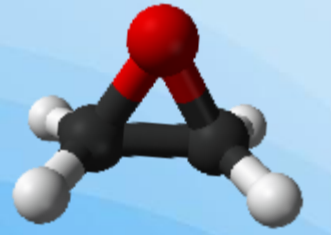
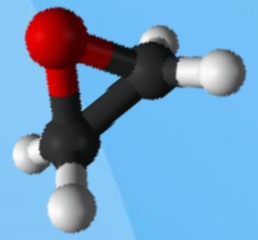
Ethylene Oxide Emissions Investigation

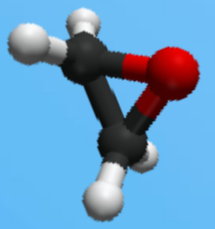
Jason Low, Ph.D.
Monitoring and Analysis Division

Ethylene Oxide (C_2H_4O)

- Characteristics:
  - Flammable, colorless, odorless, and heavier than air
  - EtO stays in atmosphere (half life is for 69 days in summer, 149 days in winter)
  - Identified as a carcinogen by Office of Environmental Health Hazard Assessment (OEHHA). Chronic Hazard Index. No Acute Hazard Index
  - Wide explosive range (LEL 3%, UEL 100%)
- Key EtO Uses:
  - Antifreeze, textiles, solvents, detergents, and adhesives production
  - Ensure safety by fumigating cosmetics and some foodstuffs like spices
  - Sterilize medical devices and equipment
- EtO usage in South Coast is primarily for medical or veterinary use





