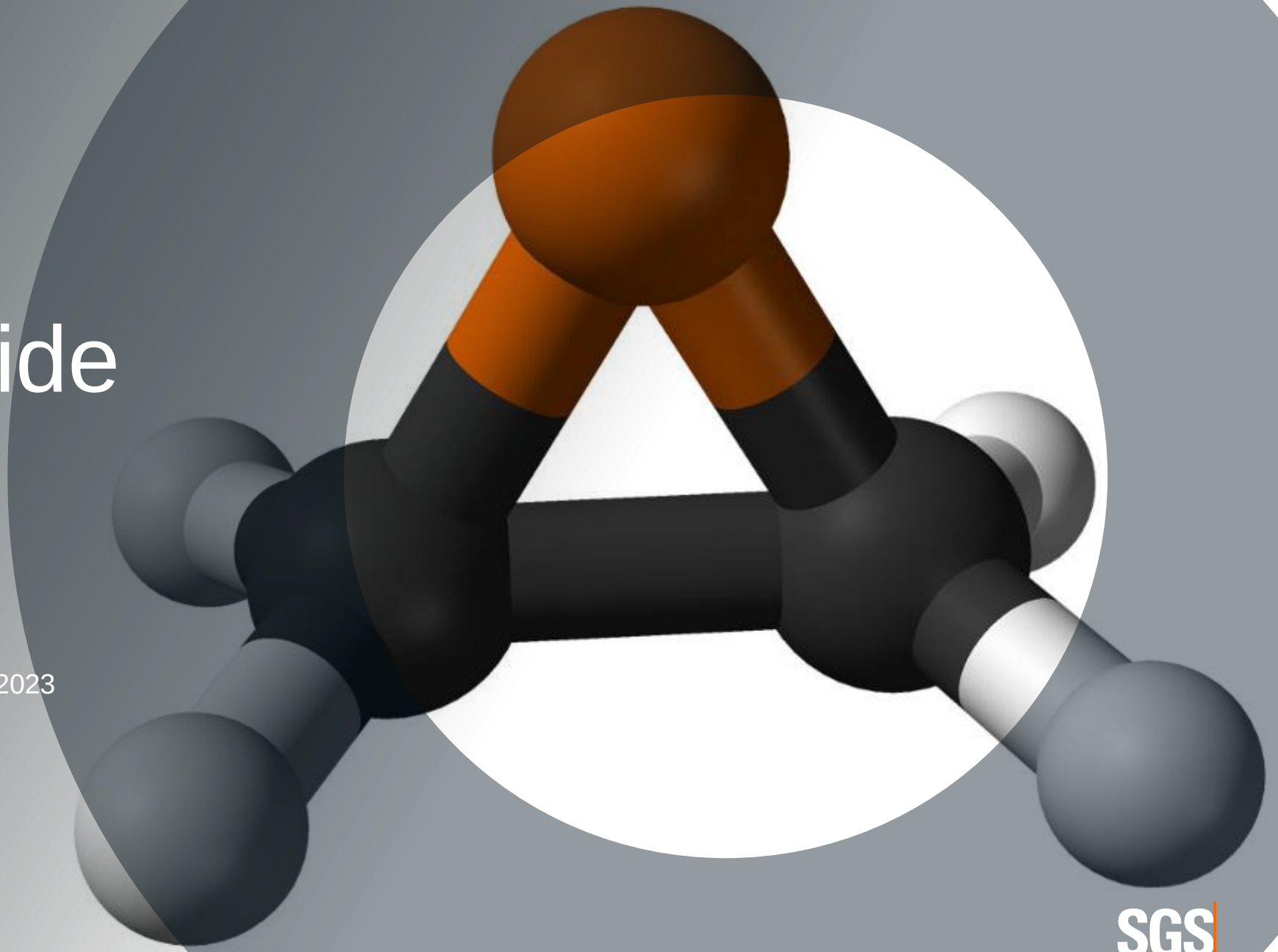
I&E INDUSTRIES & ENVIRONMENT

Ethylene Oxide

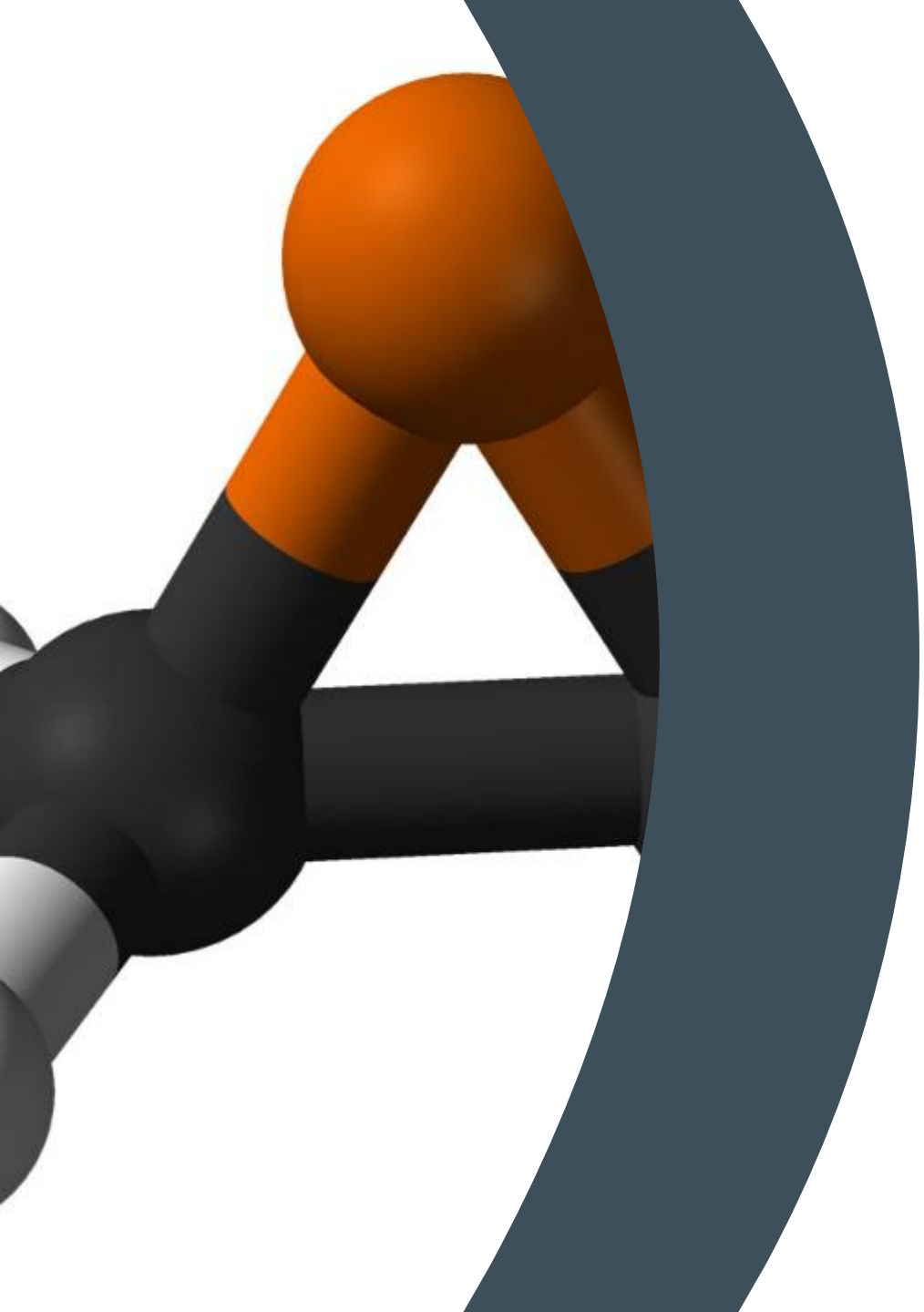
Update From the ITRC and EPA



Ed Stuber , CIH, ROH, FAIHA | August 8, 2023

SAFER
GREENER
SMARTER

SGS



Agenda

- All About Ethylene Oxide (EtO)
- ITRC Update
- Latest Proposed Legislations from the EPA
- FDA Innovation Challenges

