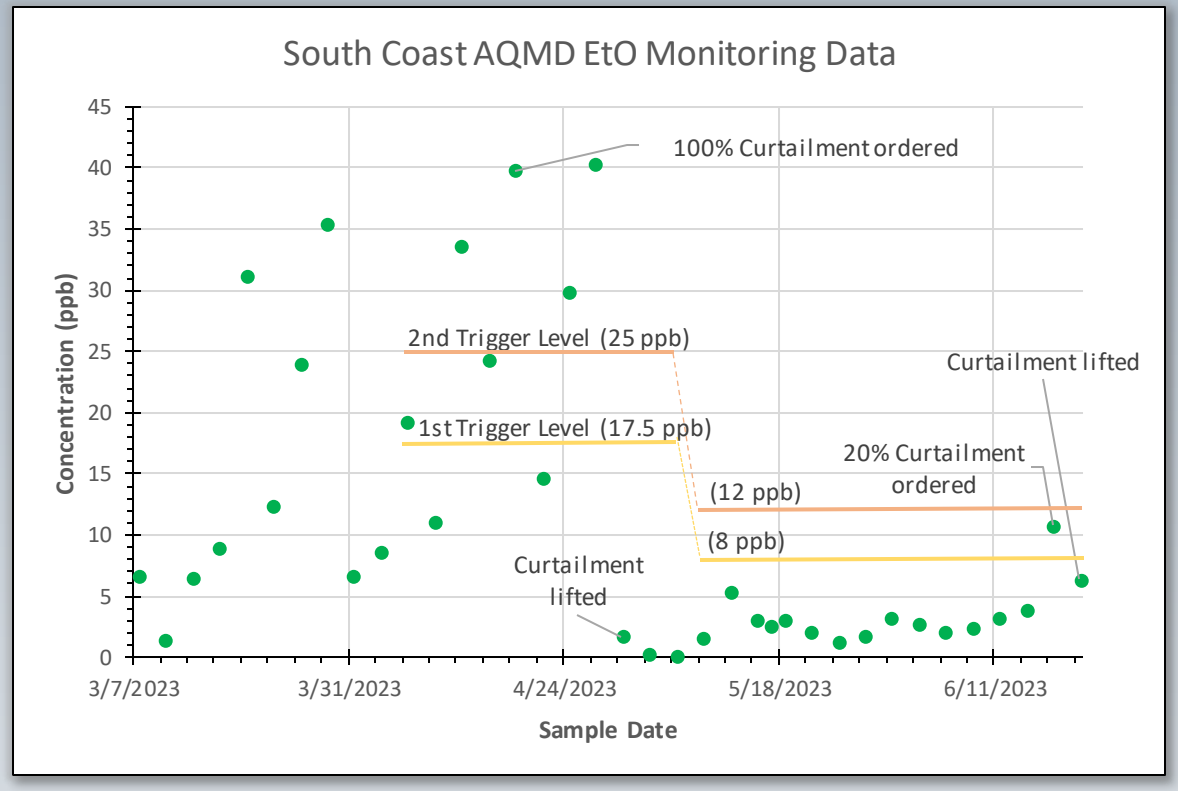
EARP Implementation - Vernon

- Facility is in the process of implementing measures in the Early Action Reduction Plan
- Facility has not upgraded stack control systems or fully implemented negative pressure PTE
- Since EARP approval, one (1) curtailment ordered due to elevated fenceline EtO levels
  - Facility was required to curtail operations by 20%
  - Fenceline EtO concentrations decreased during curtailment period



