

# Sampling The Air for Ethylene Oxide Near the Steri-Tech, Inc. Facility in Salinas, PR

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USEPA Region 2

Update – January 25, 2023

# Outline

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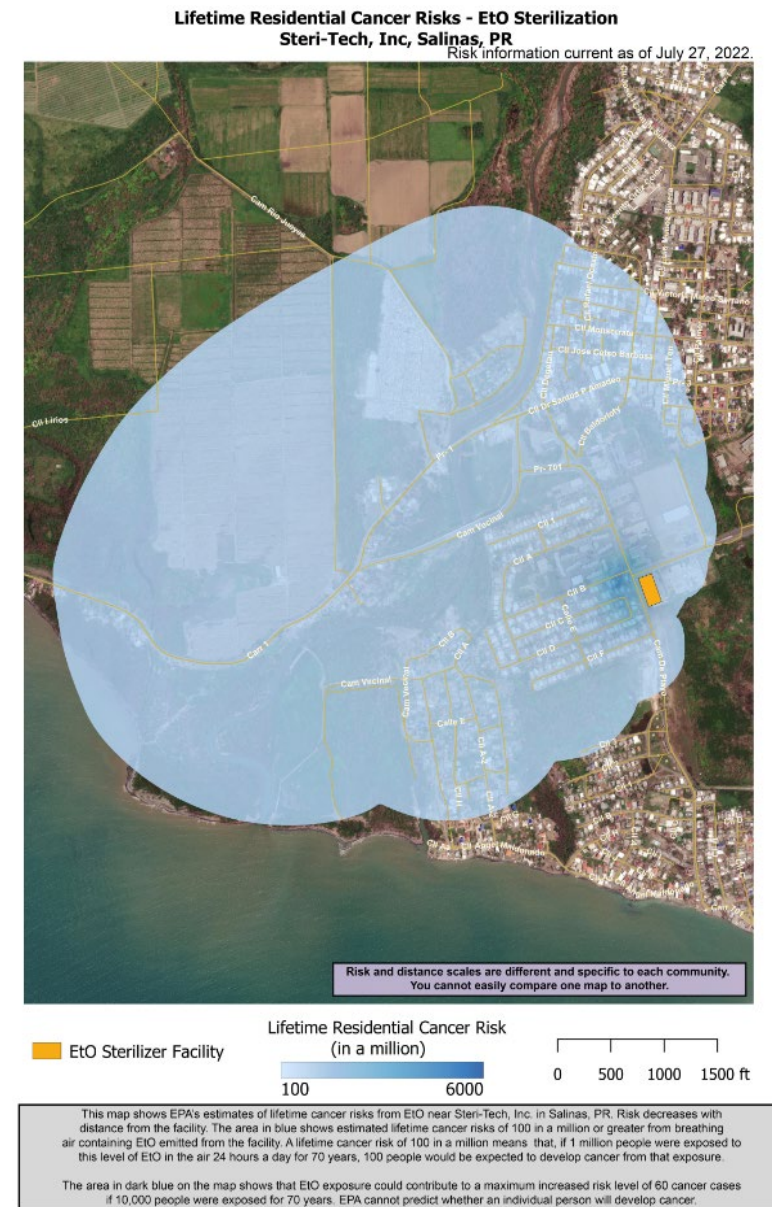
# Background

- EPA completed a *modeling* risk assessment in July 2022 for communities near the commercial sterilizers currently operating in the United States.
- Steri-Tech, Inc., located in Salinas, PR, is a facility that uses ethylene oxide (EtO) to sterilize medical equipment and materials.
- Steri-Tech, Inc. is one of the 23 facilities nationwide that the EPA's July 2022 assessment identified as sterilizers posing elevated risks at or above 100/million to nearby communities with the highest risk.
- EPA undertook air *monitoring* to better understand EtO concentrations in the community.

*"We use 100-in-1-million as our benchmark for identifying whether risk levels are considered "high" and are of concern to EPA. When we say, 100 in a million we are saying that we estimate EtO exposure could contribute to an increase of 100 cancer cases if a million people were exposed at those levels for 24 hours a day, 7 days a week, from birth to age 70. "*

# Monitoring Project Description

- EPA previously performed *modeling* and the results indicate that the area west of the facility is impacted by EtO emissions
- The purpose of EPA's August 2022 *monitoring* project was to determine the concentrations of EtO in the air near the facility over a 1-week period at locations around the facility and in the neighboring community.
- Six (6) sampling sites were selected for this project based on the EPA modeling and wind data.
  - Four (4) locations downwind or west of the facility
  - One (1) location north/northeast of the facility
  - One (1) location upwind or east of the facility
- Samples taken between August 10 - 16, 2022.



