Ambient Monitoring and Health Risk Assessment of Ethylene Oxide Emissions from Commercial Sterilizers in Utah

Nancy Daher*, Rod Handy, Rachel Edie* and Trent Henry*****
***Utah Division of Air Quality**
****East Tennessee State University, formerly at the University of Utah**
*****Northeastern University, formerly at the University of Utah**

Executive Summary
Ethylene oxide (EtO) is a hazardous air pollutant of emerging concern. It is used to sterilize equipment, such as medical and dental devices. It is also used to make other chemicals that are used in the manufacturing of a range of products, including antifreeze, textiles, plastics, detergents and adhesives. The use of EtO can contribute to increased cancer risk. Utah has two medical sterilization facilities that utilize ethylene oxide. These include Sterigenics, which is located in a commercial district, and BD Medical, which is located in a residential area. To characterize the health risk associated with exposure to EtO from these facilities, the Utah Division of Air Quality (UDAQ) and the University of Utah conducted a combined air monitoring and health risk assessment study. This included collecting 24-hr seasonal canister measurements at proximate locations to the two sterilization facilities and background locations, and conducting a health risk assessment using the Human Exposure Model (HEM). The risk assessment examined multiple scenarios: (1) a baseline scenario reflecting emissions from BD Medical prior to the installation of controls for fugitive emissions, (2) a scenario illustrating emissions from BD Medical following the installation of fugitive emissions controls, (3) sensitivity scenarios considering different meteorological years, (4) a non-residential risk scenario to illustrate cancer risk due to exposure to EtO emissions from Sterigenics. To assess consistency in findings between canister-based measurements and modeled concentrations, a comparison between modeled and measured EtO levels was also performed. Measurements showed greater concentrations at near-facility sites compared to background locations. Greater EtO concentrations were also observed at all sites in summer compared to winter, suggesting increased background EtO concentrations in the summer. Additionally, pre-controls modeling results showed elevated lifetime cancer risk (Maximum Individual Risk (MIR) > 100-in-a-million) from inhaling EtO emitted from BD Medical in census blocks located close to the facility (within 147 m, a total of about 1090 people), with fugitive emissions mainly driving the risk and risk decreasing with distance from the facility. Results also show that the maximum individual lifetime cancer risk is 3.5-7 times higher for Native Americans than for the general population and other ethnic groups. Post-controls modeling results show a substantial decrease in cancer risk after the installation of controls for fugitive emissions at BD Medical. The risk, however, remains above 100-in-a-million. However, while this modeling scenario accounts for controls on fugitive emissions, it does not account for a reduction in emissions due to EtO cycle optimization, which the facility is in the process of implementing. The projected risk could therefore be lower than estimated. Modeling results from the non-residential risk exposure scenario for Sterigenics also show elevated risk at polar receptors in the vicinity of the facility (MIR > 100-in-a-million) where several businesses with on-site workers are located. Modeling risk results for BD Medical using 2018-2022 meteorological data, 2019 meteorological data, and meteorological data from 2016, which was characterized by a wintertime temperature inversion, were not statistically significantly different, indicating that results are not sensitive to the choice of meteorological year. While modeled and measured concentration values for BD

Medical exhibited differences, locations with highest predicted lifetime cancer risk are consistent between modeled and measured results. Further measurements to determine actual ambient levels of EtO near BD Medical following the installation of fugitive emissions controls and EtO cycle optimization are underway.

1. Background and Objectives

Ethylene oxide (EtO) is a hazardous air pollutant of emerging concern. It is a colorless gas that is used to make other chemicals that are used in the manufacturing of a range of products, including antifreeze, textiles, plastics, detergents and adhesives. EtO is also used to sterilize equipment and plastic devices that cannot be sterilized by steam or radiation, such as medical and dental equipment. The use of EtO can contribute to increased cancer risk, with recent epidemiological studies indicating that EtO is a more potent carcinogen than previously documented. This led the Environmental Protection Agency (EPA) to update, in 2016, the inhalation unit risk estimate for EtO, increasing its cancer risk potency through inhalation by 30-60 times[1].

Utah has two medical sterilization facilities that utilize ethylene oxide. Both facilities, Sterigenics and BD Medical, are located in Salt Lake County, with Sterigenics being located in a primarily commercial area and BD Medical in a residential area. The EtO sterilization process at both facilities consists of three main process steps: (1) Preconditioning, where the product is held at fixed temperature and relative humidity conditions before entering a sterilization chamber where the product is exposed to EtO. Maintaining controlled conditions helps ensure better penetration of EtO into the product and improves process efficiency, (2) Sterilization, where the product is transferred from the preconditioning area to the sterilization chamber where it is exposed to EtO under controlled conditions, and (3) Post-sterilization aeration, where the sterilized product is moved to an aeration chamber, maintained at controlled conditions, to remove residual EtO from the product. These processes are associated with EtO emissions, with BD Medical and Sterigenics respectively reporting 0.35 and 0.98 tpy of actual emissions of EtO in 2021. Permitted levels are estimated at 0.24 tpy for BD Medical and 2.1 tpy for Sterigenics. Fugitive emissions, which correspond to emissions that are not routed to an existing pollution control device, account for the majority of the EtO emissions (95% and 97% for BD Medical and Sterigenics, respectively). They generally occur from (1) off-gassing associated with the handling of EtO prior to charging the sterilization chamber, (2) off-gassing of sterilized product following product transfer from the sterilization chamber to the aeration room, (3) off-gassing from the aeration room, and (4) any off-gassing that may occur after products are removed from the aeration room. These fugitive emissions may exit the facility though doors, windows, and vents. At the time of the proposal submission (2020), both facilities had controls for process emissions but no controls for fugitive emissions, which were not required under their State-issued Approval Order. Both facilities are, however, currently in the process of installing or have recently installed controls for fugitive emissions. BD Medical has installed a dry bed control system to reduce their fugitive emissions of ethylene oxide and are also implementing cycle optimization to reduce total EtO consumption. The facility estimates that this upgrade will reduce their total EtO emissions by 90%. Sterigenics submitted a Notice of Intent (NOI) air permit application in 2022 to add a permanent total enclosure (per EPA method 204) around the existing process and to include a dry bed scrubber.

[1] Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide, December 2016. https://iris.epa.gov/static/pdfs/1025_summary.pdf

Collected emissions and exhaust from the existing scrubbers will be routed to the proposed dry bed scrubber.

To characterize ambient levels of EtO and its associated health risk in communities surrounding Sterigenics and BD Medical sterilization facilities, the Utah Division of Air Quality (UDAQ) and the University of Utah conducted a combined air monitoring and health risk assessment study. This included collecting 24-hr seasonal canister measurements at background sites and proximate locations to the facilities, and conducting a health risk assessment using the Human Exposure Model (HEM), where baseline pre-controls and illustrative post-controls emission scenarios were considered. A comparison of modeled concentration estimates and measurements was also conducted.

The objectives of the study included:

- Characterizing the temporal variation and spatial gradient of EtO concentrations within communities surrounding the medical sterilizers
- Assessing cancer risk associated with inhalation exposure to EtO in communities surrounding BD Medical and Sterigenics
- Comparing modeled EtO concentration estimates and measurements

2. Measurements

2.1 Sampling Sites Description

Measurements were conducted at 16 sampling locations, 15 of which were distributed throughout Salt Lake County and one in nearby Tooele County. To determine the impact of different source emissions on EtO levels, sites with different source characteristics were selected. The location and number of sampling sites selected were based on modeling using AERMOD atmospheric dispersion model and a wind field analysis. The selected sites included sites located in neighborhoods around the facilities with maximum predicted ambient concentrations. Upwind sites and sites located at different distances (i.e. concentration gradients) from the facilities were also selected. To assess the impact of roadway emissions on EtO levels, a near-freeway site was also selected. For comparison purposes, background sites, defined as sites that are located over 5 miles from the facilities, were also selected. These included mixed industrial/urban (UDAQ's National Air Toxics Trends Station*)*, urban residential, biogenic-impacted and rural locations. The rural background site consisted of a site located 3.5 miles south of the Great Salt Lake and away from any major urban emission sources. Sampling locations are shown in Figure 1 and a description of the sites characteristics is provided in Table 1. During the summer sampling, site BG5 was replaced with SG4, which was added to better assess exposure at a fire station located nearby Sterigenics. Sampling at both sites was not possible due to resource limitations.

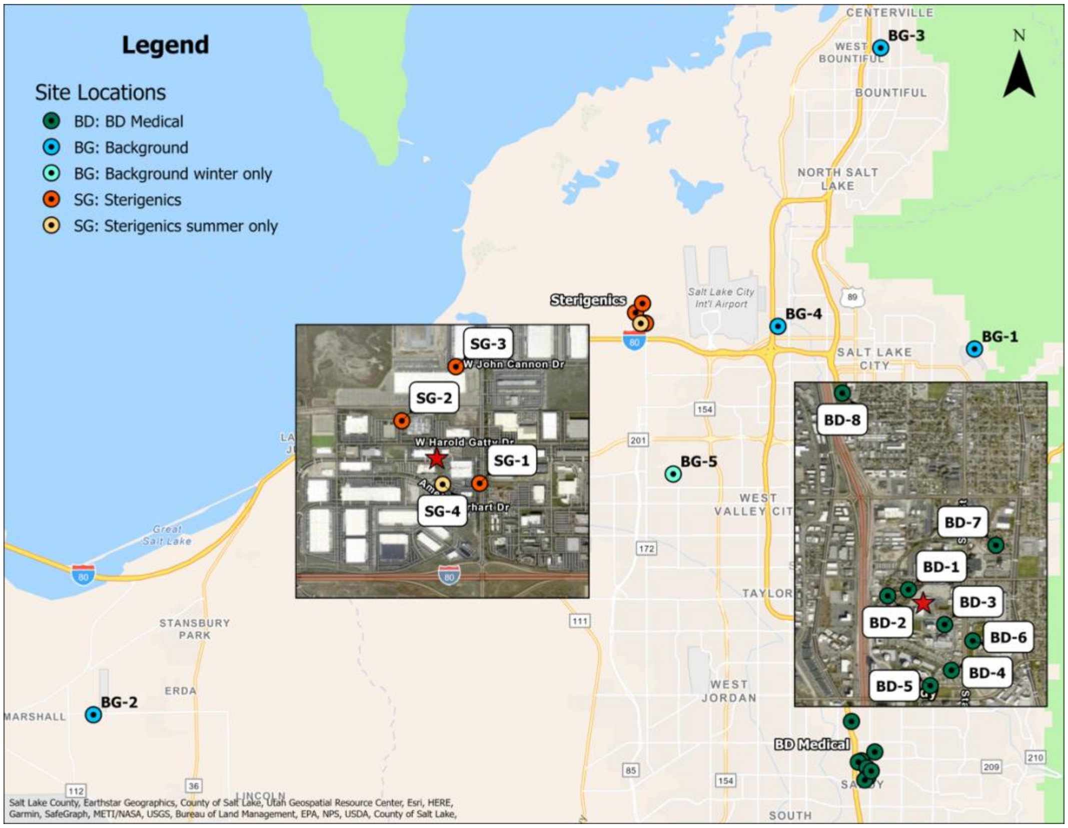

Figure 1. Location of sampling sites, BD Medical and Sterigenics facilities.

Table 1. Description of sampling sites.

Site Label	Site Description
BG1	Background- biogenic-influenced
BG2	Background- rural; located about 3 miles south of the Great Salt Lake shoreline
BG3	Background - Mixed residential/industrial
BG4	Background - within 250 m of freeway
BG5	Background - urban
BD1	Residential – 180 m west of BD Medical
BD2	Residential – 300 m west of BD Medical
BD3	Residential – 300 m south of BD Medical
BD4	Residential – 780 m south of BD Medical
BD5	Residential – 900 m south of BD Medical
BD6	Residential – 500 southeast of BD Medical
BD7	Residential – 690 m northeast of BD Medical
BD8	Near-freeway (placed 60 m of freeway during winter campaign then moved closer, within 11 m of freeway, in summer campaign)
SG1	Commercial – 285 m southeast of Sterigenics
SG2	Commercial – 450 m northwest of Sterigenics
SG3	Commercial – 700 m north of Sterigenics
SG4	Fire station in a commercial district - 230 m southwest of Sterigenics

2.2 Sampling Methodology and Chemical Analysis

At each location, 24-hr time-integrated 6L canister samples were collected every three days, based on EPA's national sampling calendar. To determine the impact of atmospheric conditions on EtO levels, sampling was conducted at each location for approximately 8 weeks in January-March 2022 (cold phase) and July-September 2022 (warm phase). Samples were collected using silonite-coated evacuated canisters fitted with a valve preceded by a timer (ENTECH TM1200) and a sampling inlet (Entech CS1200E). The timer allowed unattended sample collection. The sampling inlet consisted of a diaphragm along with a flow restrictor (#4) to regulate the flow of ambient air into the evacuated canister at a set and constant rate over the course of the 24-hr sampling period. A pressure gage was also connected to the sampling inlet to allow canister leak check and vacuum verification. To minimize contamination of the sampling system components, a particulate filter was installed on each sampling unit inlet. Sampling was conducted from midnight to midnight (local time) throughout the sampling campaigns, with the exception of a few weeks in winter. Due to the timers malfunctioning at below freezing temperatures during the winter sampling period, start and stop times for sample collection were switched during the winter sampling campaign from midnight to 3 pm, when temperatures during the day are typically highest. Canisters were all provided and certified by Eastern Research Group (ERG) laboratory following certification procedures described in NATTS Technical Assistance Document (TAD) Version 3. After collection, canisters were sent out for offline chemical analysis by ERG using EPA Compendium Method TO-15 (Determination of Volatile Organic Compounds (VOCs) in Air Collected in Specially Prepared Canisters and Analyzed by Gas Chromatography/Mass Spectrometry (GC/MS)). Method detection limit (MDL) varied throughout the project, with three different MDL values being reported (0.0219, 0.0261 and 0.048 ppbv).

3. Data Processing and Qualification

The first step in data screening consisted of reviewing each canister's chain of custody (COC) form which maintained sampling information and observations that field operators recorded during sample collection. Recorded information included canister ID, site location, initial and final canister pressure readings, sampling inlet ID, timer ID, canister valve position, sample start/stop time and date, leak check test result, and any unusual occurrences or observations that may impact the results (e.g. rain events, equipment tampering). The forms were primarily reviewed to determine any deviations from the sampling plan, sampling system leaks and potential interferences with the measurements.

3.1 Preliminary Data Processing

UDAQ canister field notes were compared with the analytical data returned by ERG, and the following additional data processing and quality assurance checks were made:

- Canisters that were voided in the field by the operator due to sampling issues, tampering, or incorrectly set timers, were removed from the final dataset, even if ERG was able to analyze the sample.
- Samples that were incorrectly labeled by ERG were cross-referenced by canister number and corrected (only a few duplicate samples and grab samples were mislabeled).
- All samples that had lab receipt pressure less than 5 in Hg or greater than 11 in Hg were removed from the final dataset. This removes samples that may have had an unidentified leak in the sampling system, had a malfunctioning pressure gauge, or had obstructions (e.g. heavy rain) reduce the volume of air collected. The choice of these thresholds was based on sampling system calibration for 24-hr sample collection.

Table 2 below summarizes the number of samples submitted to ERG and removed in preliminary data processing.

Table 2. Summary of samples removed and retained after additional data processing and qualification.

Sampling Period	Total Sample Count (i.e. count of samples sent to ERG)	Number of voided samples (% of total sample count), sample count after removal of voided samples	Samples removed due to final canister pressure > 11 in Hg or < 5 in Hg (% of total sample count), sample count after removal of voided samples and samples with final pressure outside acceptable range.	Total number of retained samples (% of total sample count)
Winter (01/08/2022 - 03/18/2022)	341	15 (4%), 329	38 (11%), 291	291 (85%)
Summer (07/10/2022 - 09/08/2022)	333	2 (0.6%) ,331	13 (4%), 318	318 (95%)

3.2 Nondetect Samples

Samples that were flagged as nondetects (ND) were replaced by half the minimum detection limit (DL) during that sample batch's processing. The summer sampling period had no samples under the detection limit. The number of ND samples and range of winter replacement values are listed in Table 3.

Table 3. Number of nondetect samples and replacement values during the winter sampling campaign.

Sampling Period	Number of ND Samples (% of Total Retained)	Minimum Replacement Value (0.5*DL) [ppb]	Maximum Replacement Value (0.5*DL) [ppb]
Winter (01/08 - 03/18/2022)	15 (5%)	0.011	0.013

3.3 Collocated Samples

The summer and winter campaigns attempted to collect 21 collocated sample sets (42 total canisters), where two canisters were placed next to each other (either on the light pole, fence, or monitoring station) and collected for the same time period. These collocated samples were first subjected to the previously mentioned data screening steps, excluding the non-detect data replacement (which impacted two winter samples), and then evaluated further following the EPA Technical Assistance Document (TAD) for the National Air Toxics Trends Stations Program (Revision 4), Section 4.4.2. These analysis steps are summarized below.

Comparison of the samples is based on calculating the relative percent difference (RPD) between the collocated samples. If the samples pass the Data Quality Indicator (DQI), the average value is included in the final dataset for further analysis.

1. If both samples are above 5xMDL, calculate RPD
    a) If RPD < 25%, collocates pass DQI.
    b) Include average of sample values in the final dataset.
2. If one sample is above 5 times the MDL, and one sample is below, substitute the low sample value for 5xMDL and calculate the RPD.

    a) If RPD < 25%, collocates pass DQI
    b) Include average of the original sample values (not substituted 5xMDL value) in the final dataset.
3. If both samples are below 5xMDL, there is no DQI recommended in the TAD
    a) Samples are averaged regardless of RPD and included in the final dataset.

Table 4. Number of collocated sample pairs excluded and retained in final data set during each of the winter and summer sampling campaigns.

Sampling Period	Number of Collocate Pairs (% of Total Retained)	Number of Collocate Pairs Rejected	Number of Single Samples Rejected (Pressure < 5 in Hg)	Number of Averaged Pairs	Adjusted Number of Retained Samples (% of Previous) Total)
Winter (01/08 - 03/18/2022)	17 pairs (34 samples ,12%)	3	0	14	267, 14 from collocates (92%)
Summer (07/10 - 09/08/2022)	19 pairs (38 samples ,12%)	6	1	12	293, 13 from collocates (92%)

Because one sample in a collocate pair was removed from the initial dataset due to a pressure of 3 in Hg, the remaining collocate sample is treated as a “normal”, single sample and included in the final dataset.

3.4 Summary of Final Dataset

After completing all data screening and collocate assessment and averaging, the final winter campaign dataset included 267 samples, and the summer campaign data included 293 samples. Table 5 includes data capture rates for each sampling period. Before collocate averaging, the winter campaign had an 85% capture rate, and the summer campaign had a 95% capture rate. The lower wintertime rate was primarily due to issues with the solenoid valve of the automated timers not closing at low temperatures.

Table 5. Data capture rate and final sample count for each of the winter and summer sampling campaigns.