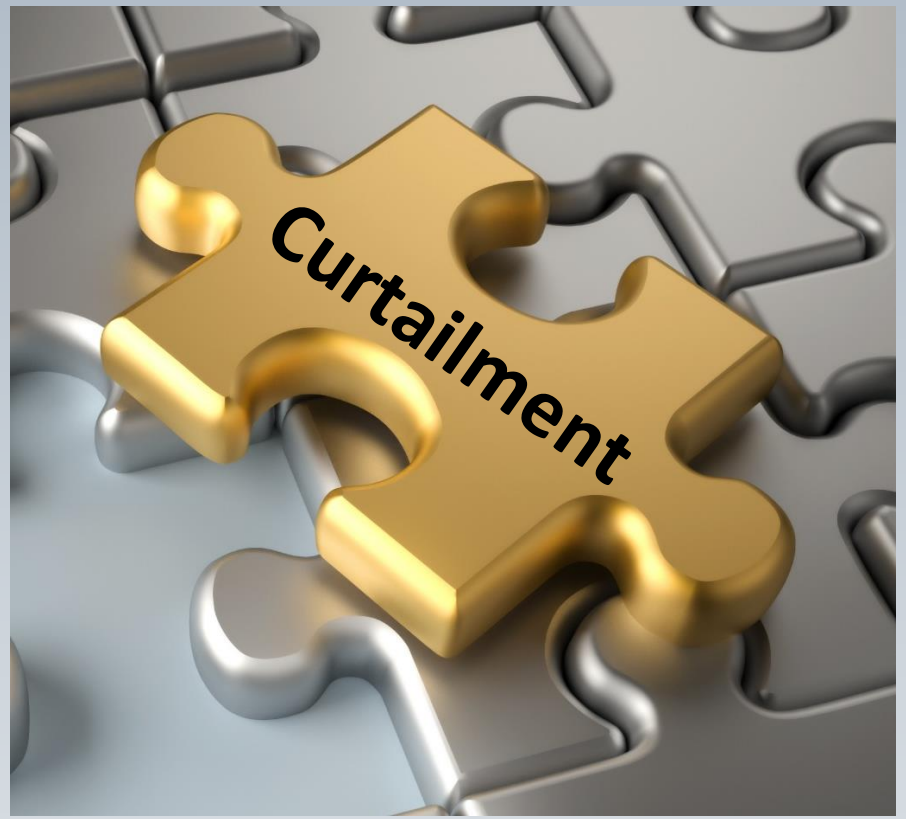
EARP Implementation - Ontario

- Facility is in the process of implementing measures in the Early Action Reduction Plan
- Facility has not upgraded stack control systems or fully implemented negative pressure PTE
- Since approval of EARP, two (2) curtailments ordered due to elevated fenceline EtO levels
  - First curtailment was 100% reduction
  - Second curtailment was 20% reduction
  - Fenceline EtO concentrations decreased during curtailment period



Conclusions from Curtailment

- Curtailment provisions are included in two EARPs addressing EtO emissions from sterilization facilities
- Prior to implementation of additional control measures, curtailment is a safeguard to reduce EtO fenceline concentrations



Proposed Amended Rule 1405

Control of Ethylene Oxide Emissions
from Sterilization and Related Operations

Rule Concept – Curtailment of EtO Sterilization Facilities

PAR 1405 Curtailment – Purpose and Goals

Purpose:

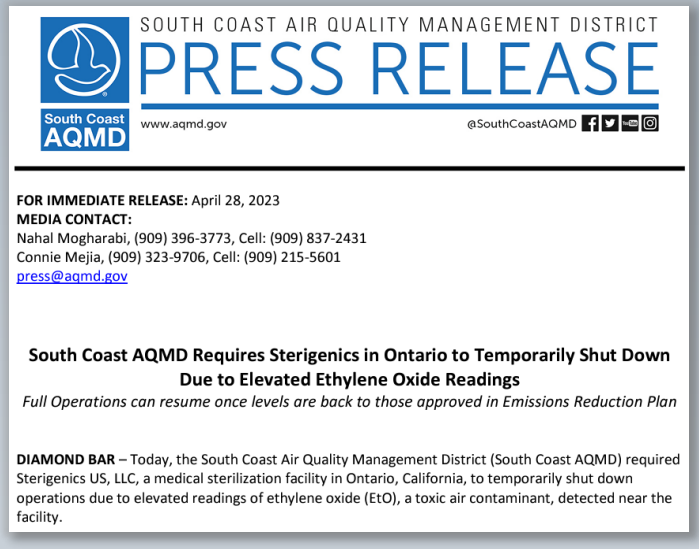
- To rapidly reduce fenceline EtO concentrations in response to observed levels

Regulatory Gap:

- PAR 1405 does not include a response mechanism to address enhanced levels of EtO
- Existing regulatory structure requires additional steps and time to curtail operations

Goals:

1. Create guardrails during interim period while facilities are installing additional controls
   - This interim period may not reflect normal operating conditions
2. Consistent with curtailment provisions of EARPs
   - EARP curtailments sunset at PTE installation
3. Provide additional assurance to community members



SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT

PRESS RELEASE

South Coast AQMD

www.aqmd.gov

@SouthCoastAQMD

FOR IMMEDIATE RELEASE: April 28, 2023
MEDIA CONTACT:
Nahal Mogharabi, (909) 396-3773, Cell: (909) 837-2431
Connie Mejia, (909) 323-9706, Cell: (909) 215-5601
press@aqmd.gov

South Coast AQMD Requires Sterigenics in Ontario to Temporarily Shut Down Due to Elevated Ethylene Oxide Readings

Full Operations can resume once levels are back to those approved in Emissions Reduction Plan

DIAMOND BAR – Today, the South Coast Air Quality Management District (South Coast AQMD) required Sterigenics US, LLC, a medical sterilization facility in Ontario, California, to temporarily shut down operations due to elevated readings of ethylene oxide (EtO), a toxic air contaminant, detected near the facility.

