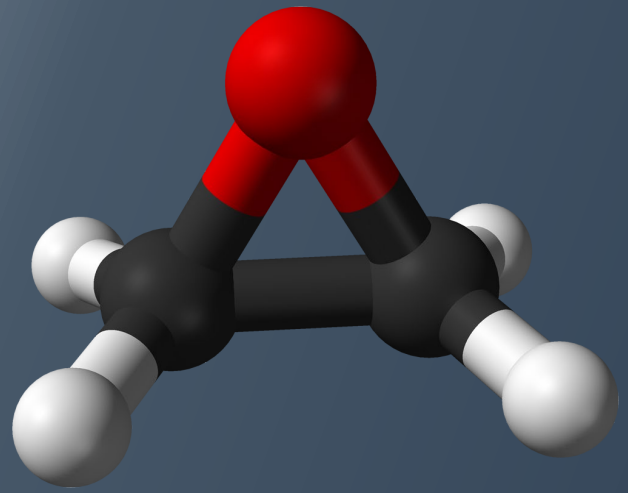
Working Group Meeting #4



Proposed Amended Rule 1405

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

January 17, 2023
1:00 PM

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

Dial In: (669) 900 6833

Meeting ID: 912 9361 3357

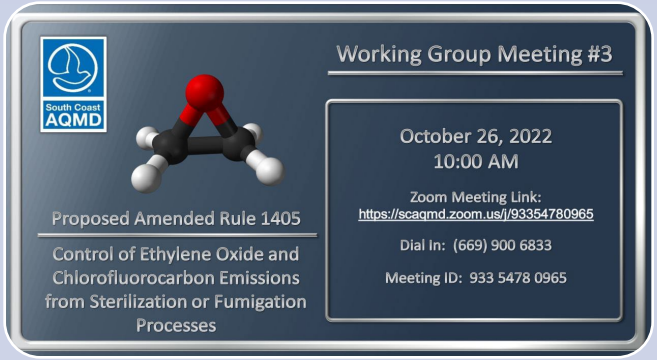
Recap from Working Group Meeting #3

- Sterilization and warehouse questionnaire results discussed
- Facility evaluations revealed regulatory gaps for stack and fugitive emissions:
  - High throughput and high inlet concentration to acid-water scrubbers result in elevated outlet emission concentrations
  - Lack of fugitive emission control requirements
  - Acid-water scrubbers conduct one-time source test only
- Case study facility in Illinois identified control technologies to further reduce EtO and requirements to quantify emissions
  - Control devices in series
  - Enclosure to reduce fugitives
  - Continuously monitor stack emissions

South Coast AQMD Staff Outreach

- Conducted site visits at large, medium, and small sterilization facilities
- Met with various stakeholders including manufacturers of controls and monitoring devices, staff from other regulatory agencies, and a medical device association
- Staff welcomes conversations with any stakeholder who would like to discuss PAR 1405

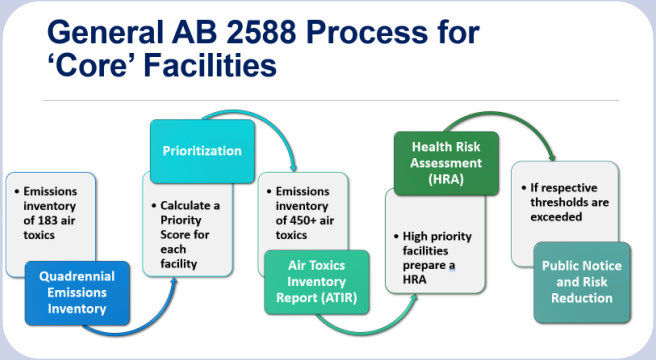
South Coast AQMD Approach to EtO Emissions



PAR 1405

General requirements that apply to industry to reduce EtO emissions

- Technology-based
- Reduce emissions using the best available technology achieved in practice



Rule 1402

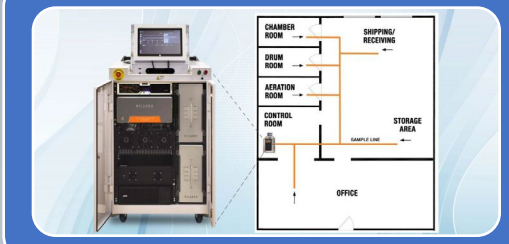
Facility-specific requirements to reduce risk to nearby receptors

- Risk to receptors determined by modeling
- Above and beyond rule requirements

Other Actions

- Ambient air monitoring
- Facility inspections
- Evaluations of process and control equipment
- Complaint investigations

PAR 1405 Overall Approach to EtO Emissions



Technology-Based

- State-of-the-art monitoring and control technologies
- Multiple pathways of compliance by different technologies

Achieved-in-Practice

- Reflecting operations and measures implemented at facilities
- Demonstrated at facilities in South Coast AQMD or elsewhere

Innovative Concepts

- Novel rule pathways to address stack and fugitive emissions recognizing different facility types and operations
- Continuous monitoring to ensure emissions are captured and controlled at all times

Agenda

- Rule Concepts – Introduction
- Rule Concepts – Stack Emissions
- Rule Concepts – Fugitive Emissions
- Rule Concepts – Other Requirements

Proposed Amended Rule 1405

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

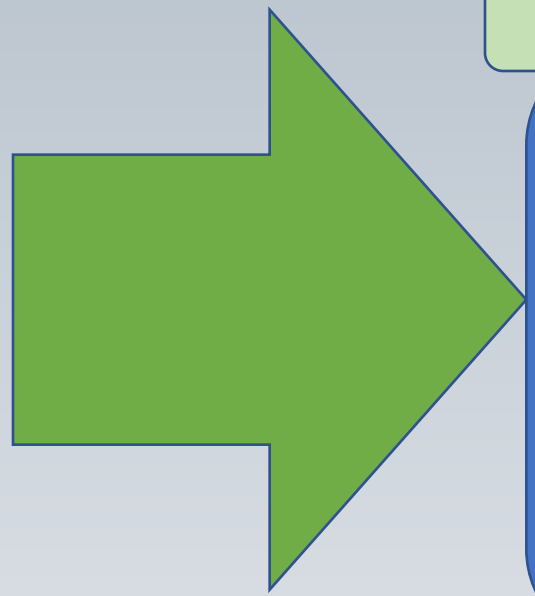
Rule Concepts: Introduction

Rule Structure – Background

- Rule 1405 was last amended in January 1991
- PAR 1405 would include key changes such as new, updated or enhanced requirements reflecting technological or scientific advancements

Current Rule 1405

a) Purpose
b) Applicability
c) Definitions
d) Requirements
e) Record Keeping
f) Test Methods
g) Exemptions



Proposed Amended Rule (PAR) 1405

- Update Applicability & Definitions
- Include new/enhanced requirements for
  - Stack emissions
  - Fugitive emissions
  - Monitoring
  - Reporting
  - Recordkeeping
- Update Test Methods

Update Definitions

Existing Definitions/Requirements

Aeration	Aeration-Only Facility
• Process during which residual EtO dissipates from sterilized material after sterilization cycle is completed • Completed when sterilized materials can be handled in same manner as similar materials that have not been sterilized by EtO	• Facility that performs aeration on materials that have been sterilized with EtO at another facility • Require installation of control equipment with an efficiency of ≥ 95% if emitting more than four pounds of EtO

Regulatory Gap

- After aeration is completed, EtO can continue to off-gas from sterilized materials