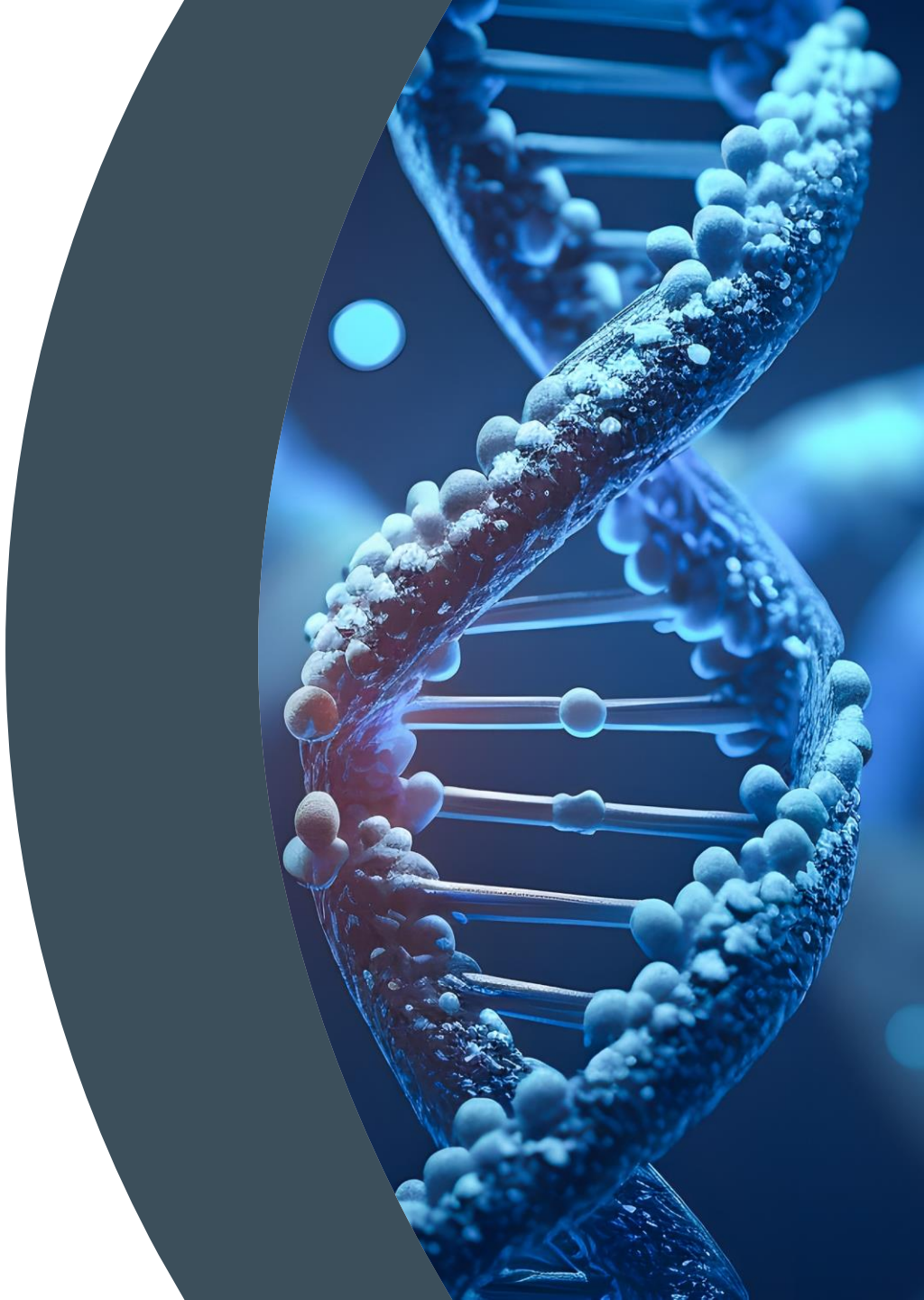
All About Ethylene Oxide (EtO)

Ethylene Oxide (EtO)

- EtO is a flammable, colorless gas used to make other chemicals for a range of products, including antifreeze, textiles, plastics, detergents, and adhesives.
- History
  - 1859 – Discovered
  - 1914 – first production of ethylene glycol
  - 1940’s – first use of sterilization
- USA production
  - 2.8 metric tons – 2019 last known figures
- USES –
  - manufacturing of other chemicals 97% (example – antifreeze)
  - Sterilization (example – hospitals)
  - Fumigation (example – spices)

Hazardous Properties of Ethylene Oxide Chronic Exposure

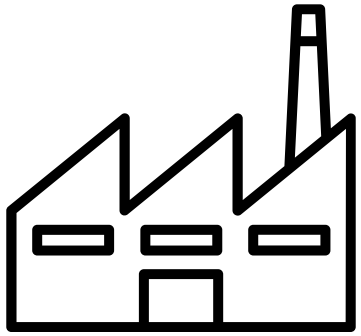
- Mutagen – Disrupts DNA
- CNS Depressant – Chronic Exposure Leads to Permanent Damage
- Damage to Eyes, Lungs, Skin
- In 2008 IARC Classified as Class 1 Carcinogen
    - Linked to:
        - Non-Hodgkin Lymphoma
        - Leukemia
        - Breast Cancer



