MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY

INTEROFFICE COMMUNICATION

TO: File

FROM: Amy Robinson

DATE: April 29, 2019

SUBJECT: Ethylene Oxide Sampling at Viant Medical, Inc.

Overview

The Viant facility in Grand Rapids, Michigan was identified by the United States Environmental Protection Agency (USEPA) NATA analysis as having elevated ethylene oxide ambient air impacts. Subsequent modeling by the Air Quality Division (AQD) showed that the impacts were above the Initial Risk Screening Level (IRSL) at 0.0002 µg/m^3 and Secondary Risk Screening Level (SRSL) at 0.002 µg/m^3. To ascertain the accuracy of the modeling, the AQD initially conducted a Phase I (limited monitoring) sampling study for ethylene oxide in the vicinity of Viant. Results of the Phase I sampling helped define the scope of the Phase II sampling detailed in this memo.

Monitoring for ethylene oxide was accomplished using the TO-15 Summa canister method. The USEPA's National Contract Laboratory, Eastern Research Group (ERG), performed the analysis. ERG's laboratory detection limit for the Phase I samples was 0.08 ug/m^3 and the detection limit for the Phase II samples was 0.111 µg/m^3. Laboratories update and revise detection limits annually and the difference between the two values is not significant. Since the SRSL is lower than the detection limit of the current method for ethylene oxide, the monitoring data will have to be carefully interpreted. For example, if a sample result is reported as non-detect, it is possible that the actual level could still be above the SRSL.

Sampling Details

Phase II sampling was designed off the results of the Phase I sampling study. The purpose of Phase I was to determine if ethylene oxide could be quantified in the ambient air around Viant. During the Phase I sampling in November 2018, five samples were collected around the Viant Facility.

Phase II sampling for ethylene oxide around the Viant facility was conducted from approximately noon on March 27, 2019, to approximately noon on March 28, 2019. During the entirety of the sampling period, Viant was operating its sterilization chamber under normal conditions. Summa canisters using fixed orifices were used to collect 24-hour samples. Three teams of two people each set up the canisters so start times could be closely coordinated. The canisters were set up at 16 locations around the Grand Rapids area on March 27, 2019; see attached map. Table 1 provides a list of sampling sites and results.

At each sampling site, canisters were set up and secured, and site photos were taken for documentation. Canisters were then opened by staff teams close to noon. On March 28, 2019, staff returned to Grand Rapids to close the valves and remove the canisters. Start times and stop times of the canisters is important to ensure that all canisters are collecting air samples while Viant is operating the same way.

Staff completed a Chain of Custody form and a Canister Sampling Field Test Data Sheet for each canister. Canisters were brought to EGLE's Filley Street warehouse in Lansing, prepared for shipping, and were sent to the laboratory on March 28, 2019, via FED EX overnight shipping. Copies of laboratory Chain of Custody forms and the Canister Sampling Field Test Data Sheets were retained.

Results

The laboratory results for all samples were received on April 11, 2019. Results are summarized in Table 2, and depicted visually in Figures 3 and 4. The highest concentration of ethylene oxide was found at Location #2, which was in a parking lot directly northeast and across the street from Viant. Location #2 was directly downwind from the sampling location with the highest ethylene oxide concentrations in Phase I sampling. All sites showed ethylene oxide values above the IRSL and SRSL, with the exception of Location #3, which had a non-detectable result. The wind direction during the sampling time was fairly steady out of the south-southwest and south with speeds of 0-10 mph. A wind rose for the time period is included as Figure 1.

ERG used the USEPA-approved method and followed all quality assurance protocols.

Discussion

The highest concentration of ethylene oxide (2.08 µg/m^3) was measured at a parking lot directly across the street from Viant, Location #2. Given the wind direction, out of the south-southwest/south at speeds of 0-10 mph on the sampling day, the discharge from the air vent at Viant was in direct line with this sample location.

Another goal of the Phase II Sampling Study was to try to determine the normal background concentration of ethylene oxide in this urban area. The Phase II sampling results appear to support a background level of around 0.18 µg/m^3 in the Grand Rapids area. This suggested background level can be seen at both Locations #10 and #11. The USEPA is currently studying levels of ethylene oxide across the country to determine background levels. Once they finalize quality assurance and quality controls on the data, they will release their findings.

Next Steps

At the time of this report, the AQD is still evaluating the need for further sampling in the community. Viant has committed to shutting down the sterilization operations by the end of the year. Operations at the facility, until the time of shutdown, are projected to remain the same or less than operations during the Phase II sampling. Additionally, the AQD would like

the opportunity to evaluate the data with more information on background levels of ethylene oxide once the USEPA releases their findings.

