Two years of ethylene oxide measurements near three sterilization facilities in the South Coast Air Basin

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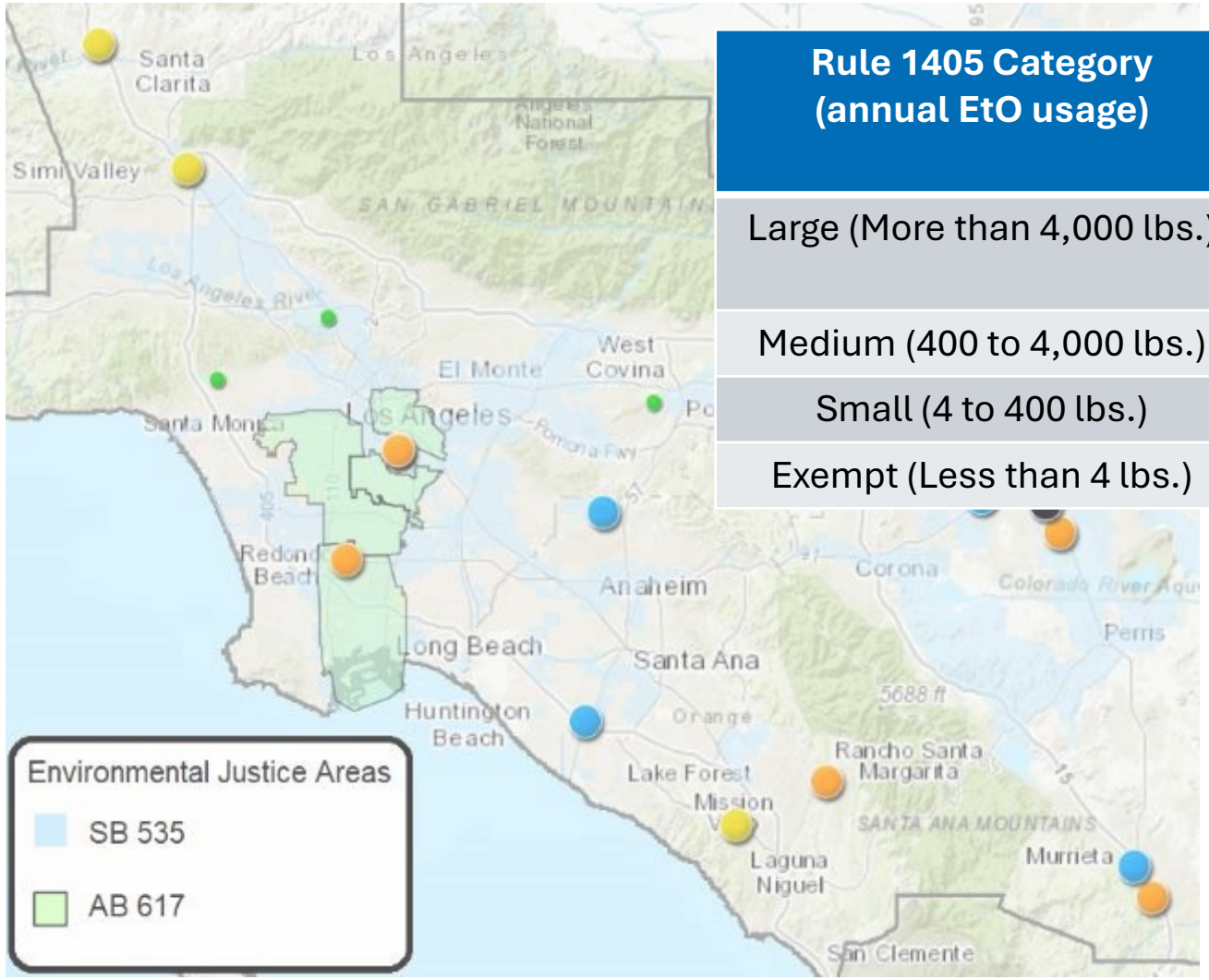
South Coast Air Basin Facilities



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)

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Initial Investigation

- Site Visit to Vernon facility in March 2022
- 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
  - Wet Scrubber – Tank Hatch opened
- EPA Method TO-15A grab sample indicated elevated EtO concentrations offsite
- Stationary ambient monitoring at Vernon facility commenced on July 10, 2022
  - Elevated ambient levels detected at fenceline

