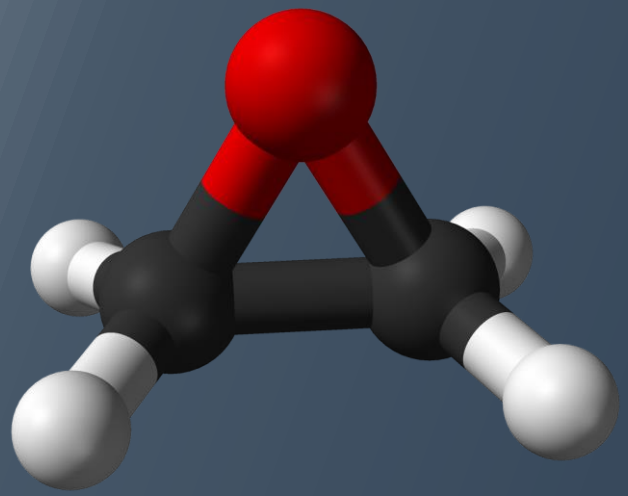
Working Group Meeting #2



Proposed Amended Rule 1405

Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes

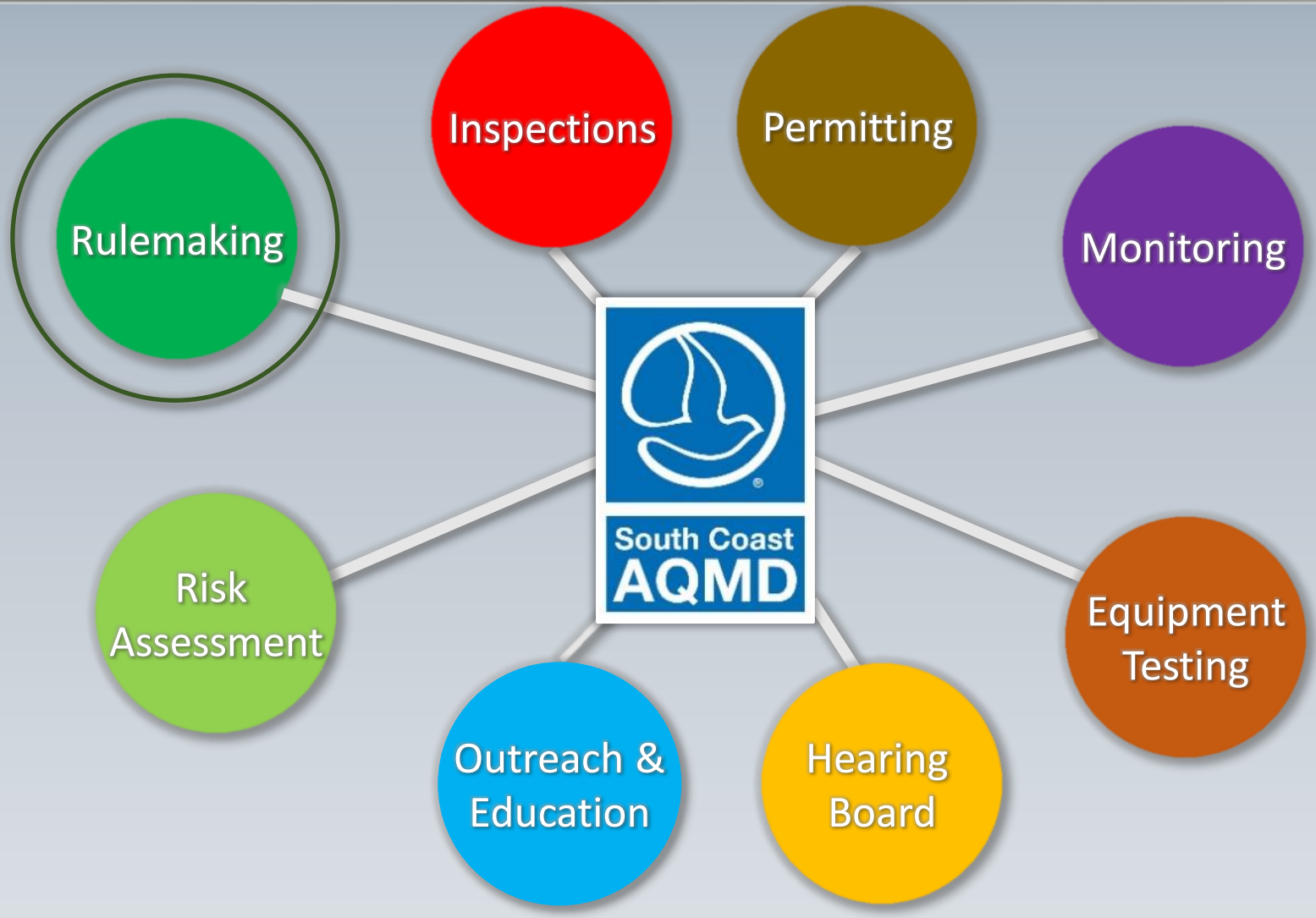
September 28, 2022
10:00 AM

Zoom Meeting Link:
https://scaqmd.zoom.us/j/93707198058

Dial In: (669) 900 6833

Meeting ID: 937 0719 8058

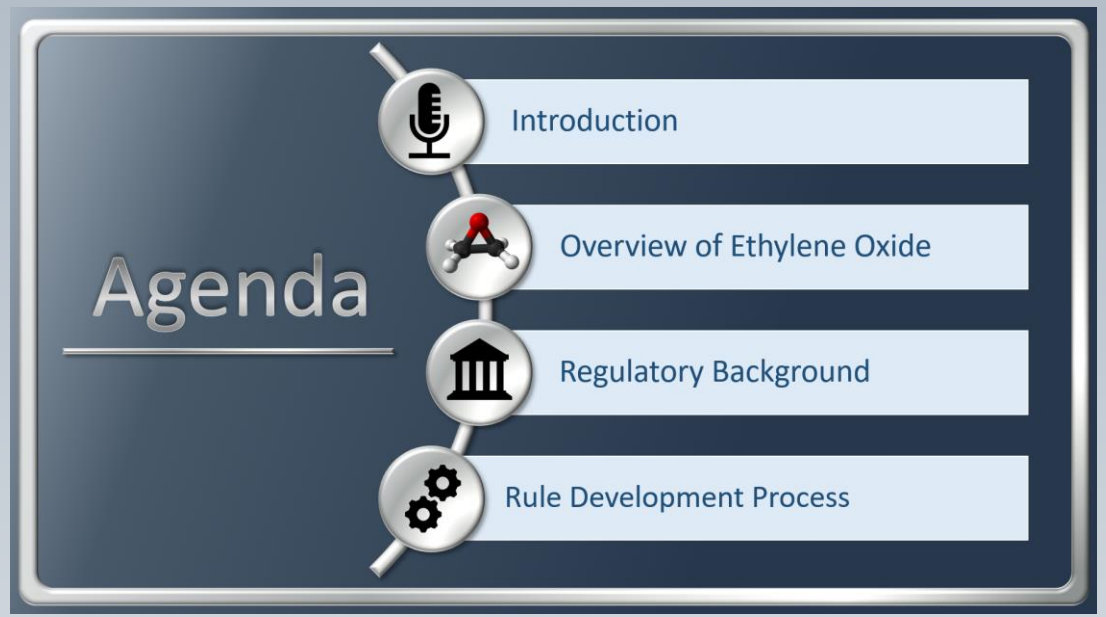
South Coast AQMD EtO Activities Overview



Visit aqmd.gov/eto for additional information including:

- Background on EtO & EtO facilities
- Ambient Air Monitoring Data
- Comments by Leaders & Community
- Enforcement Activity

Recap from Working Group Meeting #1



- Introduction
  - South Coast AQMD background
- Overview of Ethylene Oxide
  - EtO background & health effects
  - EtO sterilization process
  - Alternative methods of sterilization
- Regulatory Background
  - Risk assessment history
  - Federal, state, and local regulations
  - Existing Rule 1405 requirements
- Rule Development Process
  - Working Group Meetings

Key Comments and Responses

RESPONSES

Comment #1 Risk and Impacts	Comment #2 EtO Alternatives	Comment #3 Control Technology	Comment #4 Warehouses
• AB2588 Toxic Hotspots risk assessment • Ongoing ambient air monitoring • Monitoring findings will be discussed today	• EtO is the primary method of sterilization in the US • For many medical devices, EtO is the only proven method of sterilization	• To be discussed today 	• Written questionnaires sent to over 70 FDA-registered locations • Mobile measurements will be conducted near warehouses