Sampling Period	Samples sent to ERG	Samples Retained After Cleaning	Capture Rate	Adjusted Final Count After Collocate Averaging
Winter (01/08 - 03/18/2022)	341	291	85%	267
Summer (07/10 - 09/08/2022)	333	318	95%	293

3.5 Additional Data Screening

Increased scrutiny of the analytical method TO-15 and possible canister contamination due to reuse resulted in additional data flags being added to the summertime data with a result greater than 3xMDL after August of 2022. The 'LK' flag indicates a reported sample value may be biased high. This flagging approach was intended to remove erroneously high EtO values from the NATTS network, which are sampling stations primarily sited away from major EtO sources. The high NATTS EtO values were thought to be influenced by canister growth effects, wherein the EtO concentration increases after the sample has been collected due to contamination or reactions within the canister.

Because this study focused on near-source sampling, high values should not be excluded based on the 3xMDL threshold alone. After speaking with ERG, an additional parameter was included to help isolate canisters that had a hold time (time between sample collection and lab analysis) greater than 14 days. If an EtO sample is greater than 3xMDL *AND* has a hold time greater than 14 days, it was flagged as LK. This flagging criteria allows for flagging of "older" samples that might have canister growth, while still including higher EtO concentrations found in near-source sampling.

Despite most of the sampling occurring before August of 2022, the LK flagging criteria was applied to both the summer and winter datasets. Table 6 includes the number of samples that would have been flagged using the EPA criteria and the number of samples flagged using the ERG criteria. The summer sampling period has almost double the number of LK flags following the EPA criteria, largely because the EtO concentrations measured during the summer were much higher and more frequently exceeded the 3xMDL threshold.

Table 6. Count and percent of samples flagged with "LK" using EPA criteria vs. ERG criteria.

Sampling Period	**EPA LK Flag (Number, % of Total)**	**ERG LK Flag (Number, % of Total)**
Winter (01/08 - 03/18/2022)	99 37%	76 28%
Summer (07/10 - 09/08/2022)	195 67%	83 28%

To further visualize how the samples are impacted by LK flagging, Figure 2 identifies the 3xMDL threshold (black line) and the 14-day hold time (orange line). More of the summer canisters were analyzed before the 14-day hold time threshold because of fewer weather-related shipping delays.

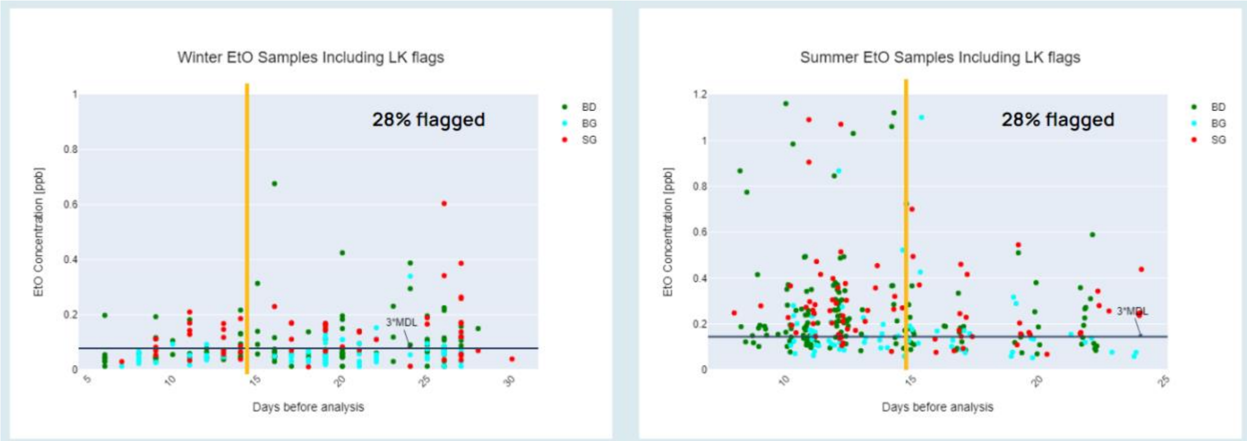

Figure 2. Samples concentration as a function of holding time and relative to 3xMDL threshold during each of the winter (left) and summer (right) sampling campaigns.

A table summarizing the number of canisters included at each sampling site, including and excluding LK flags is included in the Appendix (Table A1).

4. Results

Results from the sampling campaign were analyzed for seasonal variability and changes in EtO concentration with relation to the source (spatial variability). Analysis that excludes the LK flagged samples (No Flags or NF) to assess the importance of these samples is also considered. Statistical and graphical methods were leveraged in an attempt to summarize the relevant findings.

4.1 Air Quality During Sampling

The winter (January 10 - March 18 2022) sampling period was characterized by 40 good AQI days (PM2.5 values less than 12 µg/m^3), 24 moderate AQI days (PM2.5 values between 12.1 - 35.4 µg/m^3), and 4 days classified as unhealthy for sensitive groups (PM2.5 values between 35.5 - 55.4 µg/m^3). The higher AQI days all occurred in January, and only two moderate AQI days occurred in March. These conditions are typical of wintertime in the Salt Lake area, which generally has a few sustained temperature inversion events.

The summer sampling period (July 10 - September 8 2022) had fewer poor air quality days than previous years due to the lack of significant wildfire impacts. Unlike the winter, when inversions could conceivably concentrate EtO emissions, leading to higher ambient concentrations, summertime AQI levels are not indicative of meteorological conditions that could lead to more EtO.

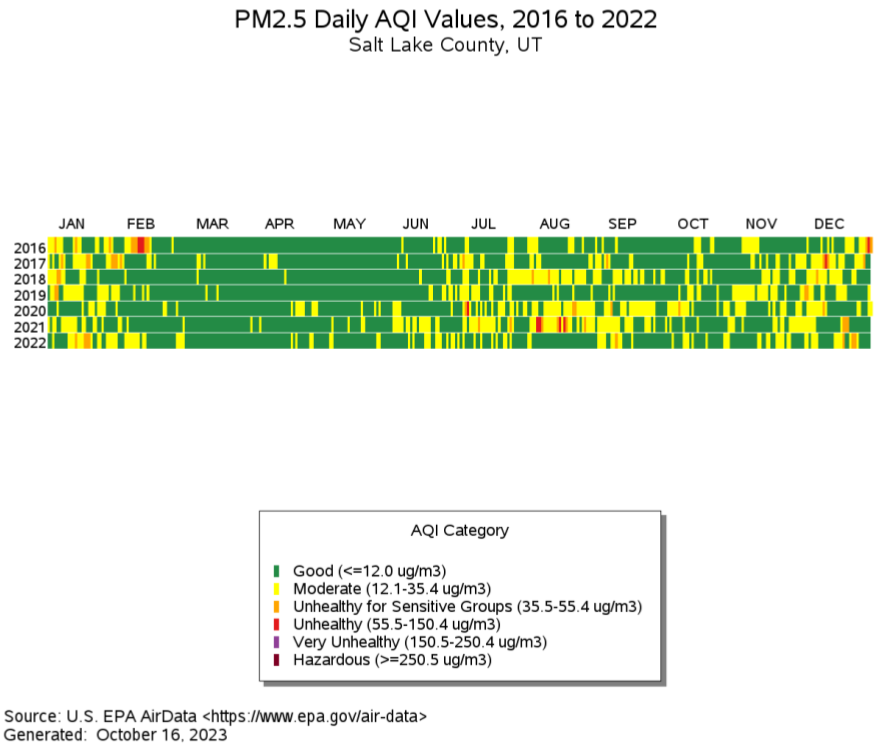

Figure 3. PM2.5 daily AQI values for Salt Lake County during 2016-2022.

4.2 24-Hour Time-Integrated Ambient Canister Sampling

4.2.1 Seasonal Variability

Despite the wintertime inversions, median summertime EtO concentrations were higher compared to wintertime concentrations at all sites. This included background sites, where concentrations were a factor of two to three times higher than the summer, suggesting that the greater summertime concentrations are likely driven by higher background EtO values. These findings are consistent with or without the LK flagged (_NF) samples (Figure 4).

Table 7 includes the range of median, minimum, and maximum for the grouped samples. For example, the BD group includes eight individual sites. Within that group, the lowest median in the winter is 0.46 ppb and the highest median is 0.150 ppb when LK flags are included in the calculations. These values drop to 0.042 ppb and 0.115 ppb when LK flags are excluded. Table 7 also shows the minimum and maximum sample values within the groups, and the maximum range when LK flags are removed. Lastly, the median sample populations at each site are compared with and without LK flags using a 2-sample Kolmogorov-Smirnov (KS) test. If the p-value of the test is greater than 0.05, then the two distributions are statistically similar at the 95% confidence interval. The summer samples all fell well above this threshold, but a few of the winter sampling sites were not statistically similar, which could be related to their low sample counts. Measured concentrations did not exceed thresholds for acute health effects. However, medians at all sites for both seasons exceeded EtO's 100-in-a-million lifetime cancer risk threshold of 0.011 ppb.

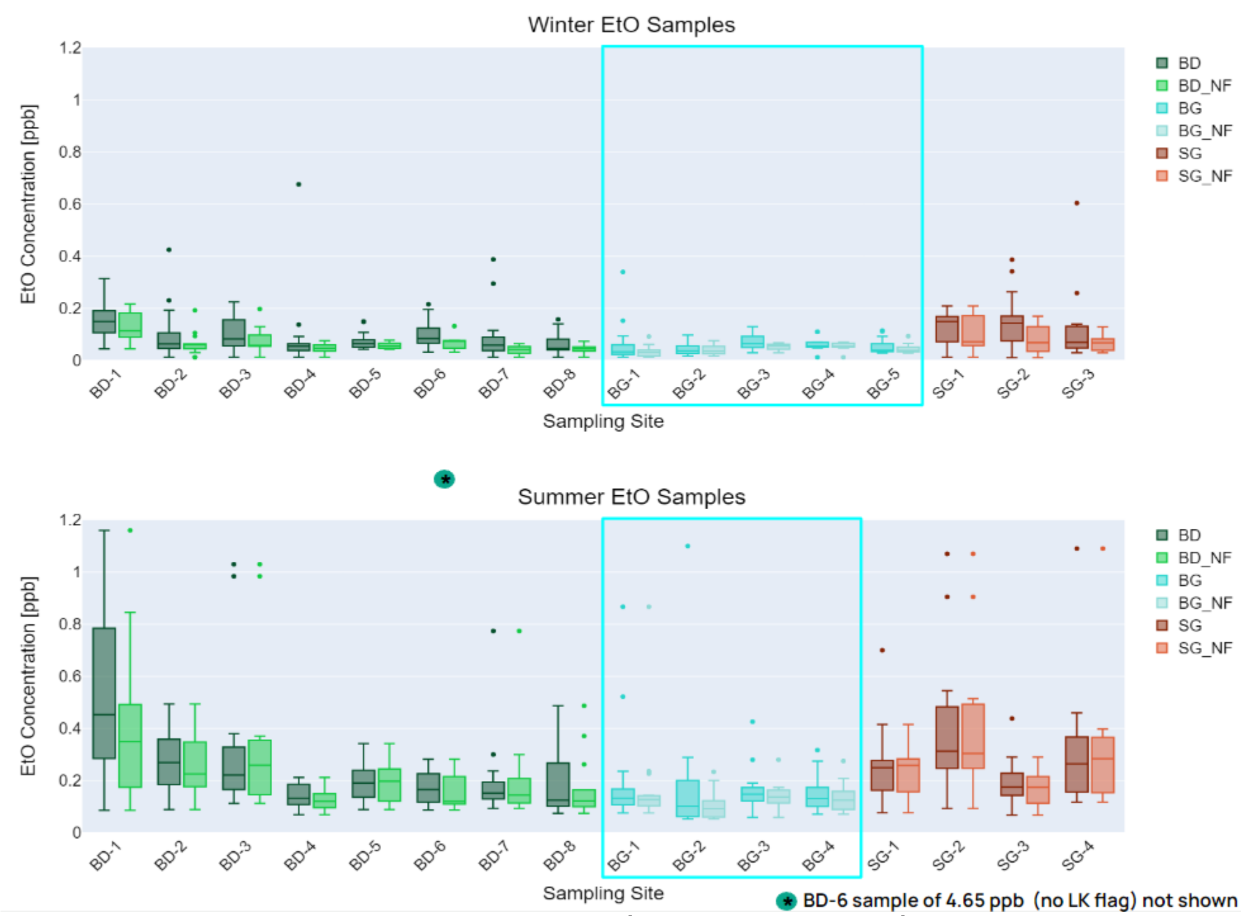

Figure 4. Box plot of EtO concentration (minimum, 25th percentile, median, 75th percentile, maximum) by site during each of the winter and summer sampling campaigns. Outliers that fall outside the interquartile range are shown as dots.

Table 7. Range of median, minimum and maximum EtO concentrations with and without LK flags by group of sites during each of the winter and summer sampling campaigns. P-value results from a 2-sample Kolmogorov-Smirnov (KS) test for comparing median sample populations with and without LK flags are shown too.

Group	range median	range median NF	range min	range max	range max NF	range 2-samp KS p-value
BD Winter	0.046, 0.150	0.042, 0.115	0.013, 0.045	0.015, 0.676	0.065, 0.217	0.205, 0.987
BD Summer	0.125, 0.453	0.120, 0.349	0.070, 0.113	0.212, 4.65	0.212, 4.65	0.621, 1.0
BG Winter	0.034, 0.065	0.032, 0.057	0.013, 0.030	0.098, 0.340	0.068, 0.093	0.0205, 1.0
BG Summer	0.101, 0.148	0.092, 0.137	0.053, 0.076	0.317, 1.100	0.234, 0.867	0.920, 1.0
SG Winter	0.071, 0.150	0.068, 0.073	0.011, 0.030	0.210, 0.604	0.129, 0.210	0.298, 0.726
SG Summer	0.176, 0.313	0.175, 0.304	0.068, 0.117	0.438, 1.09	0.290, 1.09	1.0, 1.0

4.2.2 Spatial Variability

EtO concentrations also varied spatially, with sites closer to the facilities exhibiting the highest median concentrations (Figure 5). Moreover, EtO median concentrations for each season follow the anticipated pattern of enhancement based on average wind conditions and proximity to the facilities. Summer concentrations are elevated compared to winter concentrations at all sites, including background sites, likely suggesting increased contribution from background EtO sources, as aforementioned.

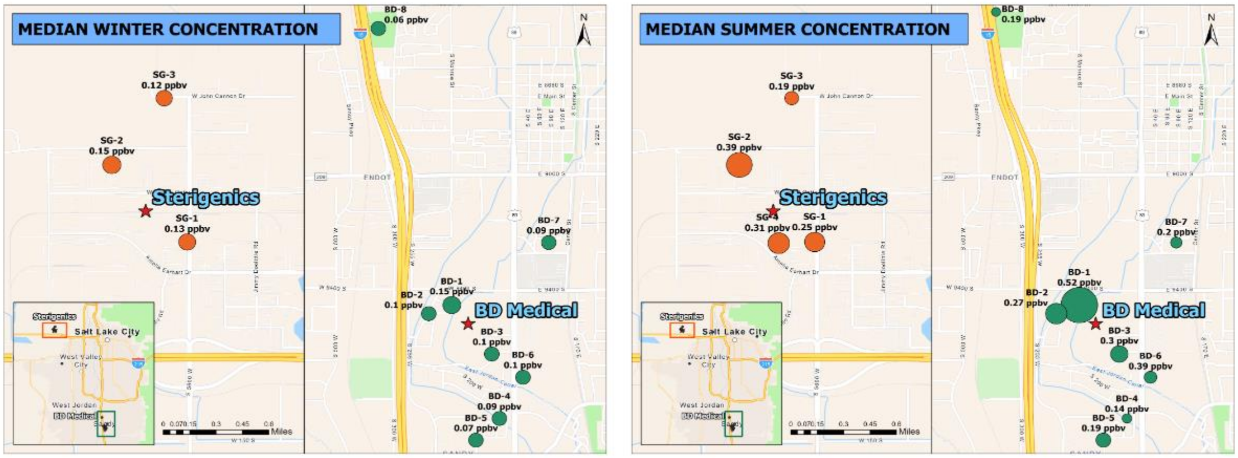

Figure 5. Spatial plot of median EtO concentrations observed at each of the facility sites in the winter (left panel) and summer (right panel). Dot size reflects the median concentration values.

5. Grab Ambient Canister Sampling

To investigate changes in EtO concentration around the facilities' fenceline and other possible EtO sources in the Salt Lake Valley, grab samples were collected after the winter and summer field campaigns. Samples were collected around both of the sterilization facilities, a suburban park, and a hospital that is permitted for EtO sterilization on-site. When possible, samples were collected in each cardinal direction (N, W, S, E). There is no corresponding information about the operating conditions during the grab sampling near the facilities, and these results should be viewed as a supplement to the study. Grab sampling is not the preferred method for EtO measurements, as it captures a very brief time period, but while the grab sampling results are limited by their short sampling duration, they provide additional insight on EtO variability along the facilities' fencelines and other potential EtO sources.

5.1 Grab Sampling Near Facilities

Sampling near the Sterigenics, BD Medical and Intermountain Hospital was all conducted in spring 2022, after the winter campaign. Canisters were opened manually for about 30 seconds, with no flow controller attached. This resulted in final pressures ranging from 4.5 - 10.5 in Hg. At the SG and BD sites, two sets of grab canister samples were collected at each sampling location. Since there is no recommended data treatment for collocate grab samples, the canisters EtO results were averaged (Figure 6).

Meteorological conditions varied between sampling events, and are likely an important factor in the different EtO concentrations found at the Sterigenics site, but could also play a factor during all sampling events. The sampling performed at SG on March 29th (pink dots) had gusty winds from S/SW at speeds greater than 14 mph. On April 19th (blue dots), winds were gusty from the N/NW at 9 mph. The lower concentrations observed in April may be due to changes in on-site emissions or be the result of random wind gusts.

The BD medical samples were collected on April 18th when the wind was gusty but generally from the S/SE at 9 mph. The sampling at Intermountain Hospital occurred on May 19th when the winds were very light and from the W/NW at 2 mph.

Although the grab sampling method is not as robust as a 24-hour sample, it does show the high variability in EtO concentrations over shorter time periods. These results are motivation for additional EtO monitoring at higher time resolution to see how EtO varies from hour to hour and along the fenceline of EtO emission facilities.