PAR 1405 Concept

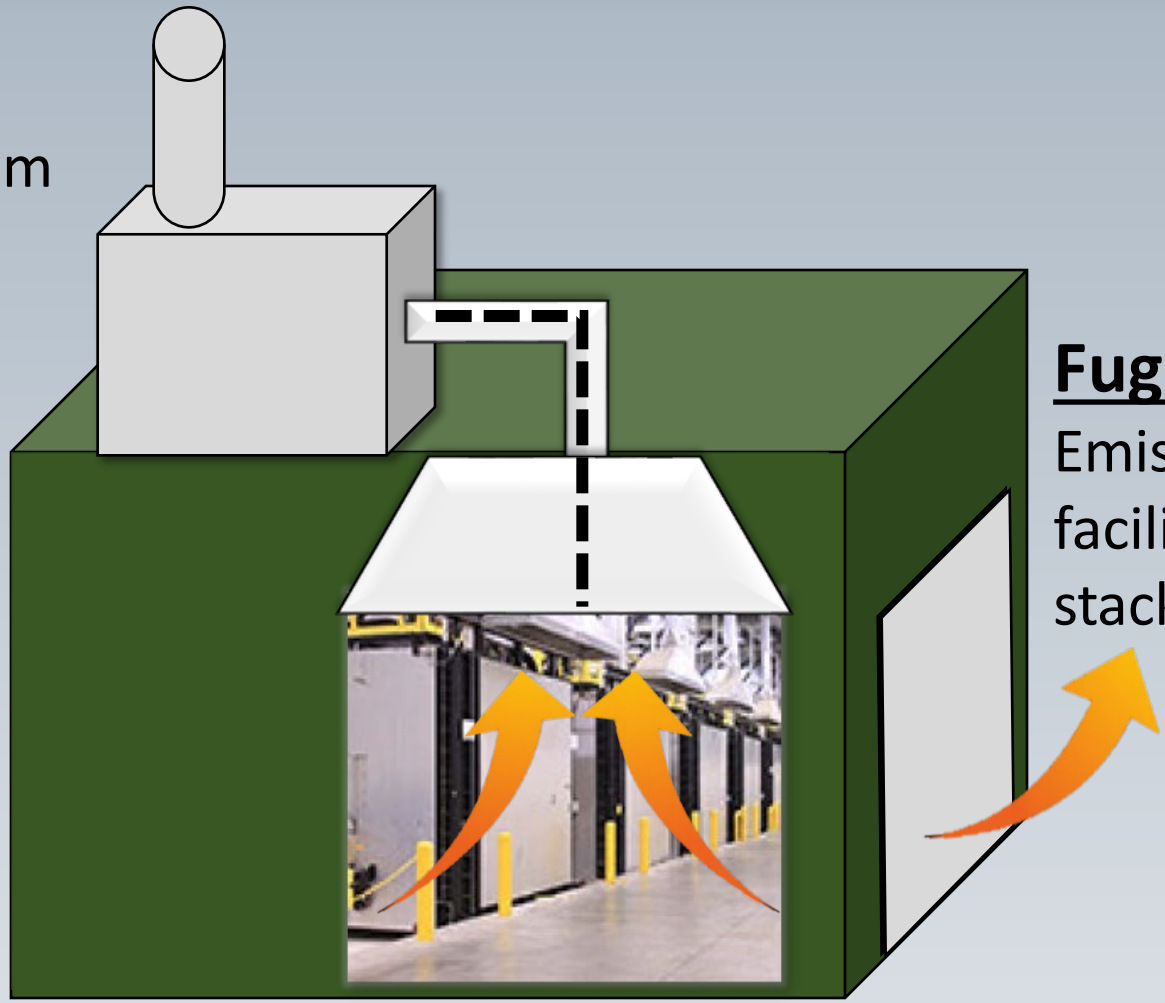
- Revise definition of aeration to be based on FDA approved aeration methods/cycles
- Add definition
  - Post Aeration: after completion of aeration
- Revise terminology of "Aeration-Only Facility" to "Post Aeration Storage Facility", defined as a facility that stores EtO-sterilized product which has been sterilized at another facility, does not operate a sterilizer, and has installed Air Pollution Control Device (APCD) to reduce EtO emissions

Definitions are still being developed and stakeholder feedback is welcomed

Facility Emission Sources – Background

Stack Emissions

Emissions originate from a fixed point, such as a stack



Fugitive Emissions

Emissions which escape facility, excluding exhaust stack emissions

Proposed Amended Rule 1405

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

Rule Concepts: Stack Emissions

Rule 1405 Stack Emissions – Background

Existing Requirement

Rule 1405 relies primarily on control efficiency as a performance standard and the required control efficiency for the Air Pollution Control Device (APCD) depends on:

- Usage of EtO at the facility
- Emission source (e.g., sterilization chamber)
- Type of facility

EtO Emission Sources Requiring Controls

Sterilizer – chamber or equipment where sterilization occurs
Aerator – room or equipment where residual EtO is removed from sterilized materials
Back-draft – equipment or system used for removal of EtO during unloading of sterilized material
Combined – multiple EtO emission sources exhausted to shared control equipment

Typically **higher** inlet concentrations

Quantity EtO Used	Sterilizer	Aerator	Back-draft	Combined
				
Large > 4,000 lbs	99.9%	99%	99%	99.8%
Medium 400 – 4,000 lbs	99.9%	95%	95%	99.6%
Small 4 – 400 lbs	99%	95%	Not required	98.8%
Aeration-only	Not applicable	95%	Not applicable	Not applicable

Typically **lower** inlet concentrations

New Stack Performance Standard Approach

Current Rule 1405

- Control efficiency is the main performance standard

Regulatory Gaps

- With high throughput and higher inlet concentration, stack outlet concentration can still be high
- With lower inlet concentrations, outlet concentrations could be below the level of detection, technologically limiting determination of control efficiency

PAR 1405 Approach

- Modifying throughput thresholds
- Address very high throughput concerns
- Address low outlet and detection limits
- Streamline performance standards

PAR 1405 Modifying Throughput Threshold(s)

- **Existing Requirement**: Rule 1405 currently requires the strictest control efficiency for EtO throughput over 4,000 lbs per calendar year
- **Regulatory Gap**
  - National Emission Standards for Hazardous Air Pollutants (NESHAP) is applicable for facilities using 2,000 or more pounds
  - California Air Resources Board's (CARB) Air Toxic Control Measures (ATCM) bifurcates requirements for facilities at 2,000 pounds
- **PAR 1405 Concept:** Modify throughput threshold from 4,000 lbs per calendar year to 2,000 lbs for the facilities requiring the strictest controls

Throughput	< 2000 lbs per year	2000-4000 lbs per year	> 4000 lbs per year
Rule 1405	Less strict control requirements		More strict control req.
PAR 1405	**Less strict control req.**	**More strict control requirements**	
ATCM	Less strict control req.	More strict control requirements	
NESHAP	Not applicable	Applicable	

Different Control Performance Metrics

Performance Standard	Definition	Units	Considerations
Control Efficiency (CE)	Ratio of quantity of emissions not released divided by quantity introduced	%	• Does not express how much of an air contaminant is emitted from a stack • May be difficult to express how effective a control device is if inlet concentrations are very low, resulting in outlet concentration below levels of detection
Emission Concentration	Amount of a pollutant in a volume	Parts per million (ppm) or parts per billion (ppb)	• Does not express how effective the control device is at reducing air contaminants • Does not express the total quantity or mass of air contaminants emitted and may be skewed by very high outlet air velocities
Mass Emission Rate	Amount of an air contaminant over a time interval	Pounds per hour (lb/hr)	• Does not express how effective the control device is at reducing air contaminants

