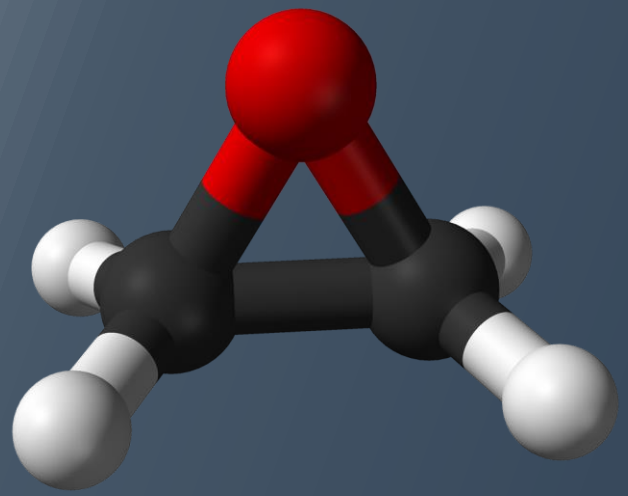
Working Group Meeting #3



Proposed Amended Rule 1405

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

October 26, 2022
10:00 AM

Zoom Meeting Link:
https://scaqmd.zoom.us/j/93354780965

Dial In: (669) 900 6833

Meeting ID: 933 5478 0965

Recap from Working Group Meeting #2

- EtO Facilities
  - Large facilities (permitted by South Coast AQMD to use more than 4,000 lbs of EtO per year) accounted for more than 99% of EtO usage
  - Offsite workers are the closest receptors to large facilities
- EtO Monitoring Efforts and Findings
  - Mobile measurements conducted near 11 sterilization facilities
  - Enhanced EtO signal, confirmed by time integrated ambient air samples, showed elevated EtO levels near 4 facilities (3 locations)
- Sterilization Process and Emission Sources
  - Identified potential sources of point and fugitive emissions
- EtO Control/Capture Technologies
  - Technologies exist to reduce point and fugitive emissions

Key Comments and Responses

RESPONSES

Comment #1
Other EtO emission sources

- 10 non-sterilizing facilities reported EtO emissions
  - 9 facilities emit 0.1 lbs or less
  - 1 facility reported about 10 lbs EtO emissions in 2021; the facility is subject to Rule 1173 and Rule 1141.2
- Rule 1405 facilities accounted for 98% of EtO emitted (2021 Annual Emissions Reporting data)

Comment #2
Methods to control fugitive emissions

- Staff is considering all approaches in addressing fugitive emissions
- "Double doors", also known as vestibules, are a compliance option in some rules, e.g., Rule 1469 regarding chrome plating

Comment #3
Environmental impacts of control devices

- Environmental impacts of proposed amendments will be evaluated under CEQA as part of the rule development process

Agenda

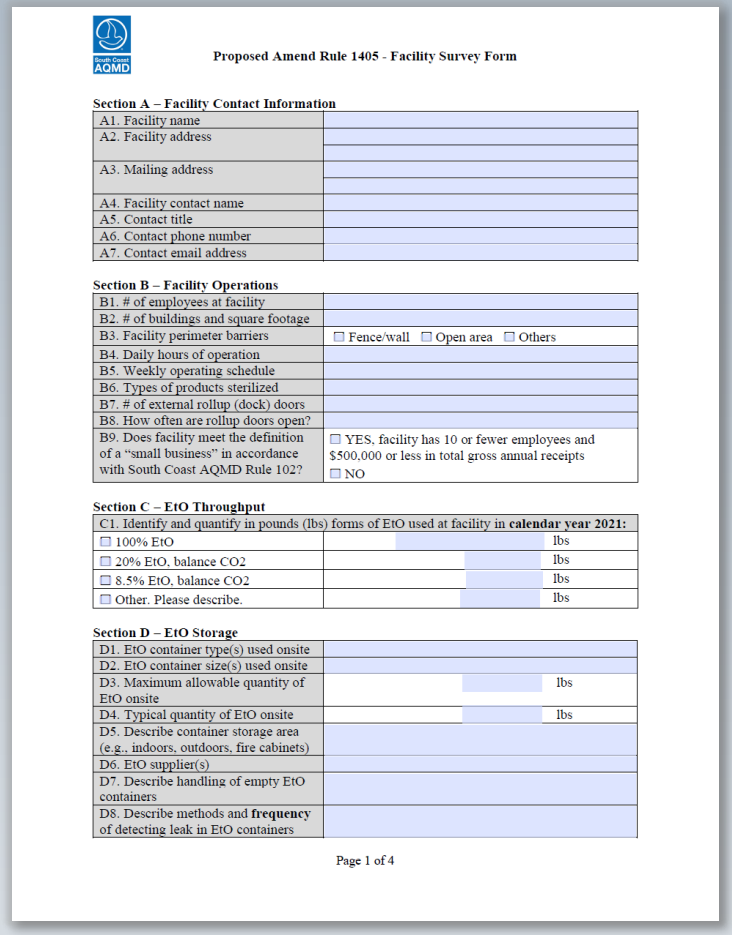
- Questionnaire Results
  - Sterilization Facility • Aeration Only/Warehouse Facility
- Facility Profiles & Evaluations in South Coast AQMD
- Other EtO Regulatory Requirements
  - Case Study in Illinois

Proposed Amended Rule 1405

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

Questionnaire Results for Sterilization Facilities

Background – Sterilization Facilities



Proposed Amend Rule 1405 - Facility Survey Form

Section A – Facility Contact Information

A1. Facility name	
A2. Facility address	
A3. Mailing address	
A4. Facility contact name	
A5. Contact title	
A6. Contact phone number	
A7. Contact email address	

Section B – Facility Operations

B1. # of employees at facility	
B2. # of buildings and square footage	
B3. Facility perimeter barriers	☐ Fence/wall ☐ Open area ☐ Others
B4. Daily hours of operation	
B5. Weekly operating schedule	
B6. Types of products sterilized	
B7. # of external rollup (dock) doors	
B8. How often are rollup doors open?	
B9. Does facility meet the definition of a "small business" in accordance with South Coast AQMD Rule 102?	☐ YES, facility has 10 or fewer employees and $500,000 or less in total gross annual receipts ☐ NO

Section C – EtO Throughput

C1. Identify and quantify in pounds (lbs) forms of EtO used at facility in **calendar year 2021:**	
☐ 100% EtO	lbs
☐ 20% EtO, balance CO2	lbs
☐ 8.5% EtO, balance CO2	lbs
☐ Other. Please describe.	lbs

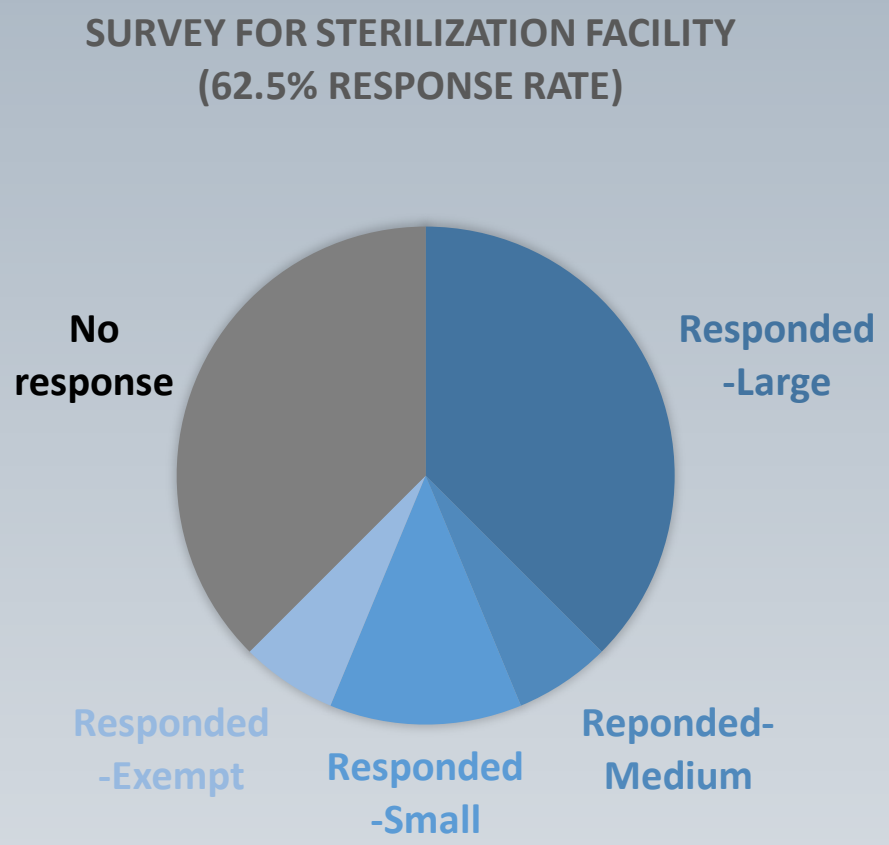
Section D – EtO Storage

D1. EtO container type(s) used onsite	
D2. EtO container size(s) used onsite	
D3. Maximum allowable quantity of EtO onsite	lbs
D4. Typical quantity of EtO onsite	lbs
D5. Describe container storage area (e.g., indoors, outdoors, fire cabinets)	
D6. EtO supplier(s)	
D7. Describe handling of empty EtO containers	
D8. Describe methods and **frequency** of detecting leak in EtO containers	

Page 1 of 4

- In early September, to better understand each facility's unique operations, a questionnaire/survey was sent to each sterilization facility
- 16 active sterilization facilities subject to Rule 1405 in South Coast AQMD were sent surveys
  - Permitted throughputs range from less than 4 lbs to about 1,300,000 lbs of EtO per year, representing a wide range of facility types

Sterilization Facility - Survey Response



Rule 1405 Category (permit limit)	Total	Response Received	No Response
Large (> 4,000 lbs)	7	6	1
Medium (400 - 4,000 lbs)	3	1	2
Small (4 - 400 lbs)	3	2	1
Exempt (< 4 lbs)	3	1	2
Overall	16	10	6

