STATE OF MICHIGAN
DEPARTMENT OF
ENVIRONMENT, GREAT LAKES, AND ENERGY
LANSING

GRETCHEN WHITMER
GOVERNOR

LIESL EICHLER CLARK
DIRECTOR

November 26, 2019

UPS NEXT DAY DELIVERY

Mr. Bryan Curry
Viant Medical Inc.
620 Watson Street SW
Grand Rapids, Michigan 49504

Dear Mr. Curry:

Enclosed is the final signed copy of the State of Michigan, Department of Environment, Great Lakes, and Energy (EGLE), Air Quality Division (AQD), Stipulation for Entry of Final Order by Consent (Consent Order) AQD No. 2019-26 for Viant Medical, Inc.

The effective date of this Consent Order is November 26, 2019. Please refer to paragraph 12 for payment information. Payment is due on or before December 26, 2019. To insure proper credit, all payments made pursuant to this Consent Order must include the Payment Identification No. AQD40231.

Thank you for your cooperation. If you have any questions, please feel free to contact me.

Sincerely,

Jeff Rathbun
Enforcement Unit
Air Quality Division
Rathbunj1@michigan.gov

Enclosure

cc/enc: Ms. Sarah Marshall, U.S. Environmental Protection Agency, Region 5
Mr. Neil Gordon, Michigan Department of Attorney General
Ms. Heidi Hollenbach, EGLE
Mr. Christopher Ethridge, EGLE
Ms. Jenine Camilleri, EGLE

STATE OF MICHIGAN
DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY
OFFICE OF THE DIRECTOR

In the matter of administrative proceedings against **VIANT MEDICAL, INC.**, a Corporation, organized under the laws of the State of Michigan and doing business at 520 Watson SW in the City of Grand Rapids, County of Kent, State of Michigan

AQD No. 2019-26

SRN: N0795

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STIPULATION FOR ENTRY OF FINAL ORDER
BY CONSENT

This proceeding resulted from allegations by the Michigan Department of Environment, Great Lakes, and Energy (EGLE), Air Quality Division (AQD) against Viant Medical, Inc. (Company), a corporation organized under the laws of the State of Michigan and doing business at 520 Watson SW, City of Grand Rapids, County of Kent, State of Michigan, with State Registration Number (SRN) N0795 (Facility). EGLE alleges that the Company is in violation of Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, MCL 324.5501 *et seq.*, Permit to Install (PTI) No. 605-89B, Mich Admin Code, R 336.1901(a) (Rule 901(a)), and the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide (EtO) Emissions Standards for Sterilization Facilities, 40 CFR, Part 63, Subpart O. Specifically, EGLE alleges that the Company has emitted elevated concentrations of fugitive emissions of EtO that have the potential to cause injurious effects to human health or safety in violation of Rule 901(a); failed to comply with the EtO emission limits for EU-ETOSTERILIZERS established in PTI No. 605-89B; failed to maintain a minimum capture and destruction efficiency of 99.5 percent by weight for EtO, as required by PTI No. 605-89B; failed to maintain a 99 percent emission reduction from the sterilization chamber vents and/or aeration room vents as required by the NESHAP, 40 CFR Part 63, Subpart O; and failed to conduct performance testing by November 30, 2018, as cited herein and in the Violation Notices dated August 23, 2017; July 25, 2018; December 3, 2018; and January 4, 2019. The Company denies the foregoing allegations and maintains that it is not liable for penalties and is agreeing to the terms and conditions of this Stipulation for Entry of a Final Order by Consent (Consent Order) solely to settle disputed claims without incurring the time and expense of additional enforcement proceedings. The Company and EGLE stipulate to the termination of this proceeding by entry of this Consent Order.

The Company and EGLE stipulate as follows:

1. The Natural Resources and Environmental Protection Act (NREPA) MCL 324.101 *et seq.,* is an act that controls pollution to protect the environment and natural resources in this State.

