Starting Soon:
ITRC Ethylene Oxide (EtO)

Ethylene Oxide (EtO) Guidance
https://eto-1.itrcweb.org/

Use "Join Audio" option in lower left of Zoom webinar to listen to webinar
Problems joining audio? Please call in manually

Dial In 312 626 6799
Webinar ID: 898 7781 5889#

Poll Question

I represent…

- Industry/ Contractor
- State
- Tribal
- Federal
- Community
- Local Government
- Academic
- Other

Housekeeping

- This event is being recorded; Event will be available On Demand after the event
- If you have technical difficulties, please use the Q&A Pod to request technical support

ITRC – Shaping the Future of Regulatory Acceptance

Host Organization

Network - All 50 states, PR, DC

Federal Partners

DOE DOD EPA

ITRC Industry Affiliates Program

Academia

Community Stakeholders

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EtO – What You Need to Know

Sponsored by: Interstate Technology and Regulatory Council (www.itrcweb.org)

Meet the ITRC Trainers

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Training Roadmap

- **ETO Training Introduction**
- **Sources, Uses, & Exposure Pathways**
- **Community & Stakeholder Communications**
- **Control Technologies**
- **Sampling & Monitoring**
- **Regulations**
- **Continuous Outreach & Resources**
- **Q&A**

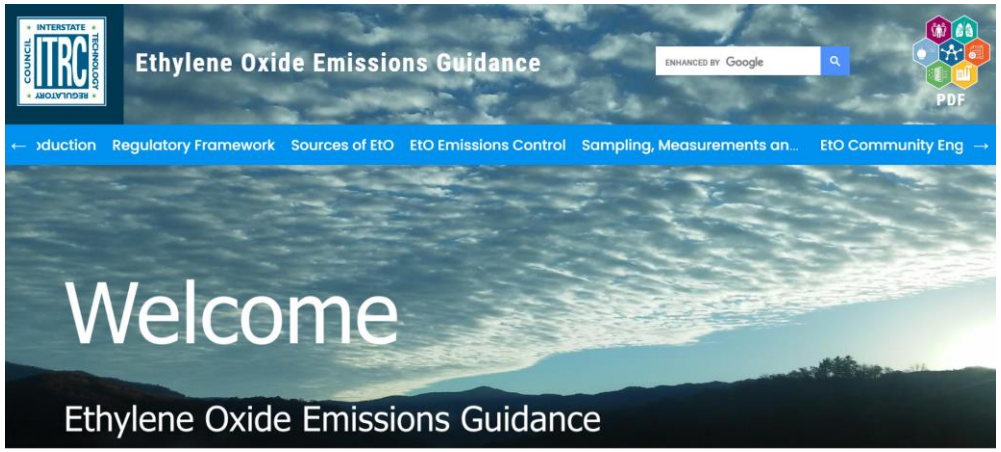
What you will learn

- Characteristics of EtO
- Health Hazards of EtO
- Best practices for sampling and analysis
- Community engagement concepts
- What regulations apply?
- Learn where to get more help

CAUTION!
Emerging Contaminant –
Changing Regulatory Landscape

EtO Guide

- Developed by subject matter experts in the field of EtO
- Includes information on what we know **now**
- Additional resources and links



Case Study – The Acme Company

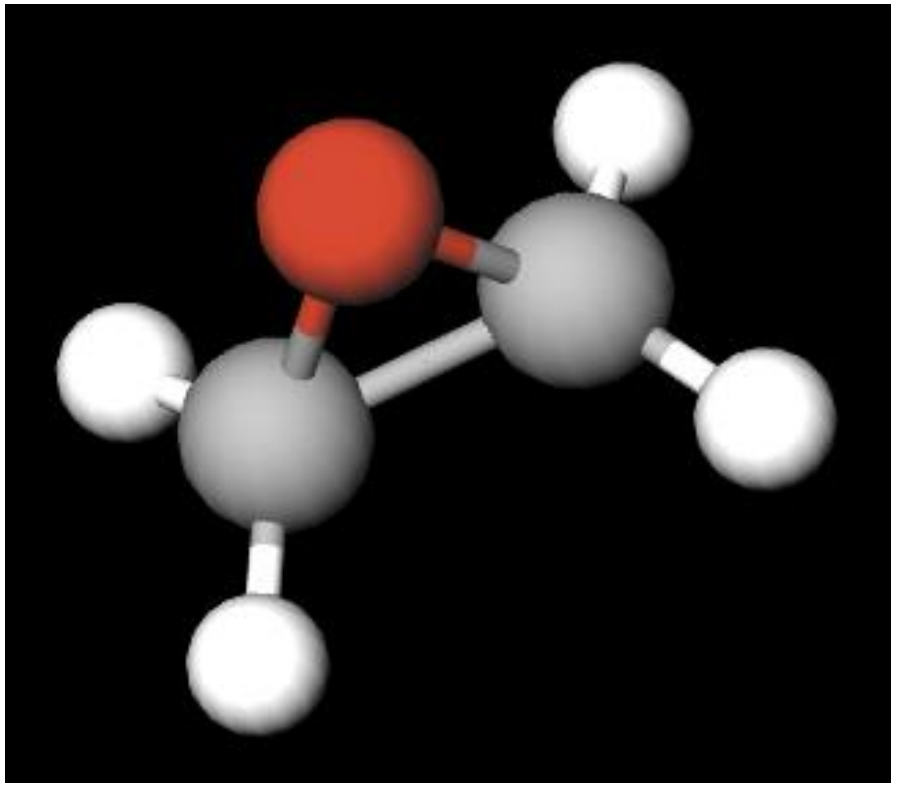
EtO Sterilizer Case Study Mock-up

What is Ethylene Oxide (EtO)

Flammable, colorless, and reactive gas

Primary source industrial

Endogenous sources



Why EtO?

Categorized as a human carcinogen.*

One of 188 **listed hazardous air pollutants (HAP)** covered under Section 112 of the Clean Air Act (CAA).

In 2016, the USEPA classified EtO as "carcinogenic to humans"

USEPA analyses show that EtO emissions may pose a greater public health concern than previously realized

* By the World Health Organization (WHO), the United States Environmental Protection Agency (USEPA), the Department of Health and Human Services (HHS), and other health agencies.

EtO Icon

Section 1.1.1

https://eto-1.itrcweb.org/

Poll Question

What is your experience with EtO?

- No experience
- Some experience
- Moderate experience
- Lots of experience

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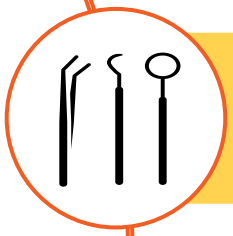
Production & Uses of Ethylene Oxide

Chemical intermediate: Used to make other chemicals, e.g., ethylene glycol (antifreeze, polyester fibers), surfactants (soap)



Commercial sterilization of medical devices and heat- and moisture-sensitive equipment (e.g., bandages, disposable syringes, tubing)

Non-commercial sterilization: hospital/clinic scale with benchtop sterilization units