Current OEHHA Guidance

MICR = 100 in a million

Offsite Worker = 3.18 ppb

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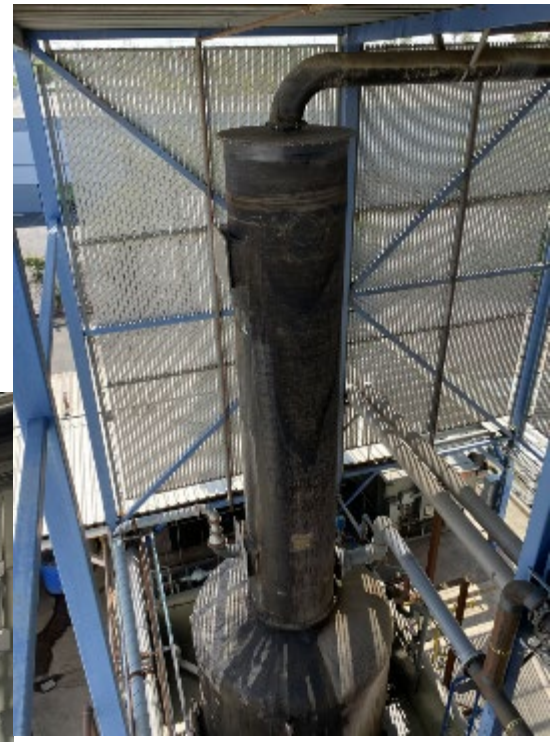
Acid-Water (Wet) Scrubber

- Uses sulfuric acid to convert EtO into ethylene glycol
- Capable of achieving 99.9% control efficiency
- Treats high concentration EtO
- Used for chamber purge cycle emissions, leaking drum cabinets
- Exhaust stream (ppm)



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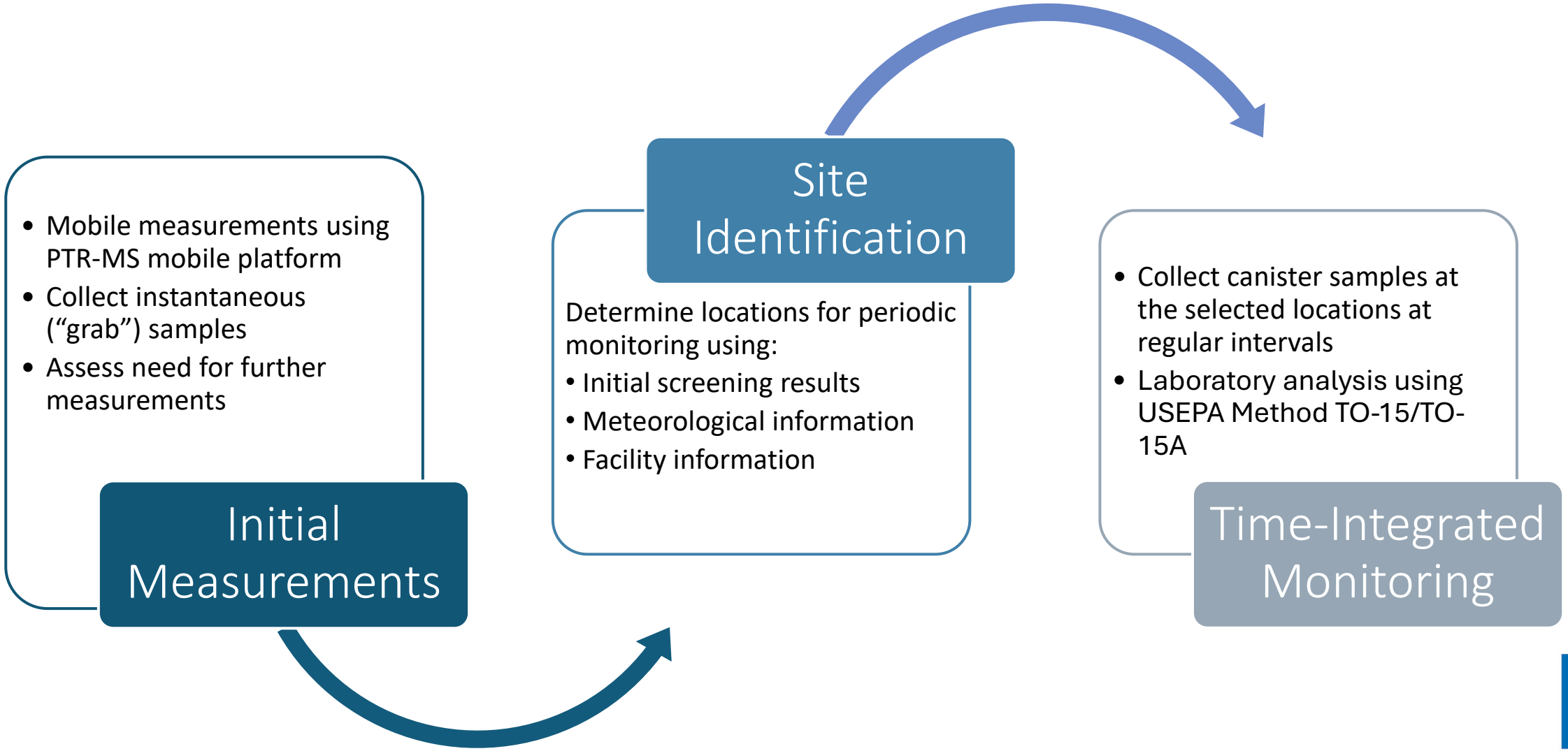
Methodical EtO Monitoring Approach