PAR 1405 Curtailment – Applicability

- Curtailment applies to the following types of Sterilization facilities:
  - Large: ≥ 2,000 lbs EtO per year
  - Medium: 400 - 2,000 lbs EtO per year
  - Small: 4 - 400 lbs EtO per year
- Requirements would be triggered by a valid 24-hour time integrated fenceline sample collected during
  - Facility-led fenceline monitoring efforts, required on an interim basis for Large Facilities by PAR 1405
  - South Coast AQMD-led fenceline monitoring
- Curtailment requirements would not sunset or expire

PAR 1405 Concept - Trigger Levels

Prior to Stack and Fugitive Emission Compliance Due Date

- Facilities have not implemented key PAR 1405 requirements
- Two trigger levels, to be established based on thresholds in approved EARP
  - **Lower level – TBD – gradual curtailment**
  - **Higher level – TBD – faster curtailment**
  - Consistent with EARP approach where permanent measures have not been installed

After Stack and Fugitive Emission Compliance Due Date and Thereafter

- Facilities would have implemented key PAR 1405 requirements
- Trigger level based on detection limit of continuous monitoring technology with a multiplier to account for uncertainty
- **Trigger level – 3.0 ppb**
  - 1.0 ppb is the detection limit for continuous monitoring
  - U.S. EPA applied a 3X multiplier in the draft NESHAP

PAR 1405 Concept – Curtailment Schedule

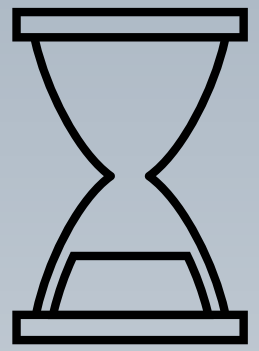
- PAR 1405 curtailment schedule would be based on an existing EARP
- Baseline EtO usage determined by evaluating the facility's daily usage

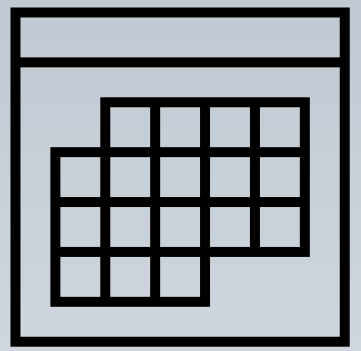
Proposed Schedule

- 1st exceedance of lower trigger level
  - 20% reduction of baseline daily EtO usage
- 2nd exceedance of lower trigger level **or** 1st exceedance of higher trigger level
  - 50% reduction of baseline daily EtO usage
- 3rd exceedance of lower trigger level **or** 2nd exceedance of higher trigger level
  - 100% reduction of baseline daily EtO usage

After Stack and Fugitive Emission Compliance Due Date and Thereafter
3 ppb would be the higher trigger level

PAR 1405 Concept - Other Considerations





- Facility would curtail operations within 24 hours of reporting fenceline results exceeding a trigger level
- Facility no longer subject to curtailment upon first subsequent monitoring result at the same location being below trigger levels
- Monitoring results below trigger levels for 30 consecutive calendar days resets curtailment schedule

Example of PAR 1405 Curtailment Concept

Date	Daily EtO Usage (lbs)	Rolling Seven Day Average (lbs)	Sample Results Received	Above Trigger Level	Subject to Curtailment	Curtailed Daily Limit (lbs)
1/1/2025	400		No samples collected	No samples collected	No	No limit
1/2/2025	600					
1/3/2025	800					
1/4/2025	900					
1/5/2025	1000					
1/6/2025	600					
1/7/2025	800	729	Yes	Yes	20%	583
1/8/2025	400	729	No samples collected	No samples collected	20%	583
1/9/2025	200	671				
1/10/2025	500	629				
1/11/2025	580	583				
1/12/2025	580	523				
1/13/2025	300	480	Yes	No	No	No limit
1/14/2025	700	466	No samples collected	No samples collected	No	No limit
1/15/2025	1000	551				
1/16/2025	1000	666				
1/17/2025	1000	737				
1/18/2025	1000	797				
1/19/2025	1000	857	Yes	Yes	50%	429
1/20/2025	390	870	No samples collected	No samples collected	50%	429
1/21/2025	380	824				
1/22/2025	390	737				
1/23/2025	390	650				
1/24/2025	390	563				
1/25/2025	390	476	Yes	No	No	No limit