2. Article II, Pollution Control, Part 55 of the NREPA (Part 55), MCL 324.5501 *et seq.,* provides for air pollution control regulations in this State.

3. Executive Order 2019-06 renamed the Michigan Department of Environmental Quality as EGLE, and EGLE has all statutory authority, powers, duties, functions, and responsibilities to administer and enforce all provisions of Part 55.

4. The EGLE Director has delegated authority to the Director of the AQD (AQD Director) to enter into this Consent Order.

5. The termination of this matter by a Consent Order pursuant to Section 5528 of Part 55, MCL 324.5528, is proper and acceptable.

6. The Company and EGLE agree that the signing of this Consent Order is for settlement purposes only and does not constitute an admission by the Company that the law has been violated.

7. This Consent Order becomes effective on the date of execution (effective date of this Consent Order) by the AQD Director.

8. The Company shall achieve compliance with the aforementioned regulations in accordance with the requirements and timeframe contained in this Consent Order.

COMPLIANCE PROGRAM AND IMPLEMENTATION SCHEDULE

9.A. Permit

1. On and after the effective date of this Consent Order, the Company shall comply with PTI No. 605-89B and any subsequent permit revision at the Facility.

2. The Company shall shut down and cease all sterilization operations at the Facility on or before December 31, 2019. The Company shall cease use of EtO at the Facility on or before January 31, 2020. During the month of January of 2020, the Company shall use EtO only for calibrating the sterilization chambers to demonstrate that medical equipment previously treated with EtO was sterilized in accordance with FDA requirements. Upon completion of the calibration operations, all containers of EtO will be removed from the Facility. Within seven (7) days after the removal of all containers of EtO, the Company shall submit notice to the AQD Grand Rapids District Supervisor that the sterilization operations have been shut down, that all

containers of EtO have been removed from the Facility, and that no further orders for delivery to the Facility of containers of EtO will be placed by the Company.

3. Within seven (7) days after EtO usage at the Facility has ceased, the Company shall submit a request to the AQD Permit Section Supervisor to void PTI No. 605-89B.

9.B. Recordkeeping and Reporting

1. The Company shall submit records of the EtO usage rates and estimated EtO emissions on a monthly and 12-month rolling basis for EU-ETOSTERILIZERS to the AQD Grand Rapids District Supervisor by the 15th day of each calendar month, for the previous calendar month the records were collected. The Company shall continue to submit these records up until the month following the shutdown of the sterilization operations and the Company has ceased usage of EtO at the Facility. The records shall include emission estimates for the use of EtO for calibration of the sterilization chambers during the month of January of 2020 (i.e., submittal on February 15, 2020 for the EtO emissions in January of 2020). The Company calculates a monthly estimate of fugitive emissions at the Facility using data it collects from a gas chromatograph designed to measure instantaneous indoor air concentrations of EtO for the purpose of evaluating compliance with Occupational Safety and Health Administration exposure limits. The Company's use of the gas chromatograph data produces an order of magnitude estimate of fugitive emissions but is not a precise method for developing quantitative estimates of EtO concentrations in ambient air.

9.C. Testing/Sampling/Monitoring

1. The Company shall implement the approved plan that was submitted to the AQD on April 30, 2019 and approved by the AQD on June 4, 2019 for monitoring EtO emissions from the Facility. The plan is attached hereto as Exhibit A of this Consent Order, incorporated by reference into this Consent Order and shall be enforceable in accordance with the provisions of this Consent Order. If the Company revises the approved monitoring plan, the Company shall submit for review and approval, to the AQD Grand Rapids District Supervisor, the revised plan prior to performing any sampling. Any subsequent approved revisions to the monitoring plan shall be attached hereto as Exhibit A of this Consent Order, incorporated by reference into this Consent Order and shall be enforceable in accordance with the provisions of this Consent Order.

2. Within forty-five (45) days after completing sampling, a report of the sampling results shall be submitted to the AQD Grand Rapids District Supervisor.