Agenda

- EtO Facilities
- EtO Monitoring Efforts and Findings
- Sterilization Process and Emission Sources
- EtO Control/Capture Technologies

Proposed Amended Rule 1405

Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes

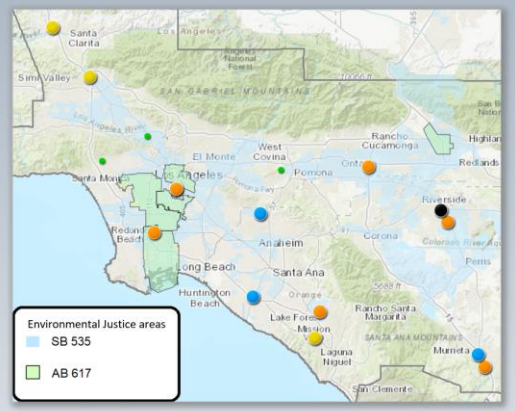
EtO Facilities

Introduction

EtO Facilities Currently Permitted

17 active, permitted facilities

- Large – permitted to use more than 4,000 lbs of EtO per year
- Medium – permitted to use between 400 and 4,000 lbs of EtO per year
- Small – permitted to use between 4 and 400 lbs of EtO per year
- Exempt – permitted to use less than 4 lbs of EtO per year
- Aeration only - do not use EtO directly

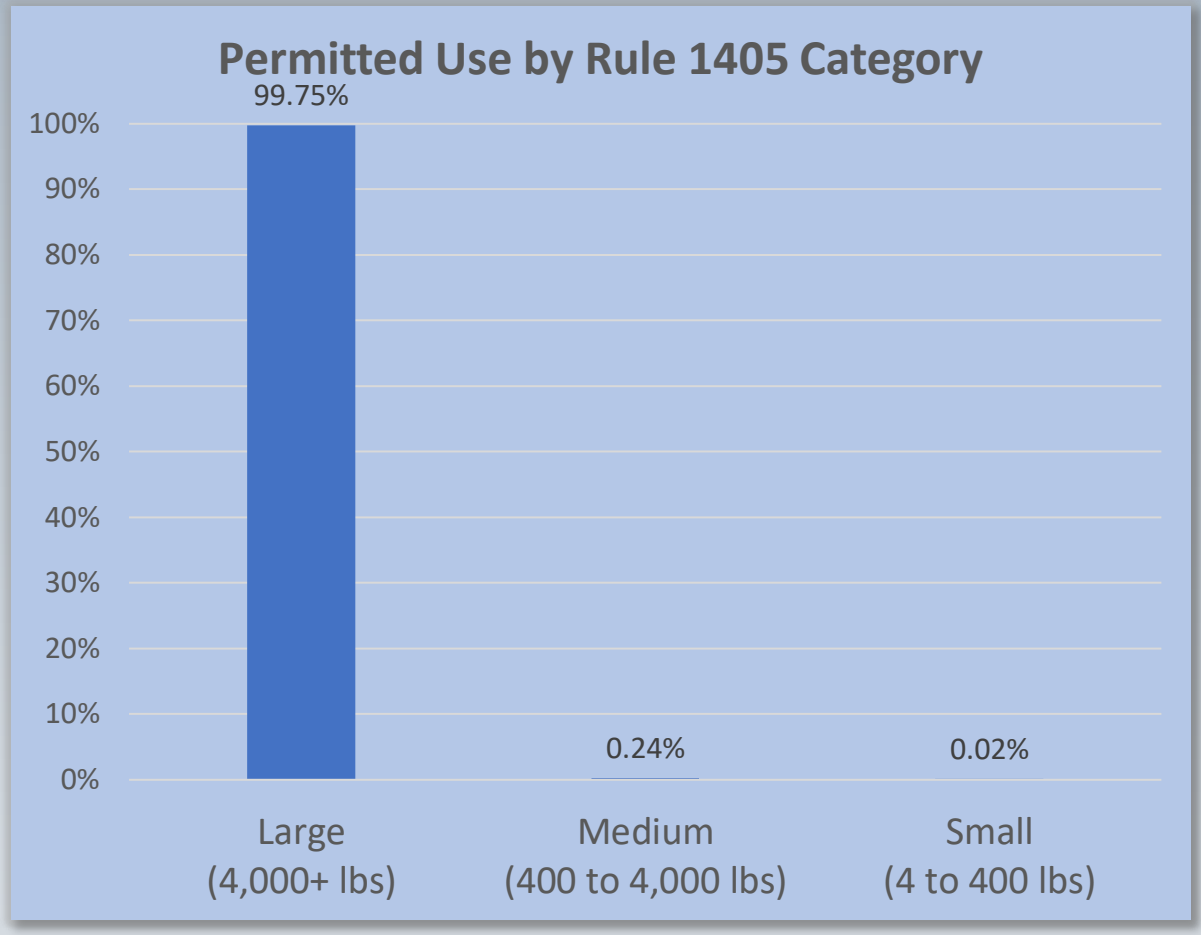


23

- EtO is used in varying amounts by different facilities
- Identify EtO usage to assess potential emissions
- Evaluate facility distance to receptors to understand potential exposure
- Overview
  - EtO permitted use
  - Actual usage of EtO
  - Facility type
  - Locations of EtO facilities
  - Distance to receptors

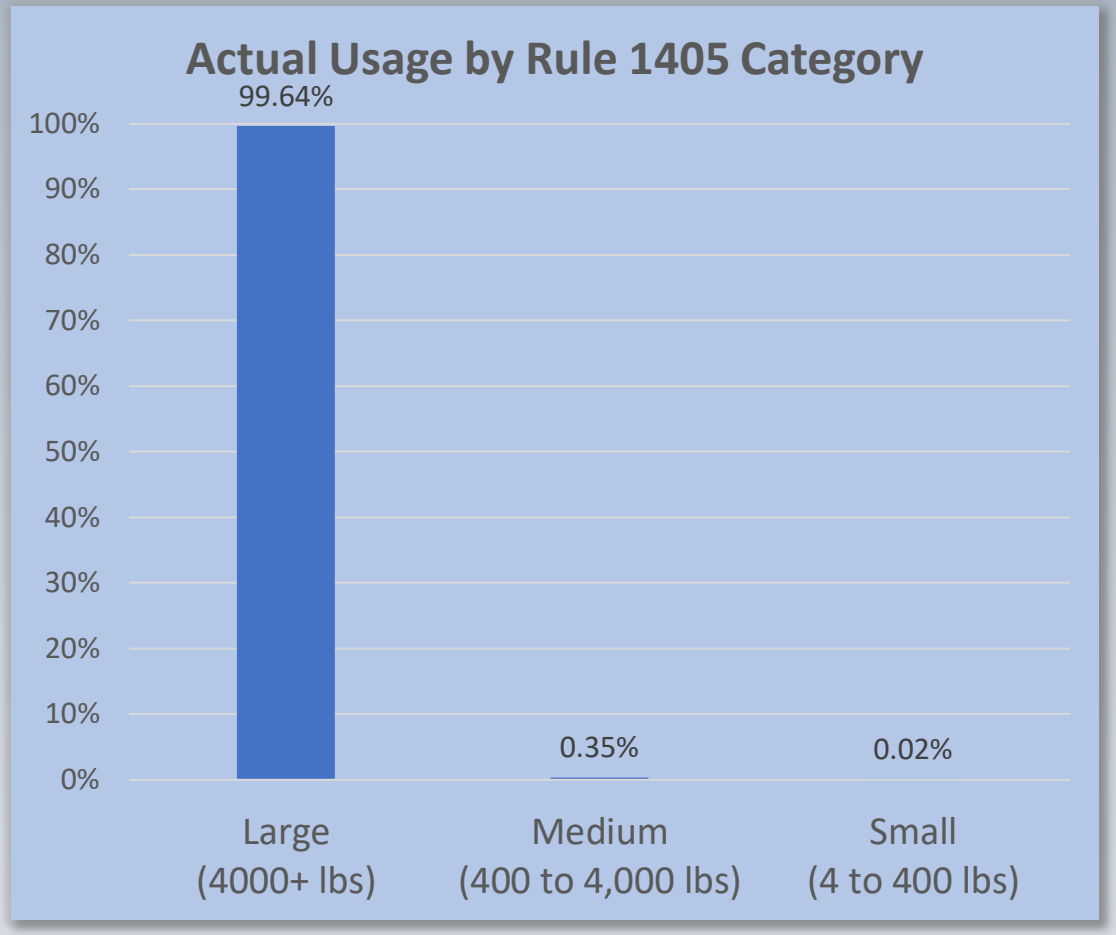
Facility EtO Permitted Use

- *Permitted Use*
  - EtO annual usage limit
  - Listed in permits and enforceable
- Existing rule requirements are more stringent for larger facilities based on permitted use
- Total combined permitted use approximately 2.7 million lbs of EtO per year
  - Vast majority from large facilities
    - Annual permitted use ranging from 10,000 to 1,314,000 lbs