What Started the EtO Discussion

- USEPA addressing ambient EtO based on August 22, 2018, National Air Toxics Assessment (NATA)
- USEPA classified EtO as a human carcinogen December 2016 (U.S. EPA. Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/635/R-16/350F, 2016.)
  - Lowered safe limits 30X to 0.2 ppb – 1 in 1,000,000
- In response to public concerns – USEPA conducted testing in a Chicago suburb in May 2018 elevated levels of EtO were found – up to 9 ug/m^3.
  - Levels were estimated to raise the cancer risk 10X above “Acceptable Risk”

Exposure Limits and Analytical Methods

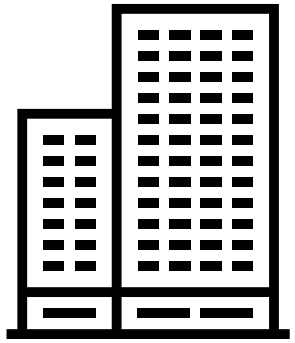


Occupational Exposures

OSHA PEL = 1 ppm; 5ppm Excursion Limit (15 Minutes)

ACGIH TLV = 1PPM

- Analytical Methods for Occupational Exposure
  - OSHA 1010v2 – Tubes coated with HBr, ECD Detection
    - LOQ = 0.6 ug
  - Modified OSHA 1010 – Passive Monitors Coated with HBr, ECD Detection
    - LOQ = 3 ug
- Ethylene Oxide Derivatized to 2-Bromoethanol



Ambient Air Monitoring

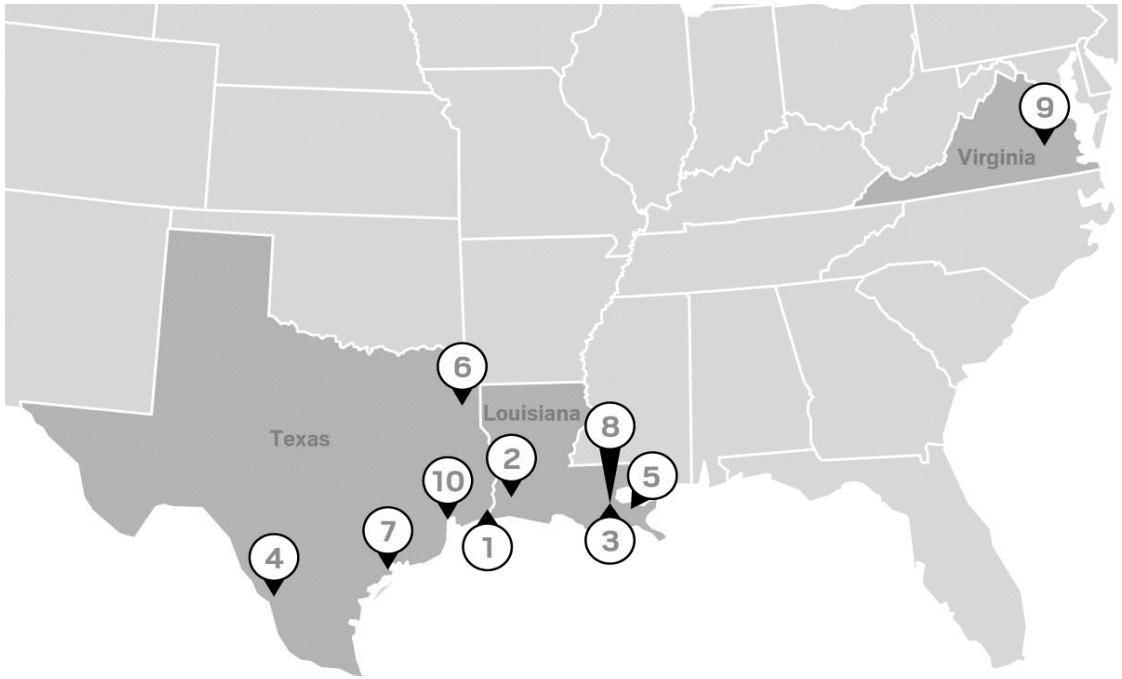
EPA Method TO-15 & TO-15a (Lower Level)