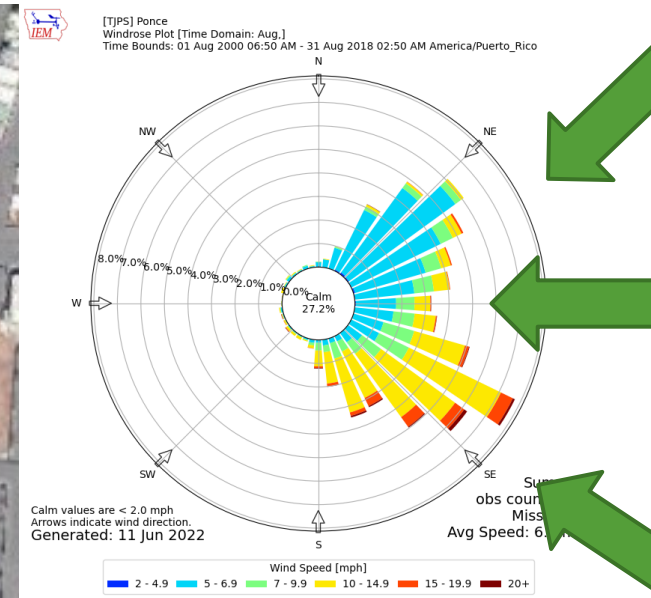
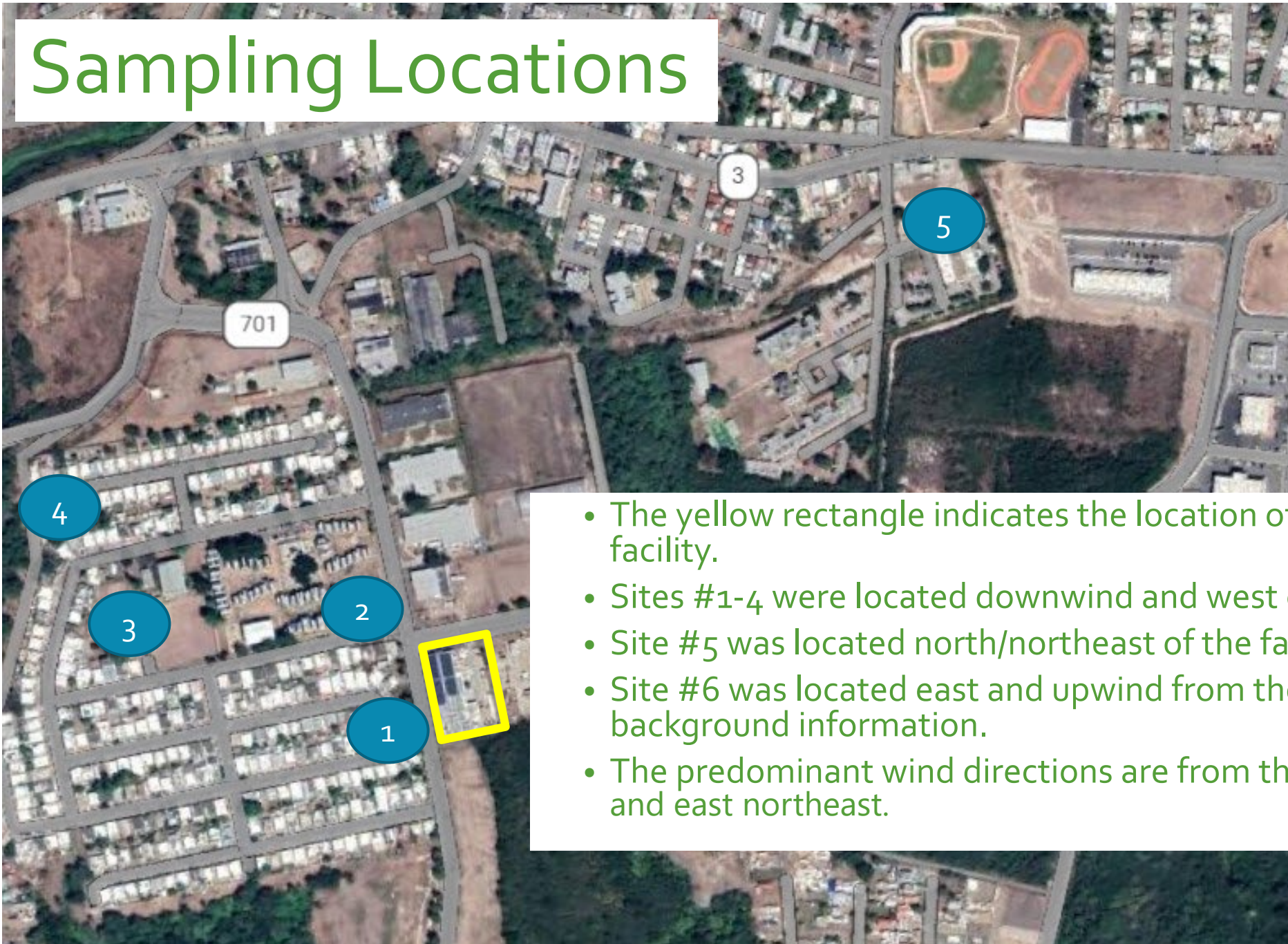
<https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/forms/salinas-puerto-rico-steri-tech-inc>

# Sampling Method

- EPA used equipment to pull in air using stainless steel SUMMA™ canisters for 24 hours each day for seven days at six locations.
- Sampling sites were selected based on EPA computer model used to estimate pollution concentrations and wind data.
- Sampling was performed in accordance with EPA scientific and approved Sampling Plan and Quality Assurance Project Plan.
- Samples were then sent to an EPA contract lab for analysis using EPA Compendium Method TO-15.