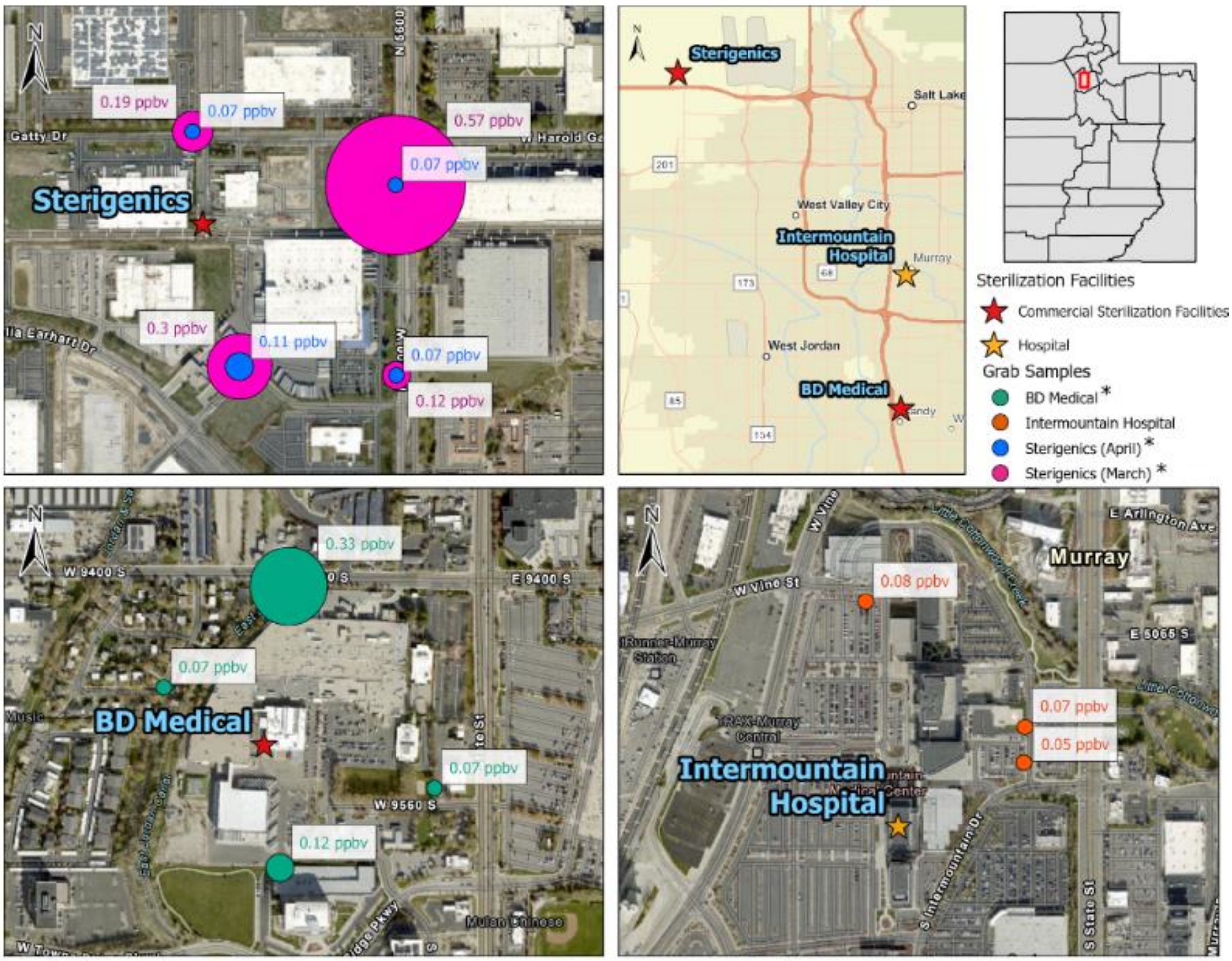

Figure 6. Grab sample canister measurements near Sterigenics, BD Medical and Intermountain Hospital.

5.2 Grab Sampling at a Suburban Park

Grab sampling at Hidden Valley Park occurred on three occasions in summer 2022 and early Fall 2022. Though still within the greater Salt Lake Valley, the proximity of the Wasatch Foothills suggests Hidden Valley Park is a more biogenic-impacted site, with pollutants levels at that site being impacted by upslope and downslope mountain flows. These grab samples were all singular samples, and EtO concentrations were highly variable between sampling events (Figure 7). Interestingly, two of these samples exceed the median summertime values for the background sites, possibly suggesting the contribution of biogenic emissions to EtO.

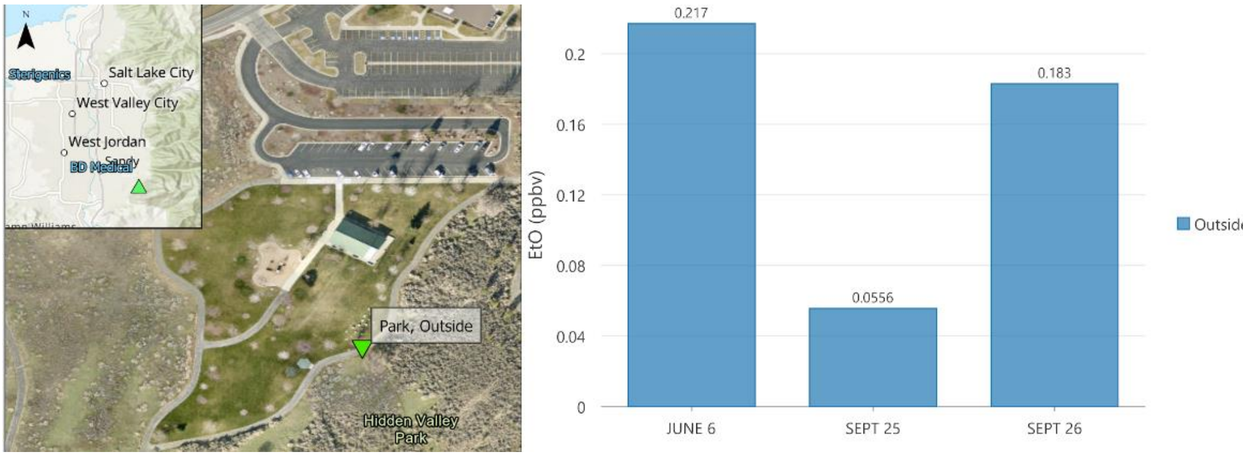

Figure 7. Grab sample canister measurements at a suburban park in the Salt Lake Valley area.

6. Indoor/Outdoor Canister Sampling

To determine exposure to ethylene oxide in indoor spaces, indoor and outdoor EtO samples were collected at two different buildings (fire station and University of Utah campus building) during two different sampling periods (May and October 2022). Investigating indoor EtO samples was not part of the submitted proposal or within the project's scope of work, but was conducted for exploratory scientific purposes and to highlight future research needs.

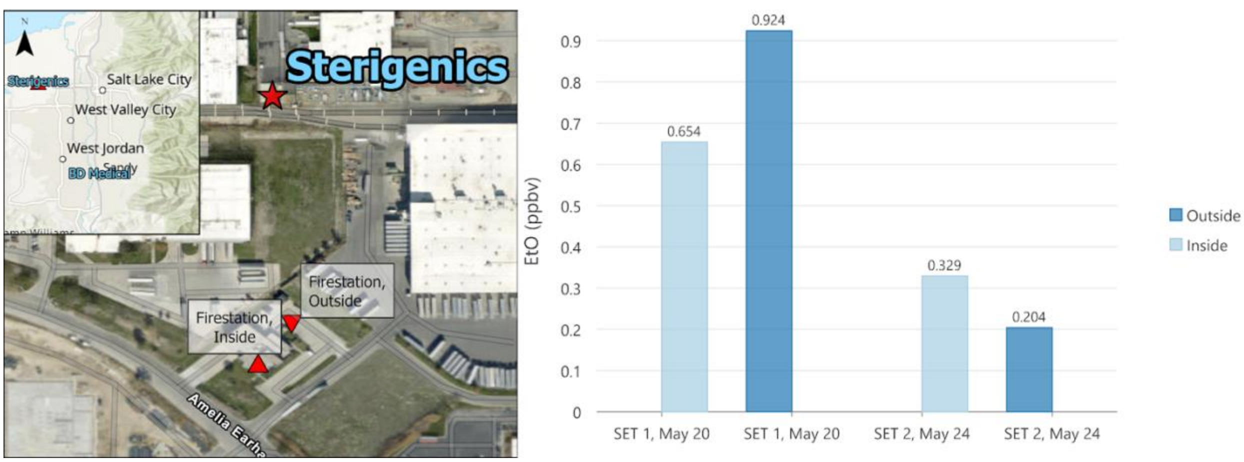

Figure 8. Indoor/Outdoor EtO concentration measurements by set at a firestation close to Sterigenics facility.

Sampling was first conducted at a fire station located 230 meters southwest of Sterigenics, where two sets of paired indoor and outdoor 24-hr canister samples were collected during May 2022 (May 20th and 24th 2022, Figure 8). The outdoor canister samples were mounted on a light pole while the indoor samples were placed in the communal kitchen area. Windows and doors were kept open during the sampling period, as is typically done during this time of year. The roof of the fire station had also been recently repaired, and there were significant tar-like odors both inside and outside of the building. Indoor and outdoor concentration levels varied greatly between the two sets of samples, with both indoor and outdoor concentrations being greater for sample set 1 compared to sample set 2. Additionally, outdoor levels were not consistently greater than their corresponding indoor levels, possibly suggesting EtO accumulation indoors and/or indoor EtO sources. These results, however, are limited to a single location and by the very small sample size, and should be interpreted with caution. More samples are needed to confirm these findings.

Concurrent indoor and outdoor sampling was also conducted at the University of Utah's Department of Family and Preventive Medicine building, which is located close to biomedical companies and within 0.5 miles of a medical laboratory that provides testing for local hospitals and medical health centers. Because of its location in proximity to a canyon, the building could also be impacted by biogenic emissions through downslope canyon flows. To investigate the diurnal variability in indoor and outdoor EtO levels, paired 12-hr indoor/outdoor canisters were collected during the daytime (8am - 8pm) and nighttime (8pm - 8am). Indoor canisters were collected inside a classroom, while outdoor canisters were mounted on a light pole in the building's parking lot. To investigate weekday variability, one set of samples was collected during the weekend (8 am on Saturday Oct. 22nd 2022 - 8 am on Sunday Oct. 23rd 2022, Figure 9), when the building was largely unoccupied, most building doors and windows were kept closed, and nearby local business activity was lower. The second sample was collected during a weekday (8 am on Thursday Oct. 26th 2022 - 8 am on Friday Oct. 27th 2022, Figure 10), when multiple lectures were held in the classroom and more people were entering and exiting the building. Because the samples were limited to 12 hours, each sample was diluted during chemical analysis, with one of the samples (5.36 ppbv) being flagged for exceeding the calibration range of the analytical instrument. Because it is flagged, this sample value should be considered as an estimate. Daytime samples were higher than nighttime samples for both indoor and outdoor weekend samples. Daytime outdoor sample was also greater than the indoor daytime sample, suggesting a greater influence from outdoor EtO sources.

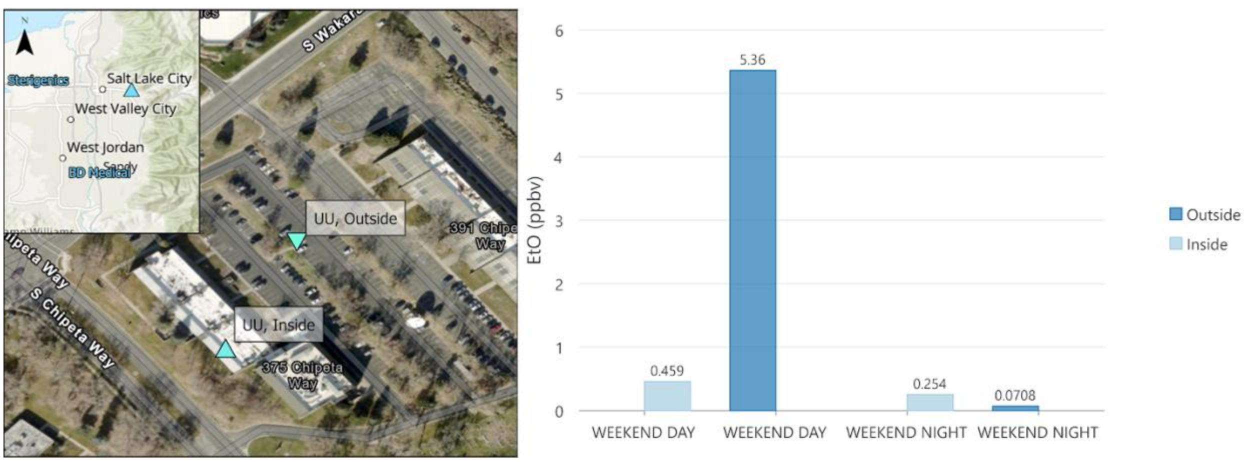

Figure 9. Nighttime and daytime indoor/Outdoor EtO concentration measurements on weekends at the University of Utah campus.

Compared to the weekend canister samples, indoor and outdoor samples collected during the weekday exhibited very different trends. On the weekday sampling day, the indoor and outdoor daytime samples, and the nighttime indoor sample were all below the detection limit (0.1 ppb for these diluted 12-hr samples), while the nighttime outdoor sample averaged 6.41 ppb. This high nighttime value could be related to EtO emissions from a nearby biomedical facility, possibly utilizing EtO. While UDAQ's emissions inventory has no record of the facility utilizing EtO, employees in the area have reported seeing EtO tanks on the property. It should also be noted that the facility is currently no longer in operation.

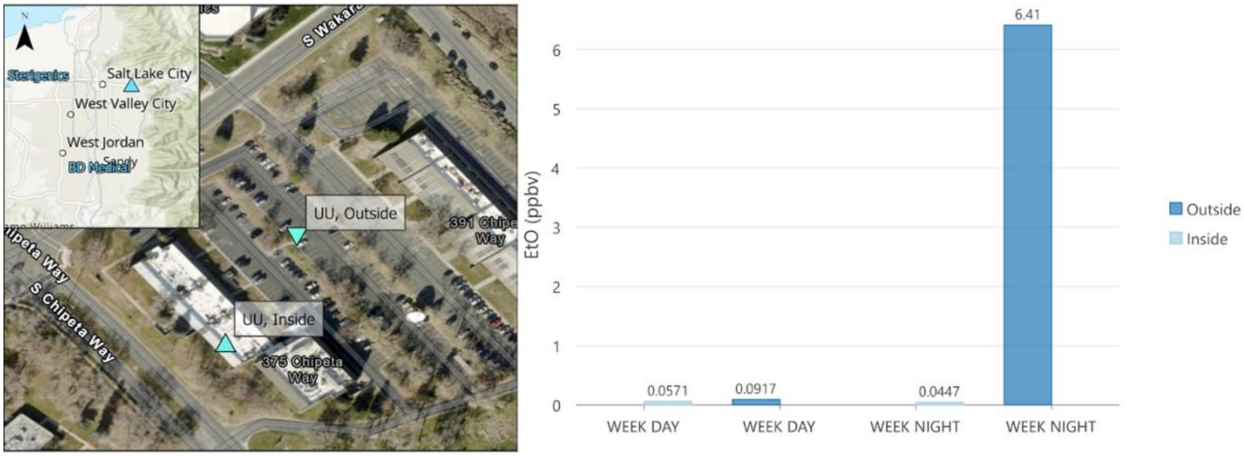

Figure 10. Nighttime and daytime indoor/Outdoor EtO concentration measurements on weekdays at the University of Utah campus.

These results for indoor and outdoor samples are limited by the very small sample size and number of locations. Findings cannot be generalized and should be interpreted with caution. However, while limited, these findings highlight the need to investigate indoor exposure to ethylene oxide, infiltration of ambient EtO into indoor spaces, and potential indoor EtO sources. Increased samples and sampling at different locations, including background sites, are needed to investigate this further.

7. Health Risk Assessment

7.1 Methodology

Unless otherwise noted, outcomes were modeled with EPA Human Exposure Model (HEM) 4.2, which included AERMOD version 22112 and population data from the US Census Bureau's 2020 census.

While emissions from both Sterigenics and BD Medical were both considered in this project, the physical locations of the facilities are very different. As aforementioned, BD Medical is physically located in close proximity to residential neighborhoods in the Salt Lake Valley. On the other hand, Sterigenics is located in close proximity to the Salt Lake City international airport in a predominantly non-residential area (Figure 1). Thus, due to this residential versus non-residential aspect, a major portion of this report emphasizes the modeling exposure characterization in close proximity to BD Medical. However, it should be noted that a stronger study on exposures to EtO would include sampling and modeling of EtO concentrations inside workplace facilities in close proximity to Sterigenics. In an attempt to begin this approach, sampling canisters were placed inside a fire department facility in close proximity to Sterigenics, as discussed in section 6. Concentrations measured from this location were not found to be insignificant and further raises the question regarding conducting additional workplace sampling and modeling efforts as a part of another study.

The pollutant of interest was ethylene oxide (EtO), whose 70-year lifetime inhalation unit risk exposure (URE) is determined by EPA to be 0.005 per µg/m^3. This value was used for hazardous air pollutants (HAP) library settings in residential modeling around BD Medical. For non-residential models involving industrial (working) zones around Sterigenics, URE was adjusted and set to 0.000261, which comprises:

- URE of 0.003 per µg/m^3 (rather than 0.005 per µg/m^3) for exposure occurring only in adulthood[2].
- Exposure multiplier of 0.087 to reflect less than lifetime exposure. This factor was based on an offsite worker as described by ATSDR[3], which assumes an 8.5-hr workday, 250 days per year for 25 years, resulting in an exposure factor of 0.087 where, Exposure factor = (8.5 hrs x 250 days x 25 years) / (24 hrs x 365.25 days x 70 years)
- Adjusted URE = 0.003 x 0.087 = 0.000261

Table 8. Ethylene oxide emission levels used in HEM pre-controls modeling scenario (source EPA).

Facility	Source	Emissions (tons/year)
SG	CEAR0001	0.020634663300
SG	CECE0005	0.004126932660
SG	CEEG0002	0.041258104396
SG	CEHC0003	0.150179500000
SG	CENO0004	0.060071800000
SG	CEPO0007	0.300359000000
SG	CEPR0008	0.240287200000
SG	CEPR0009	0.030035900000
SG	CEPR0010	0.030035900000
SG	CESC0006	0.000006935289
SG	CEVP0011	0.150179500000
BD	CEAR0001	0.000323664000
BD	CEHC0002	0.010000000000
BD	CEPO0004	0.280000000000
BD	CEPR0005	0.036923076923
BD	CESC0003	0.015631704000
BD	CEVP0006	0.003076923077

[2] https://iris.epa.gov/static/pdfs/1025_summary.pdf, Table 1.1.
[3] Agency for Toxic Substances and Disease Registry. 2016. Exposure Dose Guidance for Determining Life Expectancy and Exposure Factor.

Several modeling scenarios were conducted: (1) a baseline scenario reflecting emissions from BD Medical prior to the installation of controls for fugitive emissions, (2) a scenario illustrating emissions from BD Medical following the installation of fugitive emissions controls, (3) sensitivity scenarios considering different meteorological years, (4) a non-residential risk scenario to illustrate cancer risk due to exposure to EtO emissions from Sterigenics. To assess consistency in findings between canister-based measurements and modeled concentrations, a comparison between modeled and measured EtO levels was also performed. The intent of this analysis was not to discount one type of characterization method over another or to provide a compelling argument on the merits of conducting the assessment with either technique. Instead, the dual characterization techniques were employed to provide a comparison between methods and the values determined.

EtO emission levels from the facilities (pre-controls) used in the HEM modeling were provided by the EPA, which EPA obtained from the facilities through an information collection request sent in 2021 (Table 8).

In order to verify correct HEM configuration and input values, a duplicate re-run of EPA's 2022 risk assessment modeling for BD Medical (pre-controls)[4] was performed. To maintain consistency, for this specific analysis, we used the same HEM version as used by the EPA, rather than the latest HEM4.2 version with 2020 census data. The results from the duplicate re-run were found to be identical (results not shown here). All other modeling scenarios were conducted using the latest and updated version of HEM 4.2.

7.2 Results

7.2.1 BD Medical Residential Risk Scenarios

All residential risk modeling scenarios focused on representing lifetime exposure and involved several assumptions. These included assuming that people are exposed to ethylene oxide 24 hours per day, 365 days per year for 70 years. Long-term and short-term population mobility and its impact on exposure is not considered in this analysis. The analysis also focuses on the inhalation risk from EtO emissions from BD Medical only. It does not address comprehensive risk from other pollutants and air pollution sources. It also estimates the risk of getting cancer that is in addition to people's overall risk of getting cancer for other reasons, and cannot predict an individual person's risk of developing cancer. The analysis also predicts risk going forward and does not estimate past risk.