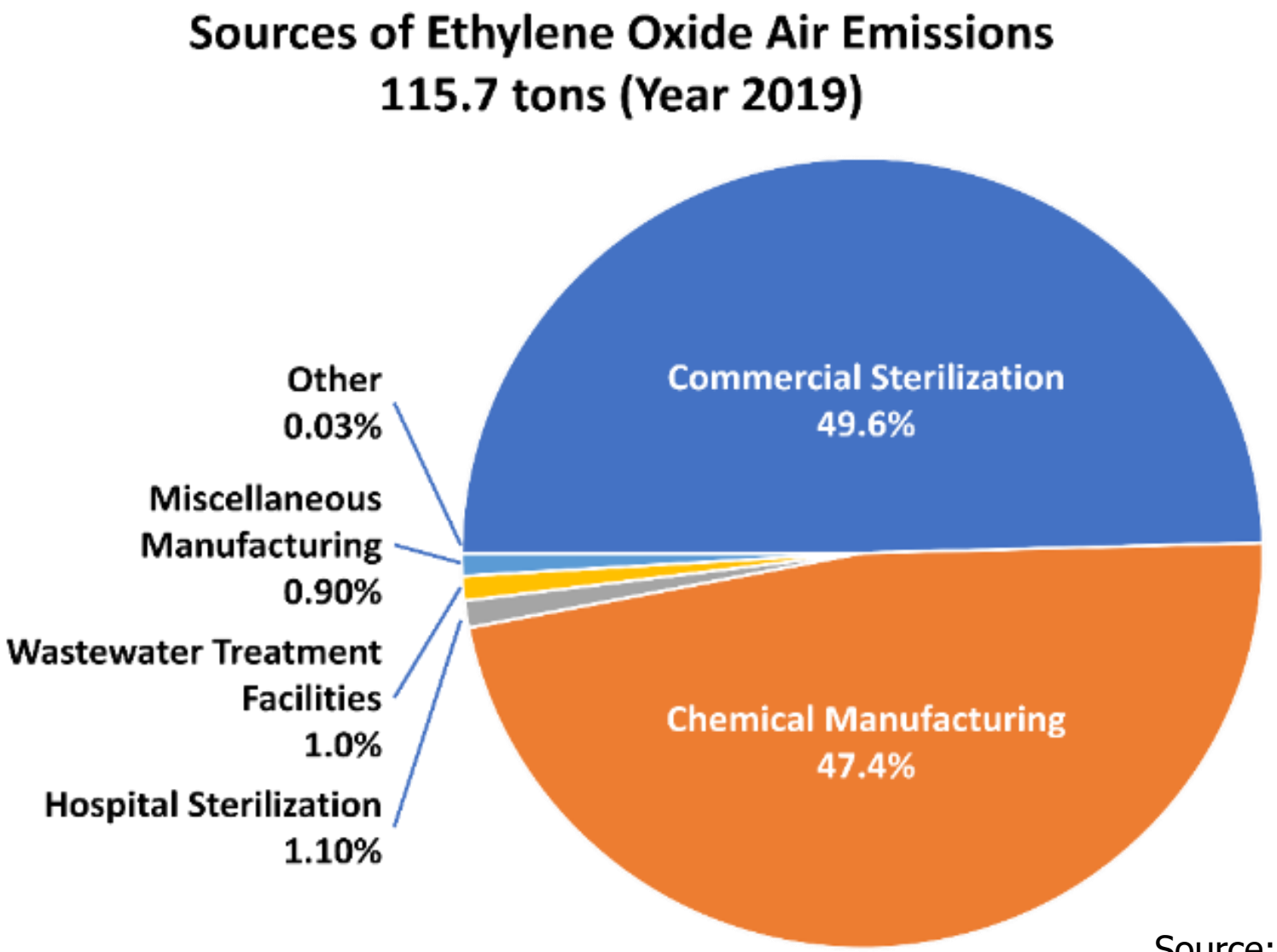
Other uses: Fumigation of spices, pest control of imported goods (country dependent)

Poll Question

Products that are made from EtO raw material include

- Carpet backing and furniture cushioning
- Motor vehicle antifreezes
- Personal care products
- All of the above
- None of the above

Emissions: Known Sources of EtO to Air



Source: USEPA AirToxScreen 2019

Known and Potential Sources of Ethylene Oxide

Section 4

1

Known Industry
Emission of EtO to Ambient Air

- Chemical Manufacturing
- Sterilizers

2

Potential Primary
Sources of EtO to Ambient Air

- Smoking
- General Combustion Byproducts

3

Potential Secondary
Sources of EtO

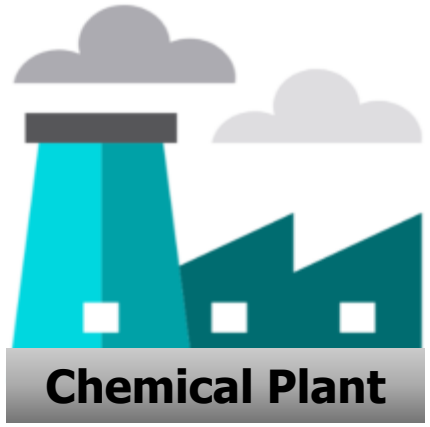
- Human Body Metabolism
- Oxidized to EtO
- Conversion to EtO in Plants & Microorganisms

Releases of Ethylene Oxide into the Environment

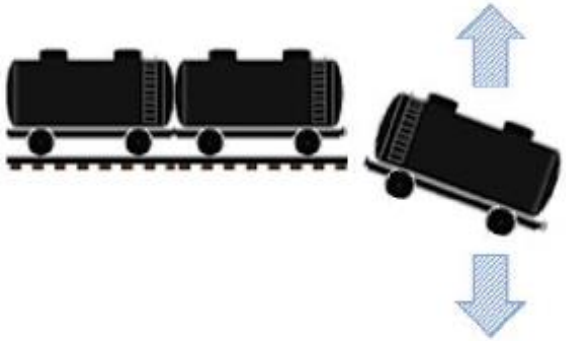
Sections 2 and 4

Atmospheric half-life of 2-5 months

Stack & Fugitive EtO Releases to Air

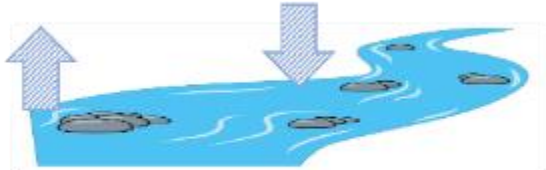


Accidental Spills during Transport



Releases to Water

Rapid Evaporation to Air (Half-Life of 1 Hour^*)



Ready Biodegradation to EG in Water
(Half-Life of < 15 Days*^)

Releases to Soil

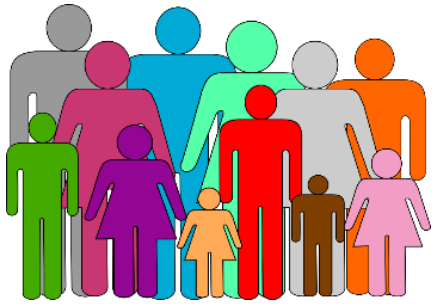
Rapid Evaporation to Air^

Rapid Hydrolysis to EG in Soil and Groundwater
(Half-Life of 11–12 Days^)

How Can I Be Exposed to EtO?

Sections 2.4 and 7.1

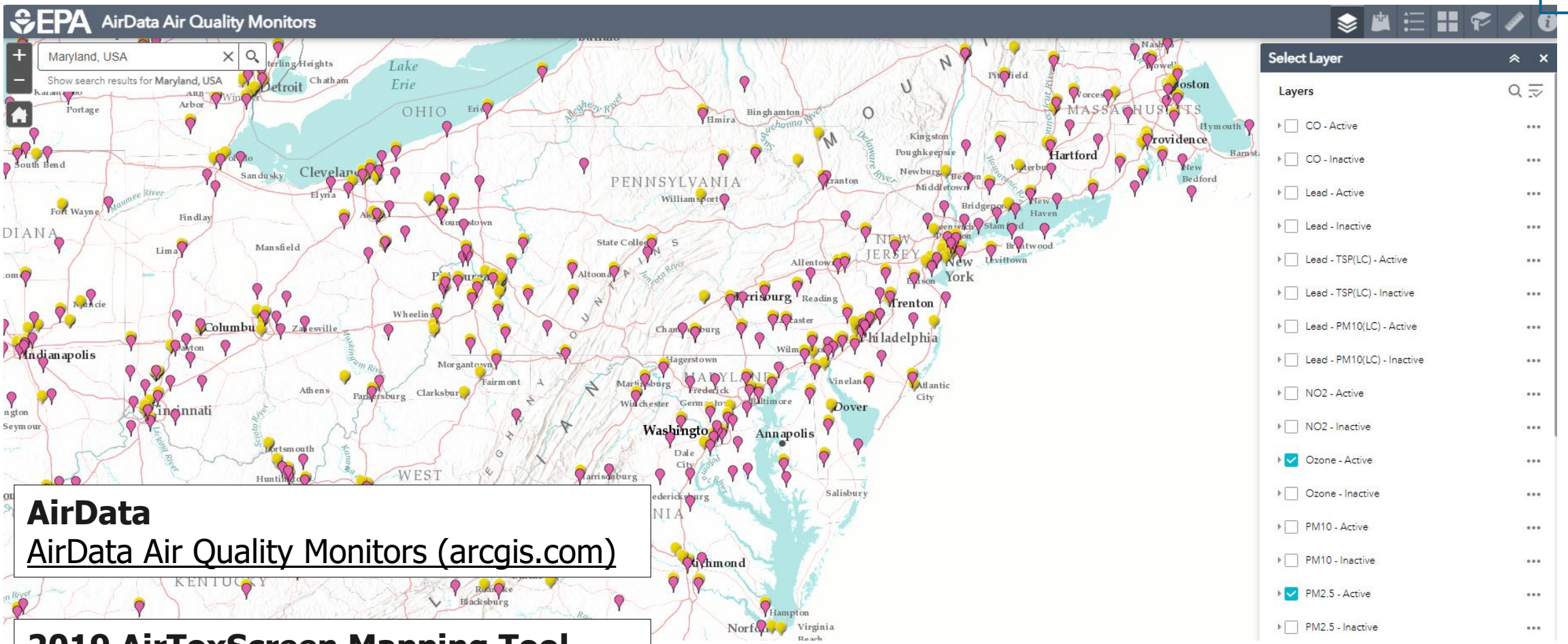
- Inhalation – the primary route of EtO exposure
- Work-Place
- Individual
- Background



https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide

Tools for Learning About Air Quality

Section 7.2



AirData
AirData Air Quality Monitors (arcgis.com)

2019 AirToxScreen Mapping Tool
https://www.epa.gov/AirToxScreen/airtoxscreen-mapping-tool

Training Roadmap

ETO Training Introduction

Sources, Uses, & Exposure Pathways

Community & Stakeholder Communications

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Continuous Outreach & Resources

Q&A

Who are the Stakeholders?