Table 1. Table of Sample Locations and Results

Phase II Ethylene Oxide Sampling Study 3/27/19 - 3/28/19									
24 Hour Summa Canister Collection - analyzed by ERG Lab GC/MS									*MDL*
	LAT	LONG	Canister ID	Canister ID - Collocated	EtO ug/m^3	Collocated EtO	EtO ppbv	Collocated ppbv	ug/m^3
Team Eric - Near Viant: (Collocated Canister)									
1. Sidewalk where Phase 1 Sample was collected	42.961705	*-85.682885*	5074		0.27		0.1500		*0.111*
2. Winter Lot - GVSU	42.962031	-85.681771	SAT063		2.08		1.1500		*0.111*
3. 622 Butterworth SW	42.960042	*-85.683694*	19661		**ND**		**ND**		*0.111*
4. 40 Gold Ave SW	42.962272	-85.684434	18822		0.16		0.0861		*0.111*
5. Watson Lot - GVSU	42.960934	-85.681728	5143	SAT057	0.29	0.29	0.1590	0.1580	*0.111*
6. John Ball Zoo South Entrance - Butterworth Ave	42.960709	*-85.700984*	A21042		0.13		0.0712		*0.111*
Team Dan - Downtown/Eastside and SW Upwind: (Collocated Canister)									
7. Crescent Park	42.9683736	-85.667086	5010-09		0.30		0.1660		*0.111*
8. Rosa Parks Circle	42.965754	-85.67144	SAT072	SAT024	0.12	**ND**	0.0683	**ND**	*0.111*
9. Heartside Park	42.957815	-85.670806	5053		0.37		0.2030		*0.111*
10. Upwind site: 2350 Ivanrest Ave SW, Grandville, MI (Clean Water	42.921617	-85.744043	SAT084		0.19		0.1040		*0.111*
Team Susan - GVSU Properties and North									
11. GR Monroe Street - AQD Air Monitoring Site	42.984456	-85.671184	5079		0.18		0.0978		*0.111*
12. Coit Park - Livingston Station	42.977494	-85.665868	A21056		0.21		0.1180		*0.111*
13. Devos Parking Lot - GVSU	42.965399	-85.680886	SAT180		0.35		0.1920		*0.111*
14. Seidman Center (collocated with GVSU)	42.961724	-85.679325	SAT043		0.34		0.1900		*0.111*
15. Finklestein Building - GVSU	42.972305	-85.661662	A21099		0.18		0.1020		*0.111*
16. Bicycle Factory (Collocated with GVSU)	42.960295	-85.681481	A21000		0.21		0.1160		*0.111*