Facility EtO Actual Usage

- *Actual Usage*
  - Amount of EtO used annually
  - Determined by inspection reports or available data
  - Most recent data available used
- Total combined actual usage is approximately 1.4 million lbs of EtO per year
  - Vast majority from large facilities
    - Annual usage ranging from 1,764 to 878,000 lbs



Facility Type

- EtO is used in varying amounts by different types of industries

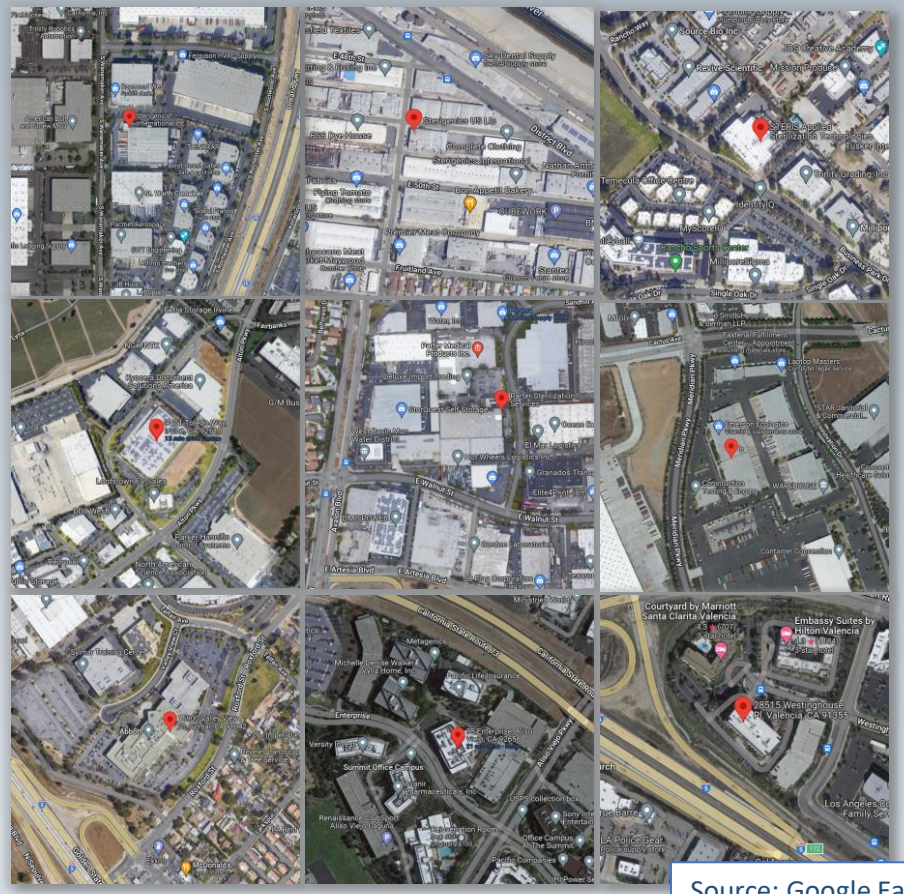



Rule 1405 Category (annual usage)	Contract Sterilization	Medical Manufacturing	Surgical or Veterinary	Educational or Zoological
Large (More than 4,000 lbs)	7	0	0	0
Medium (400 to 4,000 lbs)	0	3	0	0
Small (4 to 400 lbs)	0	1	2	0
Exempt (Less than 4 lbs)	0	0	0	3

Sources for images above: steris-ast.com, brighton-science.com, washingtonavevet.com, brevardzoo.org, respectively

Facility Locations

- Large and medium EtO facilities primarily located in commercial or industrial zones
- Worker receptor
  - Workers can be at the same location during almost their entire daily work shift
  - Offsite worker receptor within 300 ft of large or medium EtO facilities
  - Onsite worker concerns addressed by Occupational Safety and Health Administration (OSHA)



Source: Google Earth

Note: 10 facilities included above

Facility Distance to Residential/Sensitive Receptors

- *Residential/sensitive receptors*
  - Residences: private homes, apartments, and condominiums
  - Schools and daycare centers
  - Healthcare facilities
- Rule 1402 *Control of Toxic Air Contaminants from Existing Sources* and Air Toxic "Hot Spots" Program (AB 2588) risk assessments will address site-specific issues

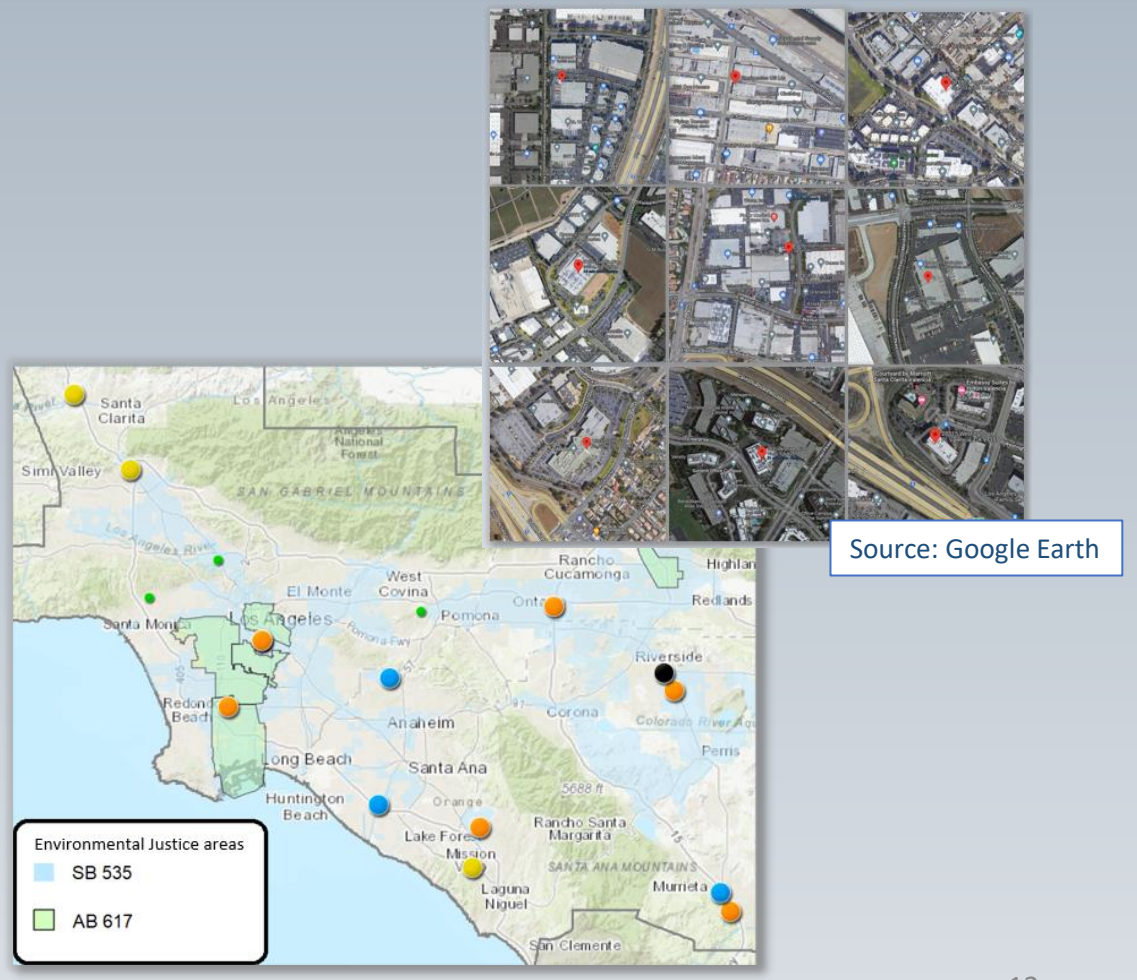
Distance from Rule 1405 Facilities to Residential/Sensitive Receptors

Rule 1405 Category	< 300 ft	300 to 1000 ft	> 1000 ft
Large	0	3	4
Medium	1	1	1
Small	1	0	2

Summary of EtO Facility Analysis

Large EtO facilities accounted for almost all EtO usage:

- Contract sterilization facilities
- Closest receptors are offsite workers
- Facilities located more than 300 ft away from residential/sensitive receptors