Communities and Communication

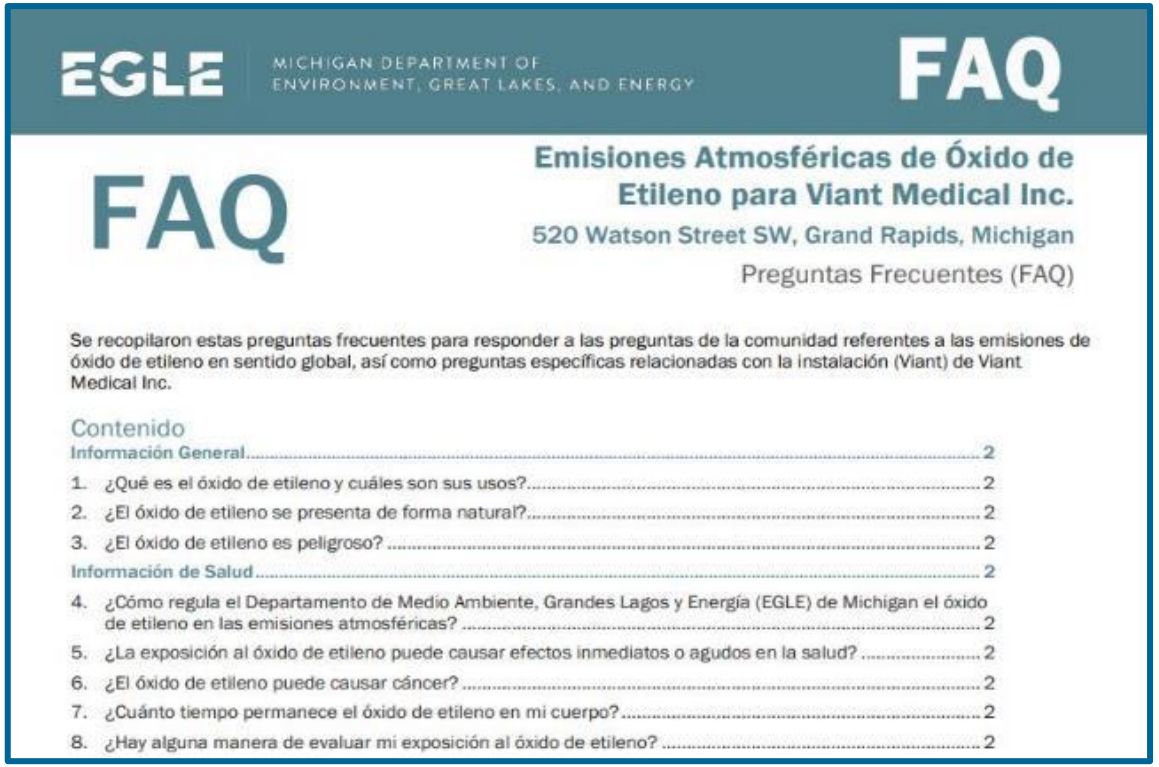
Early Stakeholder Engagement is Ideal

Active Listening

Explain Your Processes

Engaging with the Public

- Engage with stakeholders beforehand
- Gauge community interest
- Plan public meeting/hearing
- Logistics - space/sizing
- Consider limited English proficiency community needs - assess if interpreter is needed.



EGLE MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY FAQ

FAQ

Emisiones Atmosféricas de Óxido de Etileno para Viant Medical Inc.

520 Watson Street SW, Grand Rapids, Michigan

Preguntas Frecuentes (FAQ)

Se recopilaron estas preguntas frecuentes para responder a las preguntas de la comunidad referentes a las emisiones de óxido de etileno en sentido global, así como preguntas específicas relacionadas con la instalación (Viant) de Viant Medical Inc.

Contenido

Información General 2
1. ¿Qué es el óxido de etileno y cuáles son sus usos? 2
2. ¿El óxido de etileno se presenta de forma natural? 2
3. ¿El óxido de etileno es peligroso? 2
Información de Salud 2
4. ¿Cómo regula el Departamento de Medio Ambiente, Grandes Lagos y Energía (EGLE) de Michigan el óxido de etileno en las emisiones atmosféricas? 2
5. ¿La exposición al óxido de etileno puede causar efectos inmediatos o agudos en la salud? 2
6. ¿El óxido de etileno puede causar cáncer? 2
7. ¿Cuánto tiempo permanece el óxido de etileno en mi cuerpo? 2
8. ¿Hay alguna manera de evaluar mi exposición al óxido de etileno? 2

Engaging with the Public

Engage with state and local health departments – Invite them to be present at the meeting

Be Transparent

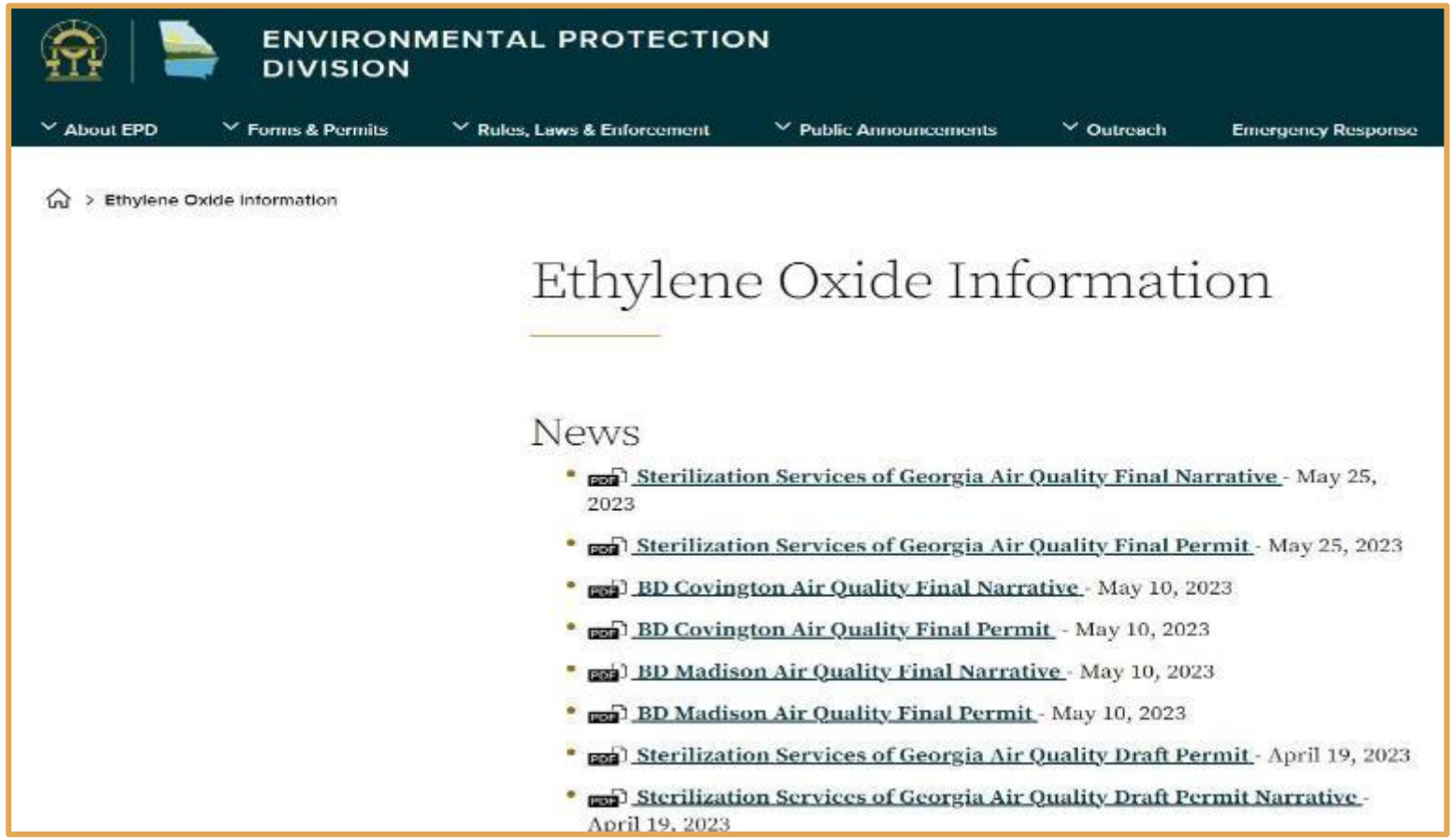
Be Prepared

Case Study – Who to Contact?