7.2.1.1 Baseline Emissions (Pre-Controls)

A baseline residential risk modeling scenario using 5 years of meteorological data (2018-2022) and reflecting emissions from BD Medical prior to the installation of controls for fugitive emissions was conducted. Results show elevated lifetime cancer risk (Maximum Individual Risk (MIR) > 100-in-a-million) from inhaling EtO emitted from BD Medical in census blocks located close to the facility (Figure 11a-b), with fugitive emissions, which account for the majority of the emissions, mainly driving the risk. Risk then decreases with distance from the facility.

[4] https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/forms/sandy-utah-bd-medical

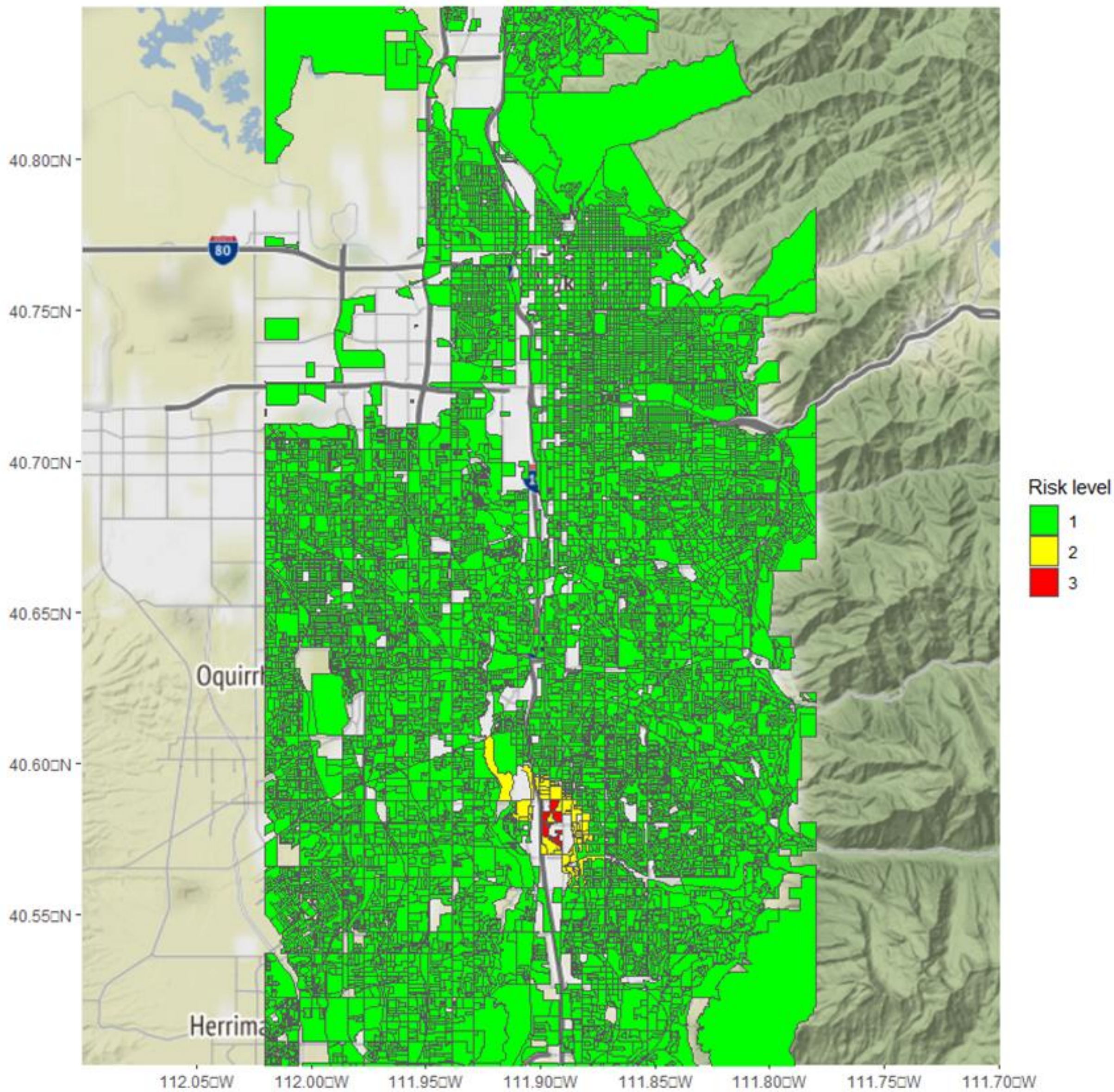

Figure 11a. Choropleth map of lifetime cancer risk levels from EtO among the 2020 census blocks near BD Medical using 2018-2022 meteorological data. Red [3] indicates a receptor with a modeled total cancer risk greater than 100 in a million, yellow [2] indicates a risk level between 20 and 100 in a million, and Green [1] indicates a risk of less than 20 in 1 million.

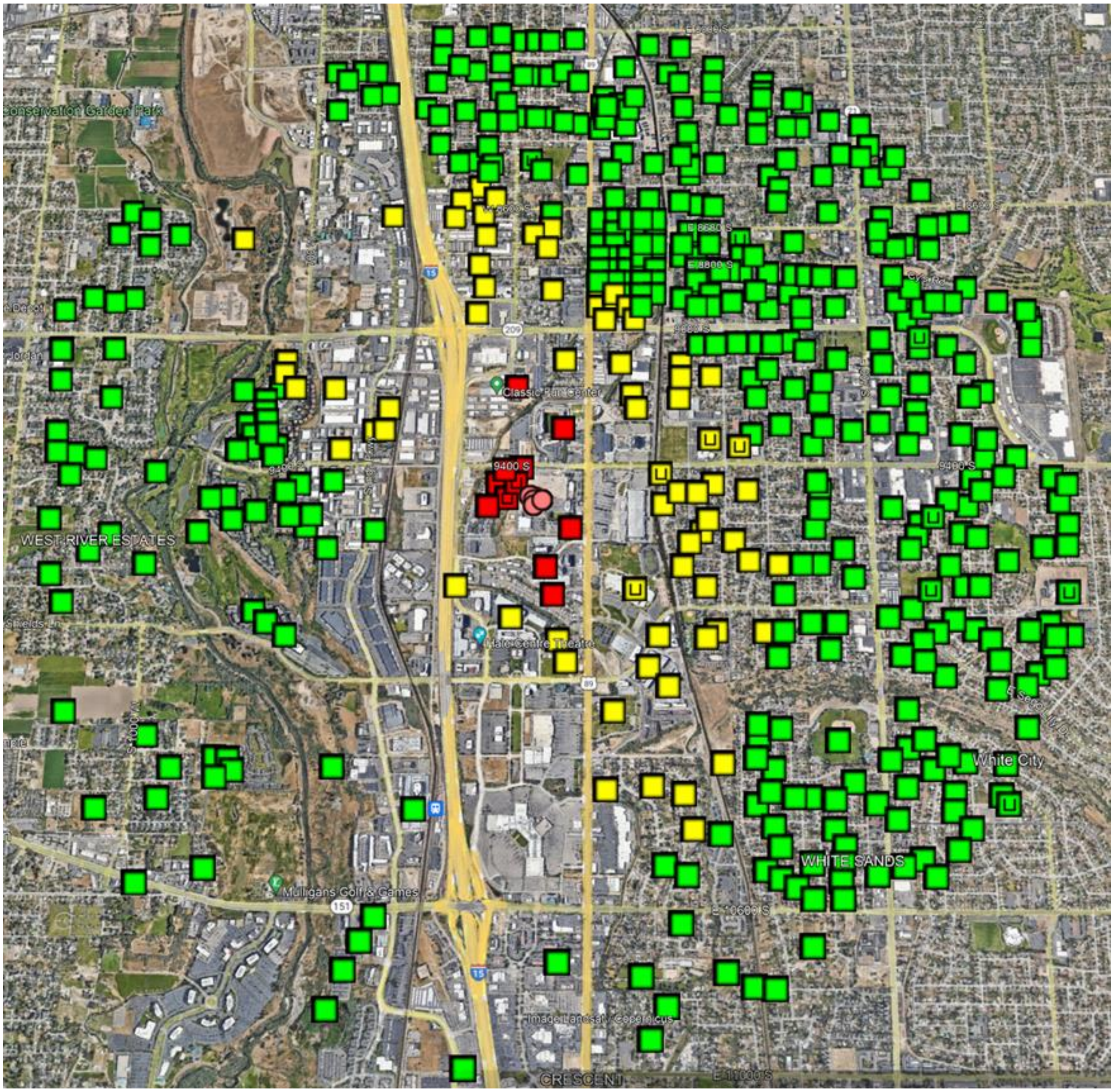

Figure 11b. Choropleth map of lifetime cancer risk levels from EtO among the 2020 census blocks near BD Medical using 2018-2022 meteorological data, zoomed to show areas of concern with more detail. Red [3] indicates a receptor with a modeled total cancer risk greater than 100 in a million, yellow [2] indicates a risk level between 20 and 100 in a million, and Green [1] indicates a risk of less than 20 in 1 million.

7.2.1.2 Sensitivity to Meteorological Conditions

To determine modeling results sensitivity to the choice of meteorological years, residential risk modeling for BD Medical was conducted using three sets of meteorological data. These included 2016, 2019 and 2018-2022, with 2018-2022 representing a wide variety of recent meteorological conditions, 2019 corresponding to a typical meteorological year and also reproducing EPA's risk modeling for BD Medical, and 2016 representing a year with a stronger wintertime inversion. All other inputs and settings were maintained the same for each of the modeling scenarios, with emissions from BD Medical prior to the installation of fugitive emission controls being used. The selection of years (i.e., 2016, 2019, and 2022) was based on an examination of PM2.5

concentrations for the Salt Lake Valley over the three selected years, where data from all "Salt Lake City" monitors was considered for the analysis. Figures 12-14 show the monthly, weekly and daily average PM2.5 concentrations for these three years. Compared to 2019 and 2022, 2016 was the year with greater PM2.5 levels and more exceedances (24-hour value > 35.5 µg/m^3). This is also reflected in Figure 3, where 2016 was characterized by more winter days with classification as unhealthy for sensitive groups (PM2.5 values between 35.5 - 55.4 µg/m^3) and unhealthy for all groups (PM2.5 values between 55.5 - 150.4 µg/m^3).

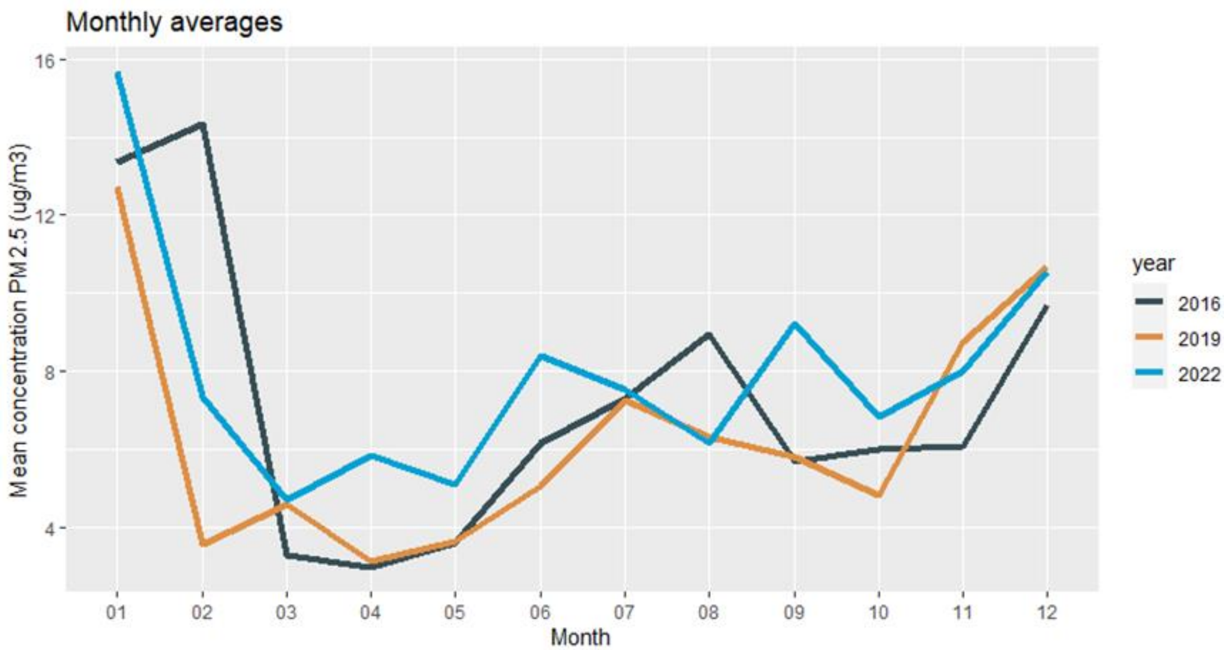

Figure 12. Monthly average for PM2.5 in Salt Lake Valley during 2016, 2019 and 2022.

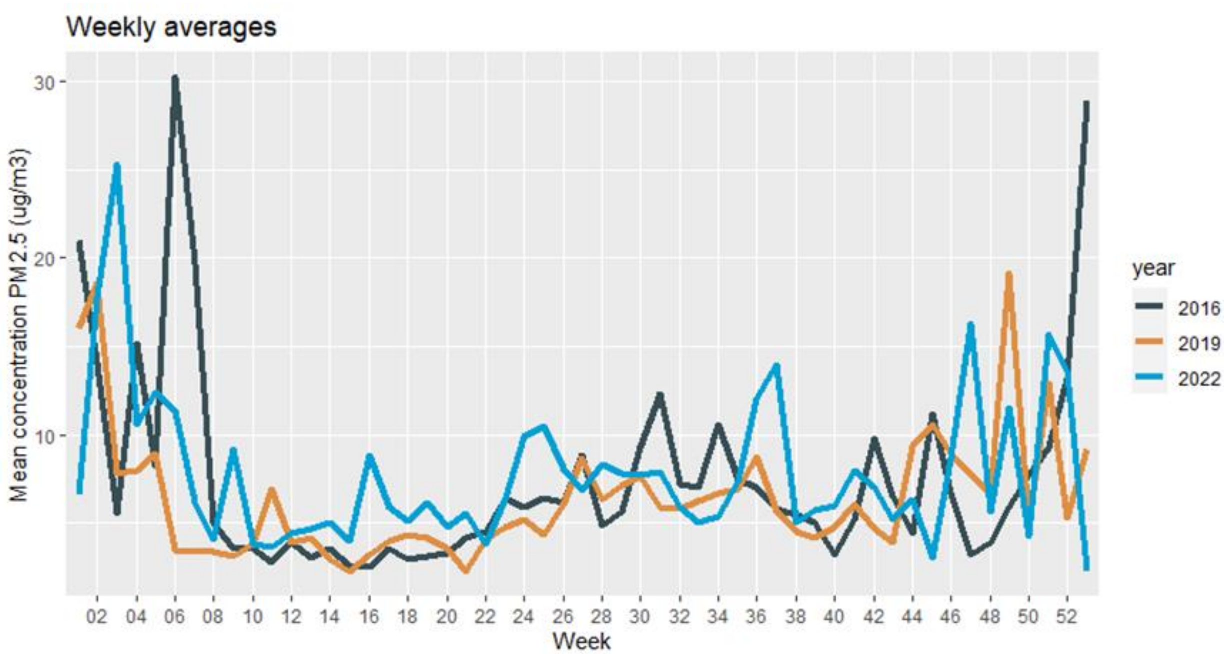

Figure 13. Weekly average for PM2.5 in Salt Lake Valley during 2016, 2019 and 2022.

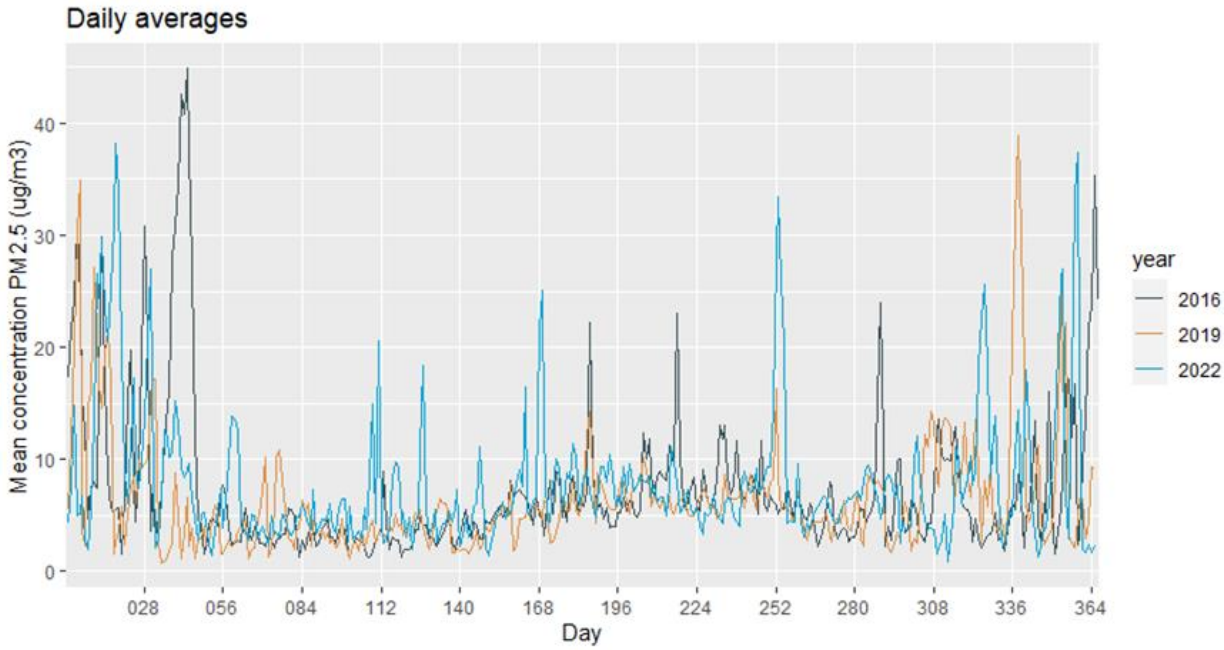

Figure 14. Daily average for PM2.5 in Salt Lake Valley during 2016, 2019 and 2022.

The following paragraphs and diagrams provide a means of comparison and contrast of human MIR values and color-coded, cancer risk blocks between the three meteorological time periods of delineation: 1-year meteorological data (2019), 5-year meteorological data (2018-2022), and meteorological data from a significant inversion year (2016).

Figures 15a-b, 16a-b and 17a-b show choropleth maps of lifetime cancer risk levels from EtO inhalation exposure among the 2020 census blocks near BD Medical using 2019, 2018-2022 and 2016 meteorological data, respectively. For these maps, cancer risks are color coded per HEM specifications. Specifically, red [3] indicates a receptor with a modeled total cancer risk greater than 100 in a million, yellow [2] indicates a risk level between 20 and 100 in a million, and green [1] indicates a risk of less than 20 in 1 million. Figures 14b, 15b and 16b are the zoomed versions, showing the area of concern in more detail.