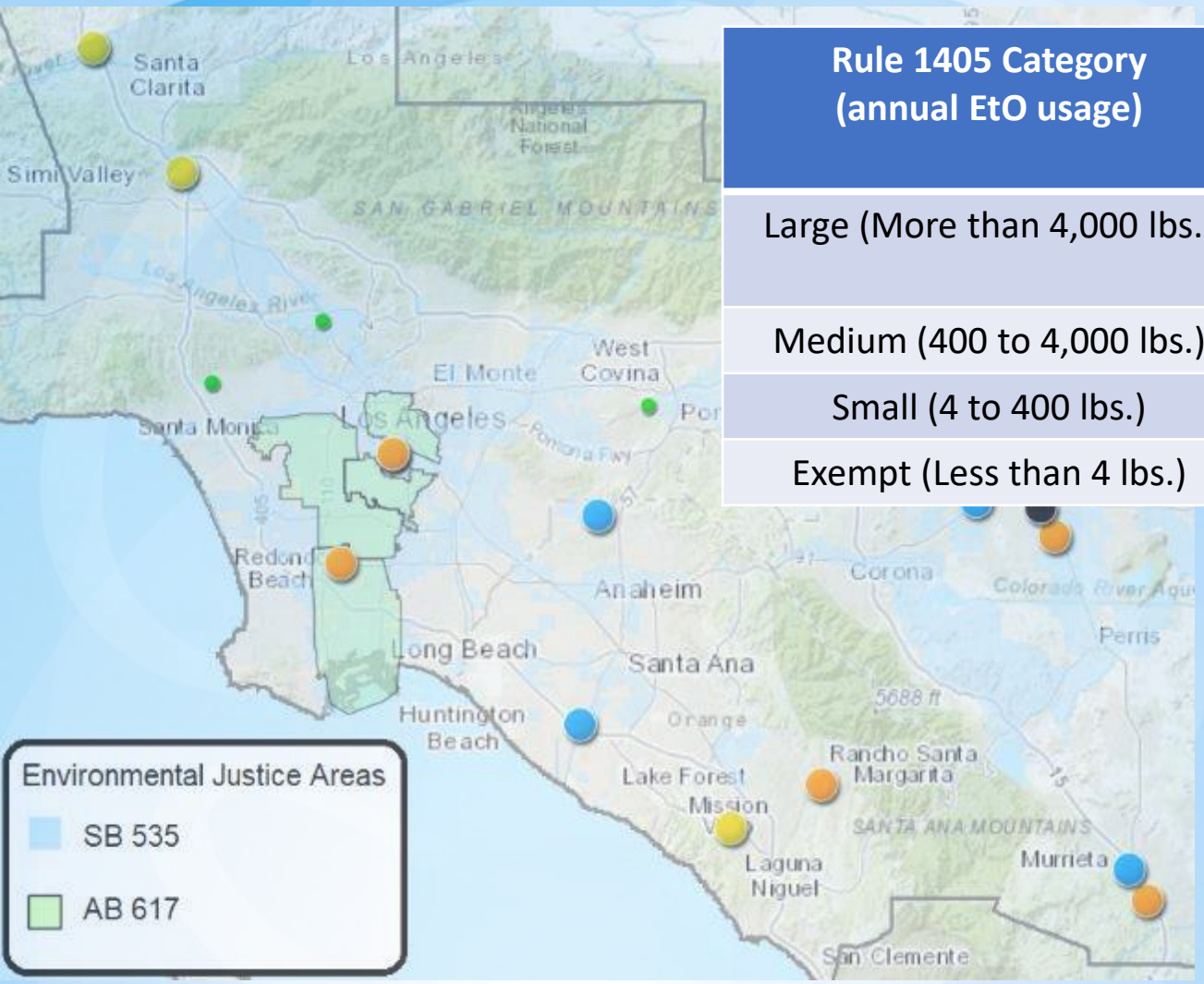


Ethylene Oxide Risk

- "A new report from the state health department revealed a higher than normal number of cases of several cancer types for people living near the Sterigenics plant in Willowbrook." - CBS2 Chicago, March 2018
- 2018 U.S. EPA ambient monitoring

- 2016 EPA risk study reveals EtO to be **30 to 50 times more carcinogenic** than previously believed
- Jan 2022 EPA confirmed 2016 findings
- More stringent than OEHHA guidance