- 20% curtailment triggered effective 24 hours of results
- Curtailment lifted after results below trigger level
- 50% curtailment triggered effective 24 hours of results

Expected Impacts of Curtailment

Facilities subject to EARP

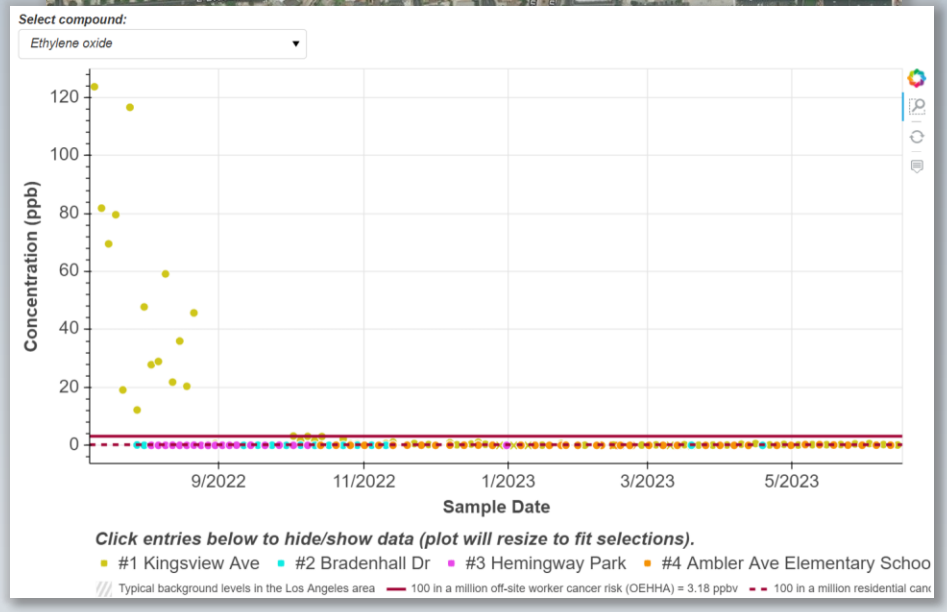
- PAR 1405 curtailment provisions would be equivalent to EARP
- Full implementation of EARP expected prior to PAR 1405 proposed compliance timeline
- Permanent trigger levels not expected to be impactful with operational negative pressure PTE and 99.99% stack emission controls