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

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Canister 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)

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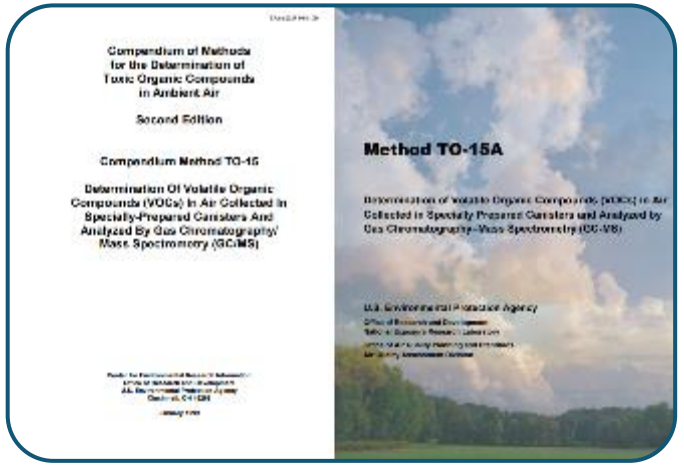
Laboratory Analysis

Samples

Silica-lined canisters provide most inert environment for VOCs



Method

U.S. EPA Compendium TO-15/TO-15A for VOCs

Instrument

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