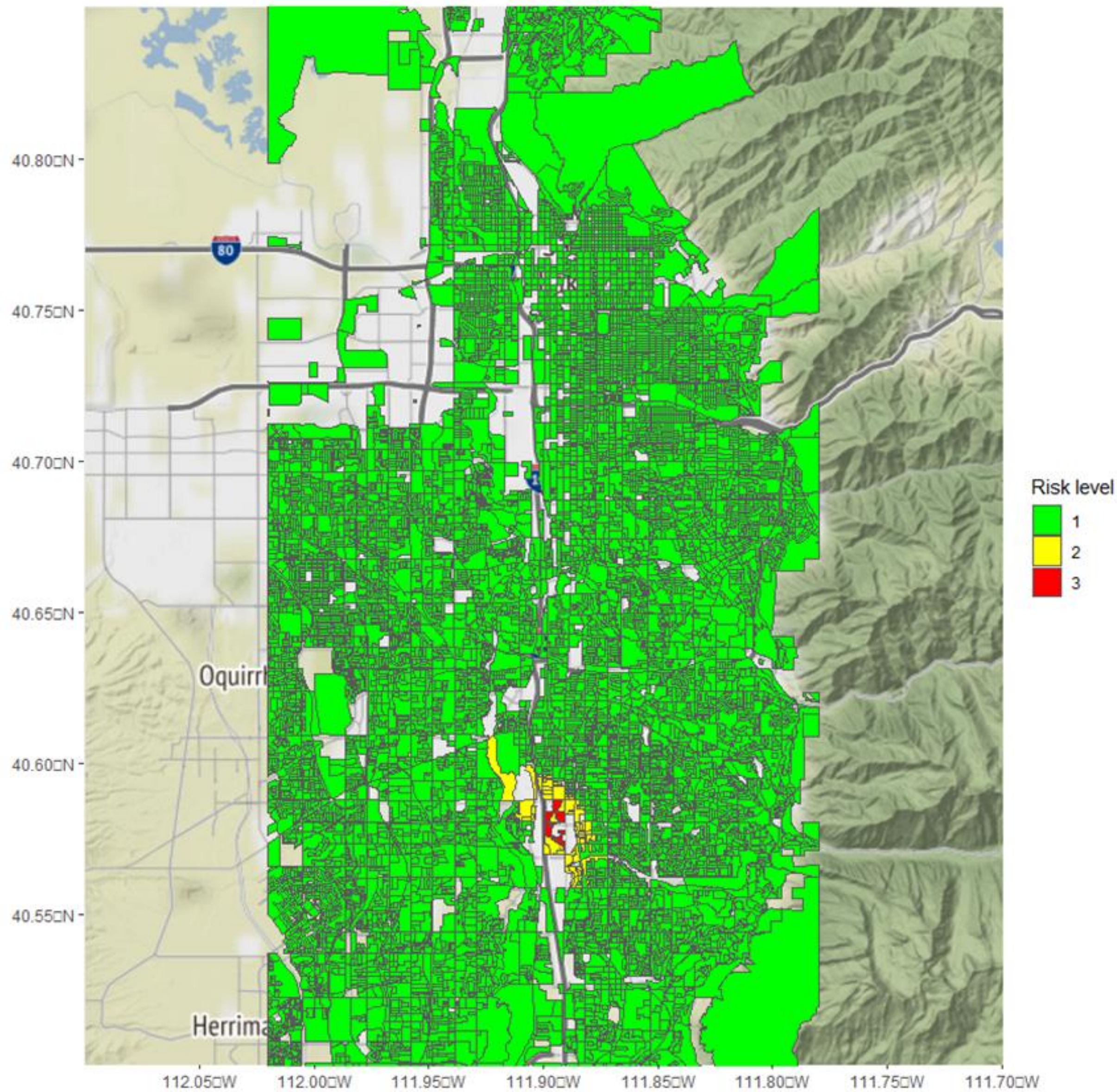

Figure 15a. Choropleth map of lifetime residential cancer risk levels from EtO among the 2020 census blocks near BD Medical using 2019 meteorological data. Red [3] indicates a receptor with a modeled total cancer risk greater than 100 in a million, yellow [2] indicates a risk level between 20 and 100 in a million, and green [1] indicates a risk of less than 20 in 1 million.

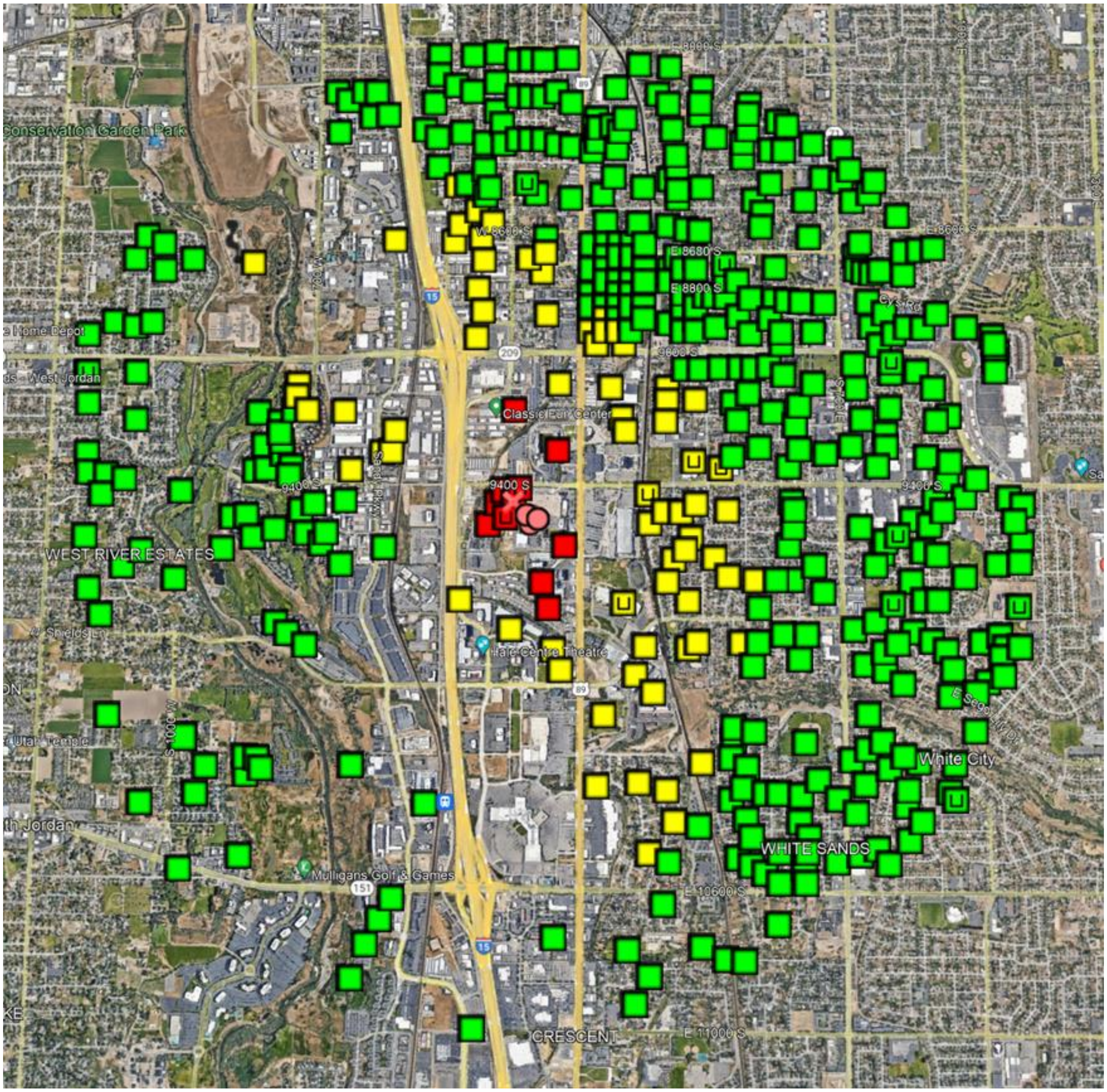

Figure 15b. Choropleth map of lifetime residential cancer risk levels from EtO among the 2020 census blocks near BD Medical using 2019 meteorological data, zoomed to show areas of concern with more detail. Red [3] indicates a receptor with a modeled total cancer risk greater than 100 in a million, yellow [2] indicates a risk level between 20 and 100 in a million, and green [1] indicates a risk of less than 20 in 1 million.

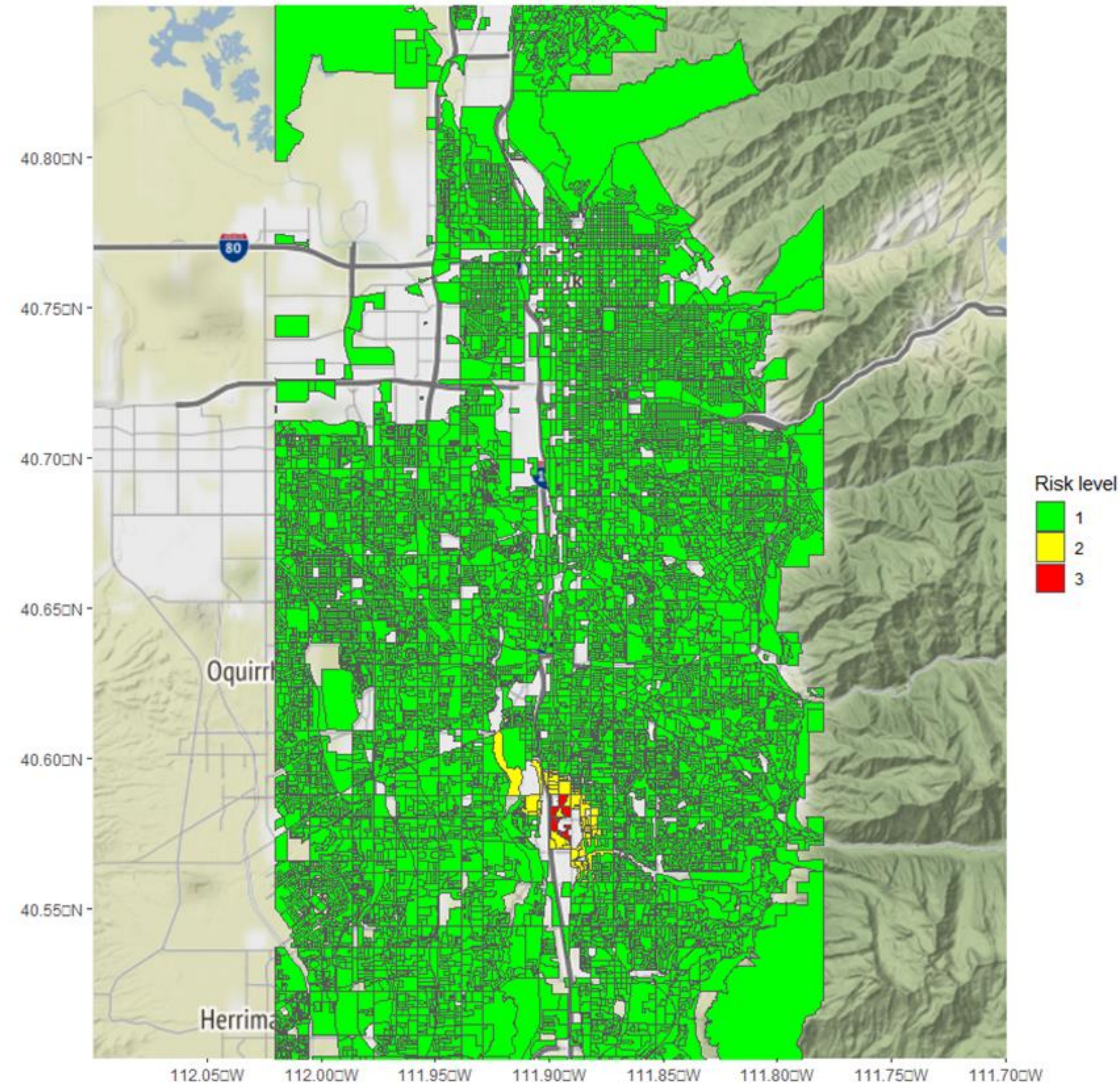

Figure 16a. Choropleth map of lifetime residential cancer risk levels from EtO among the 2020 census blocks near BD Medical using 2018-2022 meteorological data. Red [3] indicates a receptor with a modeled total cancer risk greater than 100 in a million, yellow [2] indicates a risk level between 20 and 100 in a million, and green [1] indicates a risk of less than 20 in 1 million.

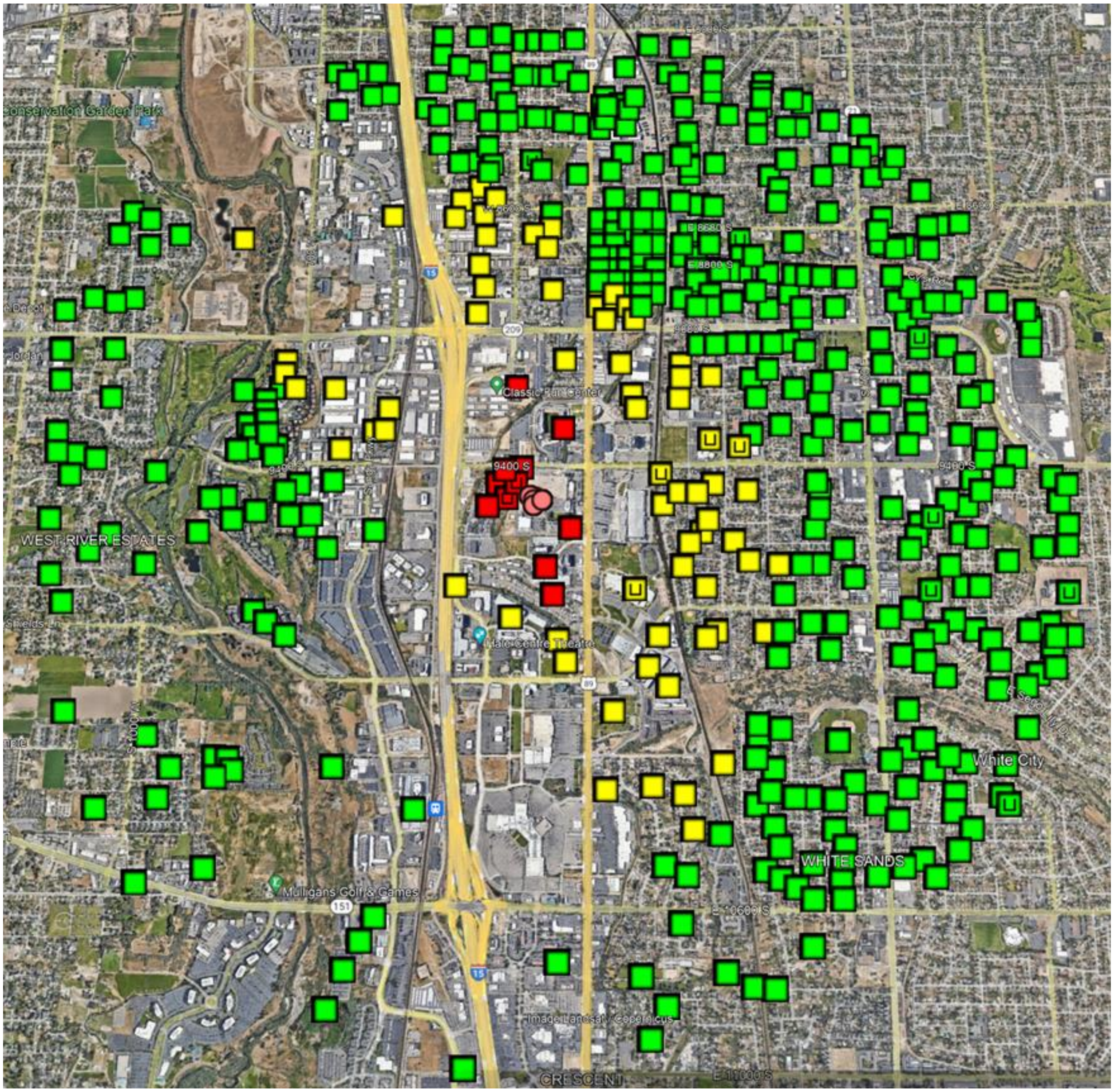

Figure 16b. Choropleth map of lifetime residential cancer risk levels from EtO among the 2020 census blocks near BD Medical using 2018-2022 meteorological data, zoomed to show areas of concern with more detail. Red [3] indicates a receptor with a modeled total cancer risk greater than 100 in a million, yellow [2] indicates a risk level between 20 and 100 in a million, and green [1] indicates a risk of less than 20 in 1 million.

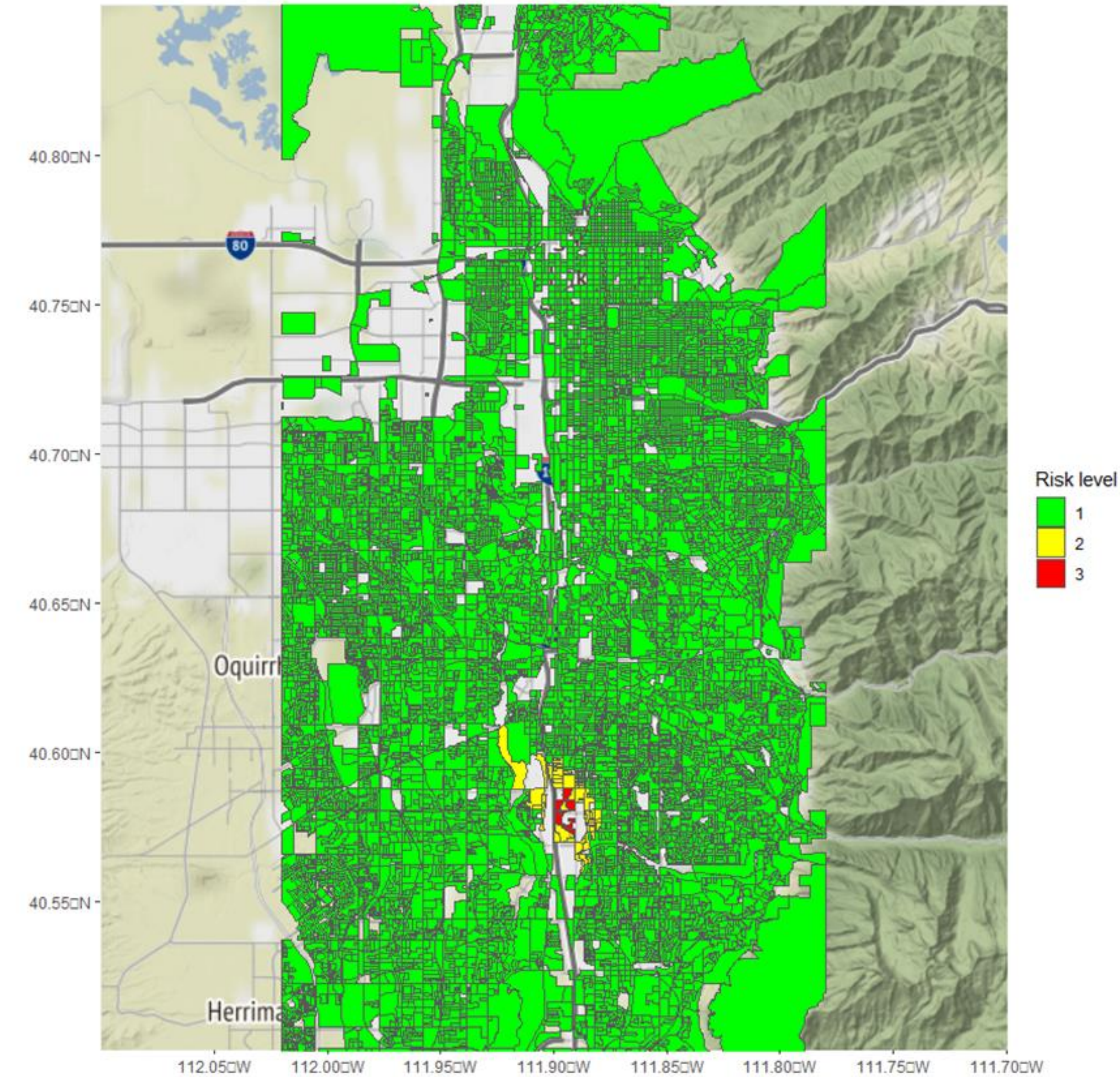

Figure 17a. Choropleth map of lifetime residential cancer risk levels from EtO among the 2020 census blocks near BD Medical using 2016 meteorological data. Red [3] indicates a receptor with a modeled total cancer risk greater than 100 in a million, yellow [2] indicates a risk level between 20 and 100 in a million, and green [1] indicates a risk of less than 20 in 1 million.