Note: Facilities categorized based on permitted throughput limit

Sterilization Facility – Sterilization Procedures

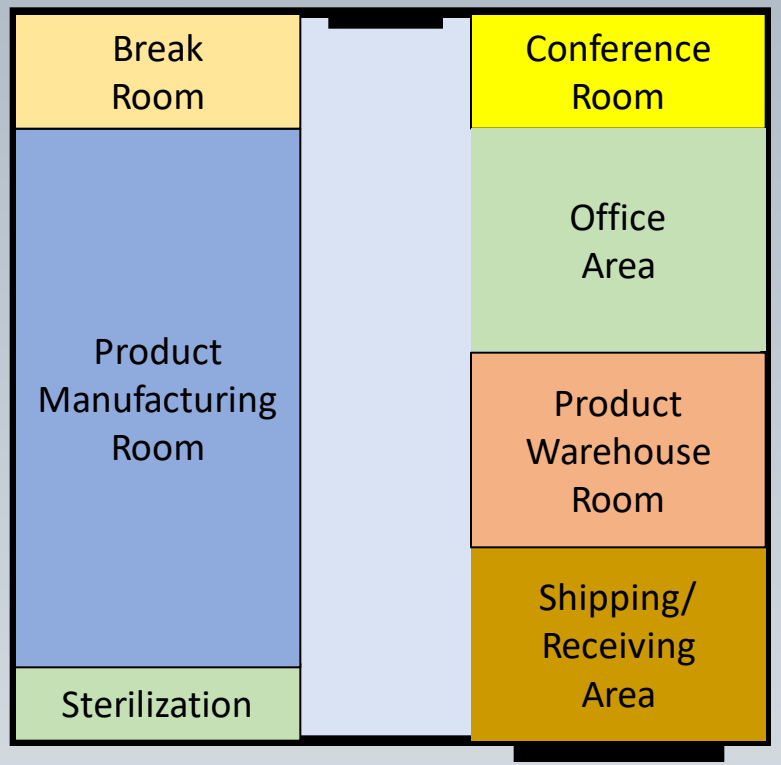
- Among the 6 large facilities that responded
  - All 6 facilities perform aeration in a separate room, equipment, or area from sterilization chambers
- All 4 exempt/small/medium-sized facilities that responded to questionnaire utilize chambers with integrated aeration process (i.e., table top/all-in-one units)
  - Products sterilized and aerated in a single sealed chamber

Source: sterility.com

Source: 3M.com

Sterilization Facility – Building Footprint

Example manufacturing facility



- Of the 6 large facilities that responded
  - 5 large facilities have a majority of the building footprint devoted to sterilization processes (preconditioning, sterilization, aeration, storage of sterilized products)
    - Different sterilization processes occur either in separate areas/units in one building or in separate buildings
  - 1 large facility is a medical device manufacturer and uses a small fraction of their total building footprint for EtO sterilization
- Of the 4 exempt/small/medium-sized facilities that responded
  - A small fraction of building footprint is used for sterilization
  - Most of the building floor is used for other activities (i.e., medical manufacturing, surgical, veterinary, educational)

Sterilization Facility – Monitoring

Of the 10 facilities that responded:

- 8 conduct EtO monitoring
  - Includes continuous indoor monitoring, safety detectors, handheld monitors, or dosimeters
- 5 of 6 large facilities have continuous indoor EtO monitoring using gas chromatography
  - Remaining facility currently adding a continuous indoor monitoring system

Section K – Monitoring of EtO

K1. Identify methods of EtO area monitoring and describe their implementation		
☐ Handheld EtO detector	# available onsite	
	Alarm setpoints	
	Frequency	
☐ Combustible gas monitors	# of monitoring sites	
	Alarm setpoints	
	Frequency	
	Location of monitors	
☐ Gas chromatography (GC) monitoring	# of monitoring sites	
	Alarm setpoints	
	Frequency	
	Location of monitors	
☐ Canisters	Contractor(s) used	
	Frequency	
☐ Other. Please describe.		

Sterilization Facility – Backup Power

Source: reactpower.com

Source: bhphotovideo.com

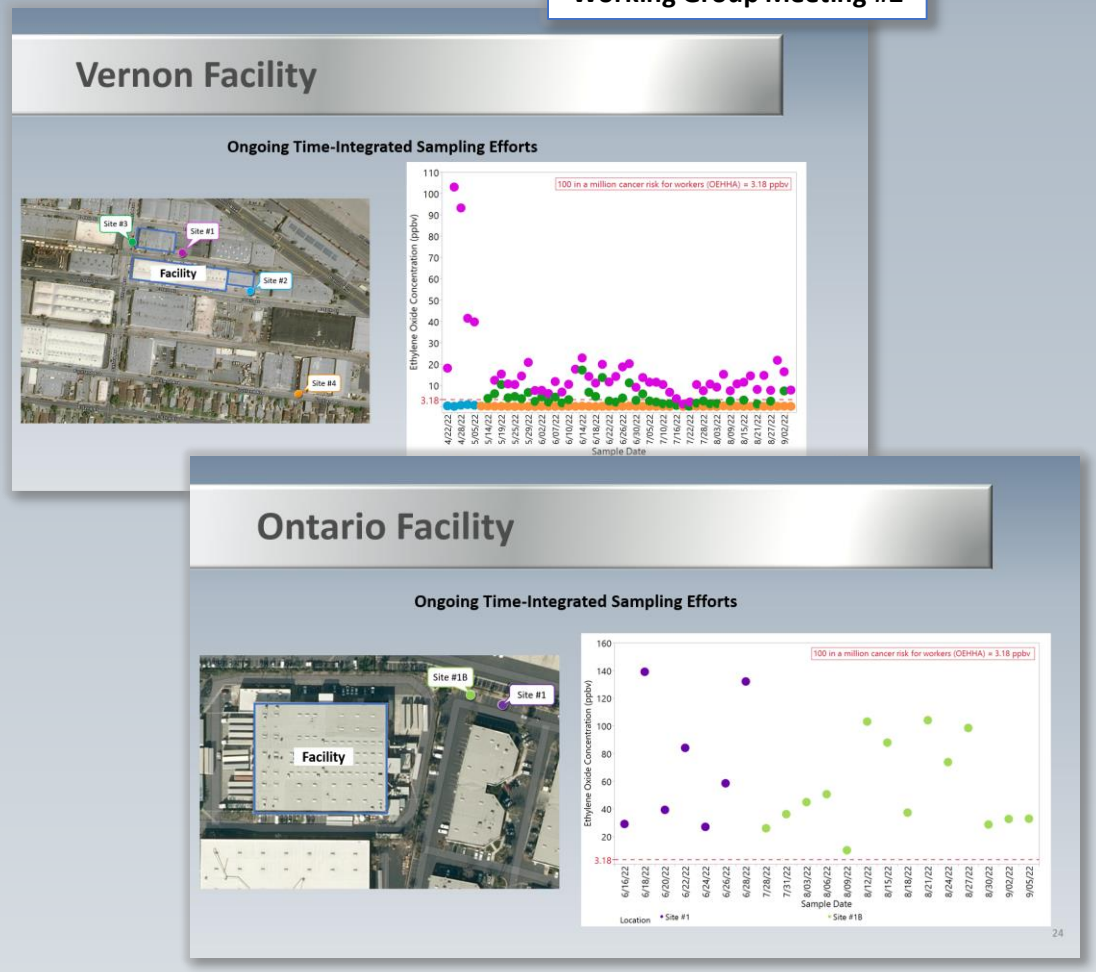
- Of the 10 facilities that responded to the questionnaire, 6 facilities reported having one or more form of backup power on site:
  - Emergency generators
  - Battery backup systems
- These backup systems are reported to support some components, including:
  - Computer controls and control rooms
  - Air monitoring systems
  - Air pollution control devices, like peak shavers or catalytic oxidizers
  - Sterilizer critical functions
  - Table-top sterilizer/aerator units

Sterilization Facility – EtO Storage

Working Group Meeting #2

Of the 10 facilities that responded to the questionnaire:

- 7 facilities store EtO indoors, some with additional secondary control
- 3 facilities store EtO outdoors, typically without secondary control
  - The 3 facilities that store EtO outdoors are the Vernon location (2 facilities) and the Ontario location (1 facility), both associated with elevated ambient EtO levels



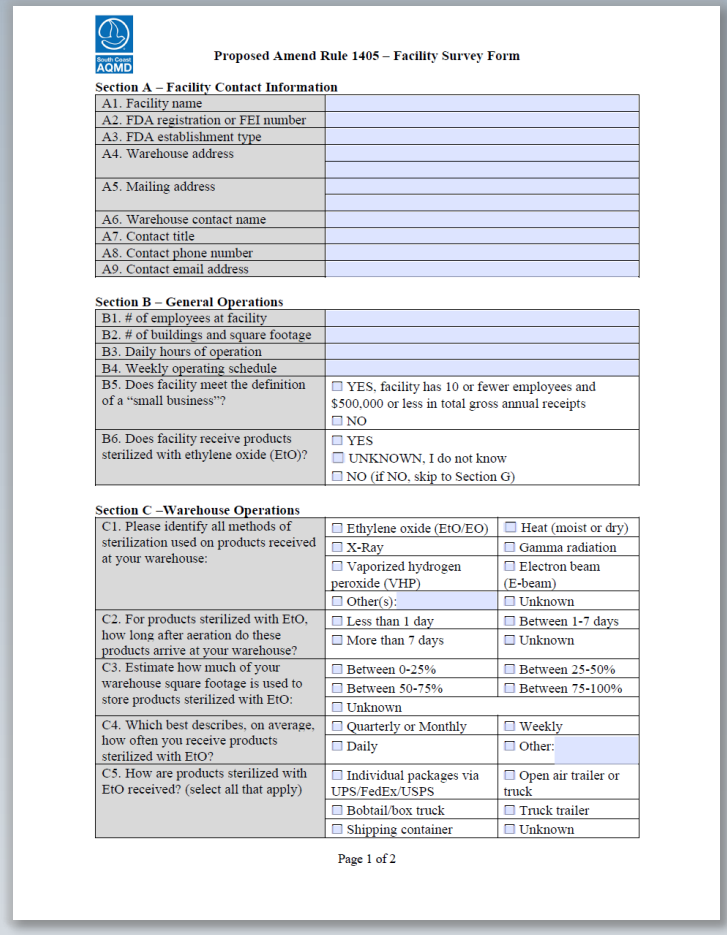
Proposed Amended Rule 1405

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

Warehouse Facility Questionnaire Results

Background – Aeration Only/Warehouse Facilities

- Working Group Meeting #2 presented that EtO-sterilized products continue to off-gas during storage
- Warehouses may be a potential source of fugitive EtO emissions if they store EtO sterilized products
- South Coast AQMD surveyed approximately 70 facilities registered with U.S. FDA as Wholesale Drug Distributors or Third-Party Logistics Providers that may handle EtO-sterilized products



Proposed Amend Rule 1405 – Facility Survey Form

Section A – Facility Contact Information

A1. Facility name	
A2. FDA registration or FEI number	
A3. FDA establishment type	
A4. Warehouse address	
A5. Mailing address	
A6. Warehouse contact name	
A7. Contact title	
A8. Contact phone number	
A9. Contact email address	

Section B – General Operations

B1. # of employees at facility	
B2. # of buildings and square footage	
B3. Daily hours of operation	
B4. Weekly operating schedule	
B5. Does facility meet the definition of a "small business"?	☐ YES, facility has 10 or fewer employees and $500,000 or less in total gross annual receipts ☐ NO
B6. Does facility receive products sterilized with ethylene oxide (EtO)?	☐ YES ☐ UNKNOWN, I do not know ☐ NO (if NO, skip to Section G)