- Fence line communities
- Local government officials
- State and local health officials
- Manufacturers and users of EtO
- Nearby businesses
- Employees at facilities that use EtO

COMMUNICATION IS KEY!!

Case Study – Engaging with the public



Update website – do what you say, say what you do!

Case Study – Your Team

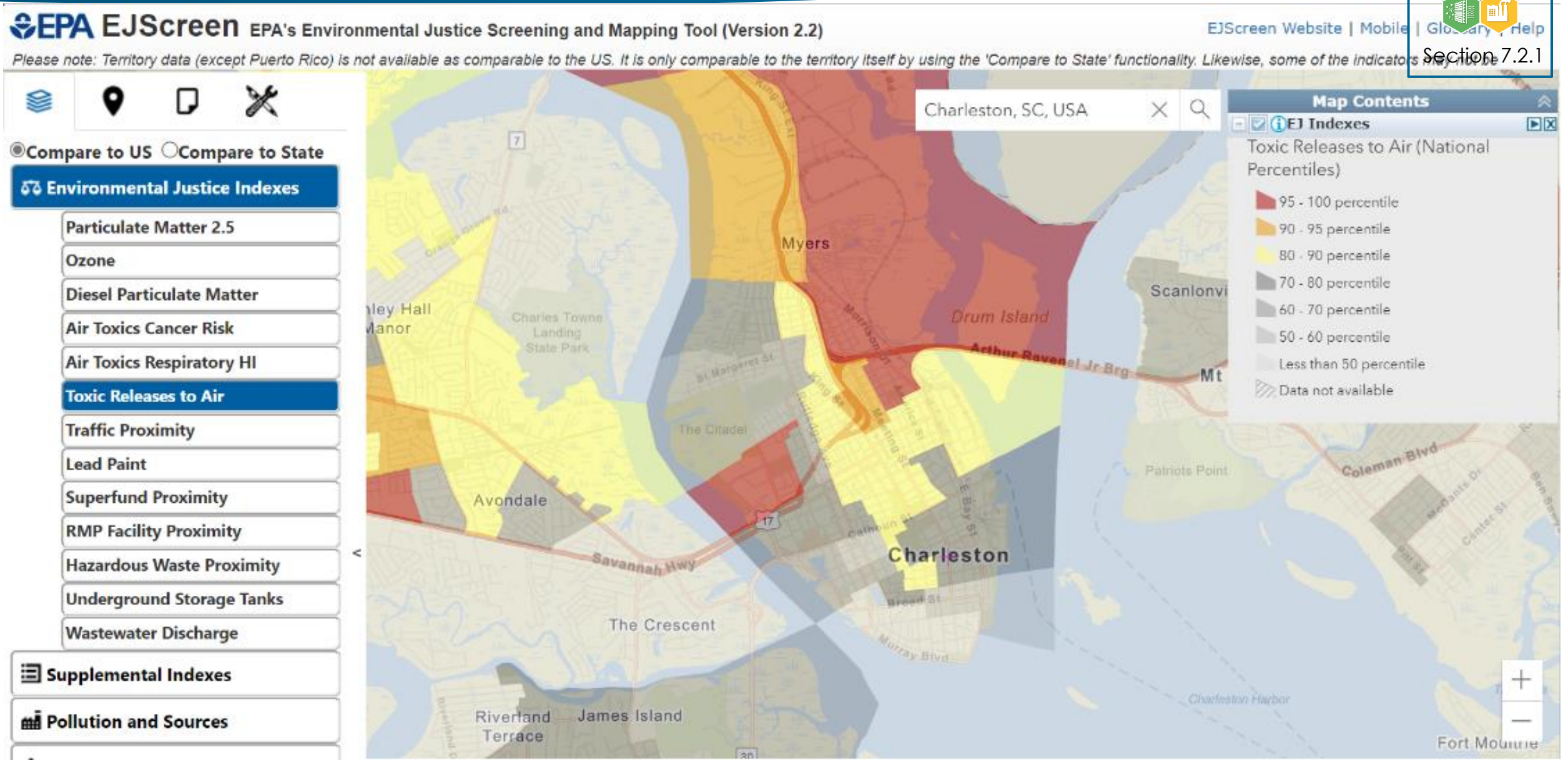
Lifetime Residential Cancer Risks – EtO Sterilization
ACME Company, Anywhere, USA

Case Study – What **Should** Be Communicated?

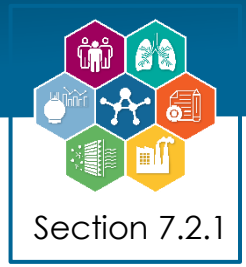
- Remember your audience
- Timely release of information
- Modeling results
- Next Steps

Environmental Justice (EJ)

Section 7.2.1



Additional EJ Resources



- USEPA's EnviroFacts
- Executive Order 14008 – Climate and Economic Justice Screening Tool
- ATSDR's Environmental Justice Index
- State-Specific Resources
- National Tribal Air Association

Poll Question

Name a potential EtO stakeholder

- Short answer

Training Roadmap

ETO Training Introduction

Sources, Uses, & Exposure Pathways

Community & Stakeholder Communications

Control Technologies

Sampling & Monitoring

Regulations

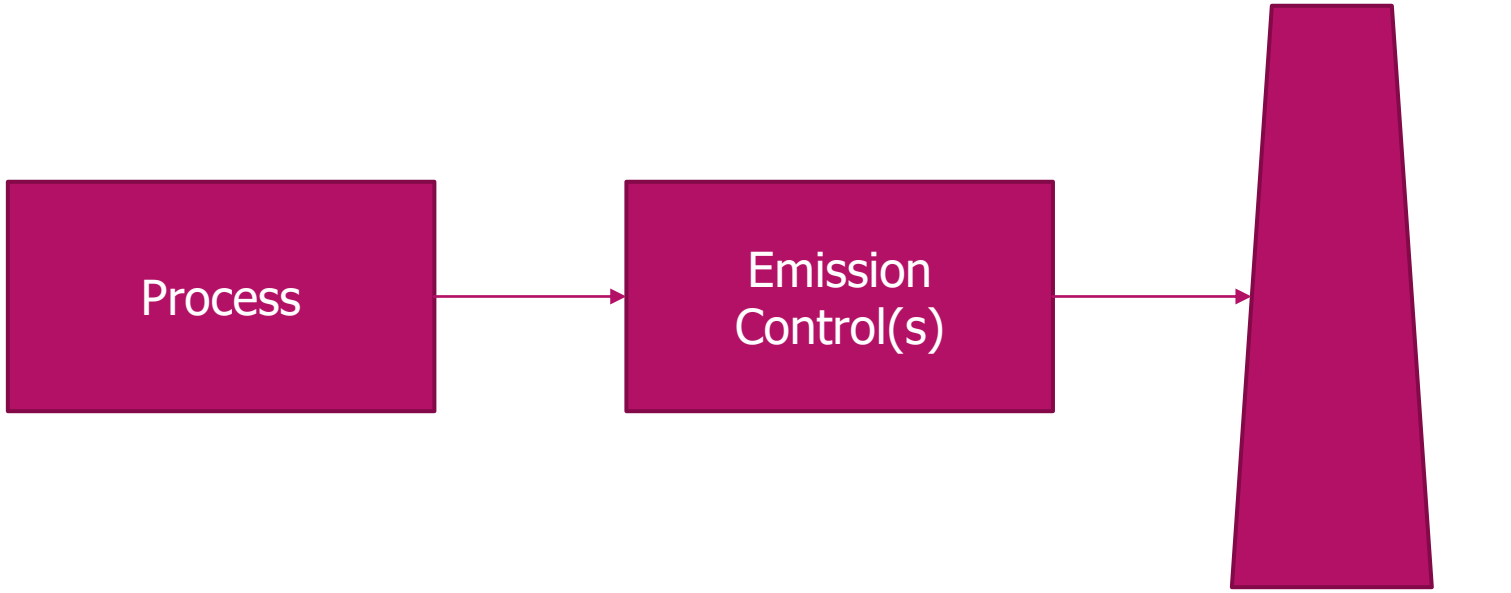
Continuous Outreach & Resources

Q&A

Control Technologies

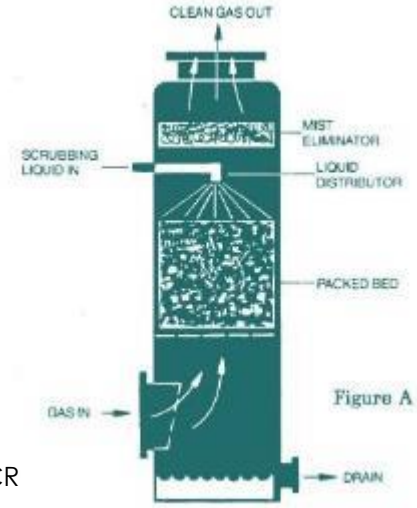
Control Technologies

- Typically apply to sources regulated under USEPA's NESHAP rules
- Control technologies
  - Reduce emissions from industrial processes, prior to venting to atmosphere
  - Are typically subject to permitting and monitoring requirements