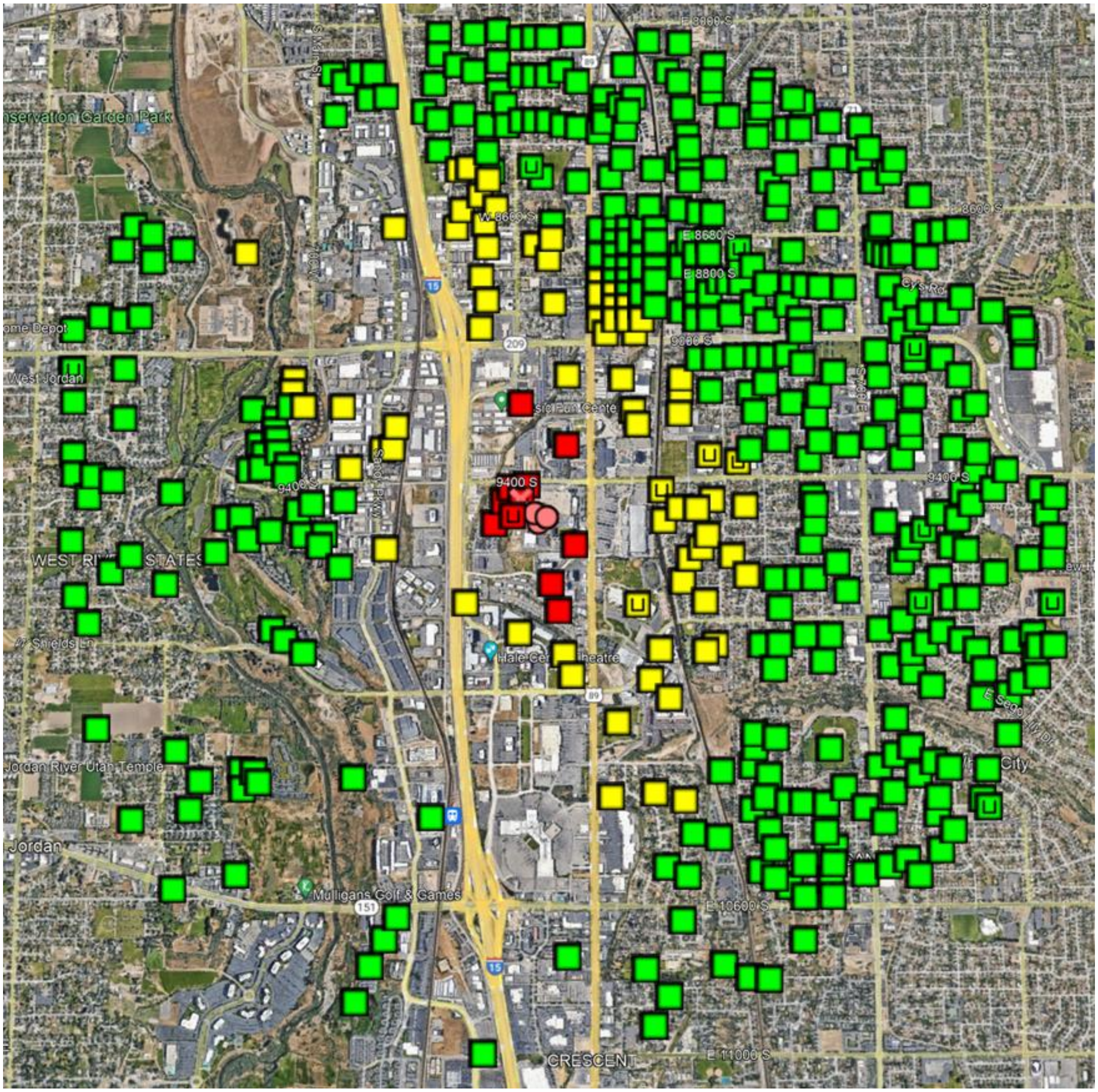

Figure 17b. Choropleth map of lifetime residential cancer risk levels from EtO among the 2020 census blocks near BD Medical using 2016 meteorological data, zoomed to show areas of concern with more detail. Red [3] indicates a receptor with a modeled total cancer risk greater than 100 in a million, yellow [2] indicates a risk level between 20 and 100 in a million, and green [1] indicates a risk of less than 20 in 1 million.

The following tables and figures provide statistical comparisons between the three meteorological time periods evaluated: 2016, 2019, and 2018-2022. Table 9 gives the top 20 MIR (per million) values for each timeframe while Figure 18 provides a boxplot of the full distribution. Note that the "U" locations in Table 9 are not census blocks but EPA-defined areas of interest and are generally in close proximity to the facility. It should also be noted in Figure 18 that the values are skewed so far toward low MIR that IQR is not visible. In essence, high MIR blocks are the outliers.

Table 9. Top 20 Maximum Individual Risk (MIR, per million) values for the residential risk modeling scenario of lifetime cancer risk from EtO near BD Medical using 2016, 2019 and 2018-2022 meteorological data. Values are shown by interest area and census block.

GEOID20	2016	2019	2018-2022
49035U000002820	2,147.3	2,287.4	2,254.4
49035U000002823	1,382.2	1,336.7	1,325.6
490351126213011	902.3	989.6	972.2
490351126213012	476.2	498.1	497.3
49035U000002821	406.6	387.8	400.3
490351126213015	406.6	414.3	431.5
490351126213017	294.4	340.5	311.9
490351126213018	166.0	198.4	181.8
490351126213010	142.2	122.8	131.6
490351126213006	136.0	114.9	124.5
490351126213001	130.8	126.9	123.5
490351126213009	79.1	95.5	86.8
49035S014200307	76.4	81.1	84.3
490351126213007	66.1	66.1	63.6
490351126213025	63.3	77.1	70.2
490351126211019	62.3	72.5	73.4
490351124024003	61.5	58.0	57.9
490351126213000	54.8	47.4	51.1
490351126203003	54.5	61.6	63.3
49035U000002822	49.2	51.3	55.7

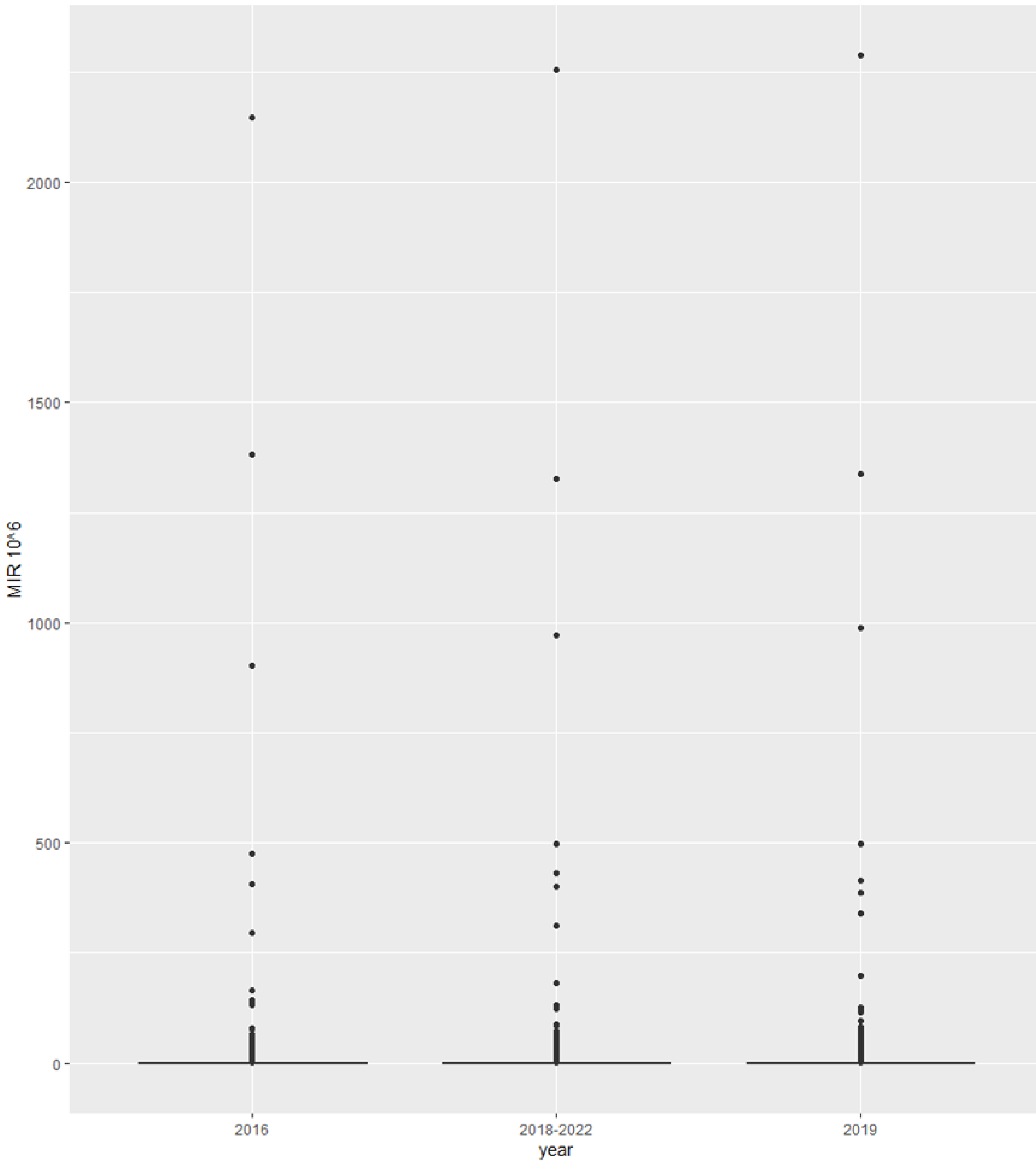

Figure 18. Boxplot of full distribution of Maximum Individual Risk (MIR per million population) values for the residential risk modeling scenario of lifetime cancer risk from EtO near BD Medical using 2016, 2019 and 2018-2022 meteorological data.

A density plot of the top 20 MIR values is shown in Figure 19. The distribution of MIR across census blocks is highly consistent, irrespective of the meteorological timeframe. ANOVA tests were run on both the full distribution and on the top risk levels. No statistically significant difference was found between the means across the entire valley over these three meteorological timeframes. In addition, among census blocks with risk > 20 in-a-million, there is no statistically significant difference across meteorological years.

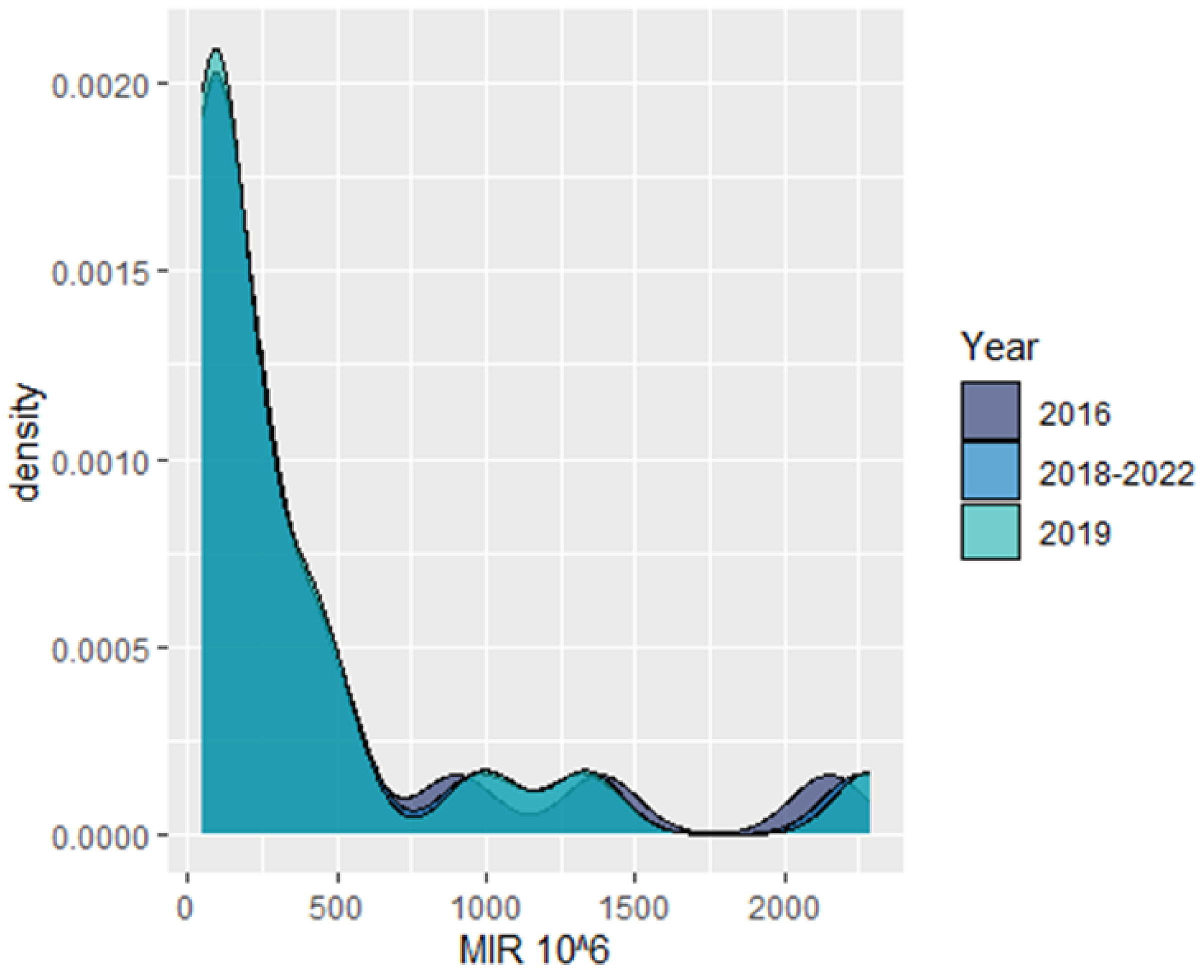

Figure 19. Density plot of the top 20 Maximum Individual Risk (MIR per million population) values for the residential risk modeling scenario of lifetime cancer risk from EtO near BD Medical using 2016, 2019 and 2018-2022 meteorological data.

7.2.1.3 Illustrative Post-Controls Scenario

A post-controls scenario illustrating a reduction in emissions from BD Medical following the installation of dry beds to control fugitive emissions by 95% was conducted. Other inputs and settings were maintained the same as those used for the pre-controls scenario, including the use of 2018-2022 meteorological data. Table 10 provides a comparison of the pre- and post-control emission values in tons/year. A comparison between pre- and post-controls modeling results showed a significant drop in the top-20 modeled MIR values, with the topmost MIR value dropping by about 91% (Table 11 and Figure 20). This also reflected in Figures 21a-b which show the change in risk choropleth with the proposed remediated emissions. These can be compared to the two risk choropleths provided in the previous section for the unremediated 2018-2022 timeframe (Figures 11a-b). However, even after the proposed controls are put into place, two MRI values, from close proximity to the BD Medical facility, are still modeled greater than 100-in-a-million. This modeling scenario, however, does not account for a reduction in emissions due to

EtO cycle optimization, which the facility is in the process of implementing. The projected risk could then be lower than predicted.

Table 10. Pre- and Post Controls Emissions Values (tons/year)

Facility	Source	Pre-controls	Post-controls
BD	CEAR0001	0.000323664	0.0003236640
BD	CEHC0002	0.010000000	0.0005000000
BD	CEPO0004	0.280000000	0.0140000000
BD	CEPR0005	0.036923077	0.0018461538
BD	CESC0003	0.015631704	0.0156317040
BD	CEVP0006	0.003076923	0.0001538462

(Light green = sources targeted for remediation)

Table 11. Change in top-20 modeled Maximum Individual Risk (MIR) values (per million population) for the pre- and post-control residential risk modeling scenarios of lifetime cancer risk from EtO near BD Medical using 2018-2022 meteorological data.