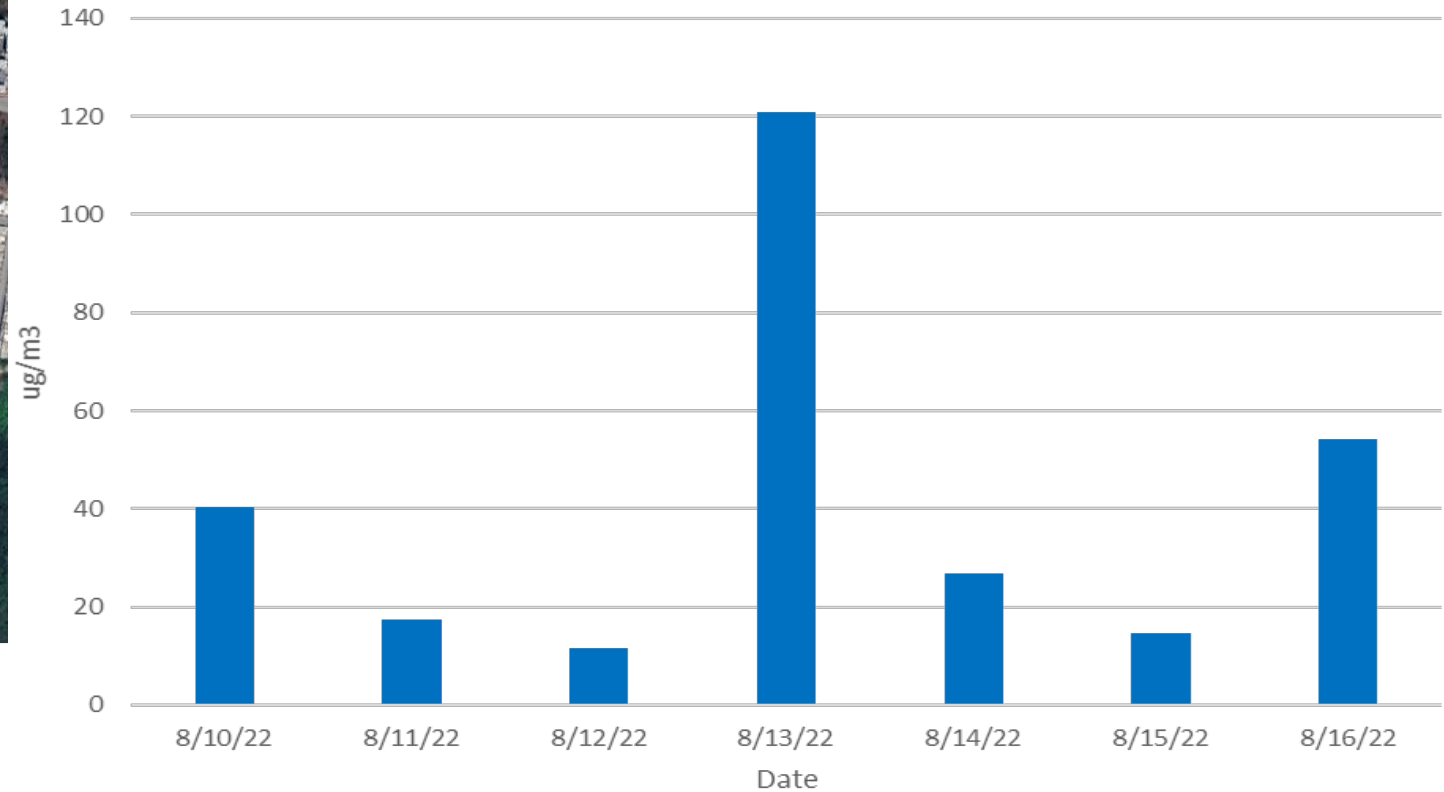
# Sampling Locations



- The yellow rectangle indicates the location of the Steri-Tech facility.
- Sites #1-4 were located downwind and west of the facility.
- Site #5 was located north/northeast of the facility.
- Site #6 was located east and upwind from the facility to collect background information.
- The predominant wind directions are from the east, southeast, and east northeast.