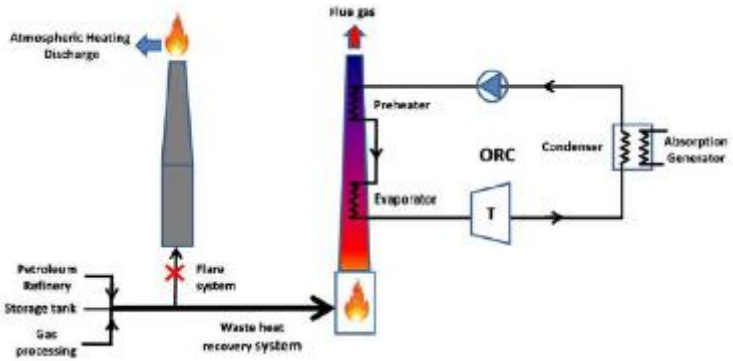
Examples of Control Technologies

Wet Scrubber



Source: CR Clean Air

Thermal Flare

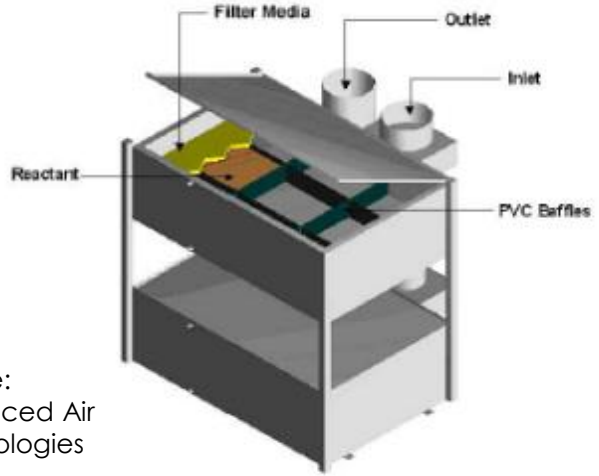


Source: Semmari and colleagues

Bubbling Scrubber

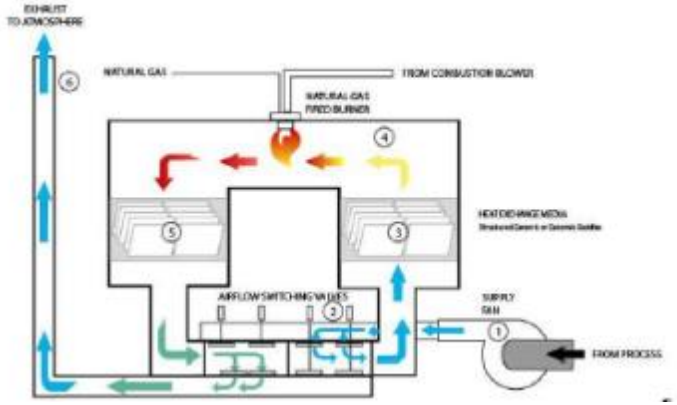
Source: Cosmed

Dry Bed Scrubber



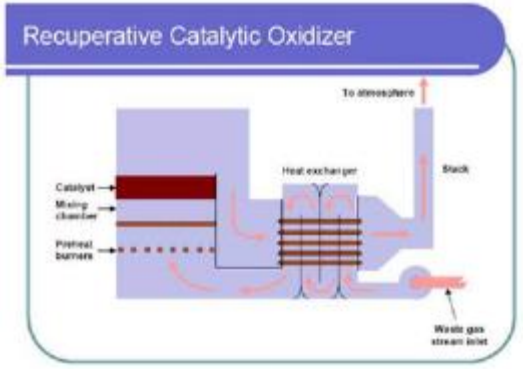
Source: Advanced Air Technologies

Thermal Oxidizer



Source: Kono Kogs

Catalytic Oxidizer



Source: USEPA

Training Roadmap

ETO Training Introduction

Sources, Uses, & Exposure Pathways

Community & Stakeholder Communications

Control Technologies

Sampling & Monitoring

Regulations

Continuous Outreach & Resources

Q&A

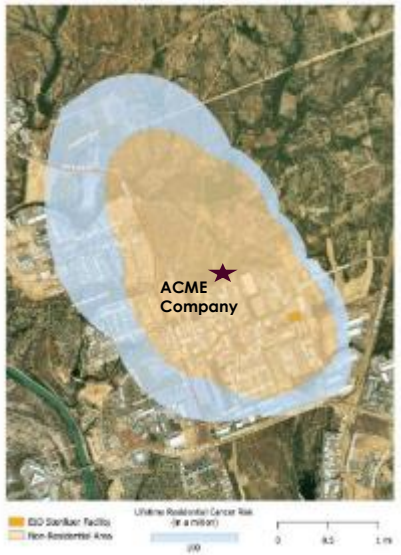
How do you Know Where to Start?

- Review of Air Permits and Source Inspections
- Research Similar Industries
  - What Emission Factors Exist?
- Emissions Inventories
- Modeling
  - To determine if site-specific or community sampling is necessary
- Stack Testing

What Types of Data are Available?

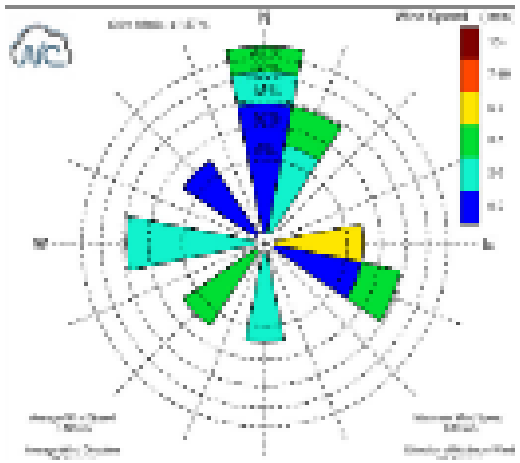
Modeling

- Estimate EtO concentrations across broad areas
- Calculate and predict EtO concentrations, including below the method detection limit, allowing study of a wider range of potential risks
- Estimate long-term average concentrations
- Used for risk assessments
- Identify areas where monitoring may provide more detailed information
- Generally, a health-protective estimate



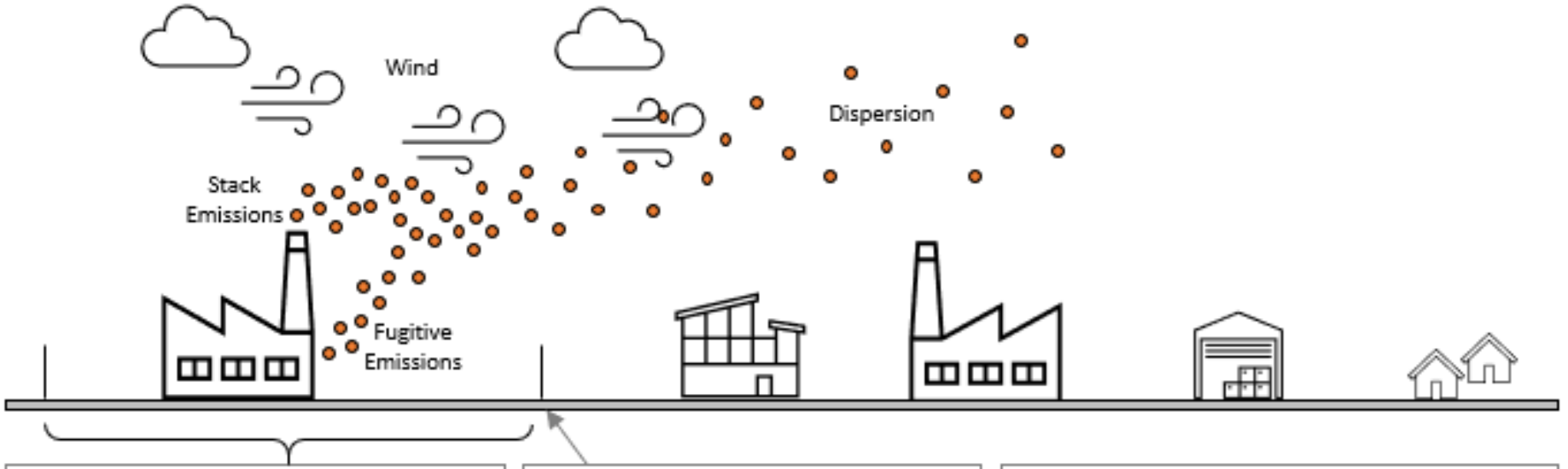
Measurement

- Determine EtO concentration at specific locations and times
- Control and limit model inputs
- Calibrate models
- Quantify any change in concentrations of ethylene oxide in the ambient air
- Confirm facility reported emissions



What are your Project Goals?