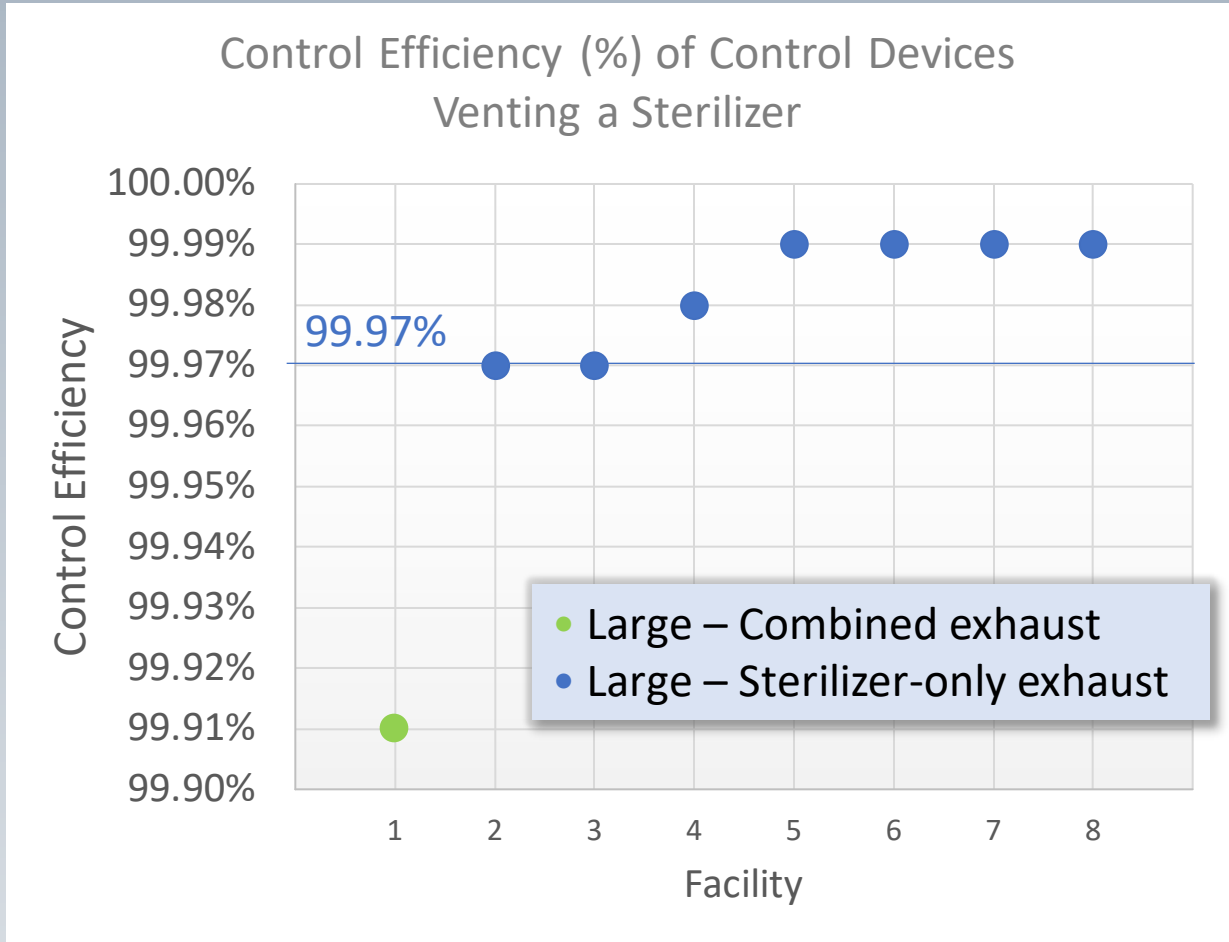
Source Testing – Background

- Source tests measure the amount of an air contaminant emitted and other operating parameters at time of testing
  - Usually conducted by 3rd party contractors
  - Follow specified protocols under typical or normal operating conditions in order to obtain accurate, representative results
- Detection tools or collection vessels set up to directly quantify emissions or to capture emissions for later laboratory analysis
  - Different instruments have different detection limits
- For EtO, stack emission concentration may be detected at 0.01 ppm (10 ppb) or lower by a variety of technologies:
  - Gas chromatography photoionization detector (GC-PID)
  - Fourier Transform Infrared (FTIR)
  - Cavity ring-down spectroscopy (CRDS)
  - Summa cannister sample collection with gas chromatograph-mass spectrometer analysis (GC-MS)

Control Efficiency – Large Facilities

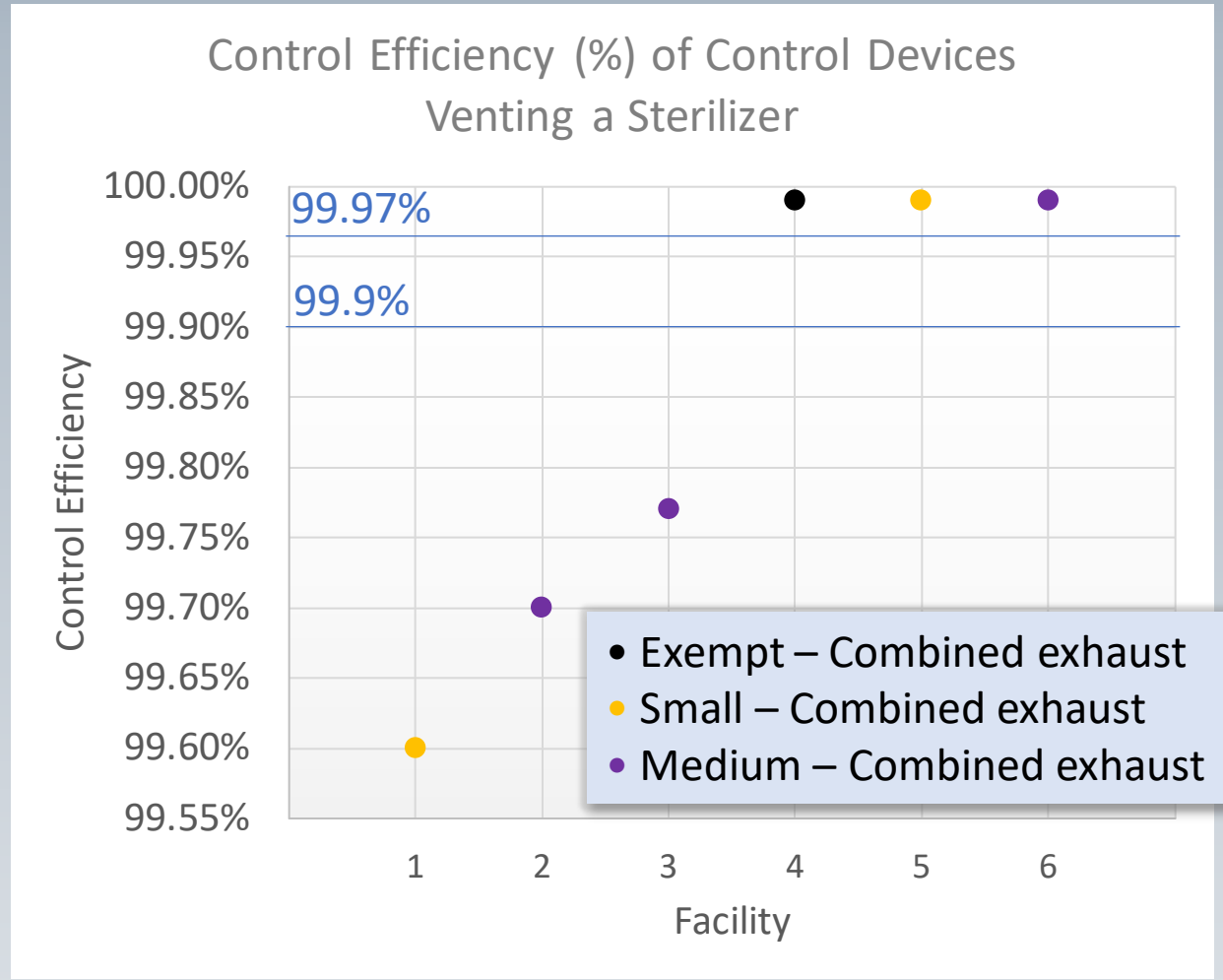
- 8 source test reports for Rule 1405 large facilities venting sterilizers were analyzed
  - 7 facilities meet or exceed 99.97% control efficiency
  - 1 facility did not meet 99.97% control efficiency
    - Reported the lower detection limit in source test results