Source: Google Earth

Proposed Amended Rule 1405

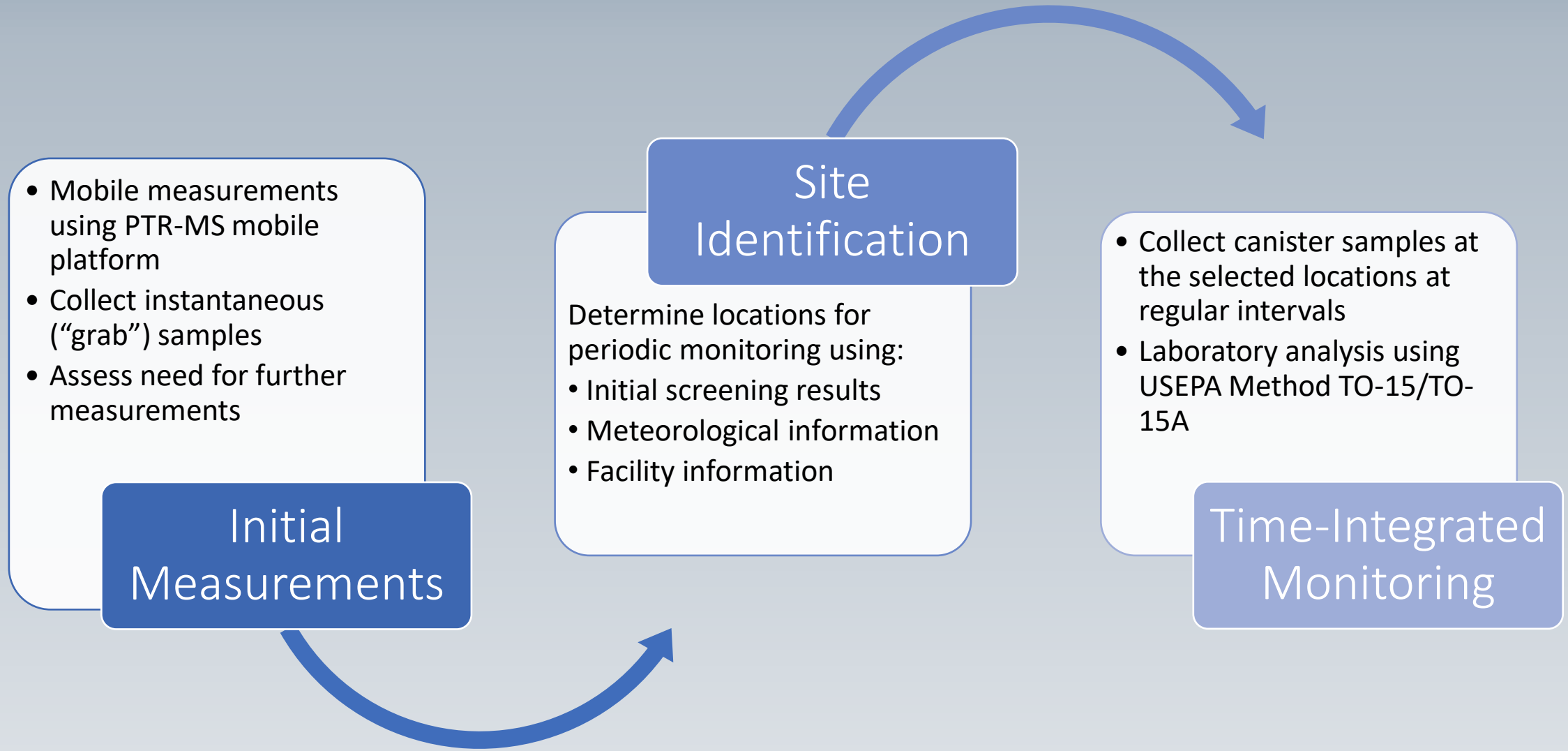
Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes

EtO Monitoring Efforts and Findings

Introduction

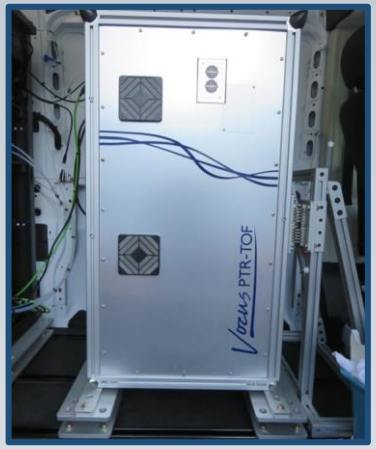
- Ambient air monitoring is the systematic assessment of pollutant levels by measuring the quantity and types of certain pollutants in the surrounding, outdoor air
  - Assess the extent of air pollution impact in the real world
  - Evaluate the effectiveness of emissions control strategies
- USEPA and OEHHA reassessing toxicity of EtO, prompting South Coast AQMD to conduct air monitoring near EtO emission sources
- Methodical approach was developed to monitor EtO levels

Methodical EtO Monitoring Approach



Exploratory Mobile Measurements

- Proton Transfer Reaction – Mass Spectrometer (PTR-MS) Mobile Platform
  - Real-time detection of Volatile Organic Compound (VOC) signals, including signals associated with EtO
- Measure near the facility, in upwind and downwind areas, and in nearby communities
- If enhanced EtO-related signals are detected, grab samples are collected for confirming and quantifying EtO levels using laboratory analysis



Sampling Options

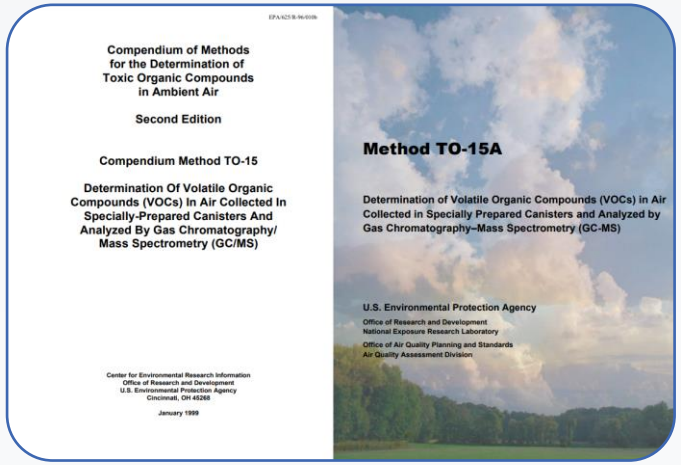
Grab (Instantaneous) Samples

- Sampling spans < 2 minutes
- Collected as needed
- Used to complement mobile measurements

Time-Integrated Samples

- Collection is typically 24 hours
- For periodic monitoring at fixed sites
- Recurring frequency (e.g., 1 in 3 days)

Laboratory Analysis



Samples

Silica-lined canisters provide most inert environment for VOCs

Method

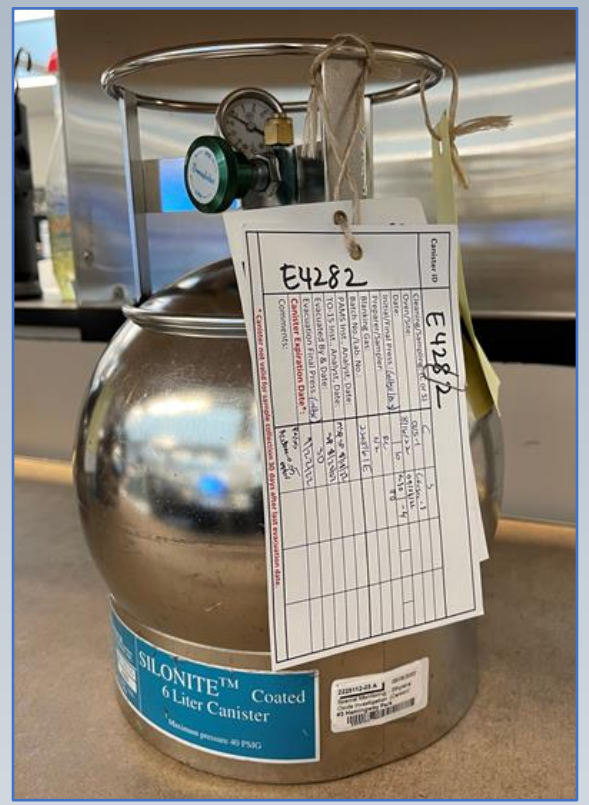
USEPA Compendium TO-15/TO-15A for VOCs

Instrument

Gas Chromatograph-Mass Spectrometer (GC-MS) with pre-concentrator

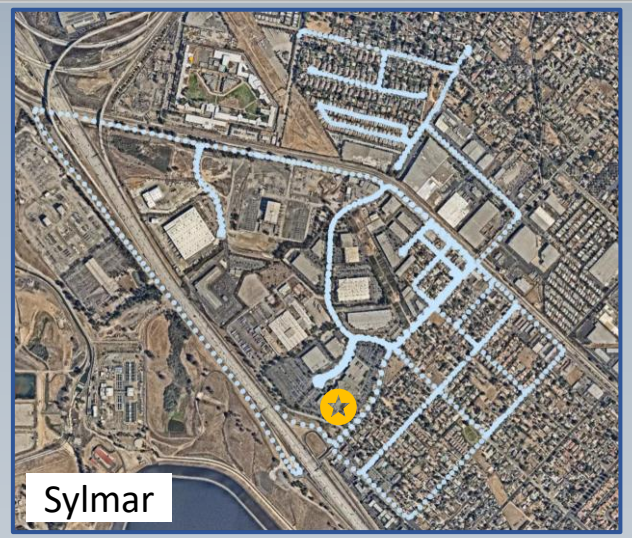
Real-time monitors for continuous EtO measurements have been developed and are being evaluated by USEPA