9.D. Operation Parameters

1. The Company shall leave all product pallets in the sterilization chambers until they can be moved directly to the aeration chambers to minimize fugitive EtO emissions by allowing more EtO emissions to be captured in the sterilization chamber and controlled by the wet scrubbers. The company has submitted and the AQD Grand Rapids District Supervisor has approved, a revision of the Company's operating procedures that implements this requirement.

2. The Company shall maintain and properly operate the gas chromatographs with catalytic bead sensor/gas chromatography combustible gas sensors/photoionization detectors (PID) within the Facility. The Company shall submit the PID monitoring records to the AQD Grand Rapids District Supervisor by the 15th day of the calendar month, for the previous calendar month the records were collected. These records shall include clearly highlighted readings taken by the PIDs during all monitoring performed by the Company or the AQD. The Company shall continue to submit these records up until the month following the shutdown of the sterilization operations and use of EtO at the Facility has ceased. In the event the PID malfunctions, the Company shall notify EGLE in writing of the malfunction as soon as reasonably possible, but not later than 2 business days after the discovery of the malfunction and provide EGLE with the dates when the PID was not fully functional, to the extent known at the time of the notice. The Company is not required to provide PID monitoring records during the period of malfunction identified in the initial notice to EGLE or any subsequent written update to EGLE regarding the duration of the malfunction if unknown at the time of initial notice.

GENERAL PROVISIONS

10. Except as specifically set forth herein, this Consent Order in no way affects the Company's responsibility to comply with any applicable state, federal, or local laws or regulations, including without limitation, any amendments to the federal Clean Air Act, 42 USC 7401 *et seq.*, Part 55, or their rules and regulations, or to the State Implementation Plan.

11. This Consent Order constitutes a civil settlement and satisfaction as to the resolution of the violations specifically addressed herein; however, it does not resolve any criminal action that may result from these same violations.

12. Within thirty (30) days after the effective date of this Consent Order, the Company shall pay to the General Fund of the State of Michigan, in the form of a check made payable to the "State of Michigan" and mailed to the Michigan Department of Environment, Great Lakes, and Energy, Accounting Services Division, Cashier's Office, P.O. Box 30657, Lansing, Michigan

48909-8157, a settlement amount of $110,000.00. This total settlement amount shall be paid within thirty (30) days after the effective date of this Consent Order. To ensure proper credit, all payments made pursuant to this Consent Order shall include the “Payment Identification Number AQD40231” on the front of the check and/or in the cover letter with the payment. This settlement amount is in addition to any fees, taxes, or other fines that may be imposed on the Company by law.

13. On and after the effective date of this Consent Order, if the Company fails to comply with paragraphs 9.A.1, 9.A.2, or 9.D.1 of this Consent Order, the Company is subject to a stipulated fine of up to $10,000.00 per violation per day. On and after the effective date of this Consent Order, if the Company fails to comply with paragraphs 9.B or 9.C of this Consent Order, the Company is subject to a stipulated fine of up to $5,000.00 per violation per day. On and after the effective date of this Consent Order, if the Company fails to comply with 9.A.3, 9.D.2 or any other provision of this Consent Order, the Company is subject to a stipulated fine of up to $500.00 per violation per day. The amount of the stipulated fines imposed pursuant to this paragraph shall be within the discretion of EGLE. Stipulated fines submitted under this Consent Order shall be made by check, payable to the State of Michigan within thirty (30) days after written demand and shall be mailed to the Michigan Department of Environment, Great Lakes, and Energy, Accounting Services Division, Cashier’s Office, P.O. Box 30657, Lansing, Michigan 48909-8157. To ensure proper credit, all payments shall include the “Payment Identification Number AQD40231-S” on the front of the check and/or in the cover letter with the payment. Payment of stipulated fines shall not alter or modify in any way the Company's obligation to comply with the terms and conditions of this Consent Order.