- EPA announced high risk facility locations
- OEHHA is currently reevaluating its assessment and update EtO risk factors
  - Expect review by Scientific Review Panel in early 2023
- https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide

FACILITIES



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

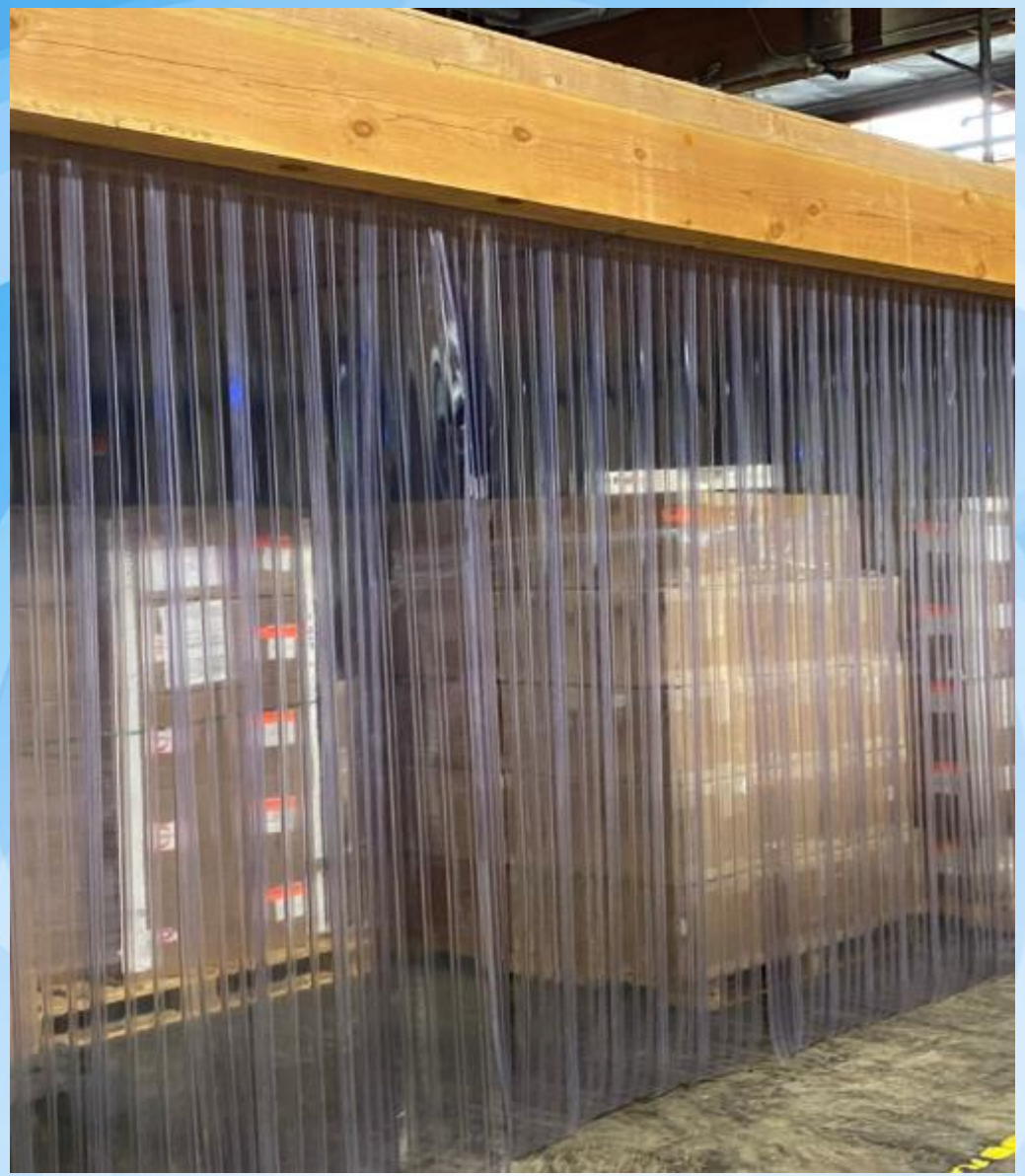
- Investigation focused on larger facilities
- Facilities supply devices to larger region
- Stationary ambient monitoring (3 large facilities)