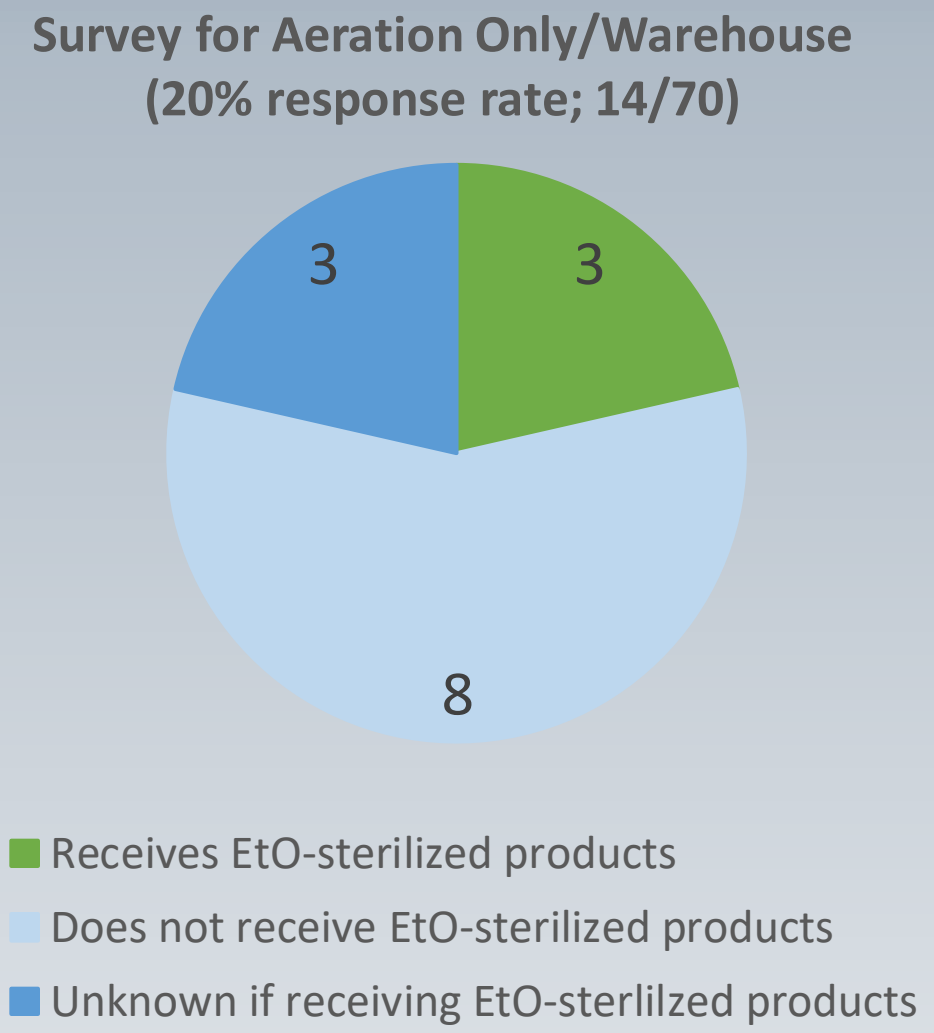
Section C –Warehouse Operations

C1. Please identify all methods of sterilization used on products received at your warehouse:	☐ Ethylene oxide (EtO/EO)	☐ Heat (moist or dry)
	☐ X-Ray	☐ Gamma radiation
	☐ Vaporized hydrogen peroxide (VHP)	☐ Electron beam (E-beam)
	☐ Other(s):	☐ Unknown
C2. For products sterilized with EtO, how long after aeration do these products arrive at your warehouse?	☐ Less than 1 day	☐ Between 1-7 days
	☐ More than 7 days	☐ Unknown
C3. Estimate how much of your warehouse square footage is used to store products sterilized with EtO:	☐ Between 0-25%	☐ Between 25-50%
	☐ Between 50-75%	☐ Between 75-100%
	☐ Unknown	
C4. Which best describes, on average, how often you receive products sterilized with EtO?	☐ Quarterly or Monthly	☐ Weekly
	☐ Daily	☐ Other:
C5. How are products sterilized with EtO received? (select all that apply)	☐ Individual packages via UPS/FedEx/USPS	☐ Open air trailer or truck
	☐ Bobtail/box truck	☐ Truck trailer
	☐ Shipping container	☐ Unknown

Page 1 of 2

Aeration Only/Warehouse - Survey Response

Survey Response	# of Responses
Written responses received	14
No written response received	56
Total	**70**



Aeration Only/Warehouse – Response Summary

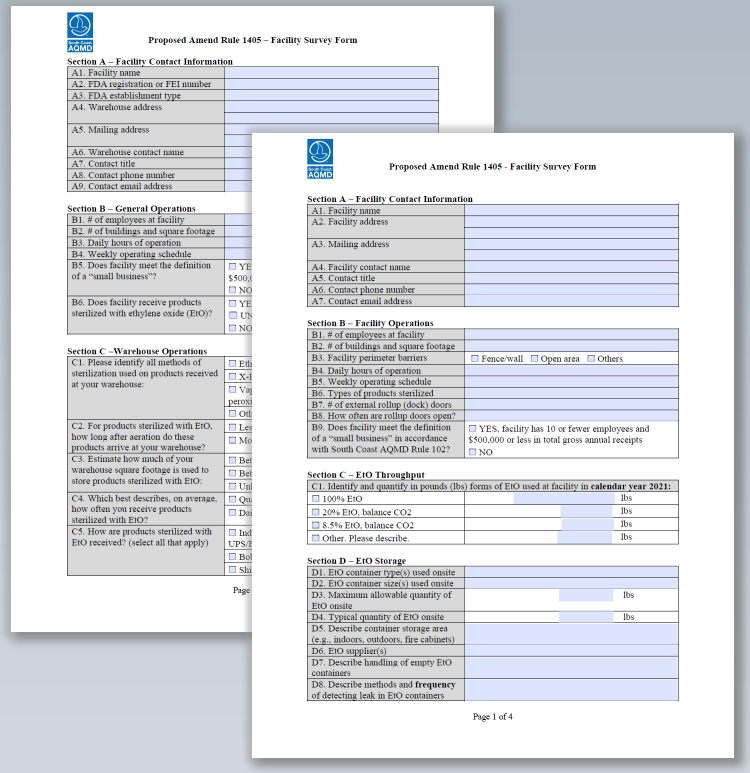
Of the 14 responses received:

- 3 facilities reported receiving EtO-sterilized products
  - All 3 facilities have special EtO handling policies and identify products sterilized with EtO
  - 2 facilities monitor EtO levels
- 8 facilities report that they do not receive EtO-sterilized products
- 3 facilities report that they do not know if they receive EtO-sterilized products

- As reported in Working Group Meeting #2, mobile measurement near potential EtO emission sources, including warehouses, is ongoing
- At the present time, EtO mobile measurements have not detected significant enhancements in EtO signals near warehouses

Summary of Questionnaire Results

- Based on survey results from permitted facilities
  - Operations are different between large and exempt/small/medium-sized facilities
  - 3 large facilities store EtO materials outdoors
  - Majority of facilities monitor EtO levels, some continuously
- Based on survey results from aeration only facilities/warehouses
  - 3 facilities reported handling of EtO-sterilized products, implementing special EtO-handling policies and procedures
  - 3 facilities do not know if they are receiving EtO-sterilized products



Proposed Amend Rule 1405 – Facility Survey Form

Section A – Facility Contact Information

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A6. Warehouse contact name	
A7. Contact title	
A8. Contact phone number	
A9. Contact email address	

Section B – General Operations

B1. # of employees at facility	
B2. # of buildings and square footage	
B3. Daily hours of operation	
B4. Weekly operating schedule	
B5. Does facility meet the definition of a "small business"?	☐ YE $500, ☐ NO
B6. Does facility receive products sterilized with ethylene oxide (EtO)?	☐ YE ☐ Un ☐ NO

Section C –Warehouse Operations

C1. Please identify all methods of sterilization used on products received at your warehouse:	☐ Eth ☐ X-r ☐ Va perox ☐ Oth
C2. For products sterilized with EtO, how long after aeration do these products arrive at your warehouse?	☐ Les ☐ Mo
C3. Estimate how much of your warehouse square footage is used to store products sterilized with EtO:	☐ Bet ☐ Bet ☐ Un
C4. Which best describes, on average, how often you receive products sterilized with EtO?	☐ Qu ☐ Da
C5. How are products sterilized with EtO received? (select all that apply)	☐ Ind UPS/F ☐ Bo ☐ Shi

Page

Proposed Amend Rule 1405 - Facility Survey Form

Section A – Facility Contact Information

A1. Facility name	
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Section B – Facility Operations

B1. # of employees at facility	
B2. # of buildings and square footage	
B3. Facility perimeter barriers	☐ Fence/wall ☐ Open area ☐ Others
B4. Daily hours of operation	
B5. Weekly operating schedule	
B6. Types of products sterilized	
B7. # of external rollup (dock) doors	
B8. How often are rollup doors open?	
B9. Does facility meet the definition of a "small business" in accordance with South Coast AQMD Rule 102?	☐ YES, facility has 10 or fewer employees and $500,000 or less in total gross annual receipts ☐ NO

Section C – EtO Throughput

C1. Identify and quantify in pounds (lbs) forms of EtO used at facility in **calendar year 2021:**		
☐ 100% EtO		lbs
☐ 20% EtO, balance CO2		lbs
☐ 8.5% EtO, balance CO2		lbs
☐ Other. Please describe.		lbs

Section D – EtO Storage

D1. EtO container type(s) used onsite	
D2. EtO container size(s) used onsite	
D3. Maximum allowable quantity of EtO onsite	lbs
D4. Typical quantity of EtO onsite	lbs
D5. Describe container storage area (e.g., indoors, outdoors, fire cabinets)	
D6. EtO supplier(s)	
D7. Describe handling of empty EtO containers	
D8. Describe methods and **frequency** of detecting leak in EtO containers	