- Required LOQ for 1 in 1,000,000 0.01 ppbv
- 6 Liter Canister Typically Sampled 24 Hours to 1 week
  - Typical LOQ ~1.0 ppbv
- ETO Modification LOQ
  - EPA 0.045 ppbv

Ethylene Oxide (EtO) Emission Sources

- Fugitive emissions during production of chemicals
- Fugitive emissions during sterilization – medical devices, spices and subsequent off gassing
- Combustion byproduct of hydrocarbon fuels
- Cigarette smoke
- Human metabolism of ethylene

Top 10 US Emitters of EtO - 2017



Sterilization Facilities

Ranking	Facility	Location	Ethylene oxide emitted (kg)
1	Huntsman Petrochemical[a]	Port Neches, TX	18,420
2	Sasol Chemicals	Westlake, LA	7,461
3	BASF	Geismar, LA	6,895
4	Midwest Sterilization	Laredo, TX	6,734
5	Union Carbide (owned by Dow)	Hahnville, LA	6,584
6	Eastman Chemical	Longview, TX	6,069
7	Union Carbide (owned by Dow)	Seadrift, TX	5,080
8	Shell Chemical	Geismar, LA	4,275
9	Sterilization Services of Virginia	Richmond, VA	3,515
10	Celanese	Pasadena, TX	2,870

Interstate Technology and Regulatory Council (ITRC)

Introduction to ITRC

Mission

- Develop innovative products and training to provide the knowledge and skills to address environmental challenges within the U.S. and worldwide.

Teams

- Currently 12 teams including:
  - ETO
  - Passive Monitors
  - PFAS
  - Contaminants of Emerging Concern

About

ITRC is a state-led environmental coalition working to create innovative solutions and best management practices.

ITRC produces documents and training that broaden and deepen technical knowledge and expedite quality regulatory decision making while protecting human health and the environment.

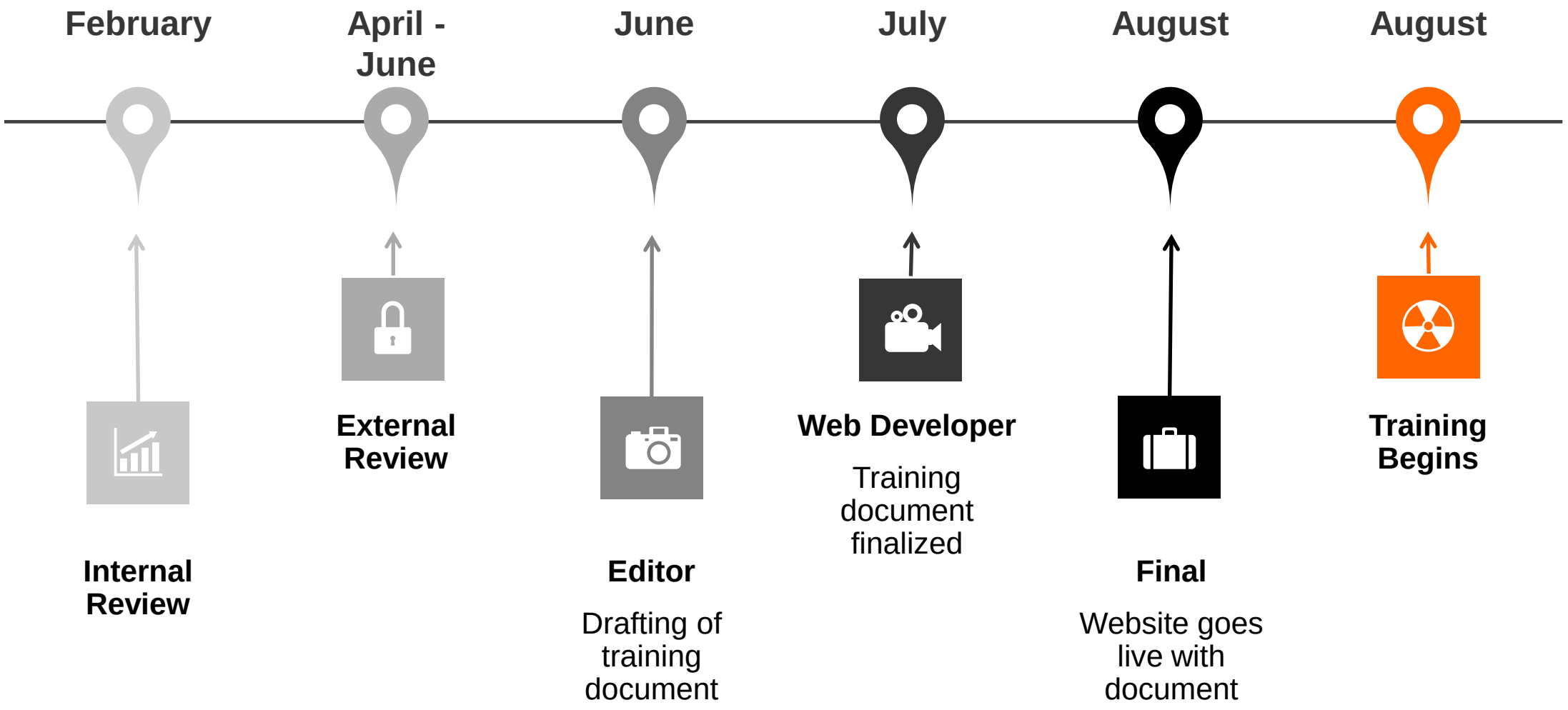
ITRC represents all 50 states with membership from state, federal, tribal, and international agencies, as well as members from academia, the private sector, and the public