Section 6.2



Inside Facility Boundary	Fenceline	Outside Facility Boundary
Monitoring to show compliance, gather inputs for models	Monitoring to show compliance, confirm model results	Monitoring to calibrate models, provide actual concentrations at specific times and locations, reflect all sources
Measurement Locations: Stack / Source; Near Source; Work Areas	Measurement Locations: Points along facility boundary	Measurement Locations: Ambient air monitoring network stations, temporary monitoring points, or mobile monitoring points
Sampling Typically Performed by: Facility	Sampling Typically Performed by: Facility or States	Sampling Typically Performed by: States

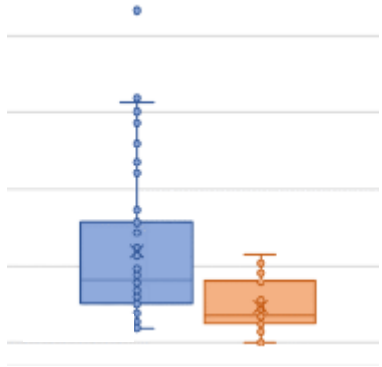
Notes: 1) Not to scale. 2) Cartoon for illustration only; not all scenarios depicted. 3) Figure after USEPA 2019b.

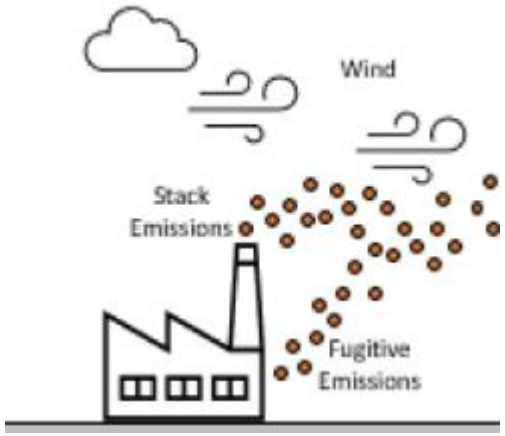
How will the Data be Used?

Section 6.2

- Understanding frequency and purpose of collection are critical
- Continuous or sampling over production cycle may be sufficient to characterize emissions and effectiveness of control equipment
- Chronic risk assessments
  - Single grab sample or small groups of samples are not sufficient
- Ambient concentrations at fence line or community
- Determine emission rate emitted from the facility at stack

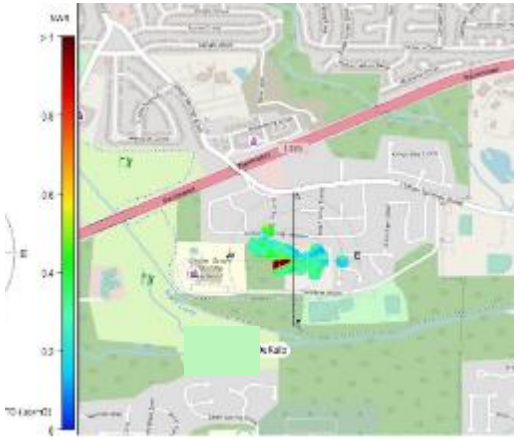
Comparison of sites/controls





Determination of stack/fugitive emissions

Characterize concentrations



What Sampling Equipment to Use?

Sections 6.3 and 6.5

TO15/TO15A Canister Sampling

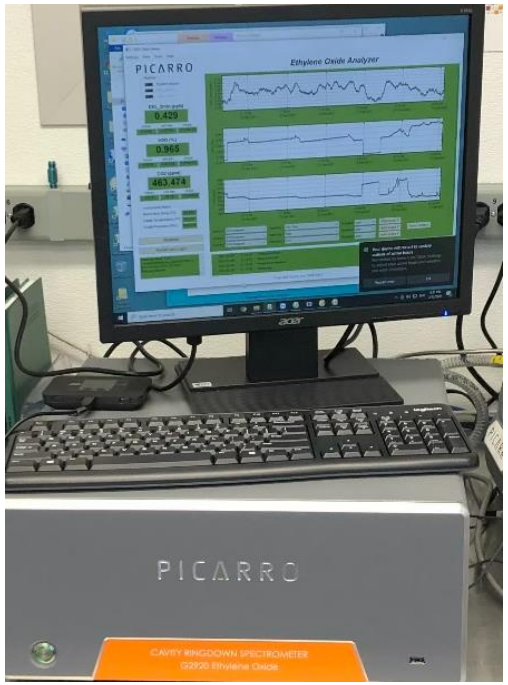
Passive Sampling

Source: MI EGLE

Active (pressurized) Sampling

Source: GA EPD

Continuous Sampling

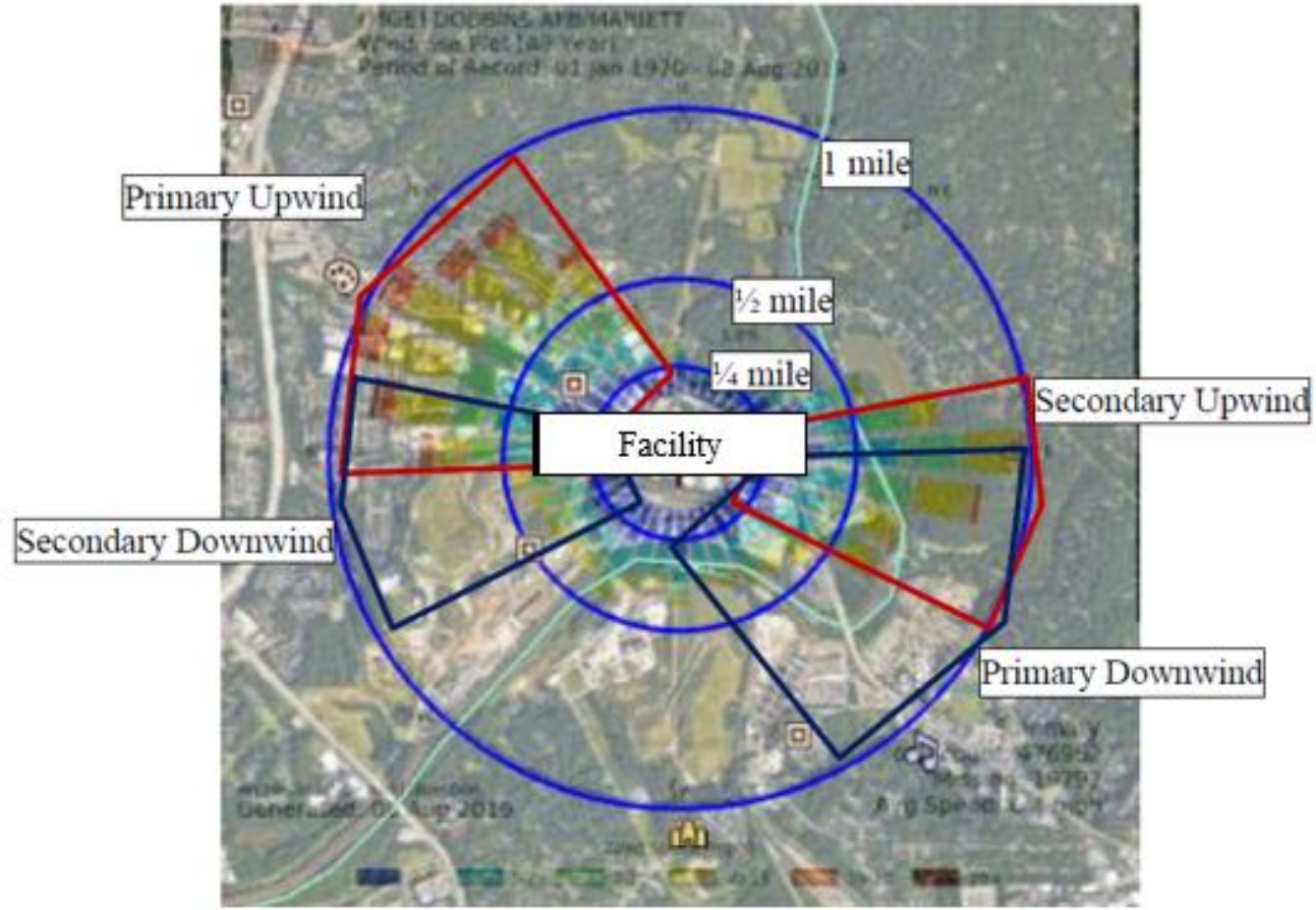


Source: GA EPD

Logistical Considerations for Sampling

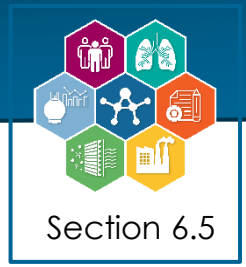
Section 6.2

- Breathing zone
- Obstructions in monitoring pathway
- Dispersion modeling to choose sampling locations
- Operations of Nearby Facilities
- Quality Assurance
- Sampling Duration



Source: Georgia Department of Natural Resources

What are Some Challenges of Sampling?