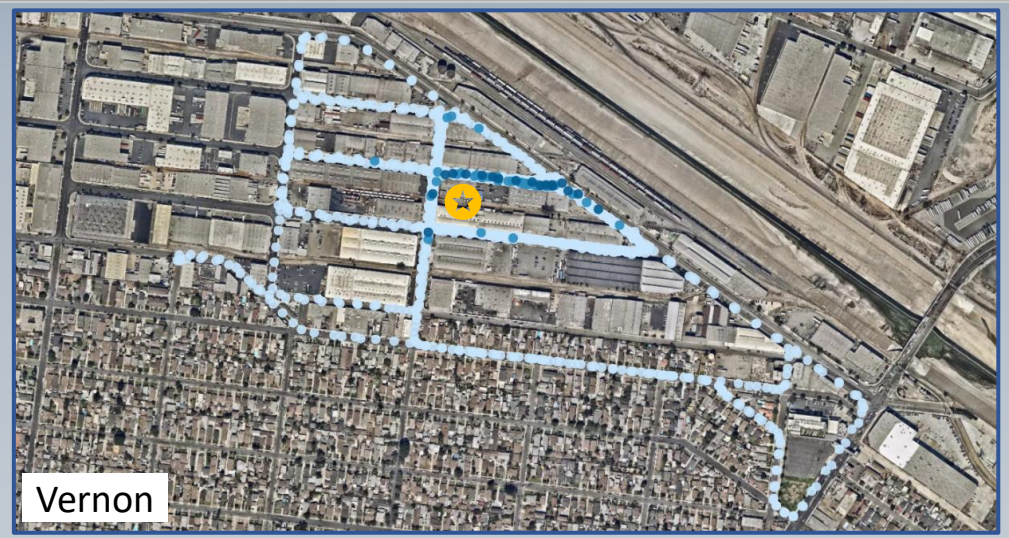
TO-15/TO-15A Measurement Challenges

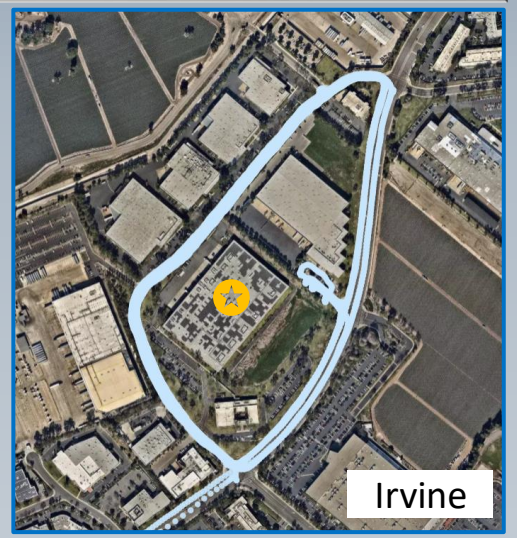


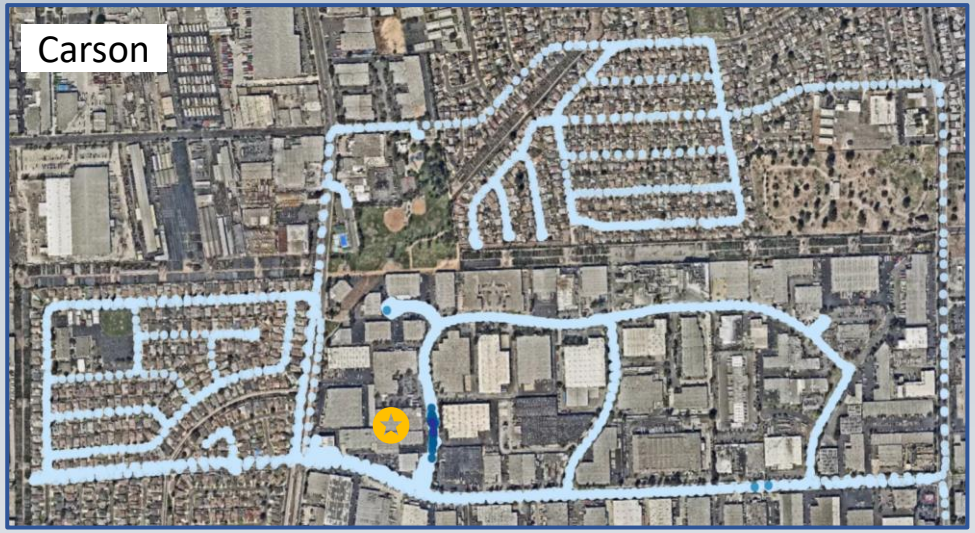
- TO-15/TO-15A is the only USEPA approved method for EtO analysis
- Other laboratories observed some EtO growth in canisters
- South Coast AQMD uses silica-lined stainless steel canisters to reduce/prevent EtO growth
- Preliminary results of in-house study confirm EtO growth *is not* observed