Lower detection limit: Lowest value that can be determined by a specific method or technology



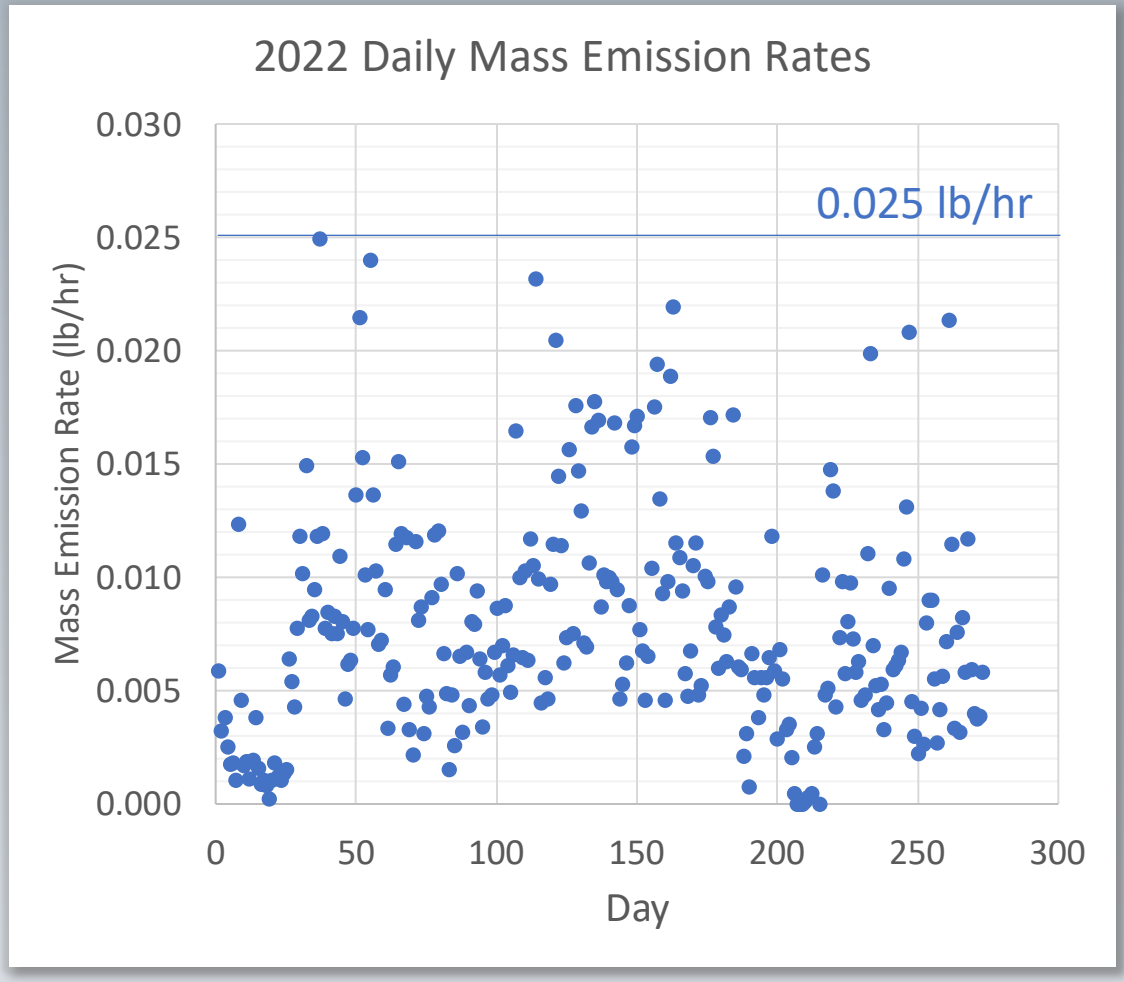
Control Efficiency – Medium/Small/Exempt Facilities

- 6 source test reports for Rule 1405 medium/small/exempt facilities venting sterilizers were analyzed
  - 3 facilities meet or exceed 99.97% control efficiency
  - 3 facilities did not meet 99.97% control efficiency
    - 1 facility reported the lower detection limit
    - 1 facility is approaching end-of-life of control device and considering replacement with new technology
- Manufacturers of all-in-one units indicate that a control efficiency of 99.9% can be achieved



Daily Monitoring Results – Mass Emission Rates

- WGM #3 presented the case study of Waukegan Facility, a sterilization facility located in Illinois
- Assessment of Waukegan facility's daily emission rates to determine an achievable mass emission rate
  - Mass emission rates obtained via continuous monitoring system and reported daily for one combined stack
- In 2022, highest hourly mass emission rate (daily average) was ~0.025 lb/hr
  - Lower mass emission rate demonstrated during source test, but not on continuous basis



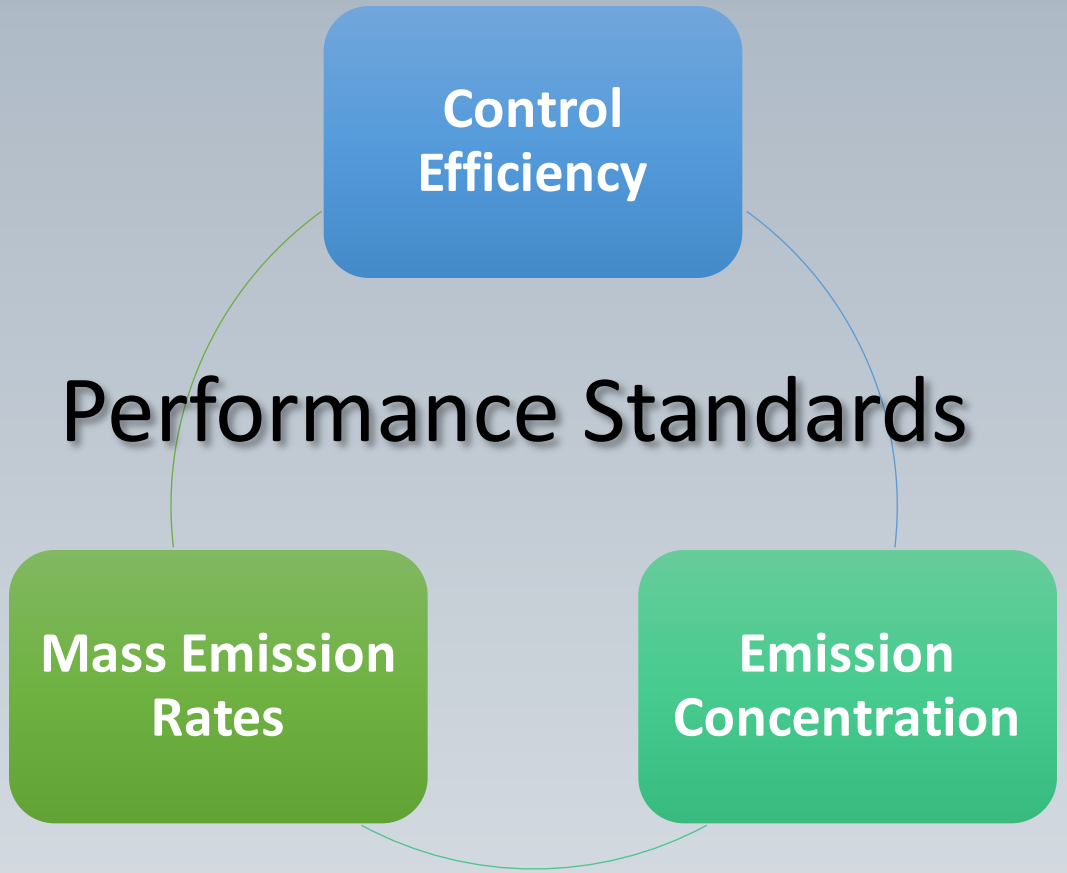
Source Test Results – Emission Concentration