PR EtO Project- Site #1

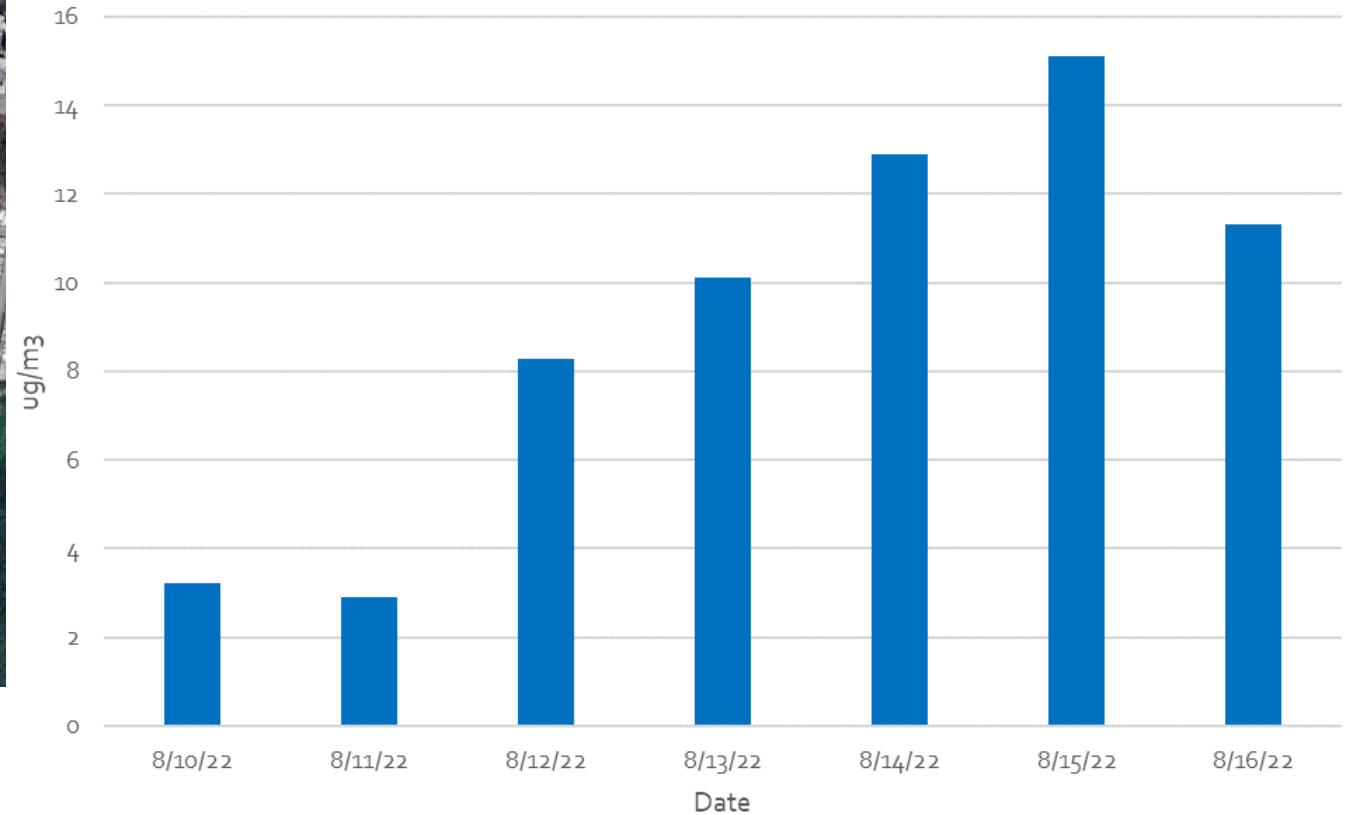


## Sample Site #1

- Site #1 was at a residence located across the street from the facility. It was the closest site to the facility.
- Site #1 had the highest maximum concentration.
- Site #1 had a maximum concentration of 121 ug/m<sup>3</sup>.
- Site #1 had the highest average concentration during the project period (40.83 ug/m<sup>3</sup>).