Page 1 of 4

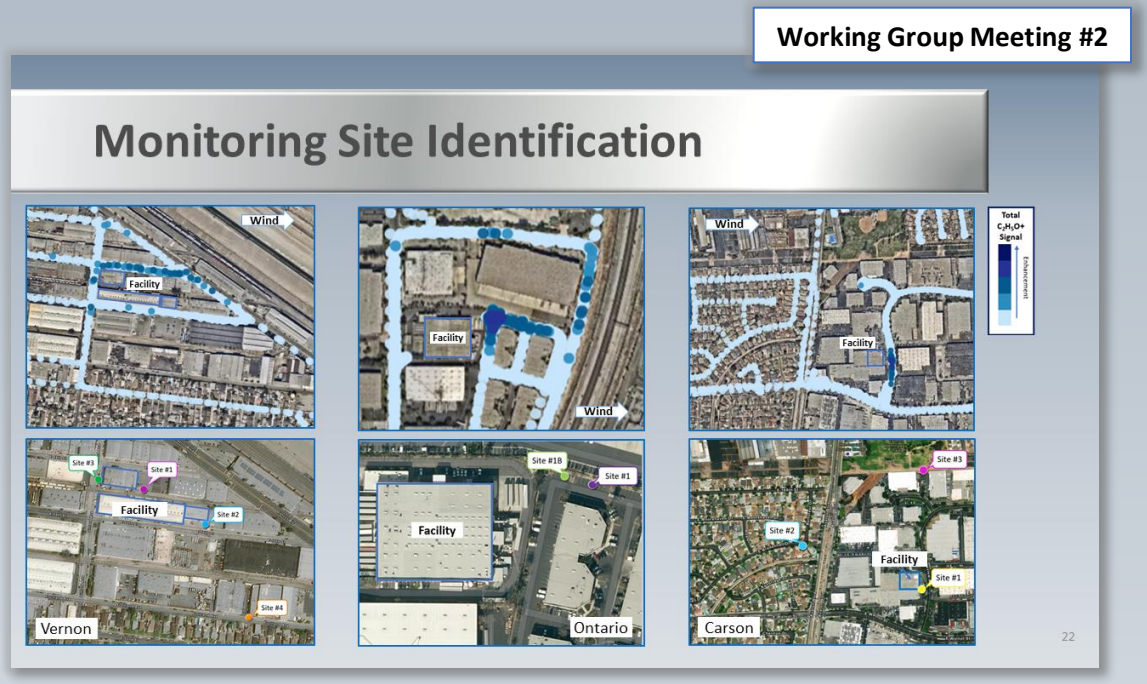
Proposed Amended Rule 1405

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

Facility Profiles & Evaluations in South Coast AQMD

Background

- In Working Group Meeting #2, discussed EtO monitoring efforts and findings:
  - Mobile measurements conducted near 11 facilities found enhanced EtO signals at 3 locations (4 facilities)
    - Ontario location (1 facility)
    - Vernon location (2 facilities)
    - Carson location (1 facility)
  - 24-hour time integrated ambient air sampling confirmed mobile measurements
- Today will report the evaluation of the 3 locations, specifically:
  - Profile of each location
  - Evaluation of key potential sources of emissions for each location



Ontario Location – Facility Profile

- Located in an industrial zone within the city limits of Ontario
- Considered a “large” sterilization facility under Rule 1405
  - Permitted to use up to 1,314,000 lbs of EtO per 12-month period
- Commercial sterilizer of medical and pharmaceutical products
- Facility configuration:
  - 9 sterilization chambers
  - 2 heated aeration rooms
  - Warehouse and shipping area
- Sterilized products remain stored in an aeration room or warehouse until pickup
- Control technology installed by the facility
  - Sterilizer emissions vented to an acid-water scrubber
  - Low concentration EtO emissions, such as backvent and aeration, vented to 2 catalytic oxidizers operating in parallel

Ontario Location – Facility Evaluation

- Ambient air monitoring around Ontario location detected elevated EtO levels
- Key potential sources of EtO emissions contributing to elevated EtO levels:

  1) Acid-water scrubber stack emissions
    - High throughput of Ontario location
      - Rule 1405 currently requires 99.9% control efficiency for sterilizer emissions
      - Potentially high stack emissions from high throughput and high inlet concentrations with a single layer of control
    - Performance of scrubber may deteriorate over time
      - Rule 1405 currently only requires a one-time performance test for acid-water scrubbers, not periodic source testing

  2) Outdoor storage of concentrated EtO and EtO-containing waste & byproducts
    - Facility performs leak tests upon barrel delivery and prior to use only
      - Rule 1405 currently does not require EtO stored be vented to control

Vernon Location – Facility Profiles

- Location consists of 2 sterilization facilities in an industrial area within the city limits of Vernon
- 50th St facility:
  - Permitted to use up to 438,000 lbs per year
- 49th St facility:
  - Permitted to use up to 333,975 lbs per year
- Commercial sterilizer of new medical and pharmaceutical products as well as reusable hospital products
- Facility configurations:
  - 9 sterilization chambers at 50th St and 8 sterilization chambers at 49th St
  - 2 heated aeration areas at 50th St and 1 unheated aeration room at 49th St
  - 1 joint area for storage of sterilized products located at 50th St facility
- Sterilized products maintained at 50th St facility until pickup, without negative pressure control
- Control technology installed by the facility
  - Sterilizer emissions vented to 1 acid-water scrubber at 50th St and 1 acid-water scrubber at 49th St
  - Emissions from chamber backdraft vent and aeration room vented to 1 catalytic oxidizer at 50th St and 1 catalytic oxidizer 49th St

Vernon Location – Facility Evaluations

- Key potential sources of EtO emissions contributing to elevated EtO levels:

  1) Fugitive emissions
     - Sterilized products stored at 50th St facility awaiting pickup without negative pressure control

  2) Acid-water scrubber stack emissions
     - High throughput of Vernon location
       - Rule 1405 currently requires 99.9% control efficiency for sterilizer emissions
       - Potentially high stack emissions from high throughput and high inlet concentrations a single layer of control
     - Performance of scrubber may deteriorate over time
       - Rule 1405 currently only requires a one-time performance test for acid-water scrubbers, not periodic source testing

  3) Outdoor storage of concentrated EtO and EtO-containing waste & byproducts
     - In April 2022, staff detected an open hatch on a storage tank of EtO-containing byproducts at Vernon location

Carson Location – Facility Profile

- Located in an industrial zone within the city limits of Carson
- Considered a “large” sterilization facility under Rule 1405
  - Permitted to use up to 21,840 lbs EtO per 12-month period
- Commercial sterilizer of medical products
- Facility configuration:
  - 7 active sterilization chambers
  - 2 heated aeration rooms
  - 1 post-aeration storage room
- Sterilized products formerly not maintained under negative pressure control, currently implementing Permanent Total Enclosure (PTE) with dry bed scrubber control
- Control technology installed by the facility
  - Sterilizer emissions vented to an acid-water scrubber formerly without secondary control
  - Emissions from backvent, aeration, and storage of sterilized products are vented to dry bed scrubber
  - Permits to Construct issued for PTE and additional dry bed scrubbers
    - New equipment onsite and in commissioning period of installation

Carson Location – Facility Evaluation

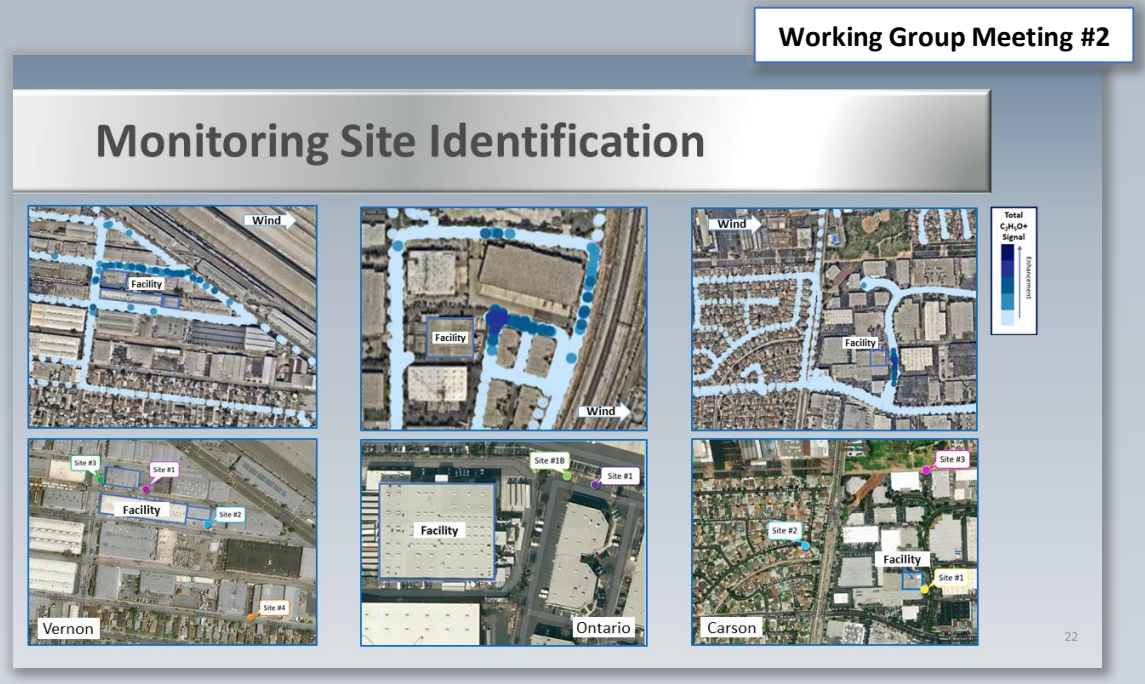
- Prior to September, ambient air monitoring around the Carson location detected elevated EtO levels
- Key potential sources of EtO emissions contributing to elevated EtO levels:

  1) Fugitive emissions
    - No negative pressure control of indoor areas
      - Permits to Construct issued for PTE with dry bed scrubber control

  2) Acid-water scrubber stack emissions
    - Similar concerns as Ontario location and Vernon location regarding high throughput and one-time performance testing
      - Permits to Construct issued for dry bed scrubber technology as secondary control
- Facility is currently in commissioning period for PTE and secondary controls
  - Further analysis and source testing will be conducted

Summary of Evaluation

- Monitoring data identified 3 locations (4 facilities) with elevated EtO levels, and additional investigations were conducted
- Key potential sources of emissions at all 3 locations include both stack and fugitive emissions
- Carson location has recently implemented new control measures
  - Further analysis and source testing will be conducted