Figure 1: Wind Rose for Sampling Time

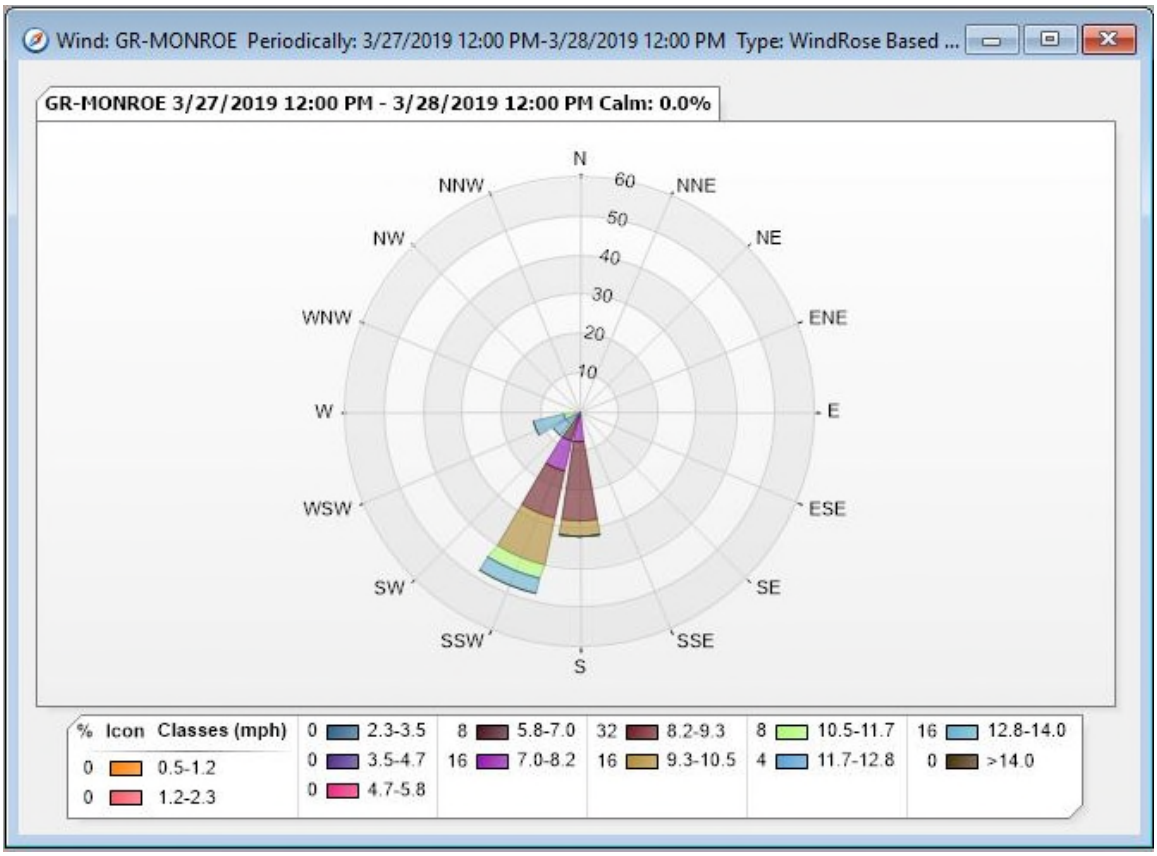

Figure 2: Map of Sampling Locations and Results Closest to Viant

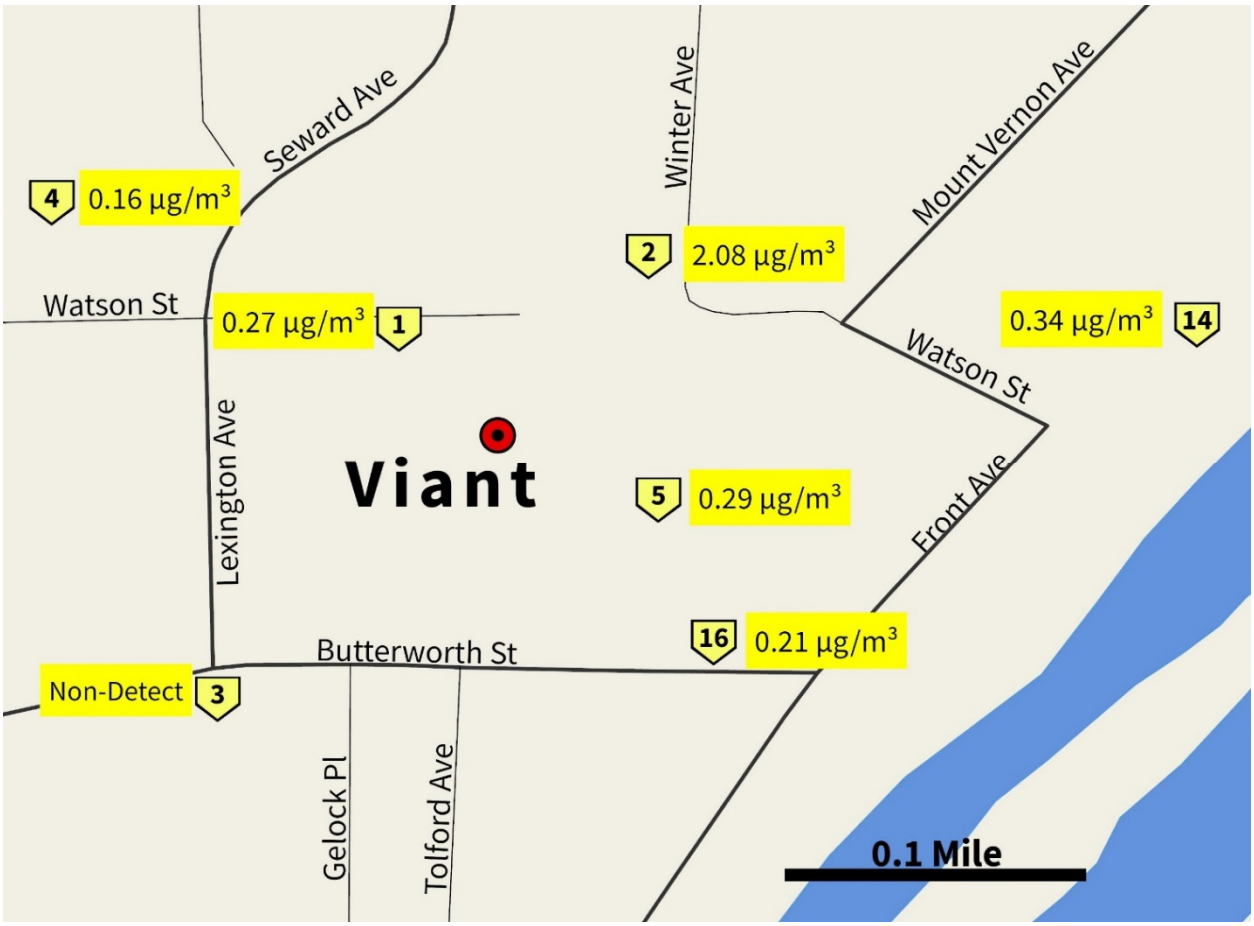

Figure 3: Map of Outlying Sampling Locations and Results