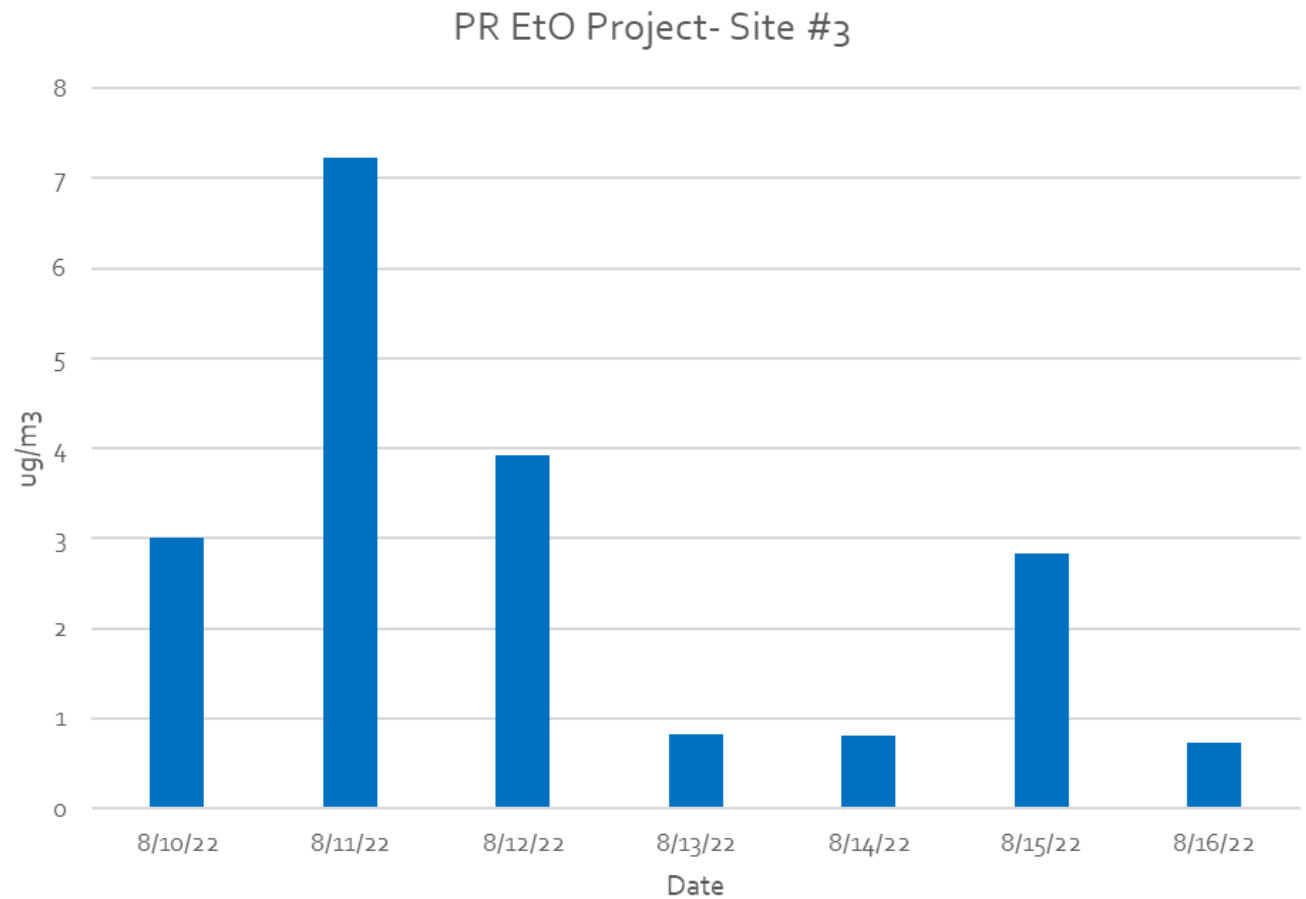
PR EtO Project- Site #2



## Sample Site #2

- Site #2 was located northwest of the facility at a PRASA property.
- Site #2 was the 2<sup>nd</sup> closest site to the facility.
- Site #2 had a maximum concentration of 15.1 ug/m<sup>3</sup>.
- Site #2 had the 2<sup>nd</sup> highest average concentration over the project period (9.11 ug/m<sup>3</sup>).