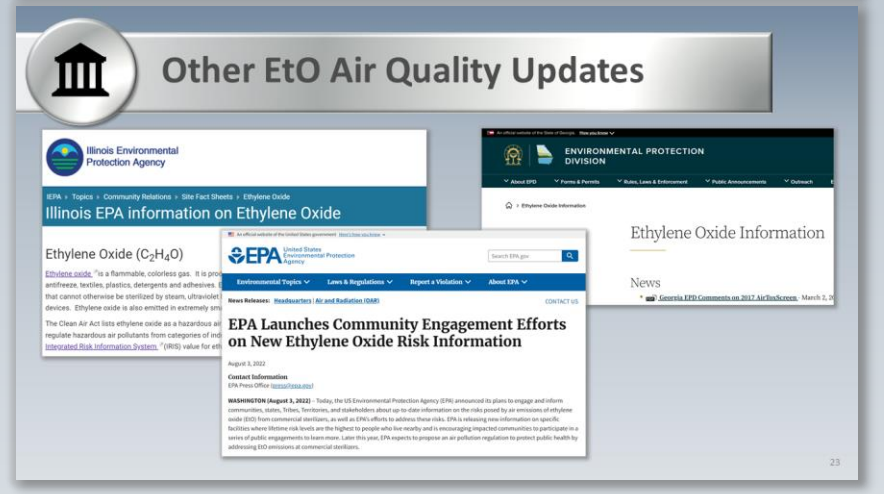
Proposed Amended Rule 1405

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

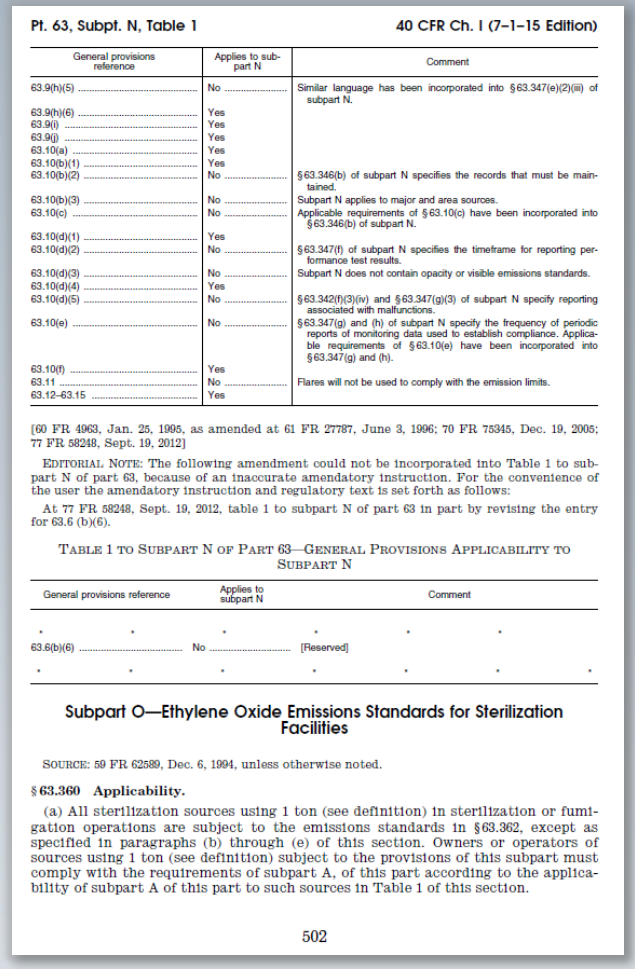
Other EtO Regulatory Requirements

Background

- In Working Group Meeting #1, introduced other air quality regulations for EtO sterilization:
  - Identified state and federal EtO sterilization regulations
  - Referenced recent EtO activities in Illinois and Georgia
- Explore the following other EtO regulatory requirements more in depth:
  - Federal U.S. EPA National Emission Standards for Hazardous Air Pollutants (NESHAP)
  - California Air Resource Board (CARB) Air Toxic Control Measure (ATCM)
  - Georgia EPD Air Quality Permit
  - Illinois Public Act 101-0022



Federal U.S. EPA NESHAP



Pt. 63, Subpt. N, Table 1 — 40 CFR Ch. I (7–1–15 Edition)

General provisions reference	Applies to subpart N	Comment
63.9(h)(5)	No	Similar language has been incorporated into §63.347(e)(2)(iii) of subpart N.
63.9(h)(6)	Yes	
63.9(i)	Yes	
63.9(j)	Yes	
63.10(a)	Yes	
63.10(b)(1)	Yes	
63.10(b)(2)	No	§63.346(b) of subpart N specifies the records that must be maintained.
63.10(b)(3)	No	Subpart N applies to major and area sources.
63.10(c)	No	Applicable requirements of §63.10(c) have been incorporated into §63.346(b) of subpart N.
63.10(d)(1)	Yes	
63.10(d)(2)	No	§63.347(f) of subpart N specifies the timeframe for reporting performance test results.
63.10(d)(3)	No	Subpart N does not contain opacity or visible emissions standards.
63.10(d)(4)	Yes	
63.10(d)(5)	No	§63.342(f)(3)(iv) and §63.347(g)(3) of subpart N specify reporting associated with malfunctions.
63.10(e)	No	§63.347(g) and (h) of subpart N specify the frequency of periodic reports of monitoring data used to establish compliance. Applicable requirements of §63.10(e) have been incorporated into §63.347(g) and (h).
63.10(f)	Yes	
63.11	No	Flares will not be used to comply with the emission limits.
63.12–63.15	Yes	

[60 FR 4963, Jan. 25, 1995, as amended at 61 FR 27787, June 3, 1996; 70 FR 75345, Dec. 19, 2005; 77 FR 58248, Sept. 19, 2012]

EDITORIAL NOTE: The following amendment could not be incorporated into Table 1 to subpart N of part 63, because of an inaccurate amendatory instruction. For the convenience of the user the amendatory instruction and regulatory text is set forth as follows:

At 77 FR 58248, Sept. 19, 2012, table 1 to subpart N of part 63 in part by revising the entry for 63.6 (b)(6).

TABLE 1 TO SUBPART N OF PART 63—GENERAL PROVISIONS APPLICABILITY TO SUBPART N

General provisions reference	Applies to subpart N	Comment
* * * * * * *		
63.6(b)(6)	No	[Reserved]
* * * * * * *		

Subpart O—Ethylene Oxide Emissions Standards for Sterilization Facilities

SOURCE: 59 FR 62589, Dec. 6, 1994, unless otherwise noted.

§63.360 Applicability.

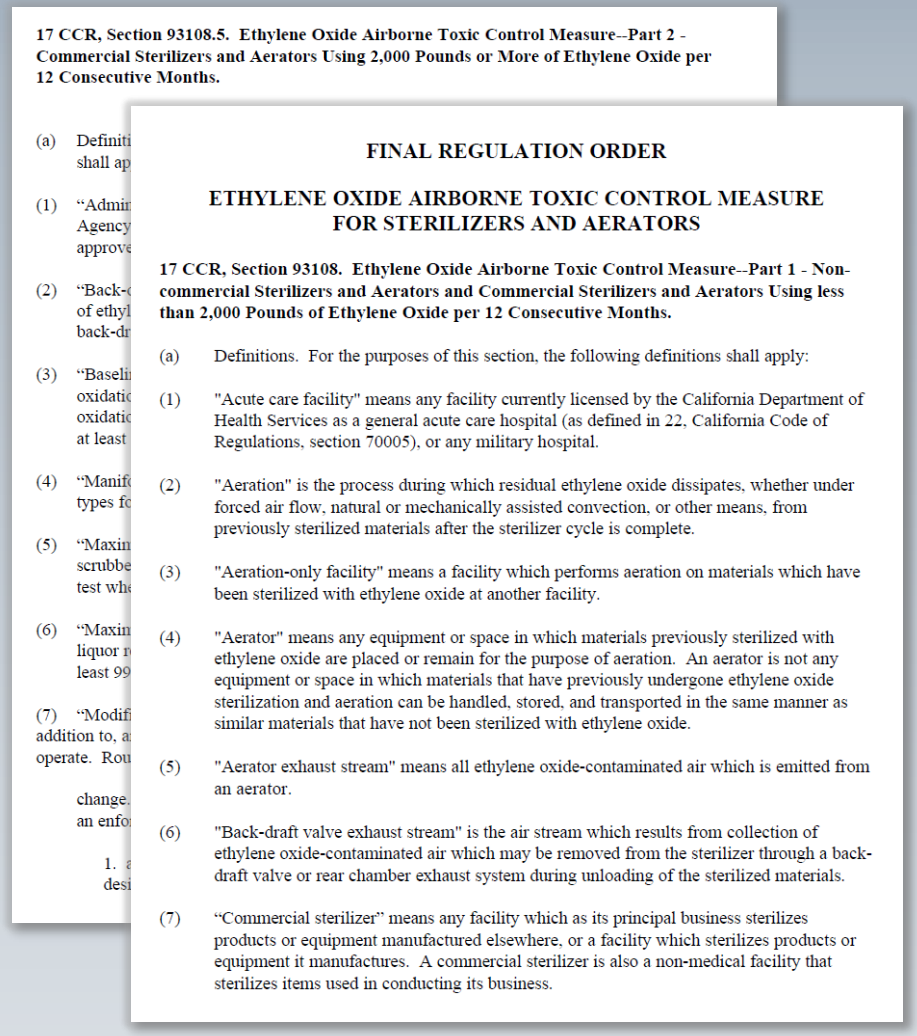
(a) All sterilization sources using 1 ton (see definition) in sterilization or fumigation operations are subject to the emissions standards in §63.362, except as specified in paragraphs (b) through (e) of this section. Owners or operators of sources using 1 ton (see definition) subject to the provisions of this subpart must comply with the requirements of subpart A, of this part according to the applicability of subpart A of this part to such sources in Table 1 of this section.

502

- Subpart O – Ethylene Oxide Emission Standards for Sterilization Facilities
  - Adopted in 1994
  - Last amended in 2001
  - Rulemaking actively ongoing
- Applies to facilities using > 1 ton (2,000 lbs) per year
- Rule 1405 currently more stringent that NESHAP

CARB ATCM

- Statewide regulation
  - Adopted in 1990
  - Last amended in 1998
- Air Toxic Control Measure
  - Part I – Using less than 2,000 lbs EtO per 12 consecutive months (17 CCR 93108)
  - Part II – Using 2,000 lbs EtO or more per 12 consecutive months (17 CCR 93108.5)
- Rule 1405 requirements currently more stringent than CARB EtO ATCM
- *Note:* California Office of Environmental Health Hazard Assessment (OEHHA) is currently reviewing carcinogenicity of EtO



17 CCR, Section 93108.5. Ethylene Oxide Airborne Toxic Control Measure--Part 2 - Commercial Sterilizers and Aerators Using 2,000 Pounds or More of Ethylene Oxide per 12 Consecutive Months.

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FINAL REGULATION ORDER

ETHYLENE OXIDE AIRBORNE TOXIC CONTROL MEASURE FOR STERILIZERS AND AERATORS

17 CCR, Section 93108. Ethylene Oxide Airborne Toxic Control Measure--Part 1 - Non-commercial Sterilizers and Aerators and Commercial Sterilizers and Aerators Using less than 2,000 Pounds of Ethylene Oxide per 12 Consecutive Months.

(a) Definitions. For the purposes of this section, the following definitions shall apply:

(1) "Acute care facility" means any facility currently licensed by the California Department of Health Services as a general acute care hospital (as defined in 22, California Code of Regulations, section 70005), or any military hospital.

(2) "Aeration" is the process during which residual ethylene oxide dissipates, whether under forced air flow, natural or mechanically assisted convection, or other means, from previously sterilized materials after the sterilizer cycle is complete.

(3) "Aeration-only facility" means a facility which performs aeration on materials which have been sterilized with ethylene oxide at another facility.

(4) "Aerator" means any equipment or space in which materials previously sterilized with ethylene oxide are placed or remain for the purpose of aeration. An aerator is not any equipment or space in which materials that have previously undergone ethylene oxide sterilization and aeration can be handled, stored, and transported in the same manner as similar materials that have not been sterilized with ethylene oxide.