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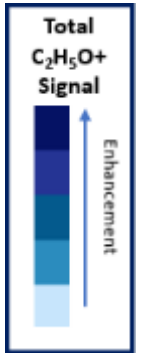
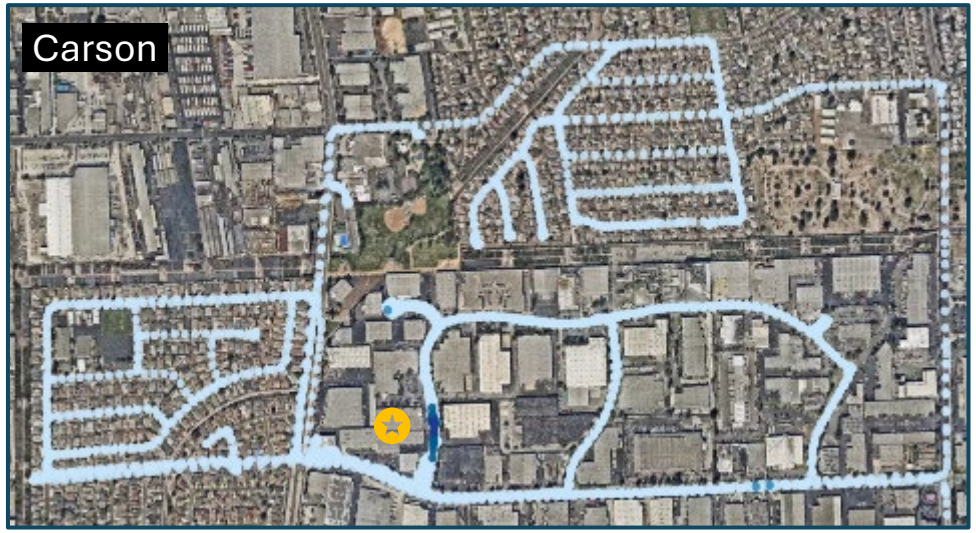
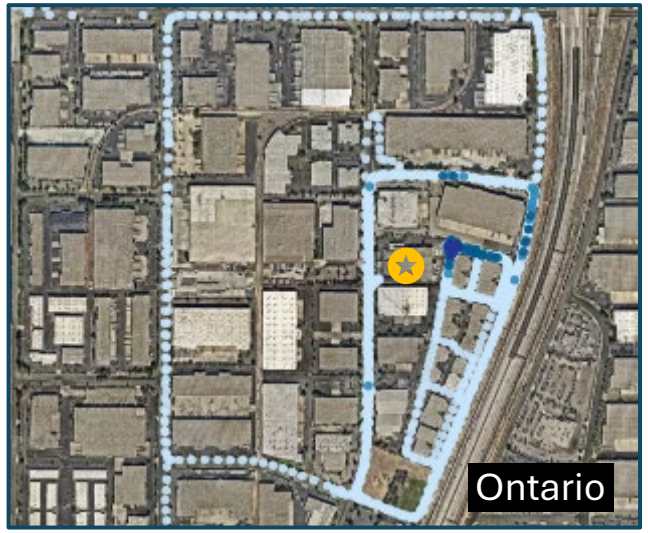
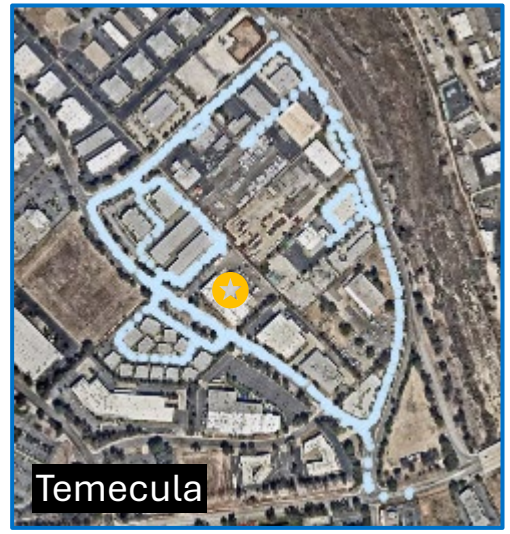
Survey Mobile Measurements









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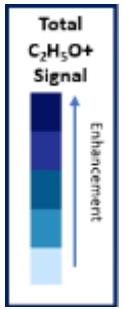
Monitoring Site Identification



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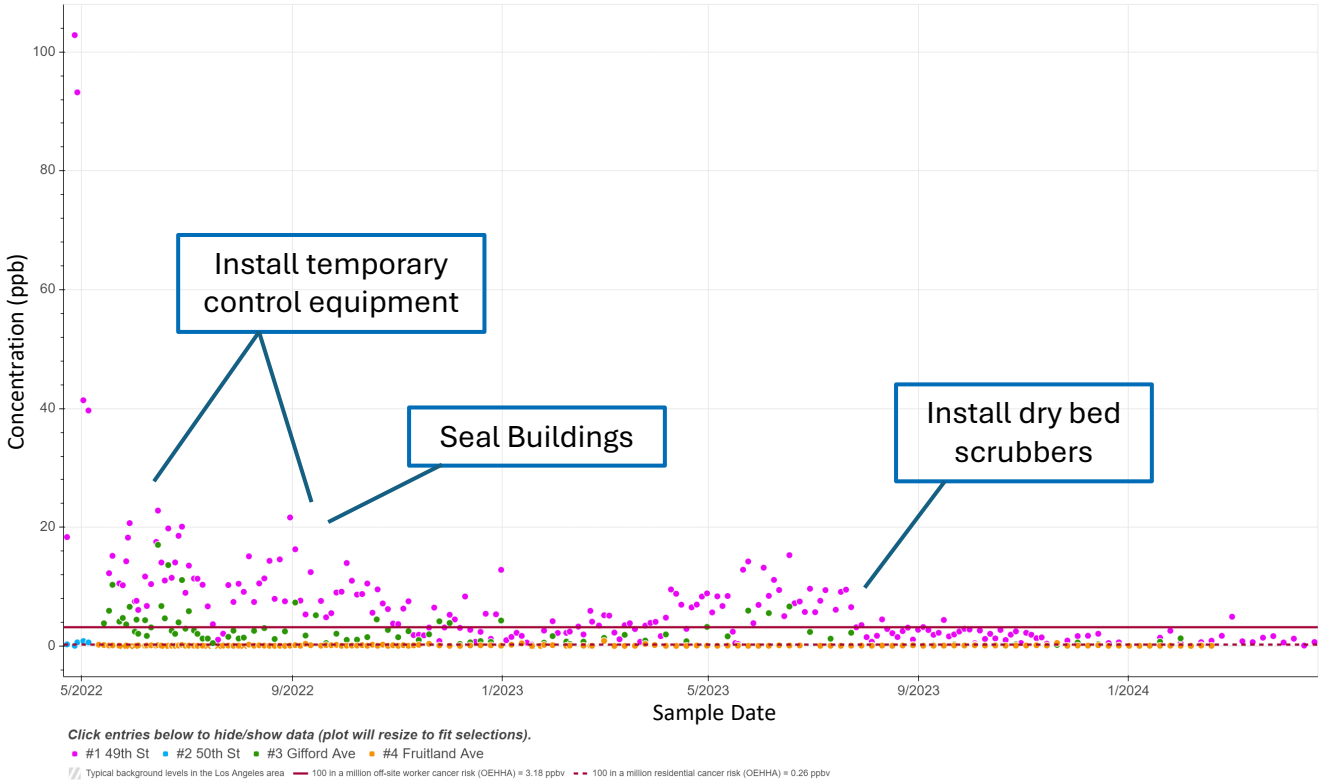
Vernon Facility