Understanding of limitations is critical

Research is ongoing to overcome issues and develop better methodology

Recommend data validation and potential biases be accounted for in data reporting

Source Testing

Section 6.3.1

Source (in-stack) Monitoring

- Continuous Emission Monitoring Systems (CEMS)
- Stack Testing – Periodic testing for regulatory compliance
- Federal or state/local regulation for the appropriate test method

Regulatory Analytical Challenges

- Is the method sensitive to interferences?
- Is there any occurrence of EtO formation in the canisters?
- Is the operation of any EtO measurement with field analysis performed by qualified individual?

EtO Uncertainties – Background EtO

Section 1.1.2

Background EtO: unsure what is being measured if we don't know where it's coming from

Studies have detected EtO in rural and rural settings with no known source of EtO in the vicinity

Analytical limitations make understanding the background challenging

Questions

Ethylene Oxide (EtO) Guidance

https://eto-1.itrcweb.org

Knowledge check: Cannot use short term sampling to calculate risk, must use modeling.

Training Roadmap

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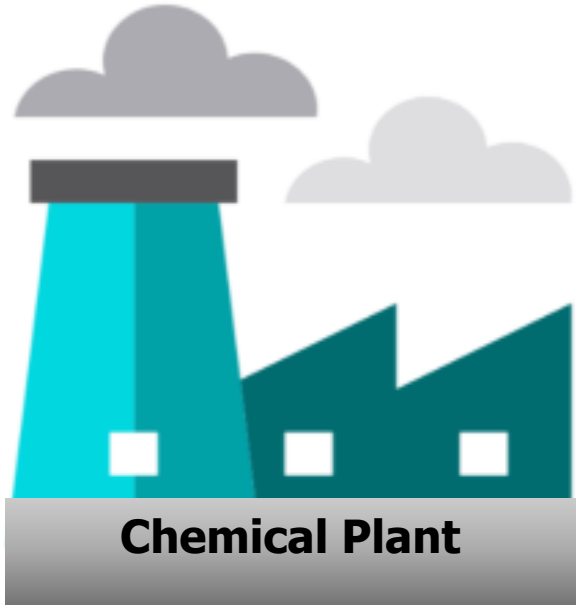
Q&A

Regulatory Framework – Categories

Section 3.4

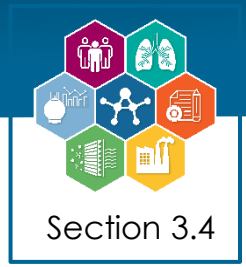


Chemical Manufacturing Industry

EtO Sterilization Industry

Note: Regulatory information presented is current as of 11/27/2023.

Regulations – Chemical Manufacturing Industry



National Emission Standards for Hazardous Pollutants (NESHAP) from the Synthetic Organic Chemical Industry (SOCMI)

- Spans four (4) Subparts of 40 CFR Part 63 (Subparts F, G, H, and I)
- Also known as SOCMI and the Hazardous Organic NESHAP, or HON

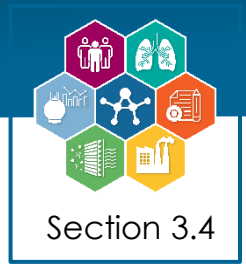
NESHAP Emissions for Polyether Polyols Production

- 40 CFR Part 63 Subpart PPP

National Emission Standards for Hazardous Pollutants (NESHAP) from NESHAP for Miscellaneous Organic Manufacturing

- 40 CFR Part 63 Subpart FFFF
- Also known as the Miscellaneous Organic NESHAP, or MON

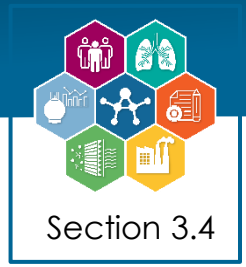
Regulations – Chemical Manufacturing Industry



	NESHAP Subpart					
	F	G	H	I	PPP	FFFF
Also Known As	SOCMI / HON					MON
Date of Current Rule	12/21/2006				3/27/2014	8/12/2020
Under Review?	Yes				No	No
Source Status	Major				Major	Major

NESHAP – National Emission Standards for Hazardous Air Pollutants

Regulations – Sterilization Industry



Ethylene Oxide Emissions Standards for Sterilization Facilities	• 40 CFR Part 63 Subpart O
NESHAP for Hospital Ethylene Oxide Sterilizers	• 40 CFR Part 63 Subpart FFFF • Also known as the Miscellaneous Organic NESHAP, or MON

Regulations – Sterilization Industry

Section 3.4.1 and 3.4.2

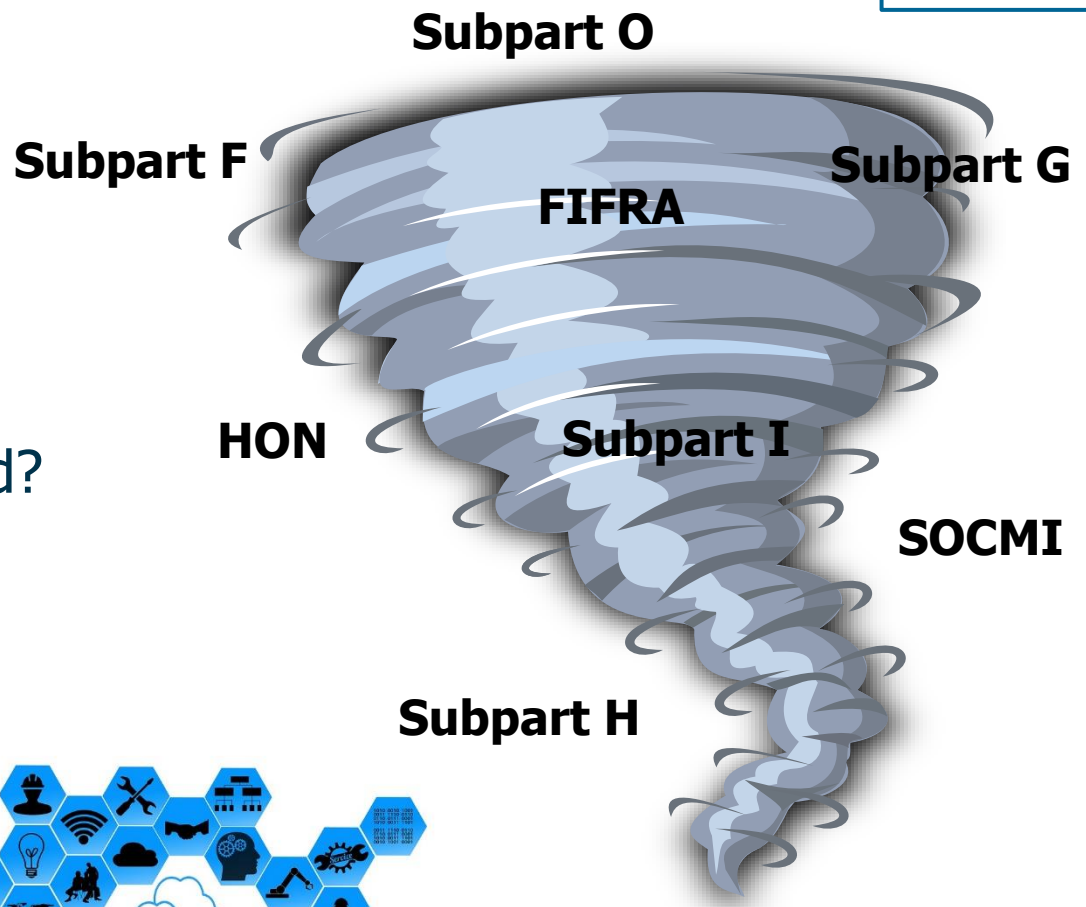
NESHAP Subpart

	O	WWWWW
Date of Current Rule	4/7/2006	12/28/2007
Under Review?	Yes	No
Source Status	Major & Area (>1 ton/year)	Area

NESHAP – National Emission Standards for Hazardous Air Pollutants

Case Study – Which Requirements Apply/Where to Start?