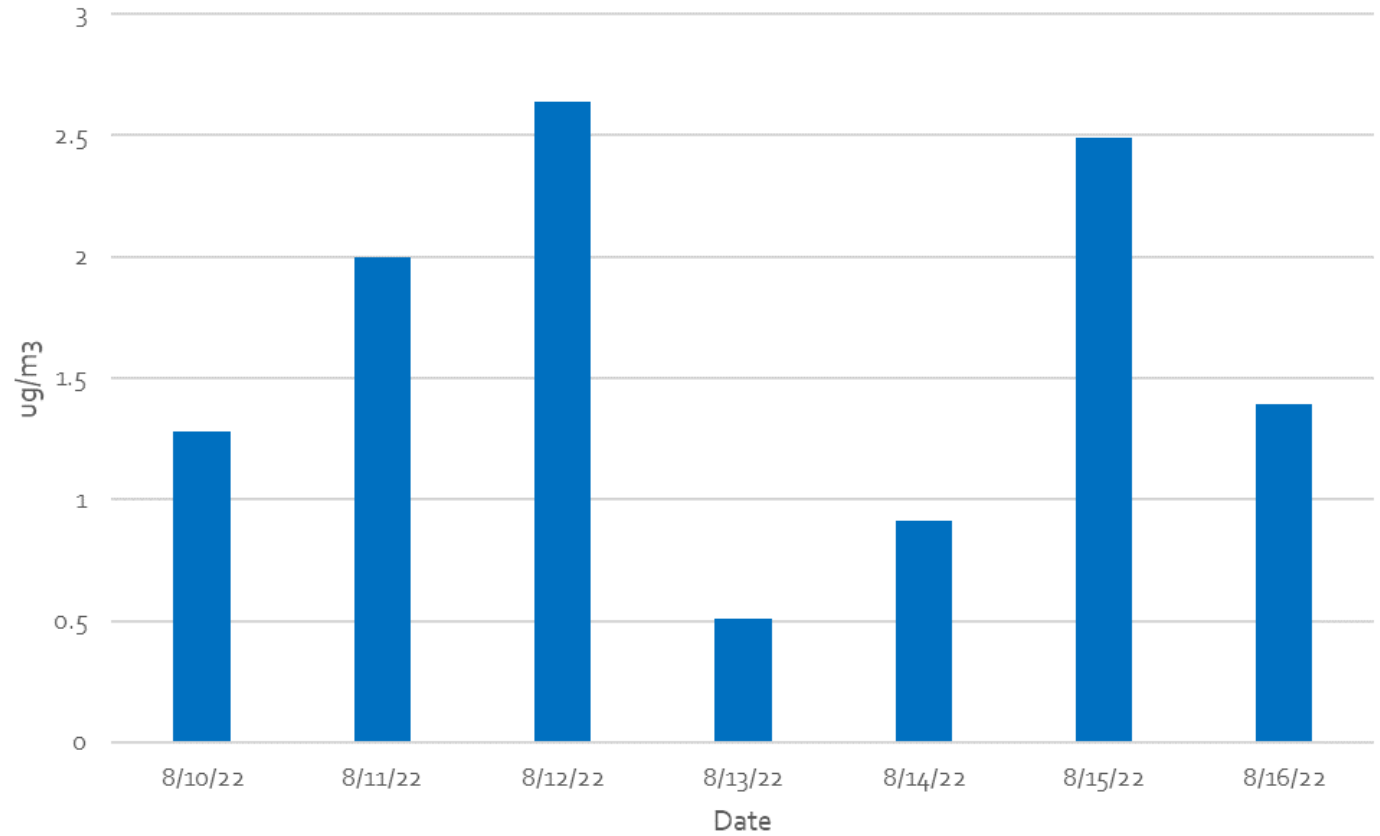


## Sample Site #3

- Site #3 was located near a park.
- Canisters were mounted on a utility pole.
- Site #3 had a maximum concentration of 7.22 ug/m<sup>3</sup>.
- The average concentration at the site was 2.76 ug/m<sup>3</sup>.