Initial Mobile Measurements





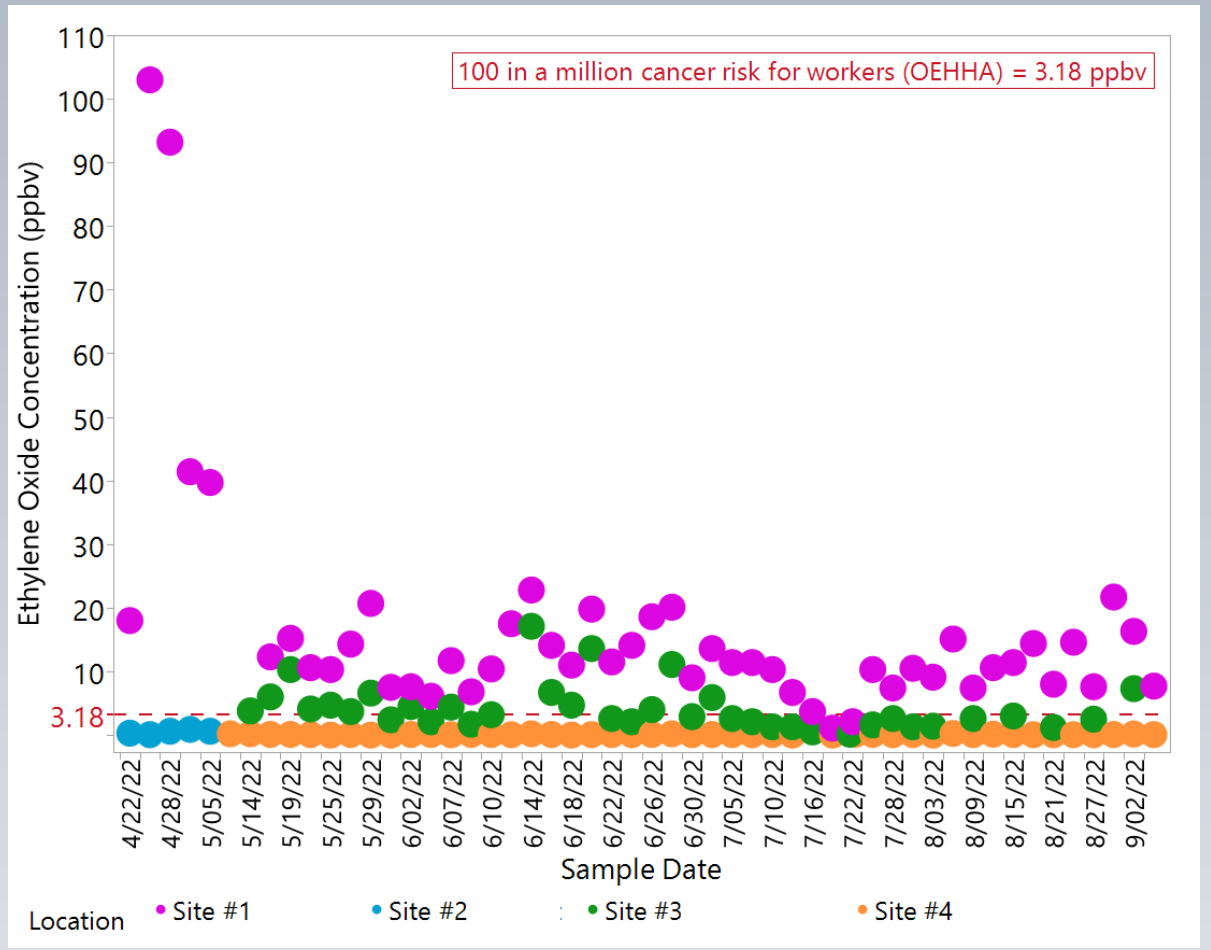




Monitoring Site Identification

Vernon Facility

Ongoing Time-Integrated Sampling Efforts

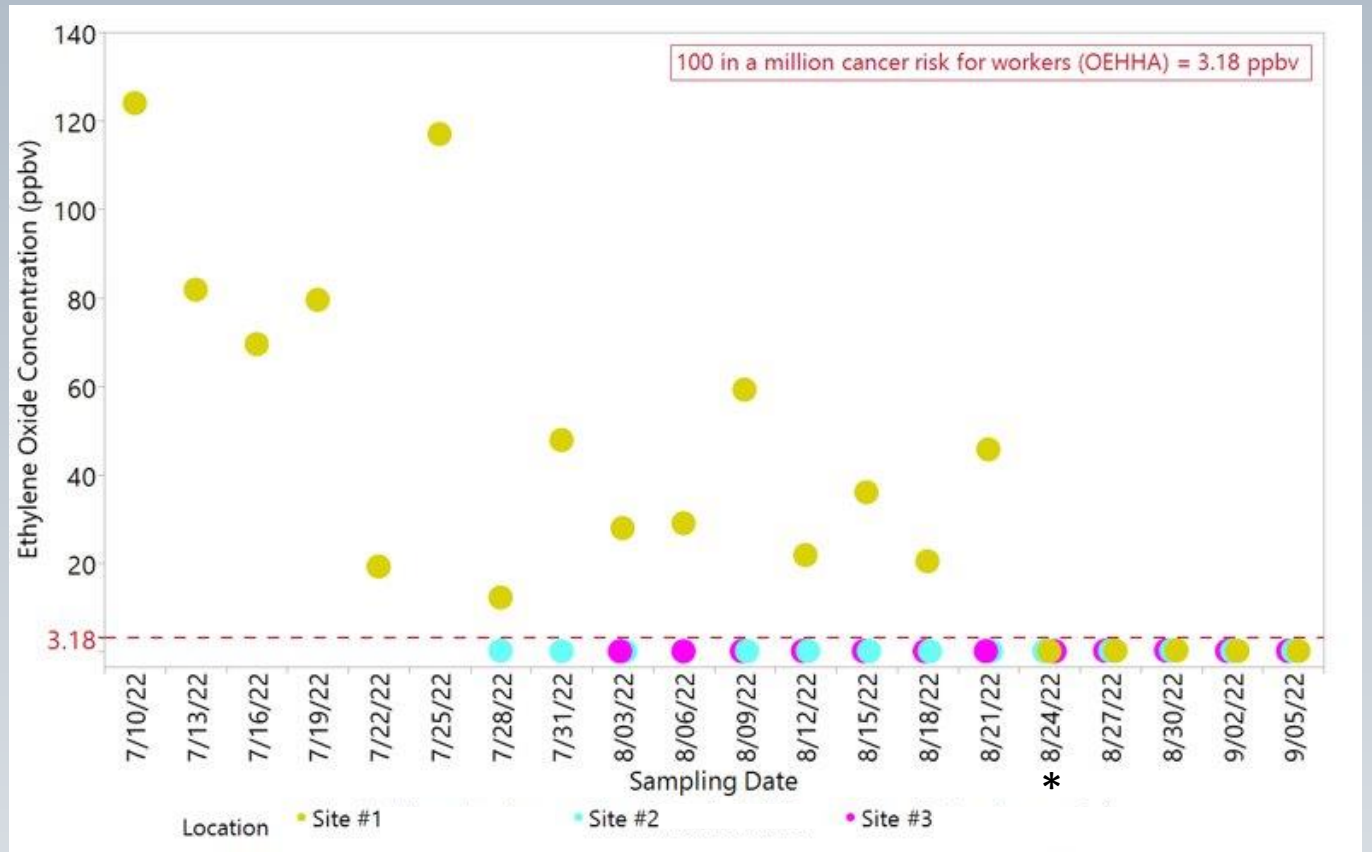


Ontario Facility

Ongoing Time-Integrated Sampling Efforts

Carson Facility

Ongoing Time-Integrated Sampling Efforts



**Voluntary shutdown starting 08/21/22*

Summary of Monitoring Efforts

- Methodical approach developed to monitor EtO levels near emission sources
  1) Exploratory mobile measurements
  2) Canister sampling followed by laboratory analysis using USEPA method
- Mobile measurements conducted near 11 facilities
  - Identified 4 facilities (3 locations) for additional monitoring
- Data *to date* identified elevated EtO levels near some large facilities
  - Elevated levels of EtO at off-site worker monitoring sites (directly outside of facilities)
  - EtO levels at nearby residential communities within typical background levels
- Measurement efforts ongoing
  - Continue mobile measurements near potential emission sources including warehouses
  - Continue canister sampling near 4 facilities with elevated EtO levels