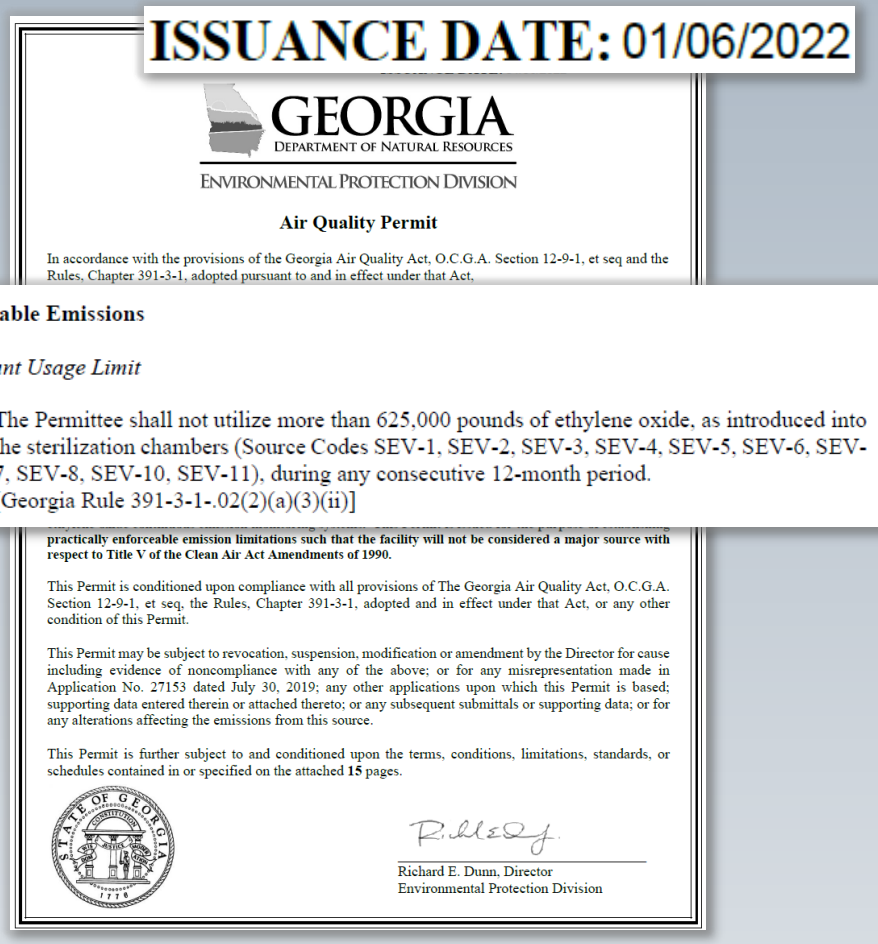
(5) "Aerator exhaust stream" means all ethylene oxide-contaminated air which is emitted from an aerator.

(6) "Back-draft valve exhaust stream" is the air stream which results from collection of ethylene oxide-contaminated air which may be removed from the sterilizer through a back-draft valve or rear chamber exhaust system during unloading of the sterilized materials.

(7) "Commercial sterilizer" means any facility which as its principal business sterilizes products or equipment manufactured elsewhere, or a facility which sterilizes products or equipment it manufactures. A commercial sterilizer is also a non-medical facility that sterilizes items used in conducting its business.

Georgia EPD Air Quality Permit

- Requirements apply to a commercial sterilization facility
  - Facility would be considered a large sterilization facility under Rule 1405
- Key requirements more stringent than existing Rule 1405
  - Control devices operated in series
  - Control device spare parts required onsite
  - Continuous emission monitoring system (CEMS) required for stack emissions
  - Periodic bag sampling of control devices to confirm control efficiency
  - Permanent Total Enclosure (PTE)
  - Leak Detection and Repair (LDAR) Program with weekly checks



ISSUANCE DATE: 01/06/2022

GEORGIA
DEPARTMENT OF NATURAL RESOURCES
ENVIRONMENTAL PROTECTION DIVISION

Air Quality Permit

In accordance with the provisions of the Georgia Air Quality Act, O.C.G.A. Section 12-9-1, et seq and the Rules, Chapter 391-3-1, adopted pursuant to and in effect under that Act,

2. Allowable Emissions

Sterilant Usage Limit

2.1 The Permittee shall not utilize more than 625,000 pounds of ethylene oxide, as introduced into the sterilization chambers (Source Codes SEV-1, SEV-2, SEV-3, SEV-4, SEV-5, SEV-6, SEV-7, SEV-8, SEV-10, SEV-11), during any consecutive 12-month period. [Georgia Rule 391-3-1-.02(2)(a)(3)(ii)]

practically enforceable emission limitations such that the facility will not be considered a major source with respect to Title V of the Clean Air Act Amendments of 1990.

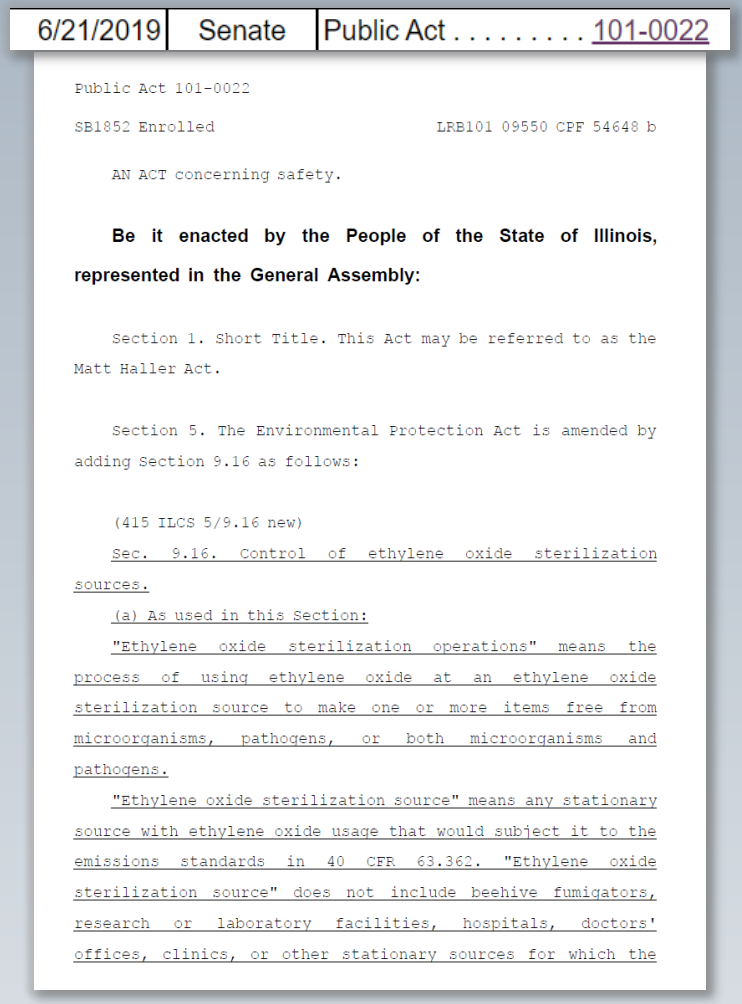
This Permit is conditioned upon compliance with all provisions of The Georgia Air Quality Act, O.C.G.A. Section 12-9-1, et seq, the Rules, Chapter 391-3-1, adopted and in effect under that Act, or any other condition of this Permit.

This Permit may be subject to revocation, suspension, modification or amendment by the Director for cause including evidence of noncompliance with any of the above; or for any misrepresentation made in Application No. 27153 dated July 30, 2019; any other applications upon which this Permit is based; supporting data entered therein or attached thereto; or any subsequent submittals or supporting data; or for any alterations affecting the emissions from this source.

This Permit is further subject to and conditioned upon the terms, conditions, limitations, standards, or schedules contained in or specified on the attached **15** pages.

Richard E. Dunn, Director
Environmental Protection Division

Illinois Public Act 101-0022 (SB 1852)



6/21/2019 | Senate | Public Act 101-0022

Public Act 101-0022

SB1852 Enrolled LRB101 09550 CPF 54648 b

AN ACT concerning safety.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short Title. This Act may be referred to as the Matt Haller Act.

Section 5. The Environmental Protection Act is amended by adding Section 9.16 as follows:

(415 ILCS 5/9.16 new)

Sec. 9.16. Control of ethylene oxide sterilization sources.

(a) As used in this Section:

"Ethylene oxide sterilization operations" means the process of using ethylene oxide at an ethylene oxide sterilization source to make one or more items free from microorganisms, pathogens, or both microorganisms and pathogens.

"Ethylene oxide sterilization source" means any stationary source with ethylene oxide usage that would subject it to the emissions standards in 40 CFR 63.362. "Ethylene oxide sterilization source" does not include beehive fumigators, research or laboratory facilities, hospitals, doctors' offices, clinics, or other stationary sources for which the

- Applicability
  - Commercial sterilizers using more than 1 ton of EtO per year
  - 1 active facility is subject to the regulation
- Key requirements
  - Ethylene oxide sterilization facilities would be prohibited from operating in Illinois unless:
    - All fugitive EtO emissions are captured
    - EtO emissions from each exhaust point are reduced by at least 99.9% or to 0.2 parts per million (ppm)
  - Continuous emission monitoring systems (CEMS) for stacks
  - Periodic EtO air monitoring near fenceline and in community
  - Conduct annual emissions tests and submit results
  - Upon receiving a failed emissions test, a facility must:
    - Immediately cease operations and notify Illinois EPA within 24 hours
    - Within 60 days, conduct a root cause analysis of the failed emission test, take corresponding corrective actions, and seek approval prior to restart of operations

Proposed Amended Rule 1405

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

Case Study in Illinois

Waukegan Facility – Facility Profile

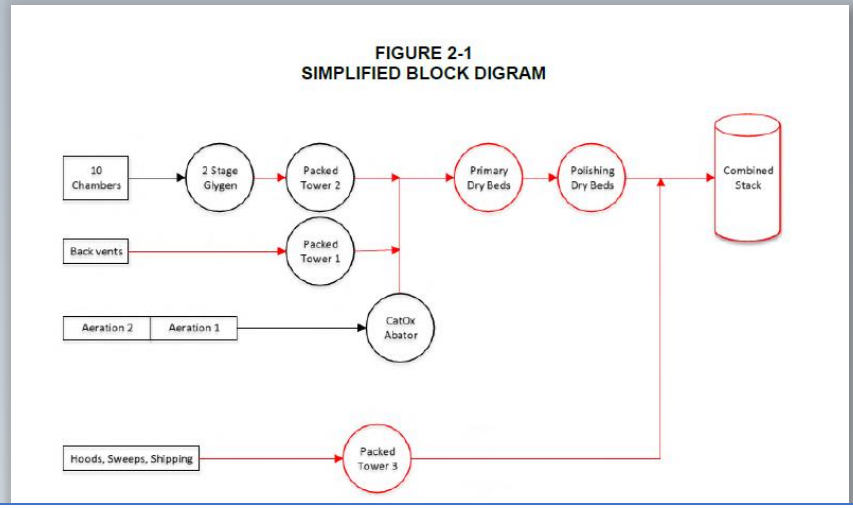
- Located in a mixed commercial/residential area in Waukegan, Illinois
- Would be considered a “large” sterilization facility in South Coast AQMD*
  - Permitted to use 770,000 lbs EtO per year
  - Emissions cap of 150 pounds per year, compliance demonstrated by CEMS
- Commercial sterilizer of disposal surgical kits for in-patient and out-patient procedures
- Facility has separate areas for different processes
  - Ten sterilization chambers
  - Two aeration rooms
  - One storage area
- Conducted ambient EtO monitoring to help verify effectiveness of controls

**Facility is subject to NESHAP which does not require backvent control; facility currently controls emissions from backvent*