Time-Integrated Sampling Efforts



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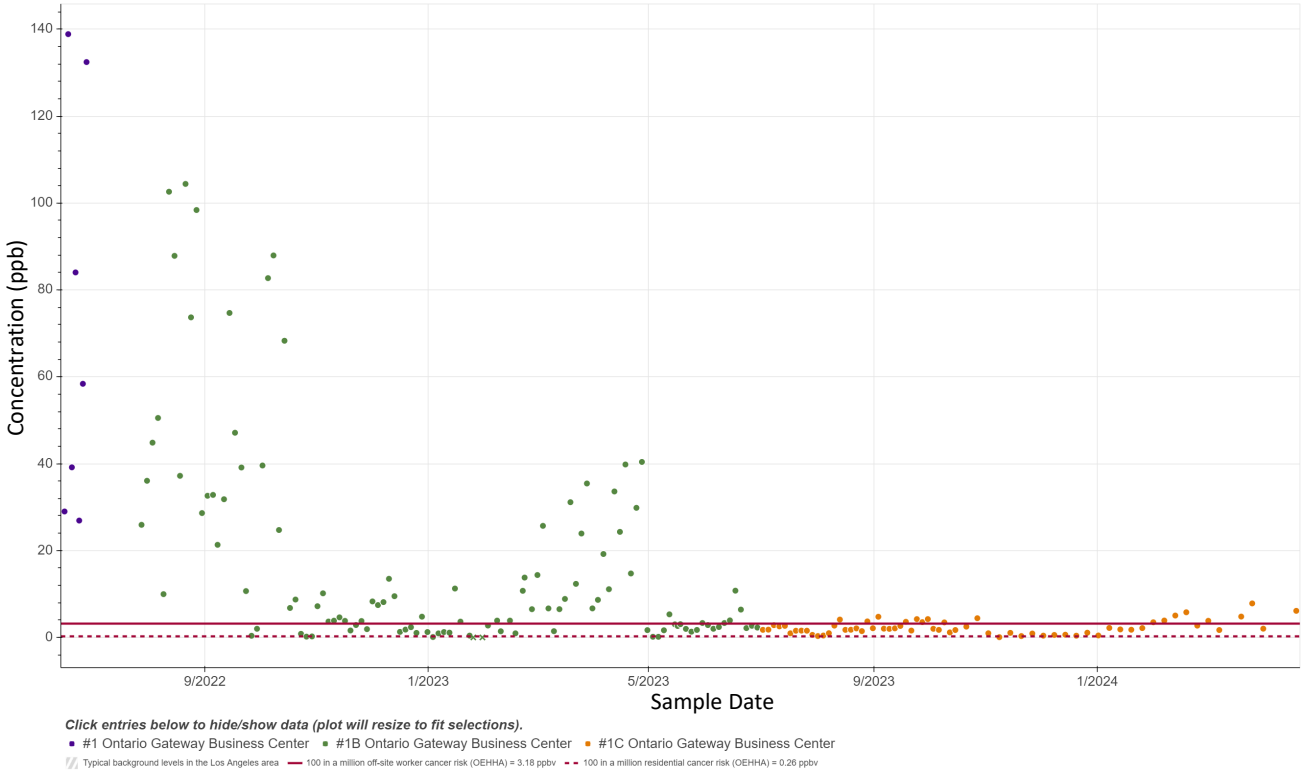
Ontario Facility