14. The AQD, at its discretion, may seek stipulated fines or statutory fines for any violation of this Consent Order which is also a violation of any provision of applicable federal and state law, rule, regulation, permit, or EGLE administrative order. However, the AQD is precluded from seeking both a stipulated fine under this Consent Order and a statutory fine for the same violation.

15. To ensure timely payment of the settlement amount assessed in paragraph 12 and any stipulated fines assessed pursuant to paragraph 13 of this Consent Order, the Company shall pay an interest penalty to the State of Michigan each time it fails to make a complete or timely payment under this Consent Order. The interest penalty shall be determined at a rate of interest that is equal to one percent (1%) plus the average interest rate paid at auctions of 5-year United States treasury notes during the six months immediately preceding July 1 and January 1, as

certified by the state treasurer, per year compounded annually, using the full increment of amount due as principal, calculated from the due date specified in this Consent Order until the date that delinquent payment is finally paid in full. Payment of an interest penalty by the Company shall be made to the State of Michigan in accordance with paragraph 12 of this Consent Order. Interest payments shall be applied first towards the most overdue amount or outstanding interest penalty owed by the Company before any remaining balance is applied to subsequent payment amount or interest penalty.

16. The Company agrees not to contest the legal basis for the settlement amount assessed pursuant to paragraph 12. The Company also agrees not to contest the legal basis for any stipulated fines assessed pursuant to paragraph 13 of this Consent Order but reserves the right to dispute in a court of competent jurisdiction the factual basis upon which a demand by EGLE of stipulated fines is made. In addition, the Company agrees that said fines have not been assessed by EGLE pursuant to Section 5529 of Part 55, MCL 324.5529, and therefore are not reviewable under Section 5529 of Part 55.

17. This compliance program is not a variance subject to the 12-month limitation specified in Section 5538 of Part 55, MCL 324.5538.

18. This Consent Order shall remain in full force and effect for a period of at least six (6) months. Thereafter, this Consent Order shall terminate only upon written notice of termination issued by the AQD Director. Prior to issuance of a written notice of termination, the Company shall submit a request, to the AQD Director at the Michigan Department of Environment, Great Lakes, and Energy, Air Quality Division, P.O. Box 30260, Lansing, Michigan 48909-7760, consisting of a written certification that the Company has fully complied with all the requirements of this Consent Order and has made all payments including all stipulated fines required by this Consent Order. Specifically, this certification shall include: (i) the date of compliance with each provision of the compliance program and the date any payments or stipulated fines were paid; (ii) a statement that all required information has been reported to the AQD Grand Rapids District Supervisor; (iii) confirmation that all records required to be maintained pursuant to this Consent Order are being maintained at the facility; and, (iv) such information as may be reasonably requested by the AQD Director regarding the Company’s compliance with the terms of this Consent Order.

19. In the event Viant Medical, Inc. sells or transfers the Facility, it shall advise any purchaser or transferee of the existence of this Consent Order in connection with such sale or transfer. Within thirty (30) calendar days following such sale or transfer, the Company shall also

notify the AQD Grand Rapids District Supervisor, in writing, of such sale or transfer, the identity and address of any purchaser or transferee, and confirm the fact that notice of this Consent Order has been given to the purchaser and/or transferee. As a condition of the sale or transfer, Viant Medical, Inc. must obtain the consent of the purchaser and/or transferee, in writing, to assume all of the obligations of this Consent Order. A copy of that agreement shall be forwarded to the AQD Grand Rapids District Supervisor within thirty (30) days after such purchaser or transferee assumes the obligations of this Consent Order.

20. Prior to the effective date of this Consent Order and pursuant to the requirements of Sections 5511 and 5528(3) of Part 55, MCL 324.5511 and MCL 5528(3), the public was notified of a 30-day public comment period and was provided the opportunity for a public hearing.

21. Section 5530 of Part 55, MCL 324.5530, may serve as a source of authority but not a limitation under which this Consent Order may be enforced. Further, Part 17 of the NREPA, MCL 324.1701 *et seq.*, and all other applicable laws and any other legal basis or applicable statute may be used to enforce this Consent Order.