- APCDs controlling aeration, back-vent, or post-aeration (non-sterilizers) typically have lower inlet concentrations compared to APCDs controlling sterilizers (chambers)
- 5 source test results for facilities with non-sterilizer APCDs were analyzed
  - All outlet concentrations reported as less than the level of detection: 0.01 ppm
  - 3 of these 5 did not meet 99.97% control efficiency

Example from Source Test A:
- Inlet concentration: 2.38 ppm EtO
- Outlet concentration: 0.01 ppm EtO (at detection limit)
- CE = (2.38 ppm – 0.01 ppm) / 2.38 ppm = 99.57%

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%

PAR 1405 Approach for Performance Standards



- Performance standards developed based on achieved-in-practice data from source testing or continuous monitoring
  - Uses a **combination** of control efficiency, emission concentration, and mass emission rates to limit EtO stack emissions
  - Data from US-based commercial sterilization facilities or by South Coast AQMD sterilization facilities
- PAR 1405 is **technology-neutral** with multiple control technology approaches and multiple source testing methodologies to demonstrate compliance with performance standards

Proposed Requirements - Source Test Performance Standards

Annual Permitted Throughput (lbs)*	Source Test Performance Standard	
	Facility-wide	Each Stack
> 2,000 (Large)	≤ 0.025 lb/hr	≥ 99.97% control efficiency **OR** ≤ 0.01 ppm
≤ 2,000 (Medium & Small)	No proposed amendment	≥ 99.9% control efficiency **OR** ≤ 0.01 ppm

Rule 1405 Stack Monitoring – Background

- **Existing Requirements:** Rule 1405 relies exclusively on source testing to monitor stack emissions, specifically control efficiency
  - Source testing, for some APCDs, is performed annually
  - For other types of APCDs, only one-time performance testing is required
  - Parameter monitoring of simultaneous inlet and outlet EtO concentration measurement required during source testing
- **Regulatory Gaps**
  - Annual source testing not required for all APCDs
  - Source tests represents normal operating conditions
  - No requirement to monitor EtO concentration or control device performance between source tests

Source: picarro.com

PAR 1405 Approach for Source Testing

Proposed Requirements

- Submit a source test protocol to South Coast AQMD to be approved prior to conducting a source test
- Report to South Coast AQMD when a source test will occur and if the testing schedule changes
- Conduct a source test for each APCD controlling EtO emissions that meets the following requirements:
  - No less than once per calendar year
  - Tested at permitted operating conditions
  - Tested pursuant to CARB Test Method 431 or an acceptable source test method approved by South Coast AQMD
    - Allow use of South Coast AQMD sampling method with U.S. EPA Method TO 15 and 15A for canister sampling during source testing
- Submit source test report to South Coast AQMD within 90 days of completing the source test

Continuous EtO Monitoring – Background

At least 4 different EtO monitoring technologies in various applications in South Coast AQMD or in other jurisdictions

1) Gas chromatography photoionization detector (GC-PID)
   - Used in South Coast AQMD and elsewhere for emission stack source testing and indoor ambient EtO detection for worker protection

2) Fourier Transform Infrared (FTIR)
   - Implemented at Illinois case study facility at emission stack to demonstrate compliance with emission limits
   - Passed Relative Accuracy Test Audit (RATA) in 2020

3) Cavity ring-down spectroscopy (CRDS)
   - In use at Puerto Rico sterilization facility for indoor ambient EtO detection for worker protection

4) AROMA-ETO
   - No known implementations at present

PAR 1405 Approach for Continuous Monitoring

- **Intent:** To ensure APCDs working properly, consistent with source test records, at all times for facilities with large throughput
- **Proposed Requirements**
  - Large facilities: Monitor continuously the outlet of APCD(s) controlling EtO emissions to verify compliance with mass emission rate or concentration limit
- **Feasibility**
  - Different EtO monitoring technologies exist to continuously monitor EtO stack concentration
    - Continuous stack emission monitoring achieved in practice in at least one facility, Illinois case study facility, using FTIR technology
  - GC-PID uses an approved method to continuously monitor EtO
  - U.S. EPA currently evaluating real-time monitors for continuous EtO measurements

Summary of Proposed Requirements for Stack Emissions

Annual Permitted Throughput (lbs)*	Facility-wide Performance Standard	Demonstrated by:		Stack Performance Standard	Demonstrated by:	
		Annual Source Test	Continuous Monitoring		Annual Source Test	Continuous Monitoring
> 2,000 (Large)	≤ 0.025 lb/hr	✓	✓	≥ 99.97% control efficiency	✓	Not required
				OR ≤ 0.01 ppm	✓	✓
≤ 2,000 (Medium & Small)	No proposed amendment	Not applicable		≥ 99.9% control efficiency **OR** ≤ 0.01 ppm	✓	Not required

Proposed Amended Rule 1405

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

Rule Concepts: Fugitive Emissions

Fugitive Emissions - Background

- In Working Group Meeting #3, fugitive emissions were identified as a key potential source of emissions at facilities in South Coast AQMD
- **Existing Requirements**
  - Bi-annual leak checks of EtO at sterilizers, aerators, control equipment, and emission collection systems,
  - Leak is ≥ 10 ppm EtO
- **Regulatory Gaps**
  - Working Group Meeting #3 identified other potential sources not included to be checked for leaks
  - Fugitive emissions are currently addressed through prevention; no requirements to capture and control
  - For leak detection, most hand-held devices measure all VOCs or total organic compounds (TOC) but not EtO

Source: gasdetectionwarehouse.com

Assessment of EtO Areas and Processes

- In previous Working Group Meetings, different processes and areas were identified as potential direct sources of fugitive emissions
- EtO levels detected in preconditioning areas, caused by migration of EtO emissions from other areas
- Locations of direct sources of EtO fugitive emissions:
  - Indoors: Sterilization, aeration, and storage/transport of EtO-sterilized materials, concentrated EtO, and EtO-containing waste
  - Outdoors: Control equipment, concentrated EtO, and EtO-containing byproducts

Source: sterisys.eu

Source: anguil.com

Control Options – LDAR vs Enclosure

Leak Detection and Repair (LDAR)

Key elements:

- Periodic inspections to identify leaks
- Operator performs repairs or replacement of equipment to prevent the release of fugitive emissions

Advantages:

- Minimal modifications and equipment required
- Feasible to implement in most environmental conditions (e.g., outside, confined space)

Disadvantages:

- Until repairs or replacements are conducted, fugitive emissions are emitted

Enclosure

Key elements:

- Enclose areas and/or processes that are sources of fugitive emissions
- Enclosure is under negative air pressure and vented to an Air Pollution Control Device (APCD)

Advantages:

- Fugitive emissions are captured and controlled

Disadvantages:

- Modification/construction of building and installation of control equipment required
- Not feasible to implement for certain situations (e.g., away from power)

Rule Concept – LDAR Program

- **Proposed Requirements**
  - Submit and maintain a plot-plan report that identifies components to be periodically inspected
  - Implement LDAR program by:
    - Conducting daily audio-visual leak checks of components
    - Conducting monthly leak inspections of components for leaks of TOC (surrogate for EtO)
      - Hand-held devices typically measure TOC/VOC
      - More frequent than other rules that require a periodic inspection of components
- **Performance Standard**
  - Leak threshold: 2 ppm TOC
    - Lower than other rules

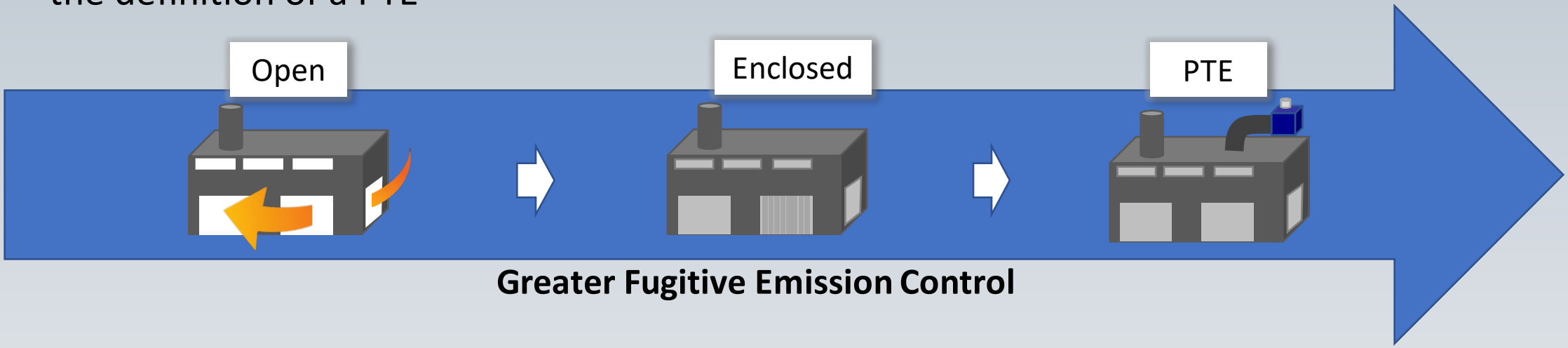
Source: gasdetectionwarehouse.com

KEY CONCEPT:

TOC (**T**otal **O**rganic **C**ompounds) means the concentration of gaseous organic compounds determined using U.S. EPA Method 21

Enclosure Strategy - Background

- As discussed in Working Group Meeting #3, the Waukegan facility modified their building airflows and internal features such that all emissions of EtO occur within an enclosure with negative air pressure and routed to an APCD, referred to as Permanent Total Enclosure (PTE)
- Other South Coast AQMD Rules require the use of an enclosure to prevent the release of toxic air contaminants
  - Different construction requirements minimize or control fugitive emissions to varying degrees
  - An enclosure under negative air pressure provides the greatest fugitive emission control
- U.S. EPA's Method 204 specifies construction, operation, and design requirements to meet the definition of a PTE



Rule Concept – Enclosure

- **Proposed Requirements**
  - Install and implement a PTE that meets the requirements specified in U.S. EPA Method 204:
    - Location of natural draft openings in relation to emission sources
    - Limits on natural draft openings surface area for walls, floor, and ceiling
    - Doors and windows closed during routine operations
    - All EtO emissions captured and vented to APCD
  - Periodically measure inward face velocity at all natural draft openings
  - Continuously monitor and record negative pressure
- **Performance Standard**
  - Inward face velocity: At least 200 feet per minute (fpm) at all natural draft openings
  - Negative pressure: At least 0.007 inches of water column, averaged over a 1-hour period
    - Indicates an air flow into the PTE

Source: grainger.com

Source: dwyer-inst.com

Assessment of Facility Operations

Large Facility

- Products sterilized with multiple layers of packaging and wooden pallets in chamber
- Products move from sterilizer to aerator/aeration room for separate aeration phase
- Multiple areas and processes have the potential to be sources of EtO fugitive emissions

Small/Medium Facility

- Sterilized with minimal packaging materials in chamber
- All identified facilities use “all-in-one” units, capable of performing aeration in a single sterilizer/aerator chamber
- Fewer areas and processes are potential sources of EtO fugitive emissions

Rule Concept – Fugitive Emission Approach

- Considerations for Control Options
  - Prioritizes the capture and control of fugitive emissions to prevent release, but considers the potential of emissions and feasibility of implementation
  - In cases where feasibility is an issue, LDAR could potentially be an alternative approach, if applicable
  - For areas with uncertain levels of EtO emissions, monitoring would quantify EtO levels
- Considerations for Applicability
  - Permitted throughput
  - Establishes fugitive emission requirements for specific processes or areas

Processes/Areas	Proposed Requirements
Control Equipment	LDAR due to feasibility
Sterilization and aeration	PTE if not performed in same chamber
Storage/transport of sterilized product	PTE for high EtO throughput (large); indoor monitoring if EtO throughput is moderate (medium) or for post aeration storage facilities
Storage/transport of EtO and EtO-containing byproducts/waste	PTE for large facilities, indoor monitoring for medium facilities, and LDAR for small facilities
Shipping area	Indoor monitoring for large facilities

Indoor EtO Monitoring – Background

- **Background**
  - Several sterilization facilities continuously monitor indoor EtO levels for worker protection or safety
    - Large facilities – monitoring in different areas/rooms
    - Medium facilities – EtO sterilization constitutes a small building footprint, monitoring typically in sterilization rooms only
    - Detection limits vary dependent on the monitoring technology
- **Existing Requirement**
  - Rule 1405 does not currently require indoor EtO monitoring
- **Regulatory Gap**
  - Some processes or areas may be potential sources of fugitive EtO emissions, but are currently uncontrolled and unmonitored