EtO Sterilization Process

- Incoming materials placed in Pretreatment Room
  - Controlled humidity and temperature. No EtO
  - Allows for better penetration of EtO in chamber
- Pallets moved to Chamber
  - EtO injected into chamber. Scales used to verify EtO throughput
  - Chamber controlled for Pressure and Temperature
  - Purge cycles –Nitrogen
- Aeration
  - In controlled room for hours to days. Dependent on packaging and part.
  - Various layouts

U.S. FDA Validation

- Finished product warehouse (typically uncontrolled) 1% EtO may remain.
- Shipped to client warehouse via truck
- Continuous production – 24/7



EtO Sterilization Process

- Process follows U.S. FDA validation procedure
- Products are shipped to contract or in-house sterilization facilities.
- Prepackaged in cardboard boxes on pallets
- Chamber sized for U.S.FDA validation procedure
- Products are not removed from packaging
  - Specimen containers
  - COVID test kits
  - Implantable devices
- Sterilization indicators
- Rejected products typically will need to be disposed

Chambers & Aeration Rooms

Control Techniques

- Industry typically uses same control strategies – VOC Control
- Oxidation and adsorption/absorption
- Catalytic Oxidizers
  - Safety considerations for oxidizers due to explosive characteristics of EtO (3% -100%)
- Wet and Dry Scrubbers
- Filtration (impregnated filters)
- Collection Efficiency - Permanent Total Enclosures

Acid-Water (Wet) Scrubber

- Uses sulfuric acid to convert EtO into ethylene glycol
- Capable of achieving 99.9% control efficiency
- High concentration EtO
- Used for chamber purge cycle emissions, leaking drum cabinets

- Exhaust stream (ppm)

South Coast AQMD Investigation

- Site Visit to Vernon facility in March 2022
  - Near residential receptors. AB 617 community
  - Large EtO throughput
- Facility had installed fugitive EtO control without permits
  - Facility was venting general warehouse and process areas with building exhaust fans
- Ethylene Glycol odors near control equipment
  - OVA indicated elevated concentrations
  - Wet Scrubber – Tank Hatch opened
- EPA Method TO-15A grab sample indicated elevated EtO concentrations offsite
- Follow up visit showed elevated EtO concentrations inside the facility
- Stationary ambient monitoring at Vernon facility commenced on July 10, 2022
  - Elevated ambient levels detected at fenceline
- Initiated District wide investigation
  - Monitoring currently focused on 3 facilities

Current OEHHA Guidance

MICR = 100 in a million

Offsite Worker = 3.18 ppb

Air Monitoring

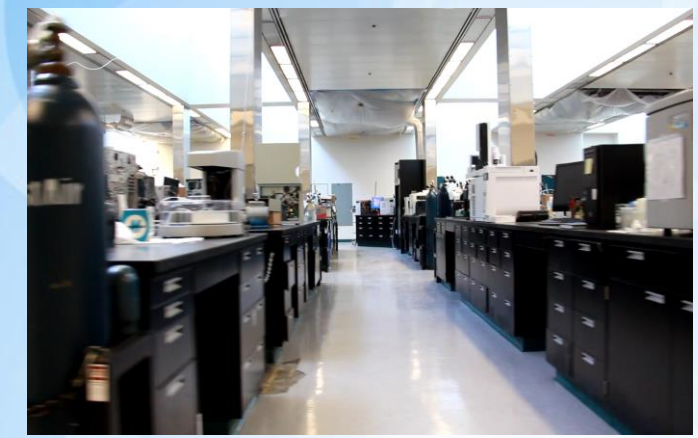
- Ambient air monitoring is the systematic assessment of pollutant levels by measuring the quantity and types of certain pollutants in the surrounding, outdoor air
  - Assess the extent of air pollution impact in the real world
  - Evaluate the effectiveness of emissions control strategies
- USEPA and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