22. The Company hereby stipulates that entry of this Consent Order is a result of an action by EGLE to resolve alleged violations of its facility located at 520 Watson SW, City of Grand Rapids, County of Kent, State of Michigan. The Company further stipulates that it will take all lawful actions necessary to fully comply with this Consent Order, even if the Company files for bankruptcy in the future. The Company will not seek discharge of the settlement amount and any stipulated fines imposed hereunder in any future bankruptcy proceedings, and the Company will take necessary steps to ensure that the settlement amount and any future stipulated fines are not discharged. The Company, during and after any future bankruptcy proceedings, will ensure that the settlement amount and any future stipulated fines remain an obligation to be paid in full by the Company to the extent allowed by applicable bankruptcy law.

The undersigned certifies that he/she is fully authorized by the Company to enter into this Consent Order and to execute and legally bind the Company to it.

VIANT MEDICAL, INC.

Bryan Curry Sr. Director Quality Assurance and Regulatory Affairs
Print Name and Title

Signature

22 NOV 19
Date

The above signatory subscribed and sworn to before me this 22nd day of November, 2019.

Notary Public Signature

Sanja Kovacevic
Notary Public Printed Name

My Commission Expires: 02/11/24

Approved as to Content:

Mary Ann Dolehanty, Director
AIR QUALITY DIVISION
DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY

Dated: 11/26/2019

Approved as to Form:

Neil Gordon, Section Head
ENVIRONMENTAL REGULATION SECTION
ENVIRONMENT, NATURAL RESOURCES, AND AGRICULTURE DIVISION
DEPARTMENT OF ATTORNEY GENERAL

Dated: 11/26/2019

FINAL ORDER

The Director of the Air Quality Division having had opportunity to review this Consent Order and having been delegated authority to enter into Consent Orders by the Director of the Michigan Department of Environment, Great Lakes, and Energy pursuant to the provisions of Part 55 of the NREPA and otherwise being fully advised on the premises,

HAS HEREBY ORDERED that this Consent Order is approved and shall be entered in the record of EGLE as a Final Order.

MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY

MaryAnn Dolehanty

Mary Ann Dolehanty, Director
Air Quality Division

Effective Date: 11/26/2019

Exhibit A

Exihibit A

STATE OF MICHIGAN

DEPARTMENT OF
ENVIRONMENT, GREAT LAKES, AND ENERGY

LANSING

GRETCHEN WHITMER
GOVERNOR

EGLE

LIESL EICHLER CLARK
DIRECTOR

June 4, 2019

Ms. Tricia L. Albert
Vice President and General Counsel
Viant Medical
2 Hampshire Street, Suite 202
Foxborough, Massachusetts 02035

Dear Ms. Albert:

The Michigan Department of Environment, Great Lakes, and Energy (EGLE), Air Quality Division (AQD) received an Ambient Air Sampling Work Plan (Sampling Plan) from Viant Medical on April 29, 2019. EGLE is approving this Sampling Plan as written. The AQD would like to reserve the right to co-locate canisters during this study to gain knowledge on interlaboratory comparisons for ethylene oxide. This Sampling Plan covers the sampling of ethylene oxide at Viant Medical in Grand Rapids, Michigan.

If you have any further questions, please contact me at 517-242-6561; robinsona1@michigan.gov; or EGLE AQD, P.O. Box 30260, Lansing, Michigan 48909-7760.

Sincerely,

Amy K. Robinson

Amy K. Robinson
Quality Assurance Coordinator
Air Quality Division

cc: Ms. Emily Kimball, Hogan Lovells
Ms. Susan Kilmer, EGLE
Mr. Jeff Rathbun, EGLE
Ms. Heidi Hollenbach, EGLE

VIANT
WE'RE IN IT FOR LIFE.