Waukegan Facility — Measures for Stack Emissions

Facility's approach to controlling EtO emissions was to install a **multi-stage air pollution system** with a **high control efficiency** that is verified **continuously**

- Air pollution control system
  - Permit to construct issued in 2019
  - Consists of a Glygen™ scrubbers, packed tower scrubbers, one catalytic oxidizer, dry bed scrubbers in series, and a permanent total enclosure
  - Emissions are vented to one combined stack
- Control efficiency demonstration
  - 3-day test conducted in March 2020
  - Control device demonstrated a 99.99% destruction efficiency
  - Outlet concentration ranged from 28-37 parts per billion (ppb)
- Continuous Emission Monitor System (CEMS)
  - Emissions for the facility are monitored through the one combined stack
  - Continuous monitoring achieved through fourier transform infrared (FTIR) technology
  - Relative Accuracy Test Audit evaluation accepted



https://www2.illinois.gov/epa/topics/community-relations/sites/ethylene-oxide/Documents/RATA%20Report.pdf

Waukegan Facility — Measures for Fugitive Emissions

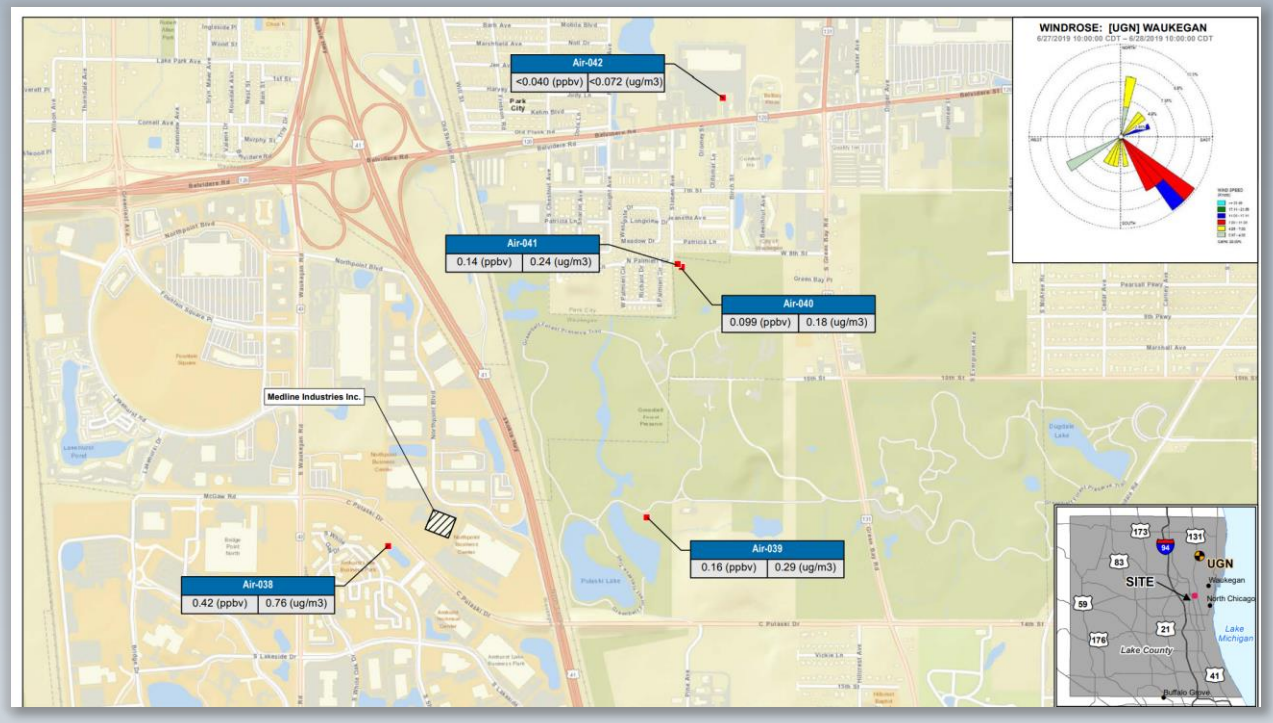
Facility's approach to controlling fugitive EtO emissions was to implement the following:

- Change building airflows and internal features such that all emissions of EtO occur within a permanent enclosure
- Control emissions from EtO storage area, sterilized product area, sterilizer chamber room hood, and other sweeps with the new packed bed scrubber
- Construction of a wall to separate sterilized and unsterilized material

Illinois Environmental Protection Agency

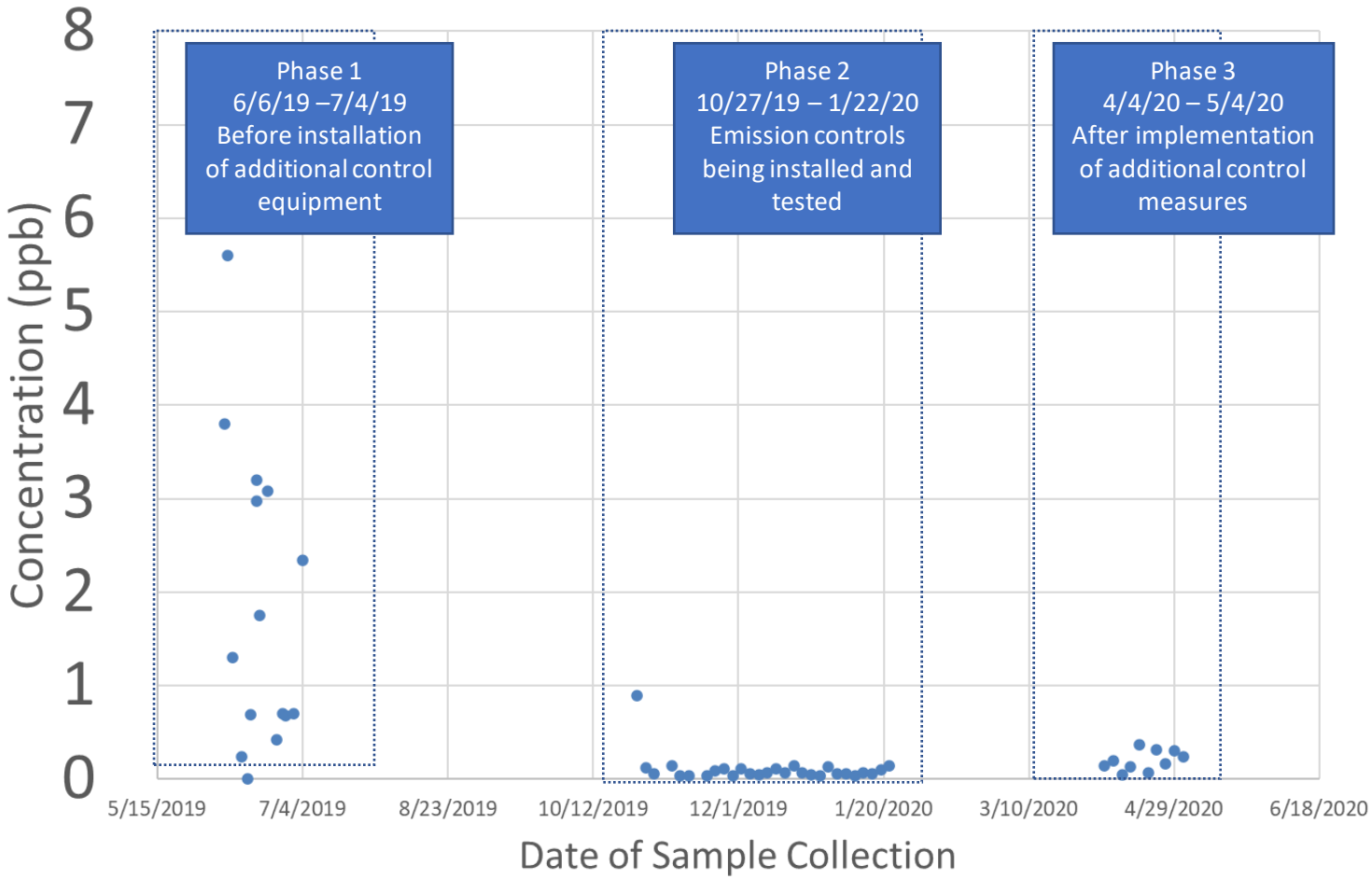
Waukegan Facility – Ambient Monitoring

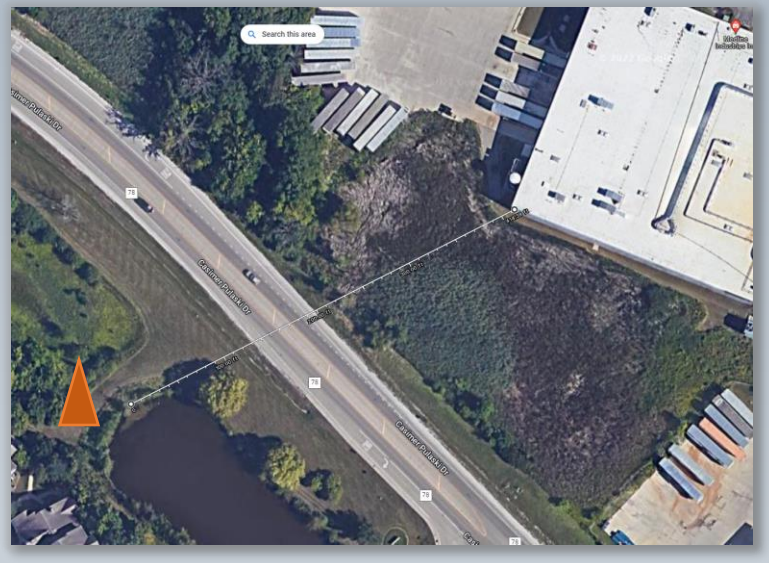
- In June 2019, air monitoring began at multiple off-site locations
- Modeling assisted in determining the sampling location
- Air – 038 data was selected for further discussion as:
  - Highest concentrations of EtO were measured at the location
  - Monitor is the closest to the facility (~400 feet away)
- Monitoring data is publicly available on Lake County's website[1]