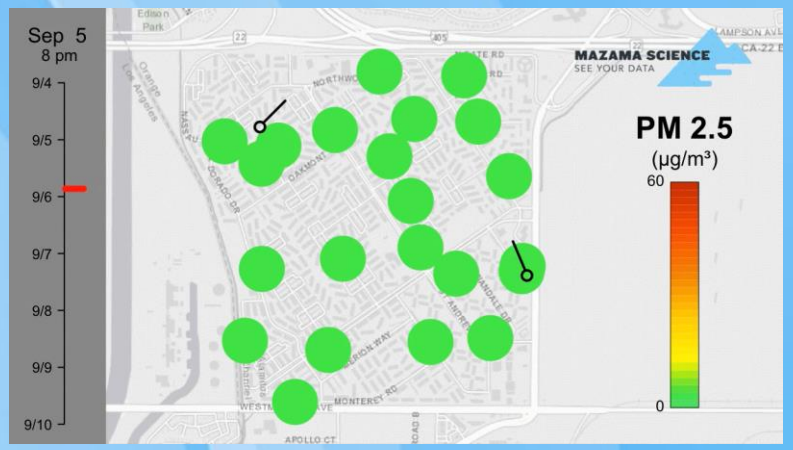
Variety of Air Measurement Methods

Field Sampling with Laboratory Analysis

Portable and Mobile Instrumentation

Low-Cost Sensors





Exploratory Mobile Measurements

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

Sampling Options

Grab (Instantaneous) Samples

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

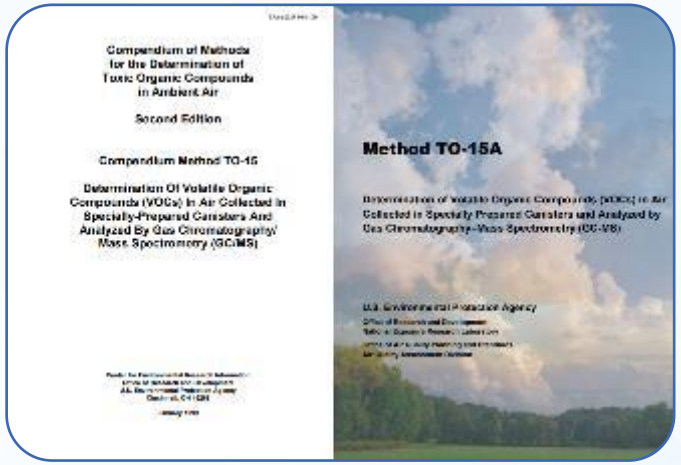
Time-Integrated Samples

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

Laboratory Analysis

Samples

Silica-lined canisters provide most inert environment for VOCs



Method

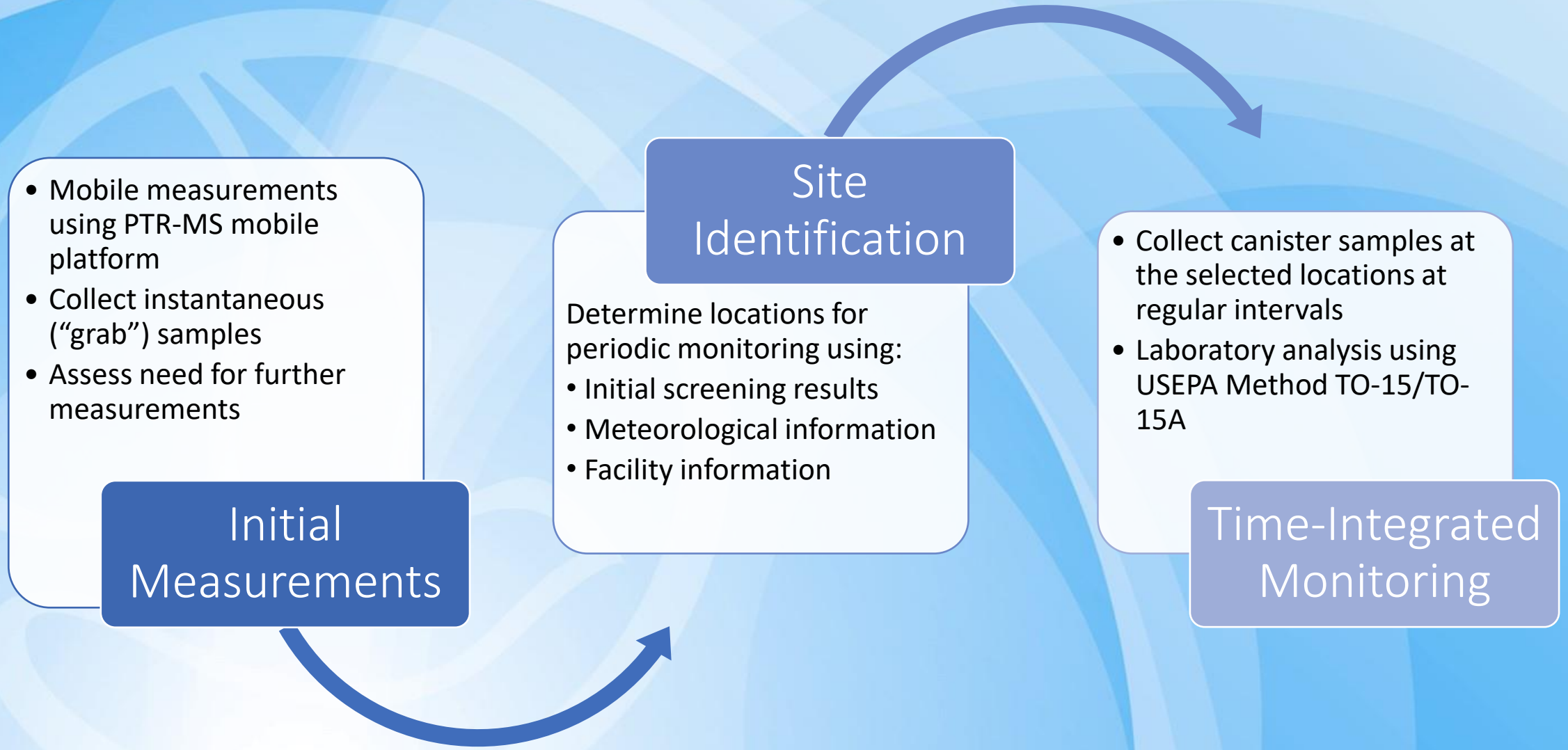
USEPA Compendium TO-15/TO-15A for VOCs

Instrument

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

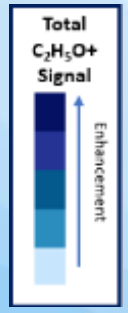
Real-time monitors for continuous EtO measurements have been developed and are being evaluated by USEPA