ITRC EtO Team Document

Document

- 80 pages and 10 sections with team members
  - Introduction
  - Properties
  - Glossary
  - Regulatory Framework
  - Potential Uses and Sources
  - Emission Controls
  - Sampling and Analysis
  - Community Engagement
  - References
  - Acknowledgements

ITRC EtO Team Timeline



Latest Proposed Legislations from the EPA

EPA Proposed Legislation

The EPA has 2 separate proposed regulations:

- one is related to the **National Emission Standards for Hazardous Air Pollutants (NESHAP)** regulations for commercial sterilizers
- the second is for proposed changes to **Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)**.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- On April 11, 2023, the U.S. Environmental Protection Agency (EPA) used its authority under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to propose increased protections for workers and community members exposed to ethylene oxide (EtO) when it’s used to sterilize products.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- EPA has also proposed a new requirement that all workers in a facility wear personal protective equipment when EtO concentrations exceed 10 parts per billion (ppb) based on real-time monitoring, including employees that aren't directly working with EtO. 10 ppb is the lowest real-time concentration of EtO that can be quantified in commercial sterilization facilities using today's technology.
- EPA will accept comment on this proposal for 60 days in docket EPA-HQ-OPP-2013-0244 at http://www.regulations.gov

National Emission Standards for Hazardous Air Pollutants (NESHAP)

- Proposed 03/27/2023 as an interim proposal. Among other things, the interim registration review decision may determine that new risk mitigation measures are necessary, lay out interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review.

National Emission Standards for Hazardous Air Pollutants (NESHAP)

- This is for emission of EtO from commercial sterilizers
  - i.e., ambient air - not worker exposures
- More info EPA Proposed Changes to the National Emission Standards for Hazardous Air Pollutants (NESHAP) regulations for commercial sterilizers concerning EtO
- Location of standard Regulations.gov
- Comments until June 27, 2023

FDA Innovation Challenges

What can manufacturers and vendors do?

Identify New Sterilization Methods and Technologies

24 Submissions | 4 Participants and 5 Submissions Chosen

- NovaSterilis - supercritical carbon dioxide sterilization (scCO2)
- Noxilizer - nitrogen dioxide sterilization
- Steris - accelerator-based radiation sterilization
- Steris - vaporized hydrogen peroxide sterilization
- TSO3, now a part of Stryker - vaporized hydrogen peroxide sterilization

https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-1-identify-new-sterilization-methods-and-technologies

Reduce Ethylene Oxide Emissions

22 Applications | 8 Participants Chosen

- Abbott - Enhanced EtO Cycle Design and Processes
- Anderson Scientific - Use of EtO-Flexible Chamber Technology
- Becton, Dickinson and Company (BD) - Enhanced EtO Cycle Design and Processes
- DMB Apparatebau GmbH - Reduced Sterilant Concentration
- Medtronic plc - Enhanced EtO Cycle Design and Processes
- Sterigenics U.S., LLC - Enhanced EtO Cycle Design and Processes
- Steris - Enhanced EtO Cycle Design and Processes
- Taiwan Advanced Sterilization Technologies Inc. - Abatement Strategy

https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions

Thank you!

Do you have any questions?
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