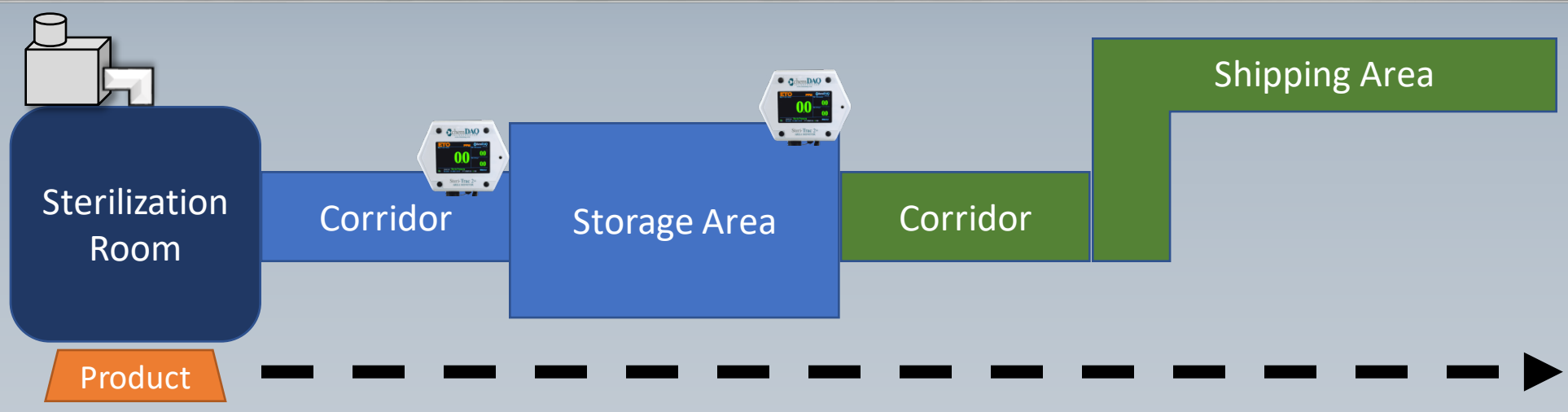
Source: srigc.comc

Rule Concept – Indoor EtO Monitoring

- **Proposed Requirements**
  - For areas not in a PTE with potential emissions, install an indoor EtO continuous monitoring device
  - Areas that are downstream of monitored areas not exceeding the performance standard would be exempt from monitoring (see example in upcoming slide)
- **Performance Standard**
  - For areas required to be monitored, indoor concentration to be below 0.1 ppm EtO, averaged over a 24-hour period

Source: chemdaq.com

Indoor EtO Monitoring Example



- Sterilization room emissions are captured and controlled via a PTE
- Corridor and storage area are monitored
- If EtO levels are below the indoor EtO monitored performance standard in the corridor/storage area (in blue), downstream areas (in green) are not subject to monitoring or controls to address fugitive emissions
  - No measurable amount would be detected as rate of dissipation decreases over time

Summary of Proposed Requirements for Fugitive Emission Control

EtO Throughput (lbs)	PTE	*If processes or areas not under PTE*	
		LDAR	Indoor Monitoring
> 2,000 (Large)	**REQUIRED FOR:** Sterilization, aeration, and storage/transport of EtO-sterilized materials, concentrated EtO, and EtO-containing byproducts and wastes	**REQUIRED FOR:** Control equipment	**REQUIRED FOR:** Shipping area
400-2000 (Medium)	**PTE NOT REQUIRED IF:** Aeration completed in combination sterilizer/aerator "all-in-one" unit **IF AERATION IS NOT COMPLETED IN "ALL-IN-ONE" UNIT, PTE REQUIRED FOR:** Sterilization and aeration	**REQUIRED FOR:** Sterilizers, aerators, and control equipment	**REQUIRED FOR:** EtO-sterilized materials, concentrated EtO, and EtO-containing byproducts and wastes
4-400 (Small)		**REQUIRED FOR:** Sterilizers, aerators, control equipment, EtO-sterilized materials, concentrated EtO, and EtO-containing byproducts/wastes	**NOT REQUIRED**
Post Aeration Storage Facility	**NOT REQUIRED**	**REQUIRED FOR:** Control equipment	**REQUIRED FOR:** EtO-sterilized materials

Proposed Amended Rule 1405

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

Rule Concepts – Other Requirements

Rule Concepts – Other Requirements

- Since Rule 1405 was last amended in 1991, significant scientific and technological changes have occurred, requiring adding, removing, or updating various requirements throughout the rule

Other Requirements for Sterilization Facilities

- Prohibitions
- Recordkeeping
- Labeling

Requirements for Warehouses

Prohibitions – Uncontrolled Emissions

- **Background**
  - Rule 1405 does not address events of potential EtO uncontrolled releases such as power failures
  - Best management practices at several facilities currently include backup power, interlock systems, or spare parts onsite
- **Concept**
  - PAR 1405 would prohibit the uncontrolled release of EtO at all times
  - Each facility to develop their own strategy to comply with prohibition
- **Proposed Requirements**
  - Prohibit the uncontrolled release of EtO at all times
  - Prohibit the storage of EtO-sterilized materials outdoors
  - Require backup power for all EtO monitoring systems
    - Ensures emissions are monitored even during loss of power

Source: bhphotovideo.com

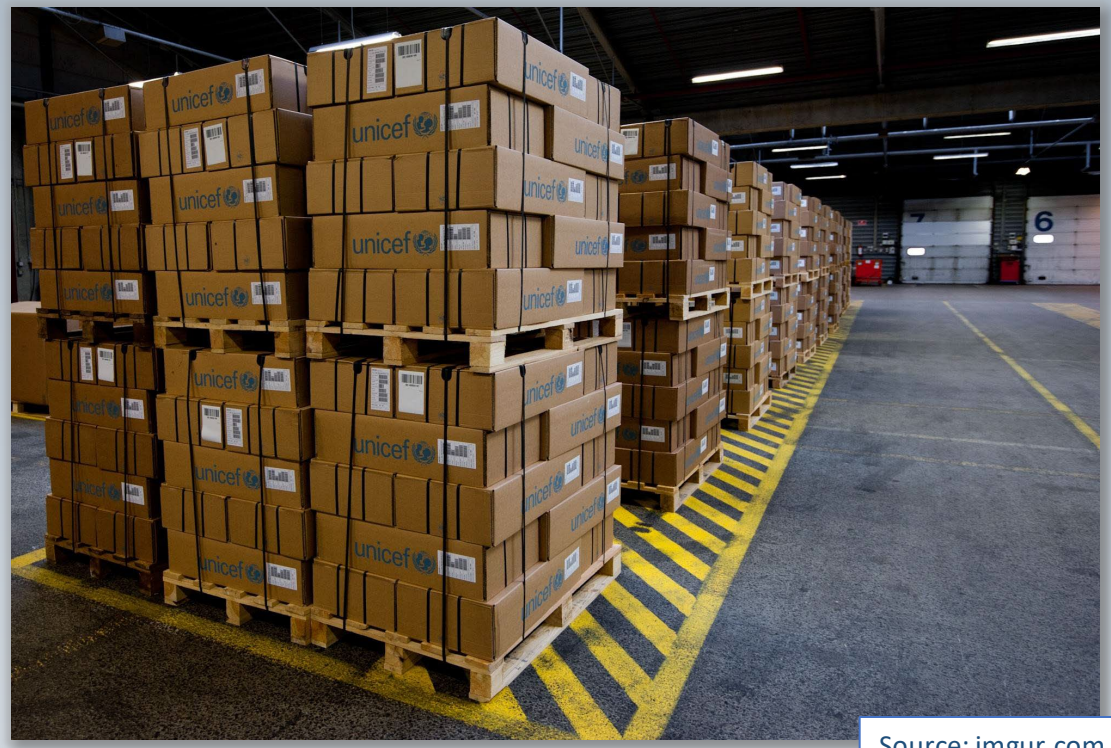
Source: reactpower.com

Recordkeeping

- **Existing Requirements**
  - Records of leak checks
  - Daily cycle and poundage records
  - Annual EtO purchase and usage records
- **Regulatory Gap:** Does not require other records maintained onsite to demonstrate compliance with Rule 1405
- **Proposed Requirements**: Additional records to be kept onsite, including:
  - Source test reports
  - Continuous monitoring data for stack emissions and indoor EtO monitoring
  - Periodic inward face velocity and continuous negative pressure measurements for PTE
  - Other documents to demonstrate compliance with Rule 1405

Labeling

- **Background**
  - Warehouses are potential source of EtO emissions as EtO can continue to off-gas from stored product
  - No enhanced EtO signals detected to date near warehouses
- **Regulatory Gap**
  - Lack of data to determine emission potential from warehouses that receive EtO sterilized product
  - Warehouses may be unaware if receiving EtO-sterilized products
- **Proposed Requirements**
  - Label pallets packages of EtO-sterilized products (i.e. one label per pallet/package)
  - Maintain records of warehouses locations receiving EtO-sterilized products