Viant Medical, Inc.
Compliance Plan Update and Supplemental Information

Attachment B

Viant's Proposed Air Monitoring Plan

AMBIENT AIR SAMPLING WORK PLAN FOR THE VIANT MEDICAL FACILITY, GRAND RAPIDS, MICHIGAN

Prepared for
Hogan Lovells US LLP
Denver, CO

On behalf of
Viant Medical
Grand Rapids, MI

Prepared By
Ramboll US Corporation
Arlington, VA

Date
April 2019

Project Number
1690010876

APPENDIX 1
FACILITY LAYOUT AND SAMPLE LOCATIONS

7. REFERENCES

Eurofins Air Toxics, Inc. 2014. Guide to Whole Air Sampling - Canisters and Bags. June. https://www.eurofinsus.com/media/161448/guide-to-air-sampling-analysis-2014-06-27_revised-logos.pdf

Eurofins Air Toxics, Inc. 2018. EPA Method TO-15 Analysis of Ethylene Oxide in Specially Treated Canisters by GC/MS Selective Ion Monitoring. Eurofins Air Toxics SOP #134, Revision 0. Methods Manual Summary. October 30.

MDEQ. 2019. Air Quality Division Response to Proposed Compliance Plan in the matter of Viant Medical, Inc. March 22.

USEPA. 1999. Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air. Second Edition. 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). January. EPA/625/R-96/010b. https://www.epa.gov/sites/production/files/2015-07/documents/epa-to-15_0.pdf

USEPA. 2002. Guidance on environmental data verification and data validation, EPA QA/G8. EPA/240/R-02/004. Office of Environmental Information. November. http://www.epa.gov/QUALITY/qs-docs/g8-final.pdf

USEPA. 2006. Guidance on Systematic Planning Using the Data Quality Objectives Process. February. https://www.epa.gov/sites/production/files/2015-06/documents/g4-final.pdf

USEPA. 2018. Quality Assurance Project Plan for Field Sampling Plan for Ambient Air Ethylene Oxide Monitoring Near Sterigenics Facility, Willowbrook, IL. November. https://www.epa.gov/sites/production/files/2018-11/documents/qapp_eto_willowbrook_v1.4_final_signed.pdf

Table 4: Quality Control Criteria for TO-15 Sample Collection and Analysis				
Quality Control Sample	**Data Quality Indicators (DQIs)**	**Frequency**	**Acceptance Criteria**	**Corrective Action**
Collocated sample	Precision	1 per day	Within 25%	Flag the data
Replicate sample	Precision	1 per batch	Within 25% for sample concentrations greater than five times reporting limit	Flag the data
Valid sample count	Completeness	N/A	85% or more of total samples	Collect make up samples on a second day or separate mobilization
Canister batch blank	Bias	After analysis of standards and prior to sample analysis, or when contamination is present.	Below the reporting limit	Inspect the system and re-analyze the blank; or subtract average concentration of the blank.
Method Detection Limit	Sensitivity	1 per method modification	0.05 ppb (0.09 µg/m3) or less	Identify sources of the problem, e.g., thoroughly clean the system
Sampling period	Field QC	All samples	24 hours +/- 1 hour	Notify project manager and flag samples
Additional data quality control requirements apply to laboratory QC procedures. See Appendix 2.				

5.3 Data Management Procedures

Laboratory data will be reported in electronic format by EAT within 10 business days of the sample receipt date. Electronic data deliverables will be available in electronic data deliverable (EDD) and PDF formats. Field logbooks, chain-of-custody forms, sample location maps, and data reports will be retained and reviewed for consistency. Any deviations will be evaluated for their impact on data quality. Data validation will be performed in accordance with procedures described in USEPA's Guidance on Environmental Data Verification and Data Validation (USEPA 2002).

6. DATA EVALUATION

Approximately four weeks after each sampling event, Ramboll will provide a draft written monthly summary to document the following:

- Tabular summary of analytical results for the sampling period in the most recent month and any preceding months;
- Operational data reported by Viant for the sampling period;
- Wind rose based on data from a nearby meteorological (MET) station for the sampling period.