Time-Integrated Sampling Efforts



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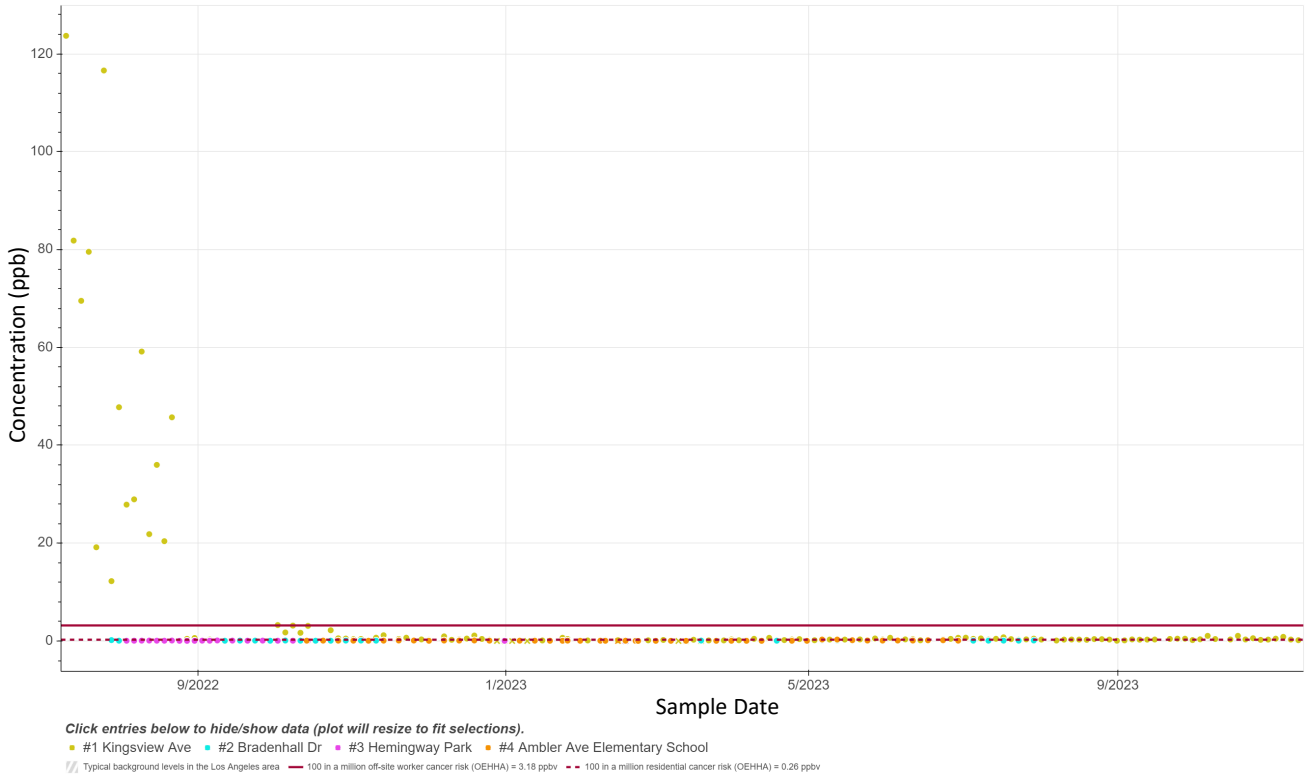
Carson Facility

Time-Integrated Sampling Efforts



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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 TO-15A
- Mobile measurements conducted near 14 facilities
  - Identified 4 facilities (3 locations) for additional monitoring
- Data identified elevated EtO levels near some large facilities
  - Elevated levels of EtO at off-site worker monitoring sites
  - EtO levels at nearby residential communities within typical background 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

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Next Steps

- South Coast AQMD Rule 1405 – "Control of Ethylene Oxide Emissions from Sterilization and Related Operations"
  - Sterilization Facilities and Warehouses
  - Fenceline Air Monitoring Provision
    - Mobile and Stationary Components
  - Permanent Total Enclosure
  - CEMS Certification Program
- Pallet Off-gassing Study

For Additional Information

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