Source: imgur.com

Warehouses – Background

- **Background**
  - Warehouses are potential source of EtO emissions as EtO can continue to off-gas from stored product
    - No enhanced EtO signals detected to date near warehouses
  - Limited data from warehouses and storage facility
  - Potential emissions difficult to determine and depend on time since sterilization, volume of products stored, and duration of storage
- **Existing Requirement**
  - Rule 1405 requires "aeration-only facility" emitting more than 4 lbs of EtO per year to control emissions
  - One active facility classified as an aeration-only facility
- **Regulatory Gap**
  - No existing requirements targeting storage of EtO sterilized products for warehouses


Georgia EPD Continues Oversight of Becton, Dickinson and Company; Issues Notice of Air Quality Rules Violation for Global Distribution Center

DECEMBER 18, 2019

Source: https://epd.georgia.gov/press-releases/2019-12-18/georgia-epd-continues-oversight-becton-dickinson-and-company-issues

Warehouses – Approach

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Data Collection

- Recognize that storage of EtO-sterilized products could be a potential source of emission, and expand applicability to include certain storage facilities
- Collect data for warehouses with potential of EtO emissions

Potential Future Actions

- Emission Assessment
- Monitoring
- Rulemaking

Warehouses – Proposed Rule Concepts

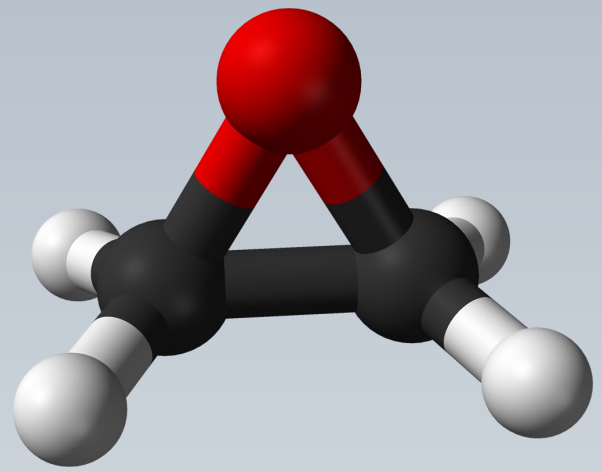
- **Applicability**
  - Warehouses 100,000 square feet and larger registered with U.S. FDA as Wholesale Drug Distributors or Third-Party Logistics Providers and store EtO-sterilized products
  - Warehouses identified by the Executive Officer (largely based on records from sterilizers)
  - Excluding end users, such as hospitals or other facilities that provide healthcare to people or animals
- **Proposed Requirements**
  - Maintain records of the number of pallets of EtO-sterilized products received
  - Submit a report on the number of pallets of EtO-sterilized products for the first applicable year
    - Submit report for a subsequent year when the number of pallets per year has increased by more than 10% of the most recently submitted report

KEY CONCEPT:

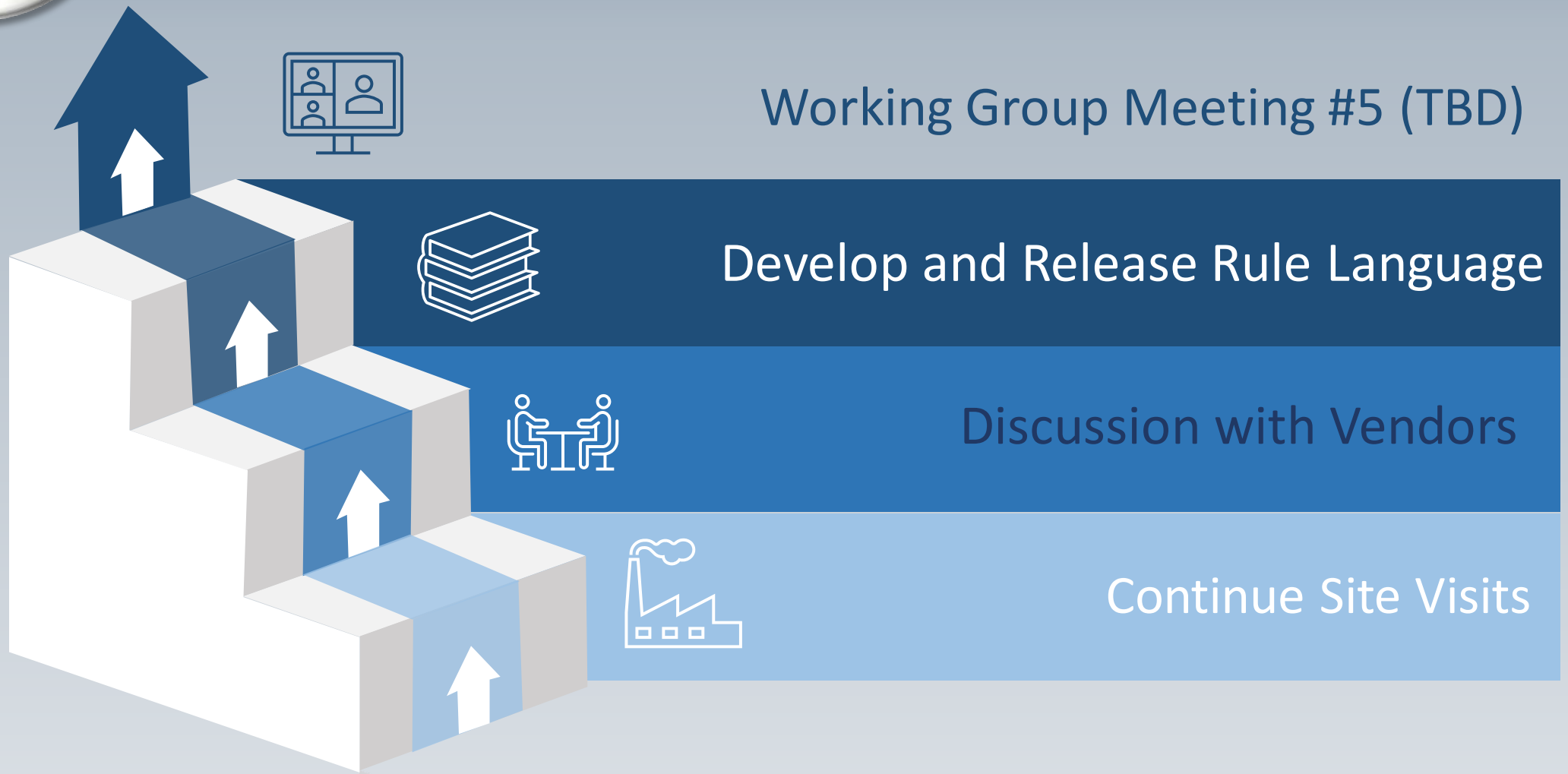
- Warehouse means a building that stores cargo, goods, or products on a short- or long-term basis for later distribution to businesses and/or retail customers.

Summary of Working Group Meeting #4

- Key rule concepts proposed for:
  - Stack emissions
  - Fugitive emissions
  - Prohibitions
  - Recordkeeping
  - Labelling
  - Warehouses
- Continuous monitoring proposed for stack emissions, certain indoor areas and permanent total enclosure
- Proposed rule concepts are based on best available control technologies achieved-in-practice, considering feasibility and different facility operations



Next Steps


Working Group Meeting #5 (TBD)
Develop and Release Rule Language
Discussion with Vendors
Continue Site Visits

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