PR EtO Project- Site #4

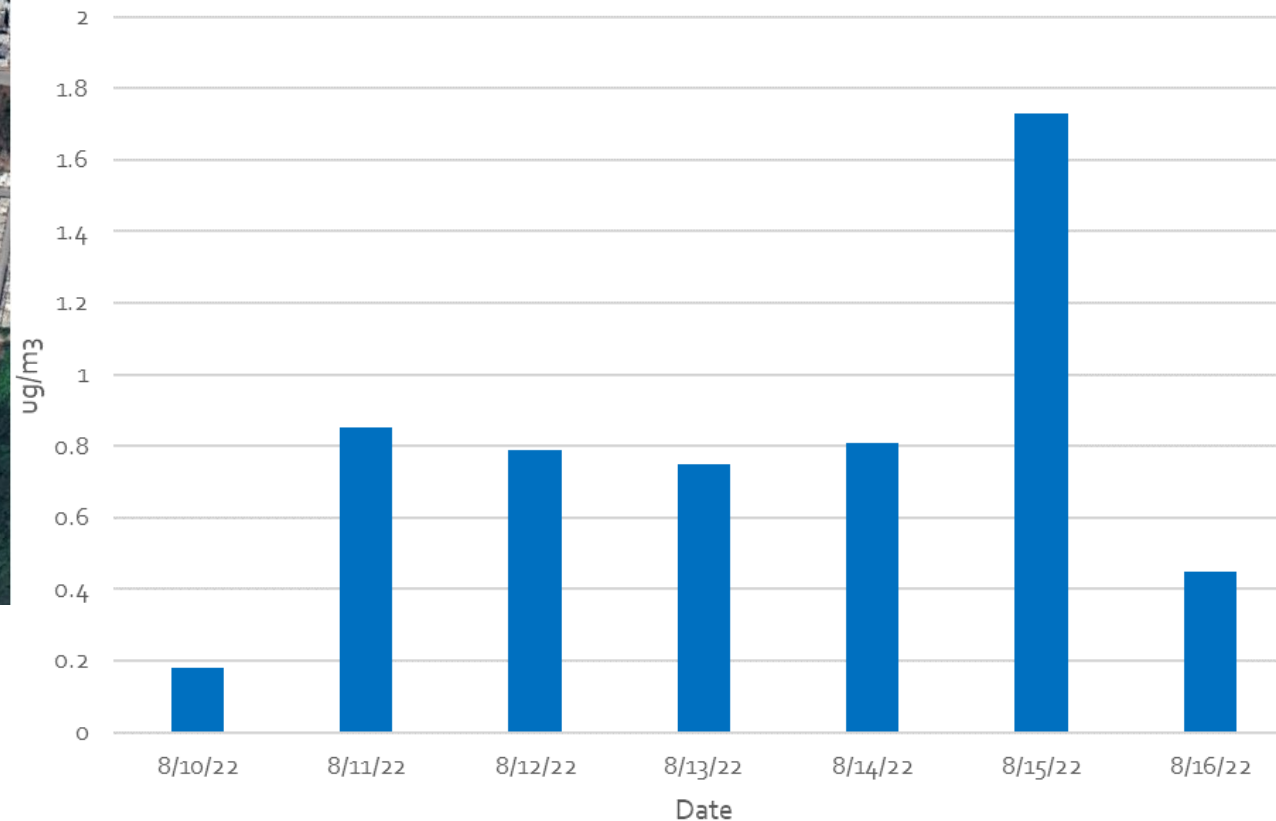


## Sample Site #4

- Site #4 was located at a residence.
- Site #4 had a maximum concentration of 2.64 ug/m<sup>3</sup>.
- The average concentration at the site was 1.60 ug/m<sup>3</sup>.



PR EtO Project- Site #5

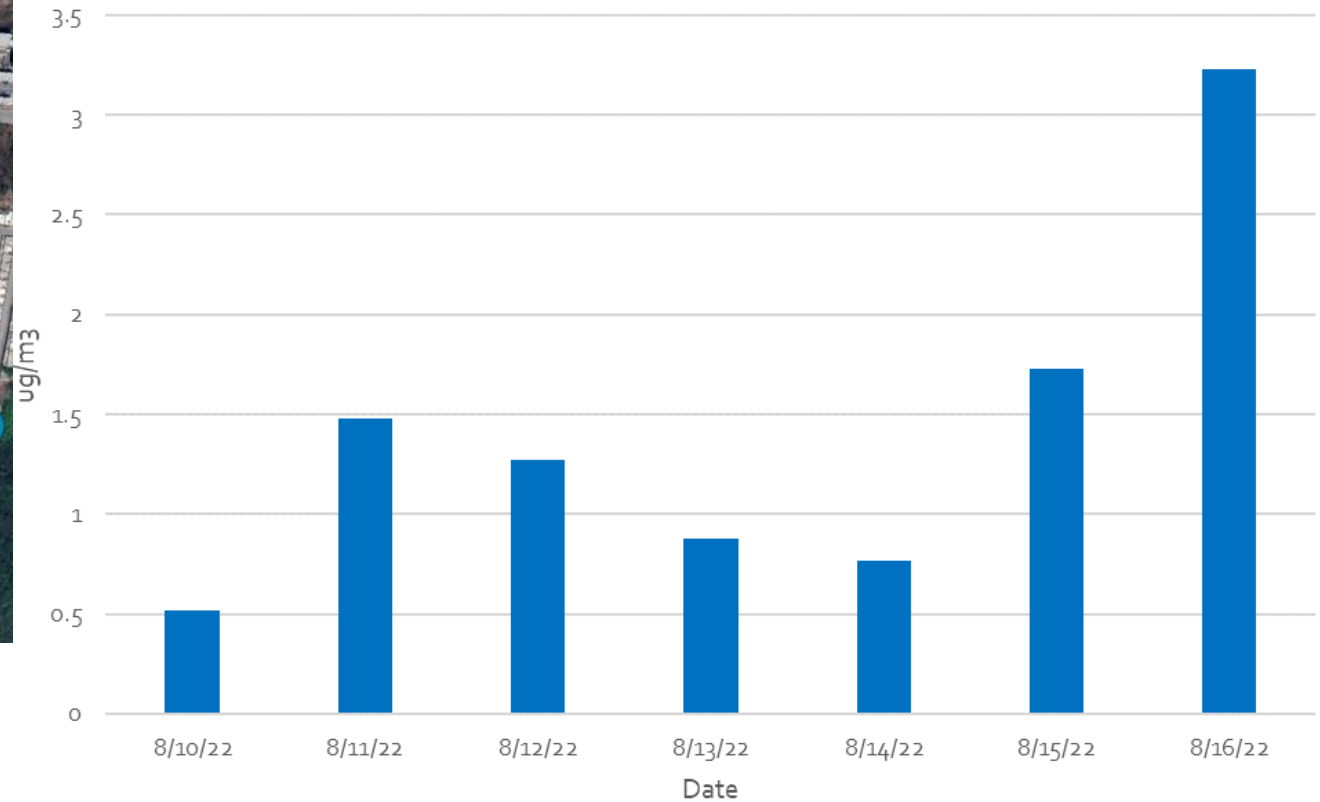


## Sample Site #5

- Site #5 was located at a hospital northeast of the facility.
- Concentrations were lower at this site than at the sites located to the west of the facility.
- Site #5 had a maximum concentration of 1.73 ug/m<sup>3</sup>.
- The average concentration at the site was 0.79 ug/m<sup>3</sup>.