GEOID20	Pre-controls	Post-controls
49035U000002820	2,254.4	204.0
49035U000002823	1,325.6	110.5
490351126213011	972.2	77.8
490351126213012	497.3	36.7
490351126213015	431.5	31.1

49035U000002821	400.3	28.5
490351126213017	311.9	21.6
490351126213018	181.8	12.7
490351126213010	131.6	8.8
490351126213006	124.5	8.7
490351126213001	123.5	9.3
490351126213009	86.8	6.4
49035S014200307	84.3	6.2
490351126211019	73.4	5.9
490351126213025	70.2	5.2
490351126213007	63.6	4.5
490351126203003	63.3	4.6
490351124024003	57.9	4.8
49035U000002822	55.7	4.0
490351126213000	51.1	3.8

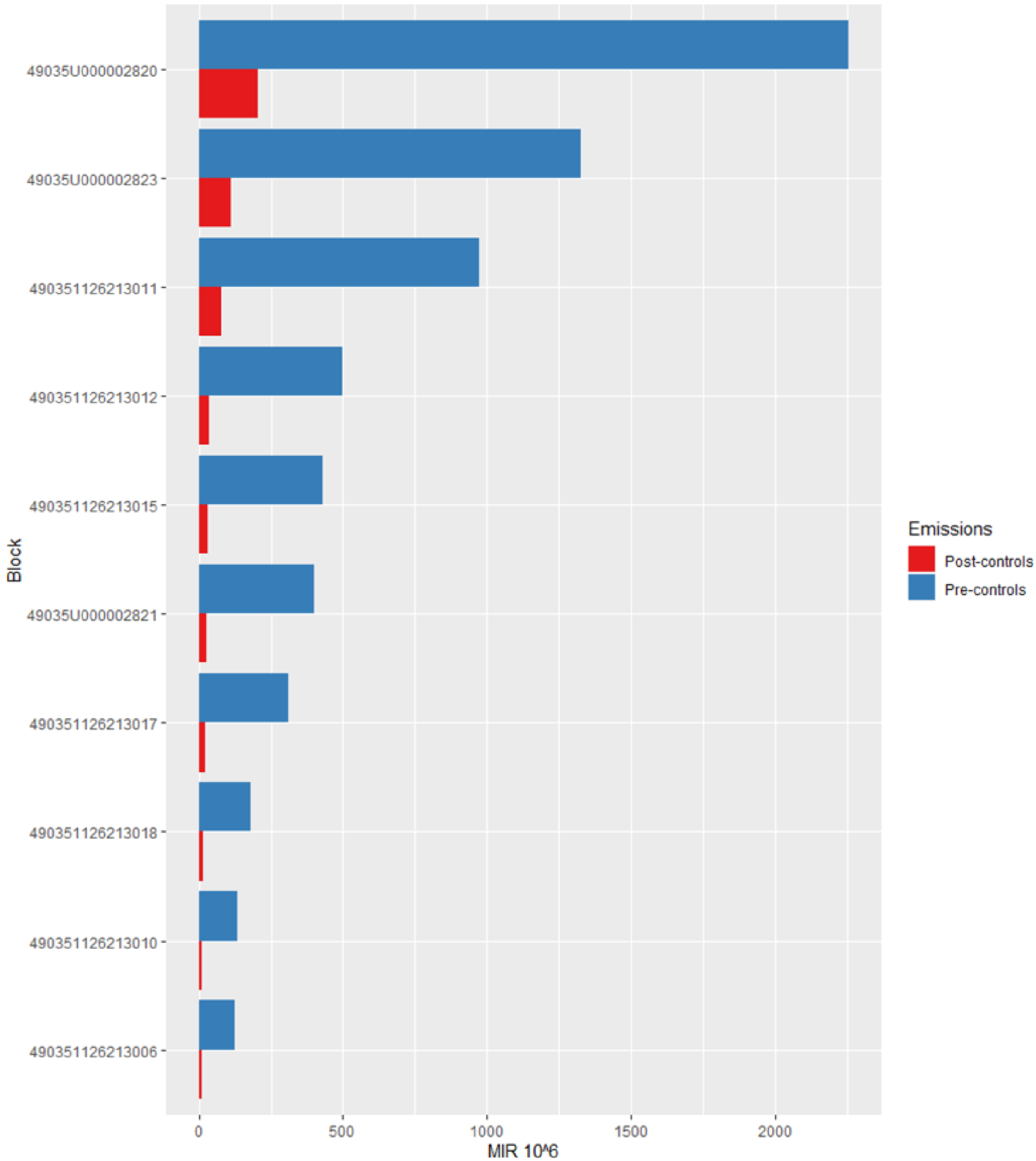

Figure 20. Comparison of the Top-10 modeled Maximum Individual Risk (MIR) values (per million) for the pre- and post-control residential risk modeling scenarios of lifetime cancer risk from EtO near BD Medical using 2018-2022 meteorological data.

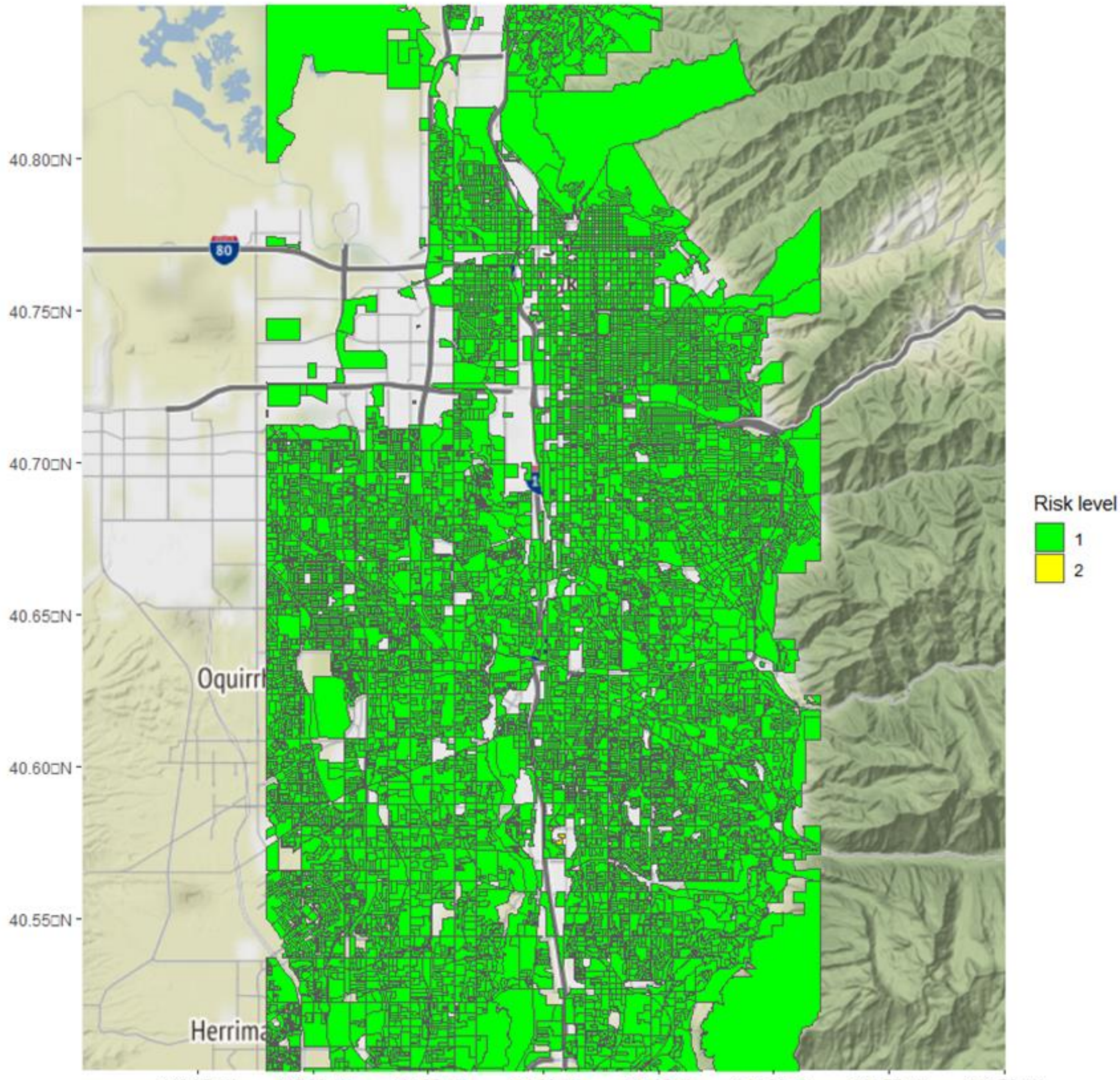

Figure 21a. Choropleth map of residential lifetime cancer risk levels from EtO among the 2020 census blocks near BD Medical using 2018-2022 meteorological data and following the installation of fugitive emission controls. Red [3] indicates a receptor with a modeled total cancer risk greater than 100 in a million, yellow [2] indicates a risk level between 20 and 100 in a million, and green [1] indicates a risk of less than 20 in 1 million.

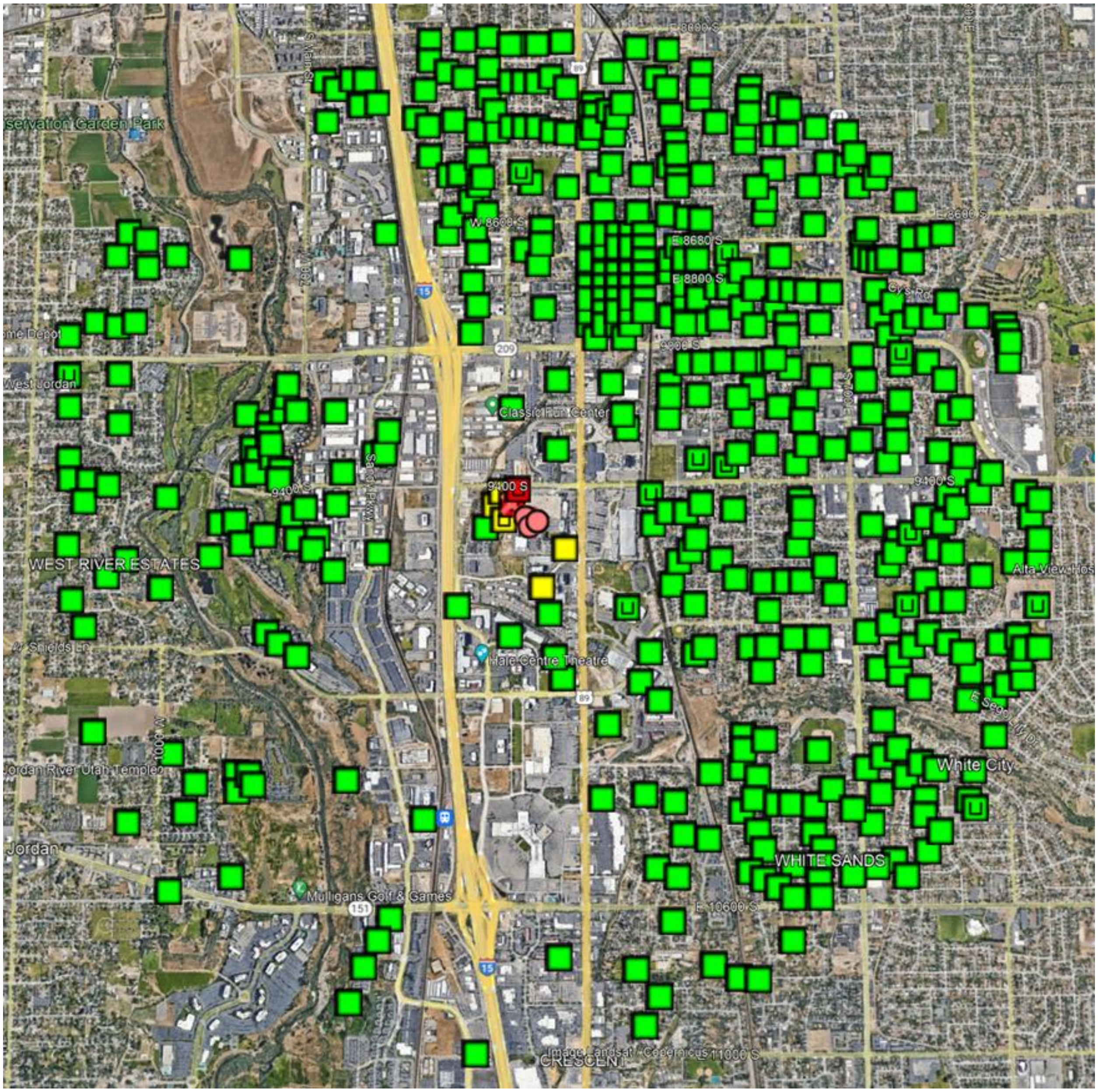

Figure 21b. Choropleth map of residential lifetime cancer risk levels from EtO among the 2020 census blocks near BD Medical using 2018-2022 meteorological data and following the installation of fugitive emission controls. Map is zoomed in to show areas of concern with more detail. Red [3] indicates a receptor with a modeled total cancer risk greater than 100 in a million, yellow [2] indicates a risk level between 20 and 100 in a million, and green [1] indicates a risk of less than 20 in 1 million.

7.2.2 Sterigenics Non-Residential Risk Scenario

A non-residential modeling scenario illustrating cancer risk due to exposure to EtO emissions from Sterigenics, which is located in a mostly commercial area, was conducted. To illustrate exposures at nearby businesses and a fire station where people spend a significant amount of time, but less than a lifetime, HEM4.2's default polar grid receptor network, which includes 13 concentric rings surrounding the facility, was used. Per the HEM 4.2 User Guide: "HEM4 selects the distance that places the first modeling ring just beyond all emission sources, but not less than 100 meters from the facility center. HEM4 will place the concentric rings at a logarithmic progression of distances starting at the inner ring distance and ending at the outer radius of the modeling domain." Figure 22 shows the estimated cancer risk contours for this non-residential scenario with focus on the first six rings, and Table 12 shows the top 20 MIR values as a function of distance and direction (angle from north) from the facility center. These estimates are based on an adjusted URE of 0.000261 per µg/m^3 (section 7.1) and an offsite worker who is exposed 8.5 hours per day, 250 days per year, for 25 years. As can be seen, the maximum cancer risk is > 100-in-a-million within a distance of 100-180 m and a direction of 320-350 degrees (from north) from the facility center.

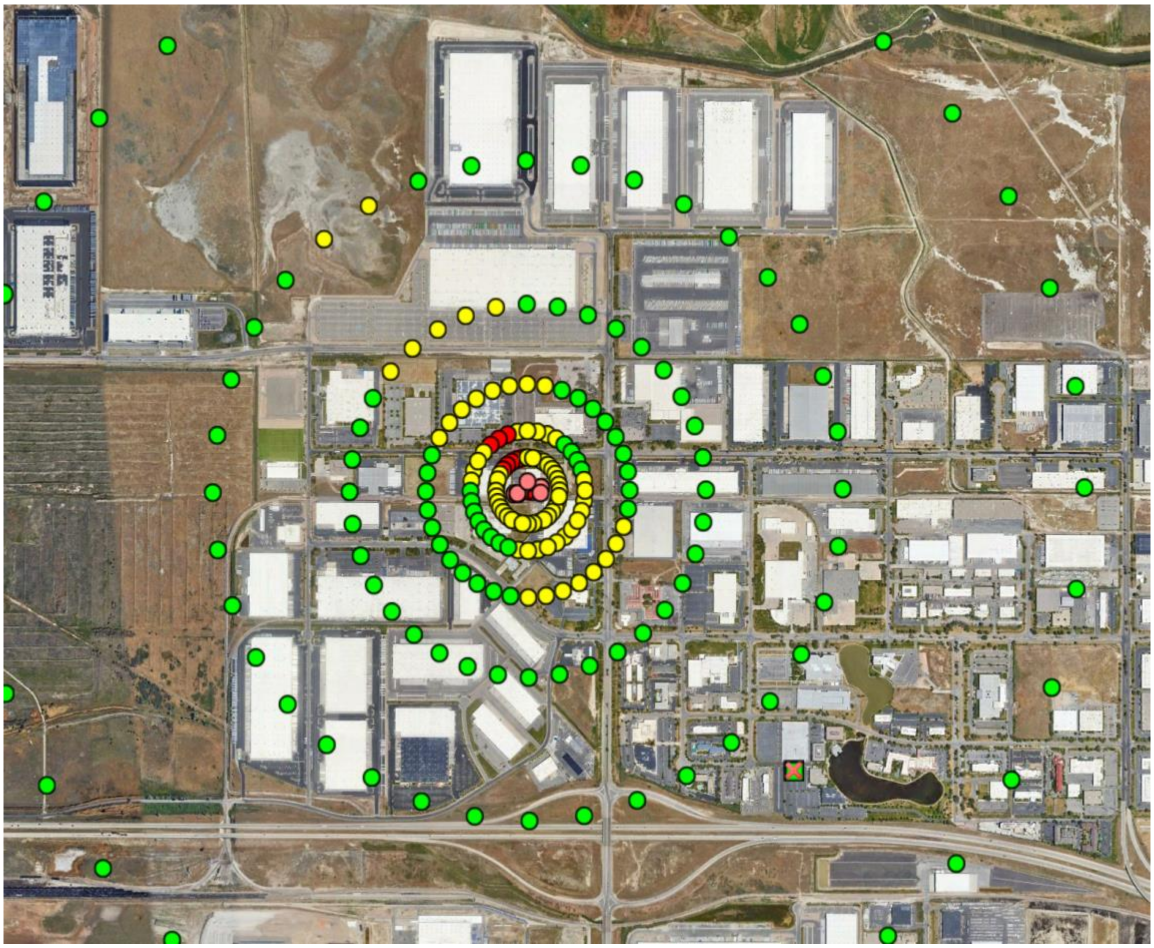

Figure 22. Modeled non-residential cancer risk levels from EtO from Sterigenics using 2018-2022 meteorological data. First 6 polar rings are shown. Red [3] indicates a receptor with a modeled total cancer risk greater than 100 in a million, yellow [2] indicates a risk level between 20 and 100 in a million, and green [1] indicates a risk of less than 20 in 1 million.

Table 12. Top-20 modeled Maximum Individual Risk (MIR) values (per million population) for the non-residential risk modeling scenarios of cancer risk from EtO near Sterigenics using 2018-2022 meteorological data.

MIR per million	Distance (m)	Angle (from north)
157.24692	100	330
153.31388	100	340
139.56282	100	320
135.09277	180	330
132.30789	100	350
127.25572	180	320
119.40670	180	340
111.04714	100	310
97.27787	100	0
96.53054	180	350
95.76653	180	310
87.59916	100	150
86.04954	100	140
83.15384	100	300
82.79103	100	160
82.59080	320	320
81.72948	320	330
78.60768	100	130
72.02383	100	170
69.89410	180	0

7.2.3 Comparison Between Modeling Estimates and Measurements

A comparison between 2022 canister-based EtO measurements and modeled EtO concentrations was also performed. The comparison was limited to the 8 sampling locations near BD Medical (B1-B8) and background sites (BG1-BG5 during winter and BG1-BG4 during summer) (Figure 23), where the exact geographical coordinates of the canisters were input into AERMOD, which was used for this analysis. Meteorological data corresponding to sampling days during winter 2022 (January-March) and summer 2022 (July-September) was also considered in the analysis. Since the canister-based concentration measurements of EtO were expressed in parts per billion volume (ppbv), measurements were converted into $\mu g/m^3$ to match the modeled estimates. The modeled EtO concentrations were also adjusted to account for background values associated with the winter or summer data. Measurements at the background sites were used to compute a summer and winter background concentration using a mean-of-the-medians method. The median EtO concentration was determined for each background site and for both seasons (summer and winter). Then, the five winter and four summer background site medians were averaged together to establish a single EtO background concentration value for winter and summer, respectively. The corresponding seasonal background value in μg/m^3 was added to AERMOD's estimated concentrations. Rather than using a mean-of-the-means method, this procedure removed the significant bias that a few measurement outliers would have on the data/analysis and, in essence, established values closer to the central tendency of the true background value. The mean-of-the-median value for the winter sampling event was 0.0779 μg/m^3 while the value for the summer sampling event was 0.1962 μg/m^3 , which is about 2.5 times higher than the winter background value.

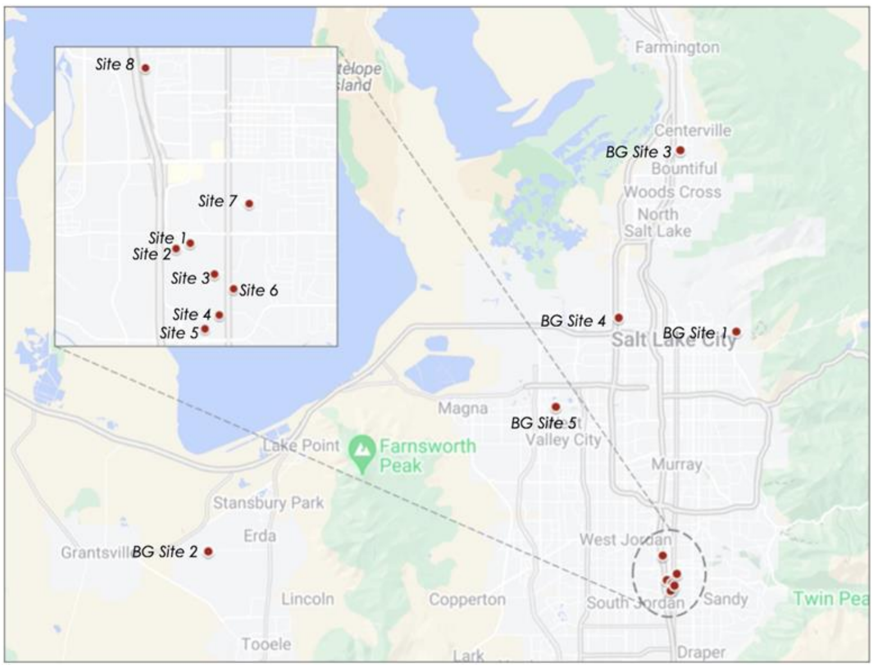

Figure 23. Location of canister-based measurements.