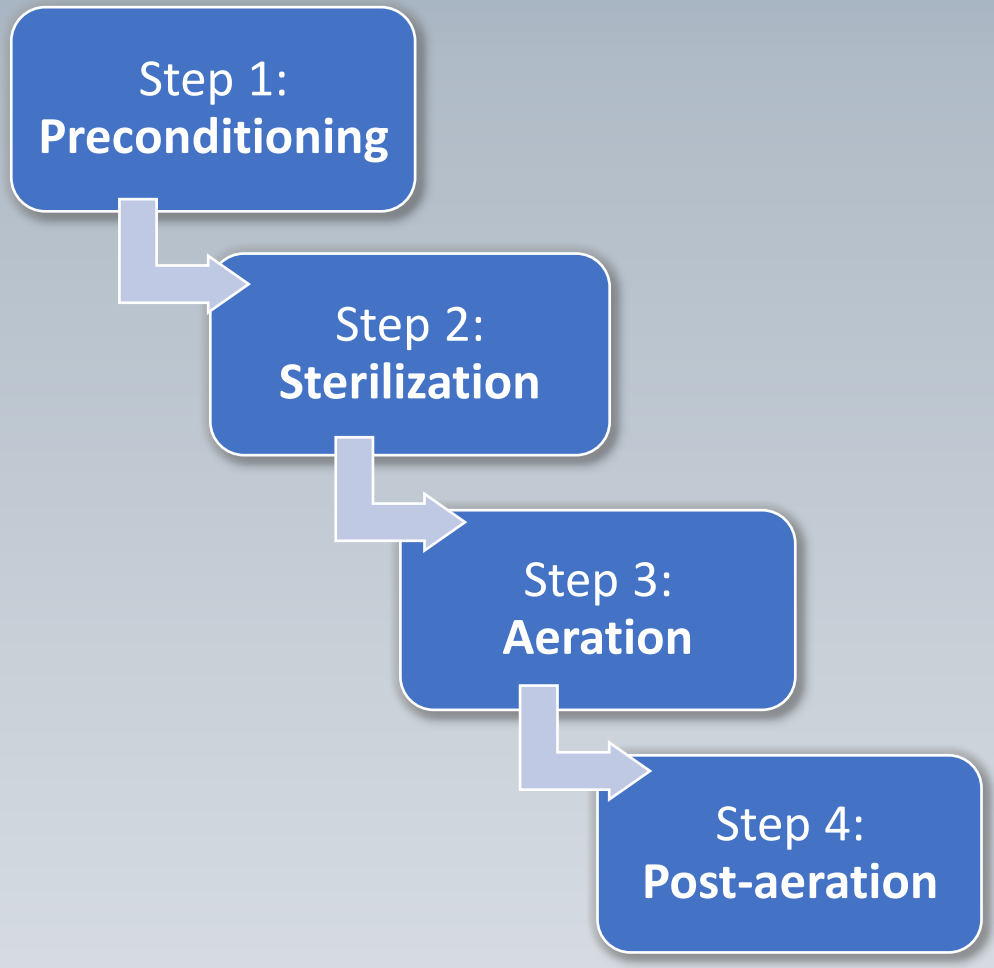
Proposed Amended Rule 1405

Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes

Sterilization Process and Emission Sources

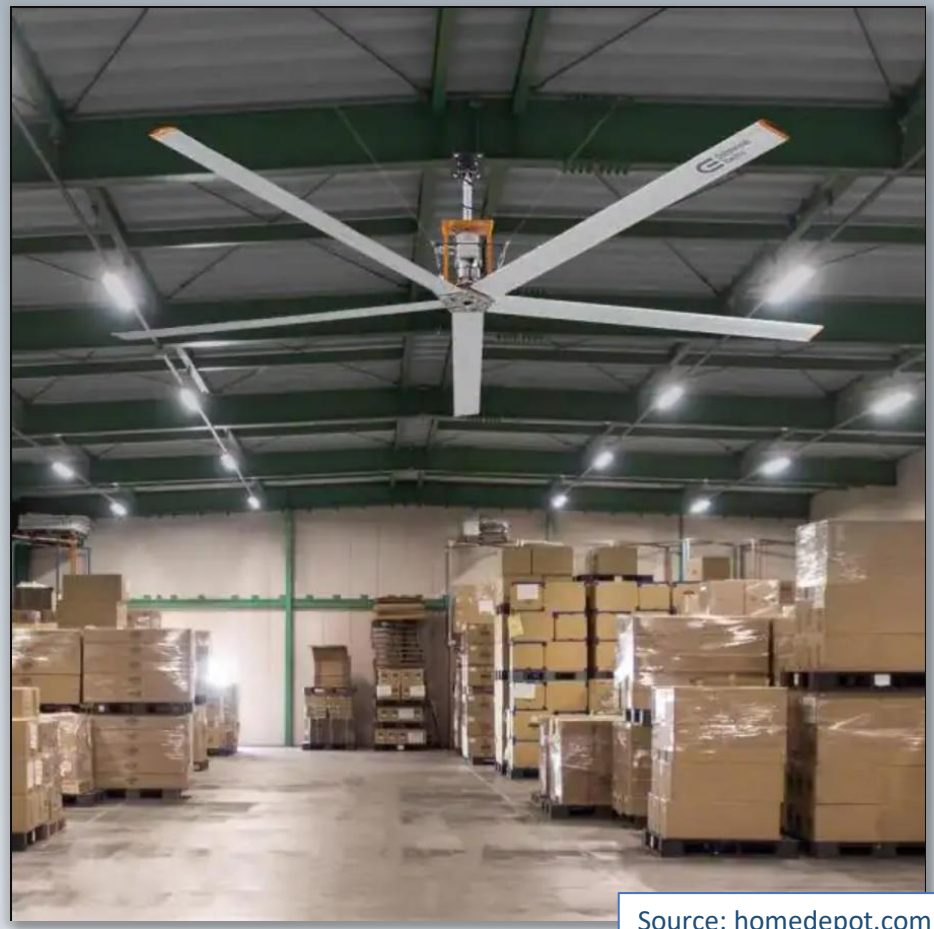
Introduction

- Two main types of emission sources
  - Point sources: a single identifiable source of pollution (e.g., stack emissions)
  - Fugitive sources: emissions not captured by control devices or uncontrolled emissions
- Identify potential emission sources from each step/component of the sterilization process



Step 1: Preconditioning

- **Preconditioning** is the process of bringing products to optimal temperature and humidity prior to sterilization with EtO
- On site measurement data has shown the presence of EtO in preconditioning rooms at three separate facilities
- Fugitive EtO emissions may be migrating to preconditioning rooms/areas



Source: homedepot.com

Step 2: Sterilization

- **Sterilization** introduces EtO gas in a chamber filled with products followed by EtO removal then removal of sterilized products
- Source of stack emissions
  - Rule 1405 currently requires 99% to 99.9% control efficiency (CE)
- Potential source of fugitive EtO emissions during unloading of sterilized products from chamber

Source: steris-ast.com

Source: Google Street View

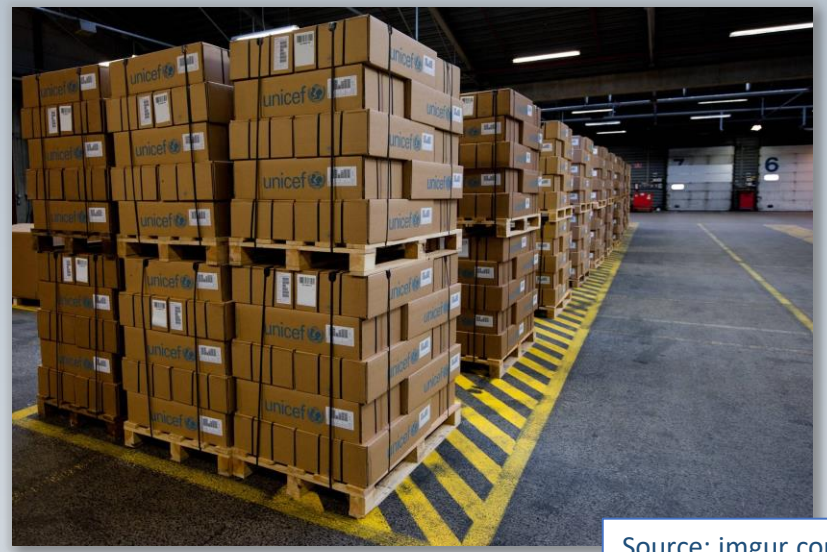
Step 3: Aeration

- **Aeration** allows residual EtO to off-gas to ensure that sterilized medical devices meet the standard acceptable limits for EtO residuals
  - Occurs in enclosed rooms or areas (usually over several hours to days) in a heated or unheated negative air pressure environment
- Source of stack emissions
  - Rule 1405 currently requires 95% to 99% control efficiency
- Potential sources of fugitive emissions:
  - Insufficient negative pressure
  - Ingress and egress

Source: cobaeurope.com

Step 4: Post-aeration

- **Post-aeration** is the handling of sterilized products after completing aeration
  - Typically uncontrolled and a potential source of fugitive emissions
- On site measurement data has shown elevated EtO levels in post-aeration areas at four separate facilities
- As much as 1% of EtO used remains on sterilized products even after aeration, per USEPA
  - Sterilized products could continue to off-gas at warehouses and distribution centers



Source: imgur.com

Other Potential Emission Sources

- Storage of concentrated EtO

Source: balchem.com

- EtO-containing waste & byproducts

Source: snydernet.com

†Revised

Summary of Potential Emission Sources

Process	Current Rule 1405 Requirements*	Potential EtO Emissions?	Fugitive Emission Sources
Preconditioning	✗	✗	None identified at this time
Sterilization	✓ 99-99.9% CE† ✓ Leak checks (annual)	✓	Residual EtO following sterilization
Aeration	✓ 95-99% CE ✓ Leak checks (annual)	✓	EtO escaping aeration area
Post-Aeration	✗	✓	Residual EtO on sterilized products off-gassing
Storage of concentrated EtO	✗	✓	Potential leaks from storage containers
EtO-containing waste & byproducts	✓ No liquid discharge ✓ Leak checks (annual)	✓	Potential leaks from storage containers

**For sites using more than 4 lbs EtO*

- Rule 1405 includes control requirements for stack emissions
- Rule 1405 has no existing requirements for some potential sources of fugitive emissions (i.e., post-aeration, EtO storage); fugitive emissions will be addressed
- Existing rule requirements, such as leak check frequency, will be evaluated