Facilities not subject to EARP

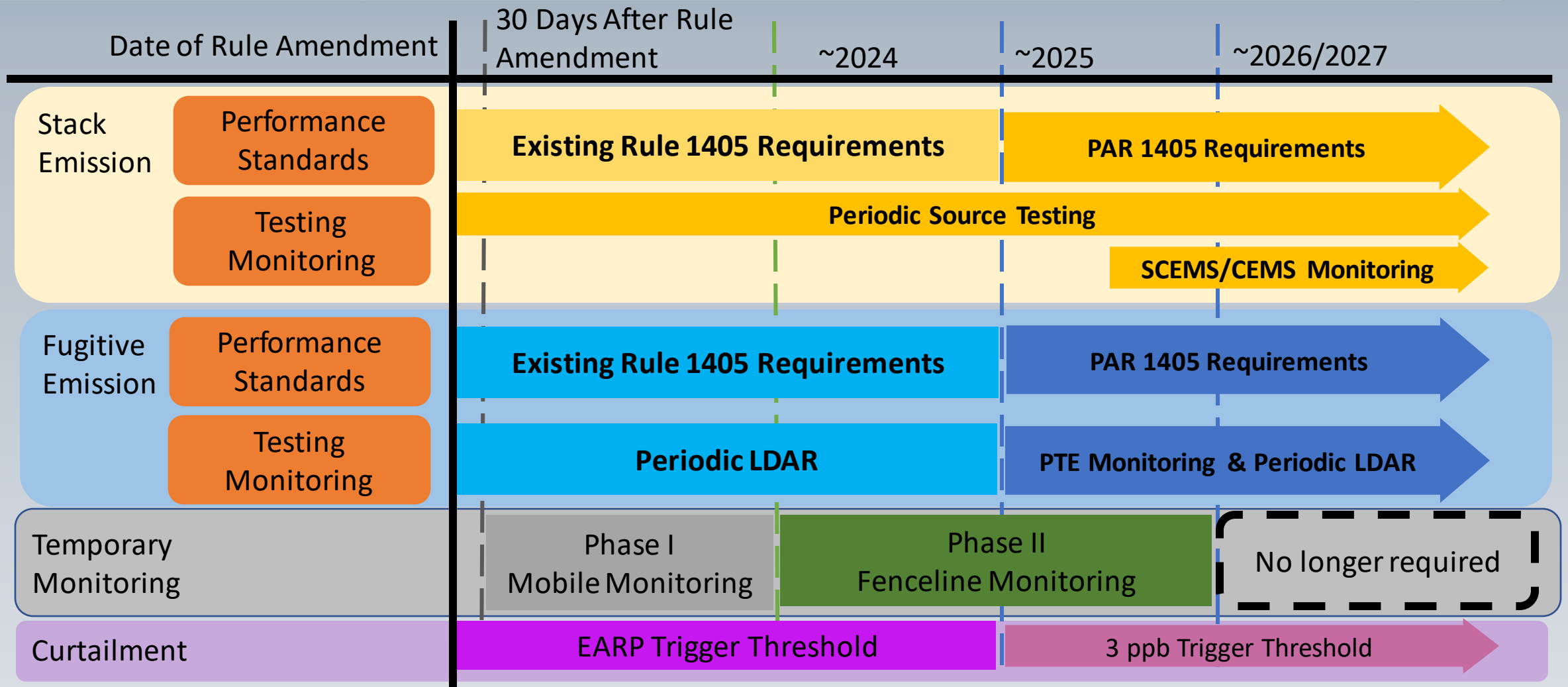
- Parter Carson has implemented negative pressure PTE and multistage stack control
  - Fenceline monitoring levels have been below 0.5 ppb since control measures implemented
- Mobile monitoring did not identify any other sterilization facilities with elevated EtO signal
- Interim and permanent trigger levels not expected to be impactful with operational negative pressure PTE and 99.99% stack emission controls

Parter Carson EtO Fenceline Monitoring

- Fenceline monitoring began in July 2022
- Facility voluntarily shut down operations until additional air pollution controls were implemented
  - Added multistage stack control and negative pressure PTE for fugitive control
- Fenceline monitoring now indicates EtO concentrations at or near background levels
  - Ambient EtO concentration range was **0.02 to 0.17 ppb** at Central LA monitoring site in 2021



PAR 1405 Regulatory Timeline for Large Facilities*



Based on revised concepts, rule language to be released

Summary of PAR 1405 Curtailment Concept

- Curtailment provides a fenceline EtO level where the facility would be required to reduce or cease operating
- PAR 1405 curtailment provisions would be consistent with current South Coast AQMD approach to reducing EtO based on elevated fenceline monitoring
- Monitoring has demonstrated that a facility meeting PAR 1405 proposed requirements for fugitive and stack emissions would have fenceline levels below trigger levels

Next Steps

Public Hearing
(expected October)

Stationary Source Committee
(August 18)

Public Consultation Meeting
(late July)

Develop and release updated
rule language (mid July)

Stay Informed

Sign up to Receive Newsletter Updates via **aqmd.gov/sign-up**

Sign Up

The SCAQMD offers periodic newsletter updates via Email on a variety of topics . Click on the Manage Subscriptions link at the bottom of the form to update your subscriptions (unsubscribe from lists, subscribe to additional lists, or change your Email address).

If you wish to receive daily pollution forecasts or alerts for specific pollution levels in your area, sign up for Air Alerts.

For printed copies of AQMD publications that mailed to you, please visit Subscription Services (charges may apply).

Enter the following information:

Email Address: | Re-Enter Email Address:

First Name (optional): | Last Name (optional):

Subscribe by checking the box adjacent to the EMail List(s) you are interested in and then CLICK on the Subscribe button below:

General Notifications:

☐ SCAQMD News	Brief updates highlighting what is current at SCAQMD, such as conferences, equipment exchanges, advisories, etc.
☐ SCAQMD Advisor	SCAQMD's comprehensive bi-monthly newsletter containing the latest news, including rule

Subscribe to:

☑ **Rule 1405**

PAR 1405 Staff Contacts

Please contact staff with any questions or comments

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

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

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

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