- State issued permits
- State air toxics regulations
- Control device operating parameters
- Stack test data
  - Does data exist or is a new stack test needed?
- Federal Regulation
  - NESHAP – Subpart O
    - Area Source or Major Source?
- FIFRA
  - Who enforces this in your region or area



Poll Question

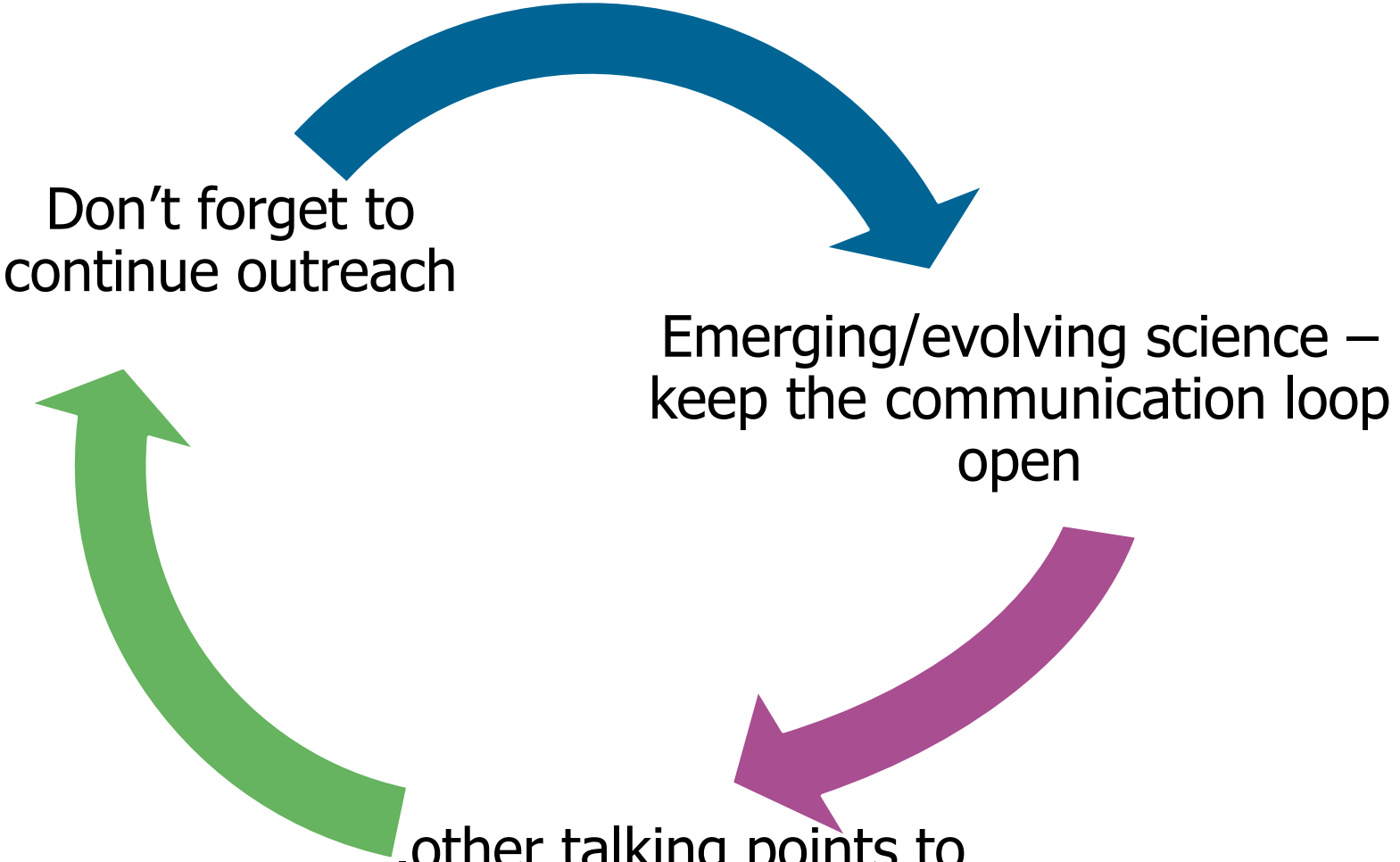
What EtO regulations are you aware of?

- Short answer

Training Roadmap

- ETO Training Introduction
- Sources, Uses, & Exposure Pathways
- Community & Stakeholder Communications
- Control Technologies
- Sampling & Monitoring
- Regulations
- Continuous Outreach & Resources
- Q&A

Stakeholder – Continuous Outreach



Risk Communication

Section 7.3.1

- Webpages & fact sheets
- Community is an important source of information
- ITRC Risk Communication Toolkit https://rct-1.itrcweb.org/

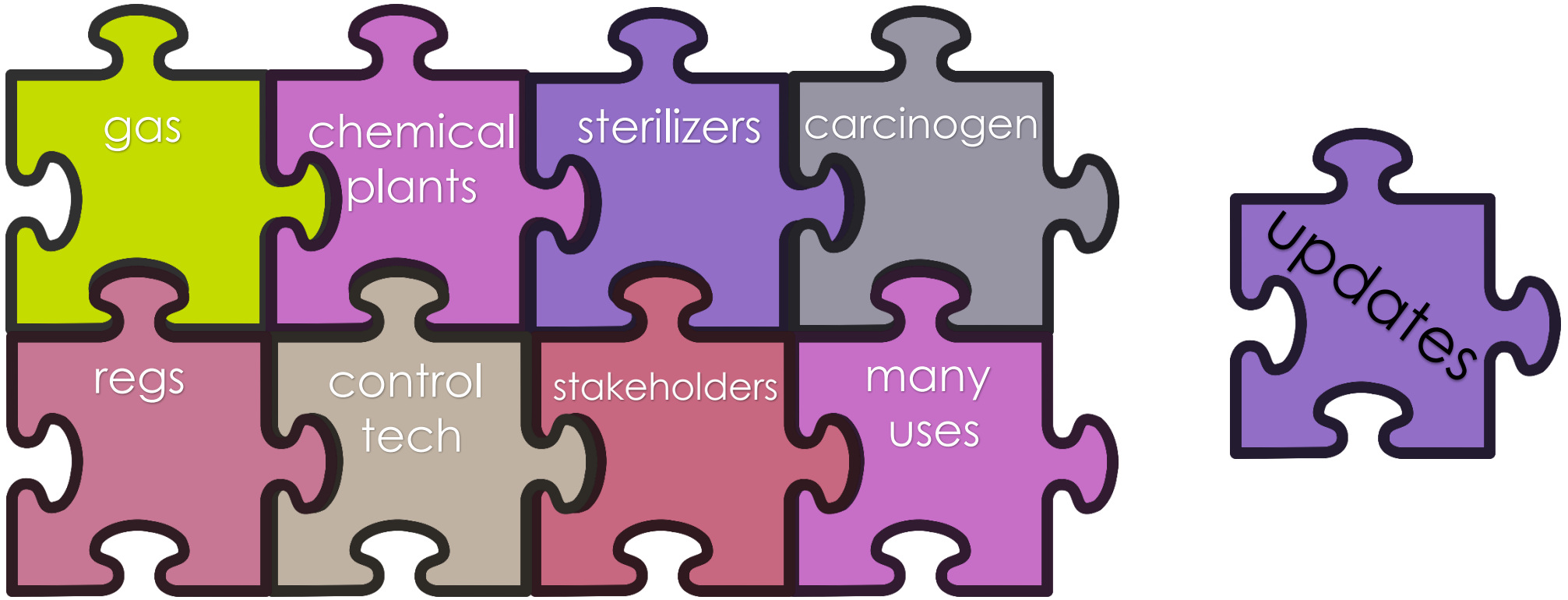
Figure 1. Five Key Aspects of Risk Communication

Additional Resources

Sections 7.2.2-7.2.4

- USEPA Ethylene Oxide (EtO) FAQs
- ATSDR Clinician Brief: Ethylene Oxide, ATSDR's Community Engagement Playbook
- OSHA Safety Data Sheet for Ethylene Oxide
- U.S. Food and Drug Administration (FDA)
- CDC Toxicological profile for Ethylene Oxide
- States: Refer to the Regulatory Framework Section

Training Wrap-Up



Questions

Ethylene Oxide (EtO) Guidance

https://eto-1.itrcweb.org