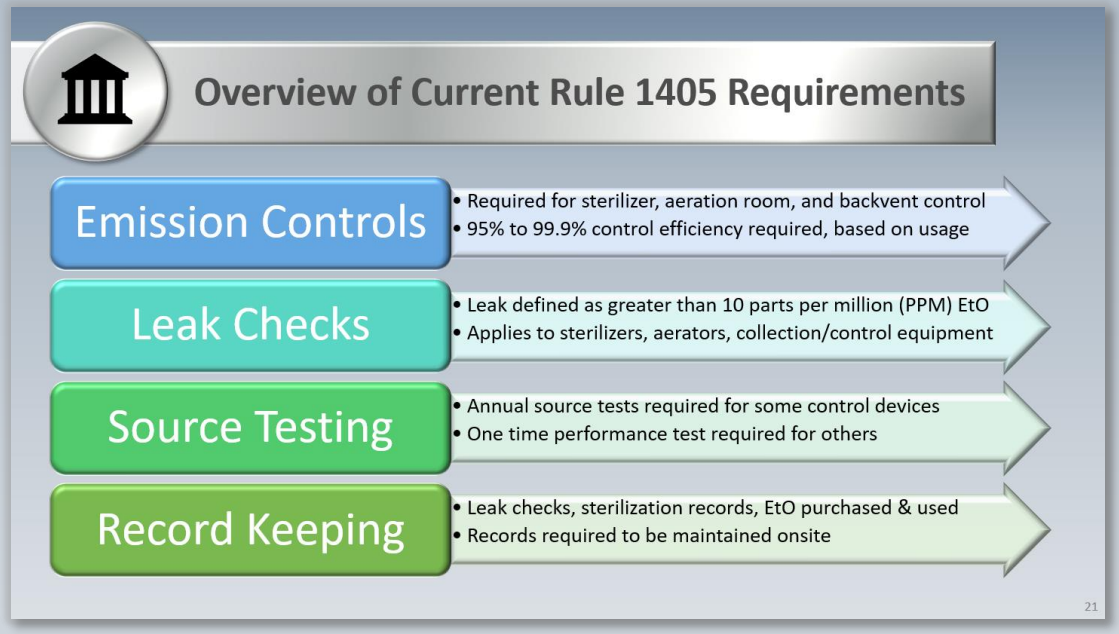
Proposed Amended Rule 1405

Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes

EtO Control/Capture Technologies

Introduction

- Air pollution control devices eliminate, reduce or control the issuance of air contaminants
- Identify different control technologies to capture and reduce EtO emissions
- Evaluate control efficiency and suitability for different types of exhaust streams



Filtration

- Proprietary **filters** claim the ability to capture and control EtO gas in air
  - May be used with negative air machines or wall-mounted fans
- Wall-mounted systems report 75% to 90% control efficiency
- Suitable for low concentration EtO when controls are not required or as secondary control
- Rule 1405 Testing Requirement:
  - One-time performance testing

Source: timilon.com

Catalytic Oxidation

- A **catalytic oxidizer** is a combustion device that uses heat and catalyst to convert EtO into carbon dioxide and water
- Capable of achieving 95% and above control efficiency
- Suitable for exhaust streams with low concentration EtO
- Rule 1405 Testing Requirement:
  - Annual source testing

Example Equipment Description

Ethylene Oxide Air Pollution Control System consisting of:

1. Recuperative Catalytic Oxidizer, Pollution Systems, Model No. Catalytic Oxidizer- RCO22, with a Preheater, a Heat Exchanger, and a catalytic bed with Carulite 500 or equivalent catalyst
2. One Eclipse Burner, Model No. Linnox ULE Natural Gas Fired, rated at 4,500,000 BTU per hour
3. Exhaust System with a 150 HP blower, 22,000 cfm, Venting and Controlling off gases from Nine ETO Sterilizer Chambers Backdraft Vents and two Aeration Rooms

Example source test results

ETO CONTROL EFFICIENCY
99.96

Source: konokogs.com

Dry scrubbing

- A **dry scrubber** is a control device that uses a solid bed of dry reactant media to bond EtO to its surface
- Capable of achieving 95% and above control efficiency
- Suitable for exhaust streams with low concentration EtO
- Rule 1405 Testing Requirement:
  - Annual source testing

Example Equipment Description

AIR POLLUTION CONTROL SYSTEM CONSISTING OF

1 ETO REACTOR, ADVANCED AIR TECHNOLOGIES SAFE CELL II MODEL NO 48 2 25 4 0 DIA X 3 6" H CONTAINING 550 LBS OF A MACRO POROUS SULFONATED STYRENE DIVINYLBENZENE COPOLYMER 4 7 EQ/KG DRY

2 EXHAUST SYSTEM WITH A 3 H P EXHAUST BLOWER VENTING AN AERATION ROOM 23 0 W X 23 0 L X 9 0" H

Example source test results

ETO CONTROL EFFICIENCY
99.89

Source: advairtech.com

Acid-Water Scrubbing

- An **acid-water scrubber** is a control device that uses sulfuric acid to convert EtO into ethylene glycol
- Capable of achieving 99.9% control efficiency
- Suitable for exhaust streams with high concentration EtO
- Rule 1405 Testing Requirement:
  - One-time performance testing

Example Equipment Description

AIR POLLUTION CONTROL SYSTEM CONSISTING OF:

1. PACKED TOWER CHEMICAL SCRUBBER, CEILCOTE, MODEL NO. SPT-48-168, 4'-0" DIAMETER AND 23'-4" HIGH, WITH 14 FEET DEEP BED WITH NO. 1 TELLERETTE PACKING.

Example source test results

Average EtO Control Efficiency:	99.9

Source: environmental-experts.com

Peak Shaving

- A **peak shaver** is a packed tower scrubber that uses water to absorb EtO then strip off at a steady rate
- Capable of achieving 99.9% and above control efficiency in series with associated control device (e.g. catalytic oxidizer or dry bed scrubber)
- Suitable for exhaust streams with high concentration EtO
- Rule 1405 Testing Requirement:
  - Annual source testing

Example Equipment Description

Adsorb/Desorb Tank, "Peak Shaver", Anguil Environmental Systems Inc, Model No. SPT-42-120, 12"-0' DIA. X 26'-0" H., 7,000 Gallons Capacity, with a 20 HP Blower and Associated Pumps and Motors

Example source test results

TIME-WEIGHTED AVERAGE COMBINED CONTROL EFFICIENCY:	**99.97**

Source: anguil.com

Permanent Total Enclosure (PTE)

- A **PTE** is a total enclosure under negative air pressure with all air within enclosure vented to control device(s)
  - More comprehensive than hoods, side-draft, or down-draft collection methods
- Designed to capture all fugitive emissions
- Requires the use of additional control device to control emissions (e.g., catalytic oxidizer or dry bed scrubber)

Source: Google Earth

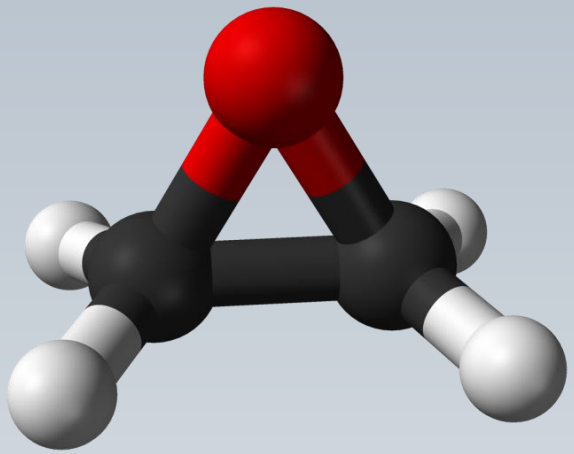
Summary of EtO Control/Capture Technologies

Technology	Control or Capture Efficiency	Suitable for high concentration EtO?	Rule 1405 Testing Frequency
Filtration	75% - 90% range	✗ aeration or post-aeration control only or if used in series	One-time performance testing
Catalytic Oxidation	95% and above		Annual source testing
Dry Scrubbing	95% and above		Annual source testing
Acid-water Scrubbing	99.9%	✓	One-time performance testing
Peak Shaving (with additional device)	99.9% and above	✓	Annual source testing
Permanent Total Enclosure	100%	Dependent on the control device that the PTE vents to	No current requirement

- Control technologies, as well as capture technologies are available to reduce stack and fugitive emissions
- Control devices operated in series could potentially result in higher control efficiencies
- Enhanced testing frequency or continuous monitoring of point sources could ensure proper operation of control devices

Working Group Meeting #2 Summary

- *Large* facilities account for almost all EtO usage in South Coast AQMD
- Ambient monitoring measurements to date identified elevated EtO levels near some *large* facilities
  - Elevated levels at off-site worker monitoring sites
  - EtO levels at nearby residential communities within typical background levels
- In addition to stack emissions, fugitive emissions could be a significant source of EtO
  - Potential sources of fugitive emissions: sterilization, aeration, post-aeration, storage of concentrated EtO, EtO-containing waste & byproducts
- Control technologies exist to further reduce EtO
  - Stack emissions could be further controlled beyond existing rule requirements (99-99.9%)
  - Fugitive emissions could be reduced by capture and control
- Control technologies and existing rule requirements will be evaluated to ensure proper operation of control devices and to further reduce EtO from point and fugitive sources



Next Steps

Working Group Meeting #3 (TBD)

Explore and develop rule concepts

Arrange site visits and meetings

Review submitted questionnaires

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