[1]https://www.lakecountyil.gov/4192/Medline-Independent-EtO-Monitoring-Resul

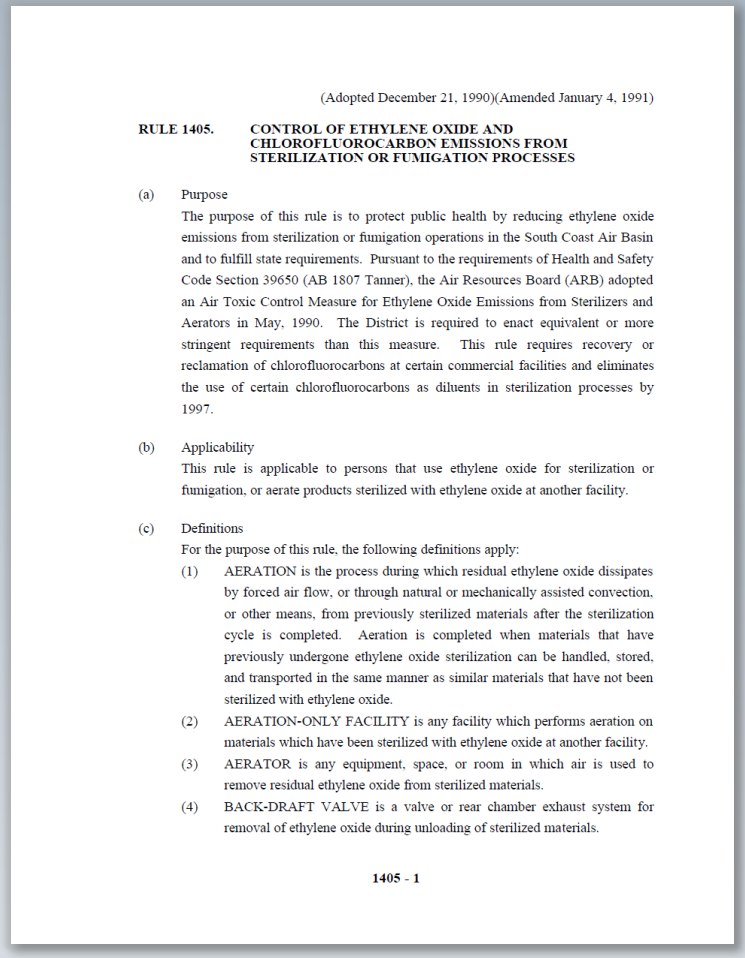
Waukegan Facility – Monitoring Data





- Monitor Air – 038 was located ~400 feet away from the edge of the facility
  - Not at property fenceline
- Ambient EtO levels were reduced after implementation of control measures

Summary of Other Regulatory Requirements & Case Study



(Adopted December 21, 1990)(Amended January 4, 1991)

RULE 1405. CONTROL OF ETHYLENE OXIDE AND CHLOROFLUOROCARBON EMISSIONS FROM STERILIZATION OR FUMIGATION PROCESSES

(a) Purpose

The purpose of this rule is to protect public health by reducing ethylene oxide emissions from sterilization or fumigation operations in the South Coast Air Basin and to fulfill state requirements. Pursuant to the requirements of Health and Safety Code Section 39650 (AB 1807 Tanner), the Air Resources Board (ARB) adopted an Air Toxic Control Measure for Ethylene Oxide Emissions from Sterilizers and Aerators in May, 1990. The District is required to enact equivalent or more stringent requirements than this measure. This rule requires recovery or reclamation of chlorofluorocarbons at certain commercial facilities and eliminates the use of certain chlorofluorocarbons as diluents in sterilization processes by 1997.

(b) Applicability

This rule is applicable to persons that use ethylene oxide for sterilization or fumigation, or aerate products sterilized with ethylene oxide at another facility.

(c) Definitions

For the purpose of this rule, the following definitions apply:

(1) AERATION is the process during which residual ethylene oxide dissipates by forced air flow, or through natural or mechanically assisted convection, or other means, from previously sterilized materials after the sterilization cycle is completed. Aeration is completed when materials that have previously undergone ethylene oxide sterilization can be handled, stored, and transported in the same manner as similar materials that have not been sterilized with ethylene oxide.

(2) AERATION-ONLY FACILITY is any facility which performs aeration on materials which have been sterilized with ethylene oxide at another facility.

(3) AERATOR is any equipment, space, or room in which air is used to remove residual ethylene oxide from sterilized materials.

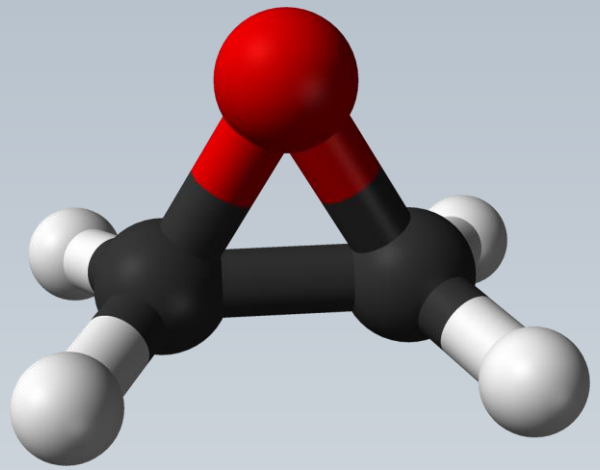
(4) BACK-DRAFT VALVE is a valve or rear chamber exhaust system for removal of ethylene oxide during unloading of sterilized materials.

1405 - 1

- Existing Rule 1405 requirements are more stringent than U.S. EPA NESHAP or CARB ATCM
- Some requirements of Illinois Public Act 101-0022 and Georgia EPD Air Quality Permit are more stringent than existing Rule 1405
- A case study for a facility in Illinois demonstrated that ambient EtO have reduced after implementing the regulatory requirements
- Staff will consider incorporating requirements that are applicable and feasible to Rule 1405

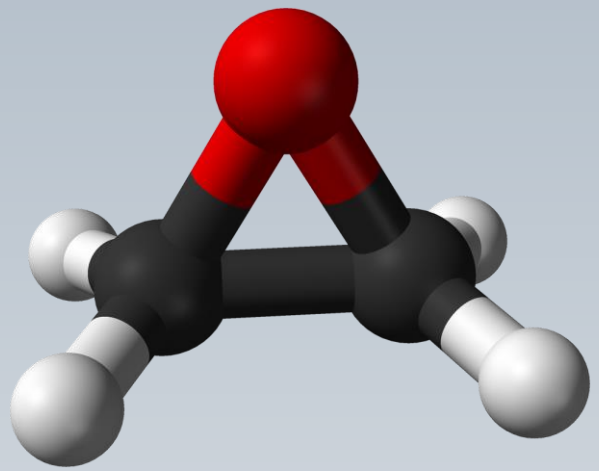
Summary of Working Group Meetings 1-3

- EtO is closely associated with cancers, with both long-term and immediate health effects
- EtO sterilization accounts for about half of medical products that require sterilization
    - For many medical devices, sterilization with ethylene oxide may be the only method that effectively sterilizes and does not damage the device during the sterilization process
- Currently there are 16 permitted sterilization facilities in South Coast AQMD
    - Operations are different between large and small/medium sized facilities
    - Large facilities account for almost all EtO usage
- Ambient monitoring measurements to date showed no elevated EtO levels near facilities except for 3 locations, all are large facilities
    - Elevated levels at off-site worker monitoring sites
    - EtO levels at nearby residential communities within typical background levels

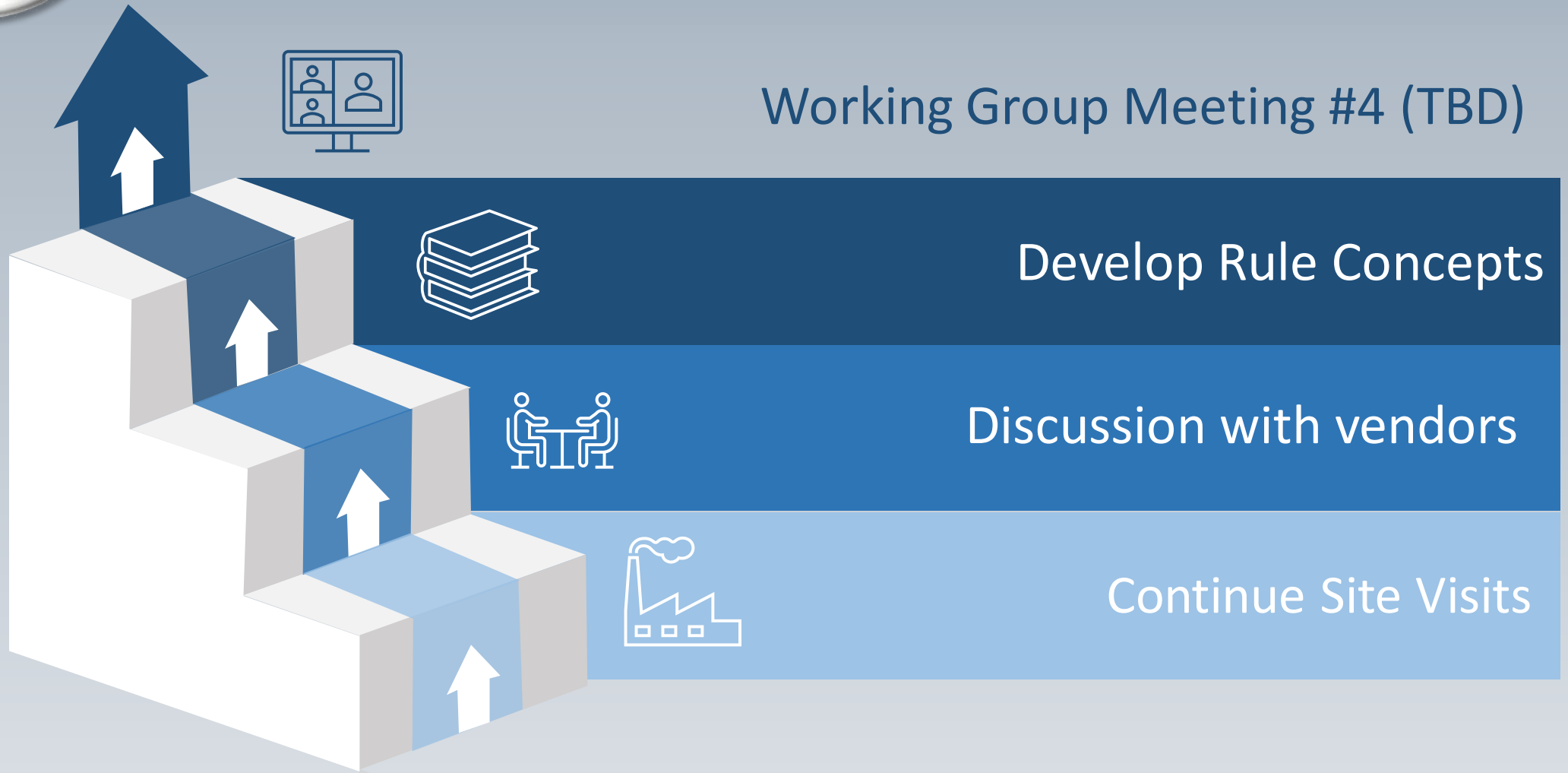


Summary of Working Group Meetings 1-3

- Identified regulatory gaps for stack and fugitive emissions
  - With high throughput and high inlet concentration, the stack outlet concentration might still be high with a single layer of control
  - Lack of requirements addressing potential sources of fugitive emissions such as storage of sterilized products, concentrated EtO, and EtO-containing waste & byproducts
  - Acid water scrubbers are required to conduct a one-time only performance test
  - Lack of a system to verify the continuous performance of control devices
- Identified control technologies to further reduce EtO
  - Stack emissions could be further controlled beyond existing rule requirements (99-99.9%) by available control technologies and/or control in series
  - 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 stack and fugitive sources



Next Steps


Working Group Meeting #4 (TBD)
Develop Rule Concepts
Discussion with vendors
Continue Site Visits

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