Methodical EtO Monitoring Approach



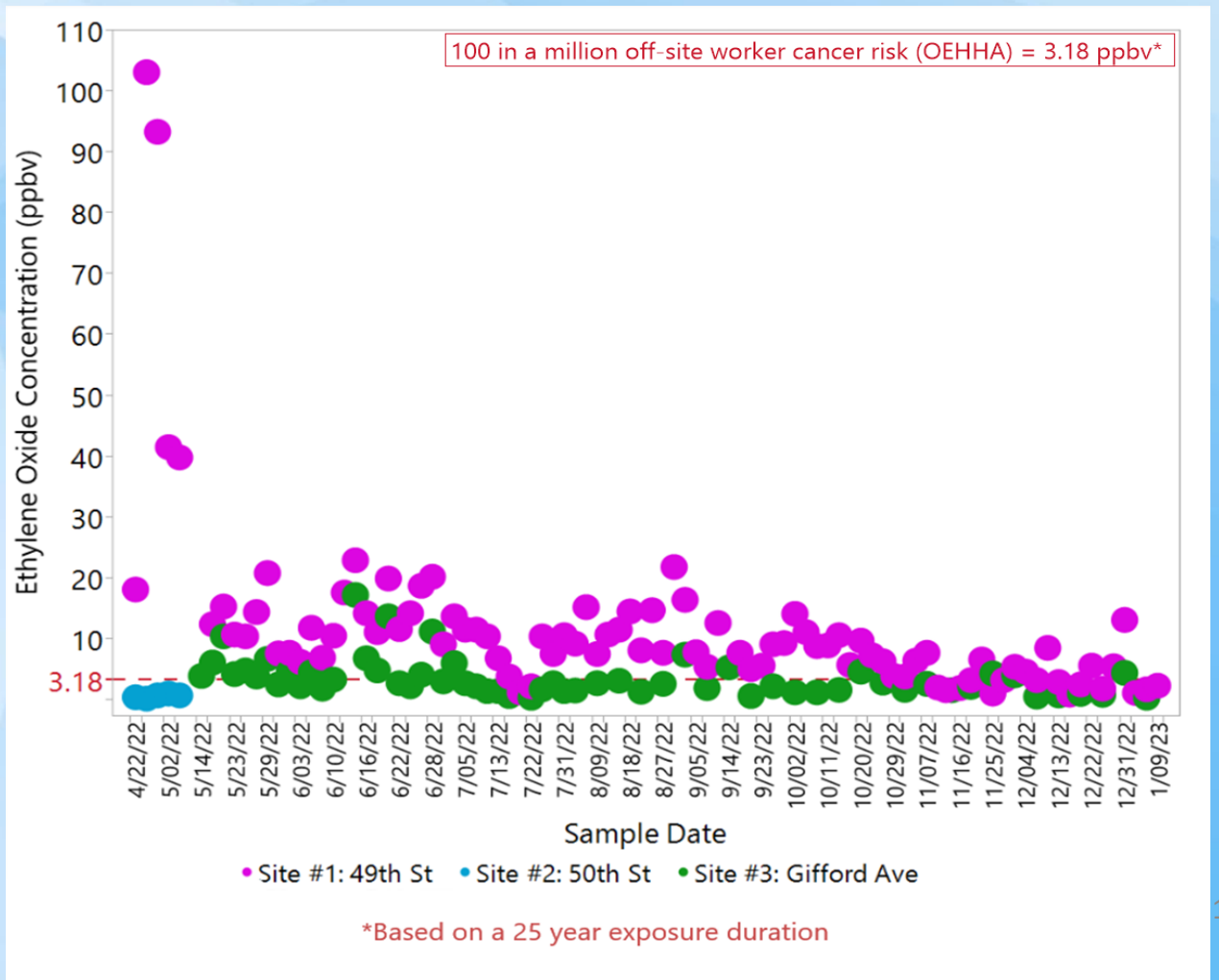
Initial Mobile Measurements

Monitoring Site Identification



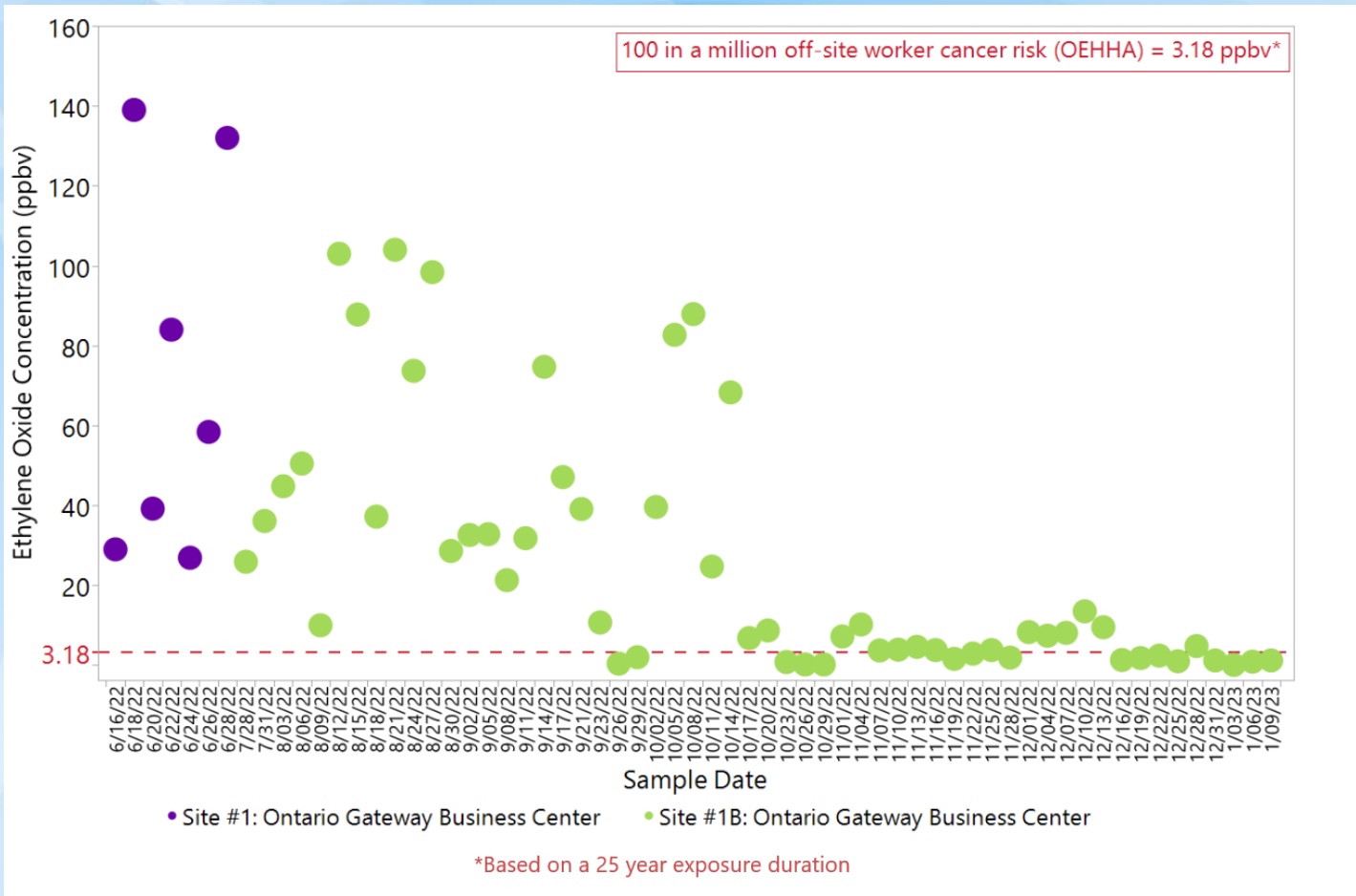
Vernon Facility

Ongoing Time-Integrated Sampling Efforts



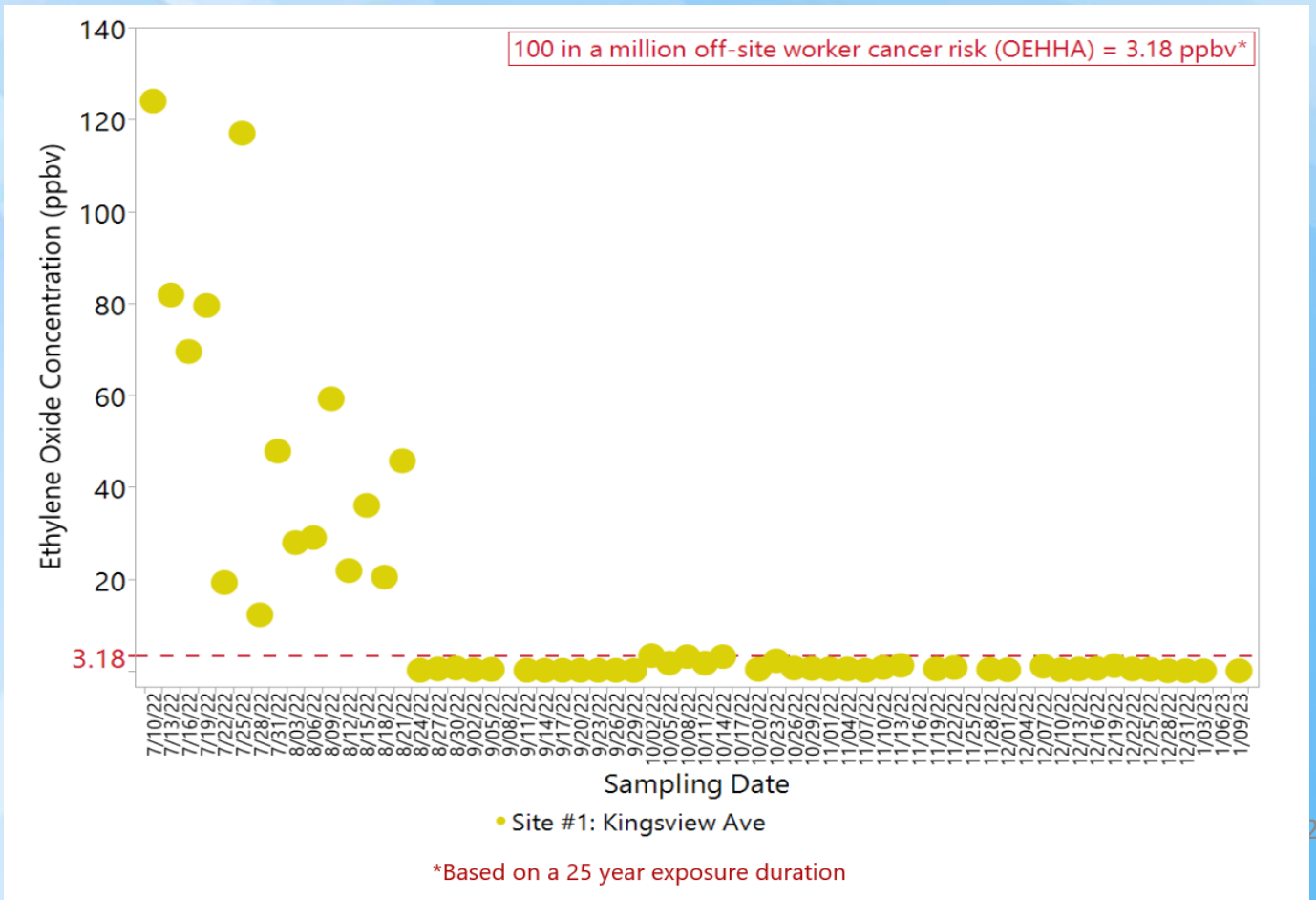
Ontario Facility

Ongoing Time-Integrated Sampling Efforts



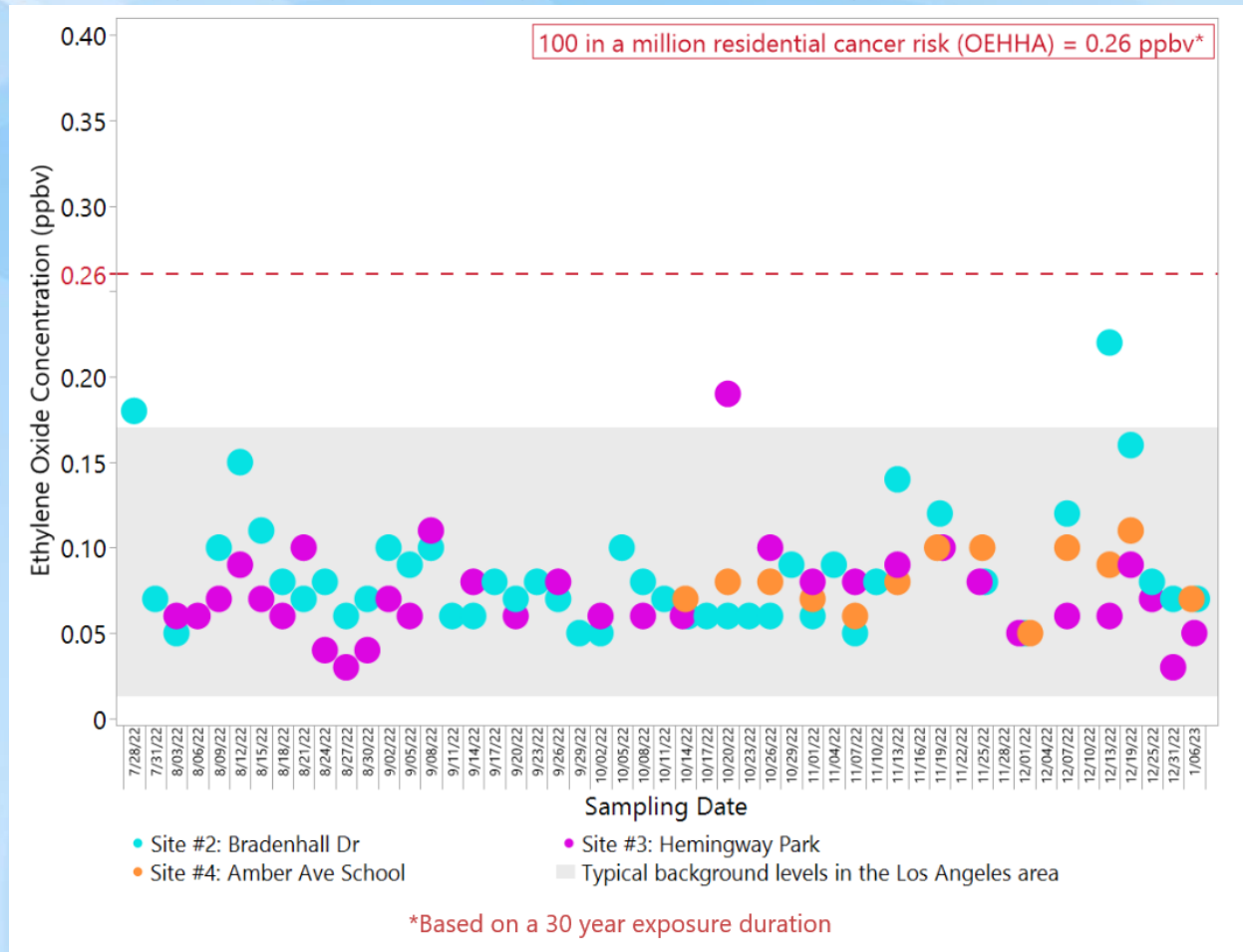
Carson Facility

Ongoing Time-Integrated Sampling Efforts



Carson Facility

Ongoing Time-Integrated Sampling Efforts



Summary of Monitoring Efforts

- Methodical approach developed to monitor EtO levels near emission sources
  1) Exploratory mobile measurements
  2) Canister sampling followed by laboratory analysis using EPA method
- Mobile measurements conducted near 14 facilities
  - Identified 4 facilities (3 locations) for additional monitoring
- Data *to date* identified elevated EtO levels near some large facilities
  - Elevated levels of EtO at off-site worker monitoring sites (directly outside of facilities)
  - EtO levels at nearby residential communities within typical background levels
- Measurement efforts ongoing
  - Continue mobile measurements near potential emission sources including warehouses
  - Continue canister sampling near 4 facilities with elevated EtO levels

Additional Findings

- EtO detected in uncontrolled areas of building (ppb and ppm)
  - EtO affinity for conditions in Pretreatment rooms
  - Building ventilation
- Transport from Chamber to Aeration room
- Continued off gassing after aeration. Post-aeration handling
- Ambient concentrations appear to correlate with production

For Additional Information

Email: jlow@aqmd.gov

Web: http://www.aqmd.gov/home/eto

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