Figure 24 provides the concentration results for both the near-facility (i.e., BD Medical) and background canister samples. Following the data correction, a Wilcoxon signed-ranked test for paired, non-parametric data was used to compare the modeled EtO estimates to the canister-based EtO measurements for each of the eight sites near BD Medical (Table 13). The statistical analysis resulted in six of the eight sample locations surrounding the sterilization facility being significantly different when comparing canister-based measurements of ambient EtO to modeled estimates. Canister-based measurements taken at sites 1, 3, and 4 were statistically greater than the modeled estimates, while sites 2, 5, and 7 were statistically less than the modeled estimates. Sites 6 and 8 showed no statistical difference. In other words, the five of the closest sites and site 7 were statistically different when comparing measured and modeled ambient concentrations of EtO. These results do not suggest whether one method is more or less conservative than the other, and are likely impacted by the limitations of both methods (Section 11). The comparison results also do not clearly indicate if a correction factor could be derived for future human exposure to cancer risk assessment modeling. However, while absolute values in modeled and measured concentrations around BD Medical were not always comparable, locations with highest EtO concentrations were consistent between modeled and measured results, confirming added cancer risk from EtO emissions from the facility. Results of this analysis were published in a peer-reviewed article[5].

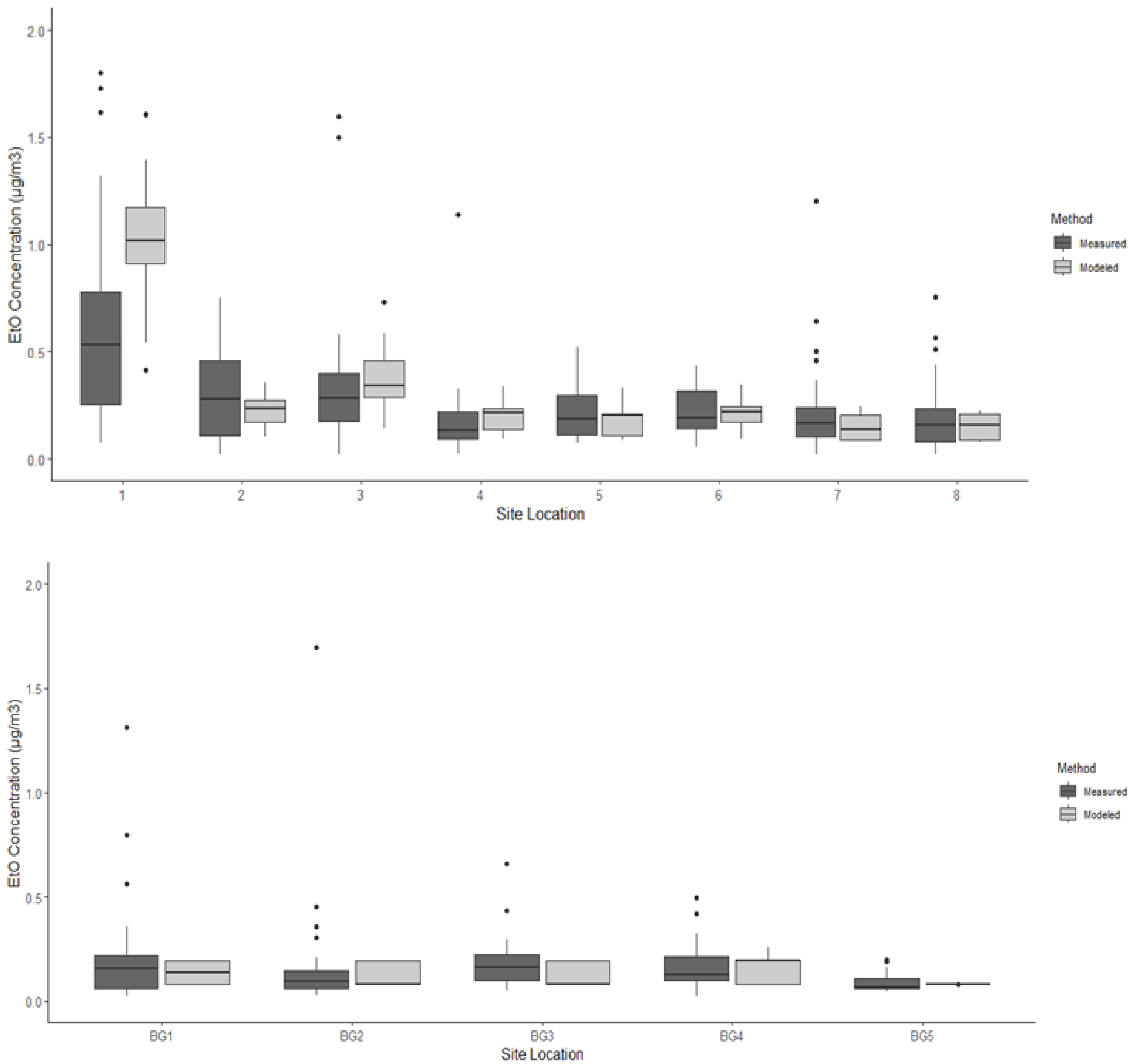

Figure 24. EtO concentrations measured with passive, whole-air canisters (dark grey) and estimated from air dispersion modeling (light gray) at eight locations near emissions source (top diagram) and from the five background locations (bottom diagram).

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[5]Spooner K., Handy R., Daher N., Edie R., Henry T., Sleeth D. A Comparison of Ambient Air Ethylene Oxide Modeling Estimates from Facility Stack and Fugitive Emissions to Canister-Based Ambient Air Measurements in Salt Lake City. Air (2023), 1(3), 175-183; https://doi.org/10.3390/air1030013.

Table 13. Wilcoxon signed-ranked test results from comparing median concentrations of EtO estimated with AERMOD modeled to canister-based measurements. Significant p-values are indicted with a *.

		Modeled Estimates	Canister Measurements	Wilcoxon *p*-Values	
Site	*n*	Median (μg/m^3)	Median (μg/m^3)	AERMOD < Canister-Based	AERMOD > Canister-Based
1	29	1.0195	0.5296	0.99	<0.001 *
2	38	0.2343	0.2765	0.03 *	0.97
3	32	0.3420	0.2812	0.99	0.01 *
4	35	0.2131	0.1295	0.99	<0.01 *
5	37	0.2023	0.1855	0.01 *	0.99
6	36	0.2211	0.1919	0.22	0.78
7	37	0.1348	0.1665	0.05 *	0.95
8	34	0.1540	0.1536	0.24	0.77

8. Environmental Justice Analysis

The following table provides output from HEM 4.2's "Demographic Assessment" module – also known as the "environmental justice" tables. These represent modeled population risks by various demographic strata around the BD Medical facility based upon the BD Medical 5-year meteorological pre-controls modeling scenario. The report shows that the lifetime individual cancer risk for the Native American group is 3.5-7 times greater compared to the total population and other ethnic groups. However, it should be noted that the implementation of post controls brings down the risk for all groups by approximately an order of magnitude.

Table 14. Distribution of Cancer Risk for Racial and Ethnic Groups - 3 km Study Area Radius.

Range of Lifetime Individual Cancer Risk from Facility BD-UT (Chance in One Million) [a]	Number of People within 3 km of the Facility in Different Ranges for Lifetime Cancer Risk [b]					
	Total Population	White	African American	Native American	Other and Multiracial	Hispanic or Latino[c]
0 to < 1	0	0	0	0	0	0
1 to < 5	3,323	2,877	8	17	301	121
5 to < 10	16,770	13,600	227	58	1,018	1,868
10 to < 20	8,517	5,811	87	58	719	1,841
20 to < 30	7,472	4,969	102	34	495	1,872
30 to < 40	2,383	1,526	4	9	157	687
40 to < 50	2,714	1,763	2	66	105	779
50 to < 100	1,961	1,350	0	122	82	406

100 to < 200	705	503	0	67	33	102
200 to < 300	160	114	0	15	7	23
>= 300	225	161	0	21	11	32
Total Number	44,230	32,674	430	467	2,927	7,732
Average Risk (Chance in One Million)[a]	20	20	10	70	20	20

[a] Modeled risks are for a 70-year lifetime, based on the predicted outdoor concentration and not adjusted for exposure factors. Risks from BD emissions are modeled at the census block level.
[b] Distributions by race are based on demographic information at the census block group level.
[c] In order to avoid double counting, the "Hispanic or Latino" category is treated as a distinct demographic category for these analyses. A person is identified as one of five racial/ethnic categories above: White, African American, Native American, Other and Multiracial, or Hispanic/Latino.

9. Community Outreach

The project included a community outreach component which consisted of conducting two public community meetings with Sandy City residents living in the vicinity of BD Medical. Community outreach was limited to residents impacted by EtO emissions from BD Medical and included representatives from EPA Region 8, Sandy City, Salt Lake County, and the Department of Health and Human Services. Information on how ethylene oxide impacts the health of local residents and actions that are taken to reduce that risk was shared through these meetings. Project updates were also presented to the State's Air Quality Board and shared through UDAQ's social media platform and press releases. A project webpage was also created to provide an overview on the study objectives, technical approach and main findings (https://deq.utah.gov/air-quality/ethylene-oxide-study). Informational flyers and social media postings linked to this website, either directly or through a QR code. The website went live in January of 2022, and has had 1,200 unique visitors and 1,900 discrete viewing sessions as of November 2023 (Figure 25). Notable traffic increases coincided with community meetings, and indicate public interest in the topic and use of the existing informational materials. Distinguishing between website hits from the QR code versus browser visits was not possible.

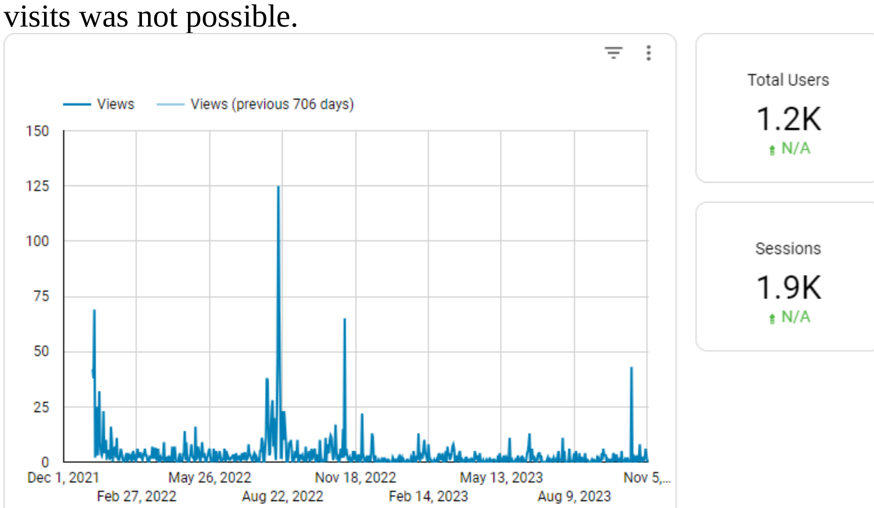

Figure 25. Number of project webpage site visits.

10. Deviations and Accomplishments

Deviations from the project plan were minimal, with no significant impact on planned project outcomes and outputs. Deviations included comparing measured EtO concentrations to modeled

EtO concentration values from HEM, rather than NATA modeling estimates. Given that HEM was used for the risk assessment component of the project, a comparison to HEM modeled values was considered more appropriate. Moreover, as aforementioned (section 2.2), due to timers malfunctioning at below freezing temperatures during the winter sampling period, the start and stop times for sample collection were switched from midnight to 3 pm, when temperatures during the day are typically highest.

Planned project outcomes and outputs were successfully accomplished. As proposed, seasonally- and spatially-resolved EtO concentration data was collected. Spatial gradients in EtO levels near Sterigenics and BD Medical were also determined through both canister sampling and modeling. Cancer risk estimates due to long-term inhalation exposure to EtO emissions from the two facilities were determined too. A comparison between modeled and measured values was also conducted. Through seasonal sampling at multiple sites with distinct characteristics, results provide additional insight on EtO background levels. Outputs also include presenting findings at three conferences (2023 Science for Solutions Conference, Utah; 2023 EPA National Air Toxics Conference, Chicago; 2023 American Industrial Hygiene Conference and Expo, Arizona) and publishing a peer-reviewed journal article[6]. Additional manuscripts are also currently being prepared. Two community outreach meetings were successfully conducted too, increasing community awareness on the health impacts of EtO emissions. A reduction in EtO emissions, ambient levels and exposure was also achieved through the implementation of mitigation measures by the facilities. BD Medical installed a new control system to reduce fugitive emissions of ethylene oxide from their facility and are implementing cycle optimization to reduce their total ethylene oxide consumption. Sterigenics is also in the process of installing EtO controls.

11. Limitations

11.1 Sampling Uncertainties

Ambient monitoring was associated with several limitations, including sensitivity of the chemical analysis method used to analyze the canister samples. It is possible that the ambient measurements are biased high for measurements that are close to the method detection limit (MDL) or below the detection limit. Other limitations include the limited sampling frequency, duration and sample size. Since time-integrated ambient measurements were restricted to 24-hr measurements, 1-in-3 day sampling frequency and 8 weeks per sampling phase, they may not be representative of long-term EtO concentrations and EtO lifetime inhalation cancer risk. There are also limitations related to the canisters ("Canister Effect"), where EtO can form and grow in canisters, depending on the individual canister characteristics, age and usage history. While measurements were corrected, absolute concentrations for measurements that approach the MDL could still be biased high. However, despite these challenges, the spatial variability in measured EtO concentrations was consistent with the spatial variability in modeled EtO concentrations. Locations with greatest and lowest EtO levels were consistent between measured and modeled values.

11.2 Risk Assessment Modeling Uncertainties

The risk assessment modeling was associated with several uncertainties. Main uncertainties included:

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[6] Spooner K., Handy R., Daher N., Edie R., Henry T., Sleeth D. A Comparison of Ambient Air Ethylene Oxide Modeling Estimates from Facility Stack and Fugitive Emissions to Canister-Based Ambient Air Measurements in Salt Lake City. Air (2023), 1(3), 175-183; https://doi.org/10.3390/air1030013.

- Assuming facility emissions remain constant over all hours of the day and the exposure period (70 years for residential scenario and 25 years for non-residential scenario).
- Not considering long-term and short-term population mobility and its impact on exposure.
- Assuming people spend all their time outdoors and are constantly exposed to EtO (24 hours/day, over 70 years for residential scenario).
- Using meteorological data from a single site (KSLC, Salt Lake International Airport) to represent atmospheric conditions in each modeling domain.
- Assuming that the topological complexity of the Salt Lake Valley is fully captured by the model.
- Estimating the chronic exposures at the centroid of each populated census block and using that as a surrogate for the exposure concentrations for all people living in that block.

12. Conclusions and Future Directions

To characterize the health risk associated with exposure to EtO from two medical sterilization facilities in Utah, BD Medical and Sterigenics, a mixed air monitoring and health risk assessment study was conducted. 24-hr canister measurements were collected at 16 sampling locations, including proximate locations to the facilities and background sites, over 8 weeks in each of summer and winter 2022. A health risk assessment using the Human Exposure Model (HEM) was also conducted. The risk assessment examined multiple scenarios: (1) a baseline scenario reflecting emissions from BD Medical prior to the installation of controls for fugitive emissions, (2) a scenario illustrating emissions from BD Medical following the installation of fugitive emissions controls, (3) sensitivity scenarios considering different meteorological years, (4) a non-residential risk scenario to illustrate cancer risk due to exposure to EtO emissions from Sterigenics. A comparison between modeled and measured EtO levels was also performed. Measurements showed greater concentrations at near-facility sites compared to background locations, indicating increased lifetime cancer risk due to continuous exposure to EtO emissions from BD Medical. Summertime EtO concentrations also exceeded wintertime concentrations by 2-3 times at all sites, suggesting increased background EtO levels in the summer. Additionally, pre-controls modeling results showed elevated lifetime cancer risk, in excess of 100-in-a-million, from inhaling EtO emitted from BD Medical in census blocks located close to the facility (an estimated 1090 population), with risk decreasing with distance from the facility. Post-controls modeling results for BD Medical showed a substantial decrease in cancer risk after the installation of controls for fugitive emissions, but the risk remained above 100-in-a-million. This modeling scenario, however, does not account for a reduction in emissions due to EtO cycle optimization, which the facility is in the process of implementing. The projected risk could then be lower than predicted. Modeling results from the non-residential risk exposure scenario for Sterigenics also show elevated cancer risk at polar receptors in the vicinity of the facility (MIR > 100-in-a-million) where a fire station and several businesses with on-site workers are located, highlighting the need to investigate workplace exposure. Modeling risk results using different meteorological years were not statistically significantly different, indicating that the results are not sensitive to the choice of meteorological year. While absolute values in modeled and measured concentrations around BD Medical were not always comparable, locations with highest EtO concentrations were consistent between modeled and measured results, confirming added cancer risk from EtO emissions from the facility. Through competitive funding from the EPA, UDAQ is currently planning a follow-up study to determine actual ambient levels of EtO near BD Medical following the installation of fugitive emissions controls and the implementation of EtO cycle optimization, which combined are expected to reduce total EtO emissions by 90%. Mobile measurements using a continuous EtO analyzer, AROMA-EtO, by Entanglement Inc., will be conducted around the facility and nearby neighborhoods.

Appendix

Table A1. Count of canisters with and without canisters flagged with "LK" at each sampling site and during each of the winter and summer sampling campaigns.

Winter				**Summer**			
Site	# samples total	Number of LK flags	# samples excluding LK flags	Site	# samples total	Number of LK flags	# samples excluding LK flags
BD-1	9	3	6	BD-1	20	7	13
BD-2	18	4	14	BD-2	20	8	12
BD-3	12	4	8	BD-3	20	7	13
BD-4	17	3	14	BD-4	18	2	16
BD-5	18	5	13	BD-5	19	5	14
BD-6	16	7	9	BD-6	20	7	13
BD-7	19	7	12	BD-7	18	4	14
BD-8	17	4	13	BD-8	17	3	14
BG-1	19	3	16	BG-1	19	4	15
BG-2	18	1	17	BG-2	14	2	12
BG-3	19	7	12	BG-3	15	3	12
BG-4	16	2	14	BG-4	19	4	15
BG-5	15	2	13	SG-1	19	6	13
SG-1	18	9	9	SG-2	20	8	12
SG-2	19	11	8	SG-3	18	6	12
SG-3	17	4	13	SG-4	17	7	10
Total	**267**	**76**	**191**	**Total**	**293**	**83**	**210**