PR EtO Project- Site #6

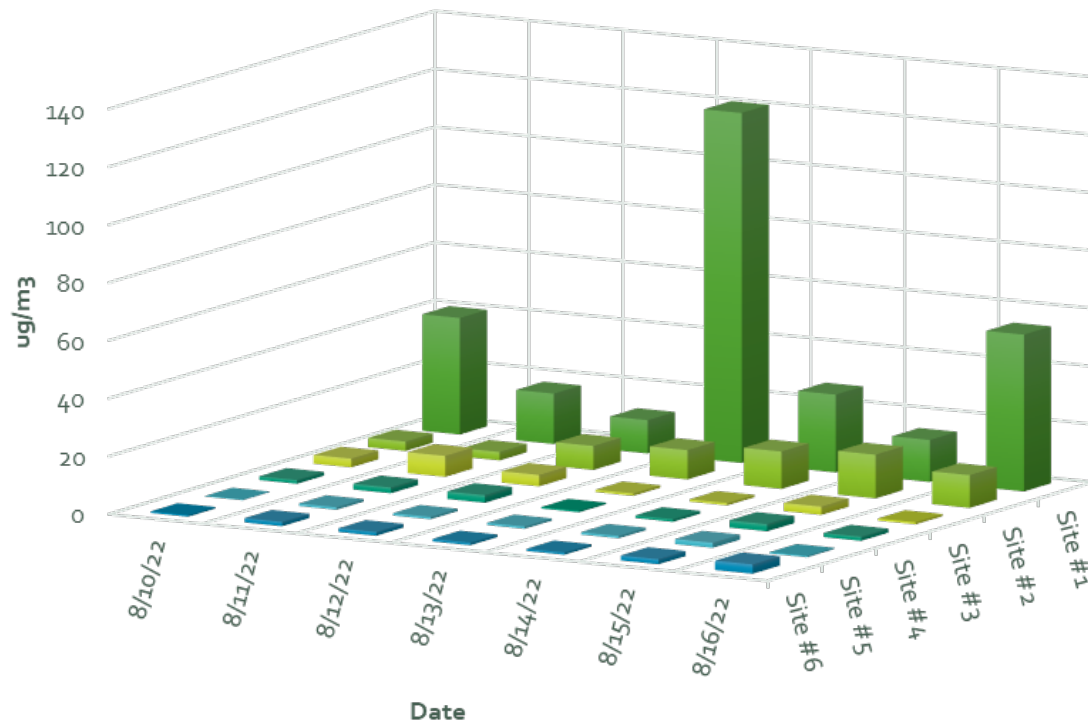


## Sample Site #6

- Site #6 was the site furthest east and upwind of the facility.
- Concentrations were lower at this site than at the sites located to the west of the facility.
- Site #6 had a maximum concentration of 3.23 ug/m<sup>3</sup>.
- The average concentration at the site was 1.41 ug/m<sup>3</sup>.

# Observations

## PR EtO Project- All Sites



- Sites closest to the facility (#1 and #2) had highest measured concentrations.
- The further from the facility the lower the measured concentrations.
- Sites west (downwind) of the facility had higher measured concentration.
- Sites east (upwind) of the facility (#5 and #6) had the lowest average measured EtO concentrations.

# Discussion/Conclusions

- The results from the August 2022 monitoring effort provide a snapshot of ambient air EtO concentrations during a one-week period and cannot be compared to a long-term or “annual” average of EtO concentrations.
- EPA’s July 2022 modeling identified elevated EtO concentrations in the area and the need to take action.
- Results of the sampling do confirm the EPA modeling that had identified elevated EtO concentrations in the area and the need to take action to reduce EtO emissions.
- EPA will continue to work with the facility to ensure that it complies with current federal regulations and reduce the EtO emissions from the facility.

# Current Actions and Next Steps

## Current, Recent Actions:

- August sampling event performed with thermal oxidizer control device.
- October 2022 DNER issued operating permit for new catalytic oxidizer (CatOx) control.
- CatOx in operation now or very soon. CatOx to operate at 99.9% removal which is more stringent than 99% removal required by current regulation. Performance test being scheduled to confirm the 99.9% removal.
  - (CatOx does not address fugitive emissions.)

## Next Steps:

- EPA in discussions with Steri-Tech about further actions to address their EtO emissions; negotiations are confidential; will inform community when we finalize an action
- Nationally, EPA will soon be proposing to strengthen the current regulations for EtO Commercial Sterilizers
- Ponce Health Sciences School of Medicine and PRDOH developing protocol for EtO epidemiology study.