For the first monthly summary, Ramboll will also provide a description of the final sampling locations and procedures. For the final monthly summary, Ramboll will provide a draft written report summarizing all the monthly data and providing our analysis of the results.

The report will be prepared in draft format for review and comment. Following receipt of your comments, Ramboll will produce the final report.

- Name of field personnel collecting the sample

In the addition, the following operational data will be requested from the facility for each 24-hour period after completion of the sampling:

- Inventory of sterilization and aeration cycles that overlapped with each sampling period, including:
  - Start date and time;
  - End date and time;
  - Aeration cell used (for aeration cycles);
  - Sterilization chamber used (for sterilization cycles); and
  - Ethylene oxide concentration in chamber and chamber pressure (for sterilization cycles); and
- Description of any upset conditions, malfunctions, or atypical operating conditions during the sampling periods that could impact indoor EtO concentrations.

Prior to the first round of sampling, a Health and Safety Plan (HASP) will be prepared that covers the sample collection activities described in this Work Plan. The HASP will inform field personnel of known or reasonably anticipated potential hazards and safety concerns at the site and incorporate Viant-specific PPE requirements. Field personnel will review and sign the HASP prior to commencing on-site activities.

4. SAMPLE ANALYSIS PROCEDURES

All SUMMA® canister samples will be shipped to EAT, a laboratory that is certified under the National Environmental Laboratory Accreditation Program (NELAP) for United States Environmental Protection Agency's (USEPA) Method TO-15 by Gas Chromatography with Mass Spectrometry (GC/MS) (USEPA 1999). EAT will analyze the samples for EtO using a GC/MS and a modified USEPA Method TO-15. The modified method was developed by Eurofins specifically to analyze EtO in ambient air, allowing for sub-part per billion, volume (ppbv) detection limits. The method has been refined to eliminate potential interference from trans-2-butene, a compound identified by USEPA as potentially interfering with EtO quantification. The method's Minimum Detection Limit (MDL) for ethylene oxide is 0.050 ppbv or 0.090 micrograms per cubic meter ($\mu g/m^3$). A summary of this method and its quality control procedures, as well as EAT's QC criteria for the method is provided as Appendix 2.

5. QUALITY ASSURANCE

5.1 Laboratory Procedures

Laboratory instrument calibration procedures and quality assurance control requirements are provided as Appendix 2.

5.2 Sampling Procedures

Chain-of-custody documents and field log books will be maintained for all samples. To evaluate the repeatability of the sampling procedures, at least one collocated sample will be collected for each round of 24-hour samples (one collocated sample per month). The inlets of collocated samples will be placed approximately 1-4 meters apart. Different monitoring locations for collocation will be selected for each sampling round by field personnel. The relative percentage difference between pairs of collocated samples will be calculated, reported, and evaluated against the acceptable range (within 25%).

The data quality will be evaluated based on acceptable criteria specified by USEPA for precision, completeness, bias, and sensitivity, as summarized in the table below. Precision will be evaluated through collocated samples and replicate analysis of the same samples. Data completeness will be set at a target of 85% (for five monitoring locations every month, that is 13 out of 15 samples every quarter), not including collocated samples). If the target is not achieved in a given quarter, Ramboll will add another sampling round before the next normally scheduled sampling round to achieve a minimum of 13 valid samples. Two spare canisters will be taken to the field as a backup in the event of equipment malfunction. Quality control criteria for TO-15 are listed in Table 4 below.

Table 3: Schedule for Each Sampling Round	
Timing	**Activity**
Weeks 2-3	Laboratory receives canisters, completes analysis, and sends analytical data to Ramboll.
Week 4-5	Ramboll reviews laboratory results, conducts internal quality assurance review, and prepares draft written summary.

3. SAMPLE COLLECTION PROCEDURES

Each sample will be collected in a 6-liter, stainless steel SUMMA® canister, equipped with a 24-hour mass flow controller. The canisters, mass flow controllers, and fittings will be shipped to the facility (c/o Tom Campbell) by Eurofins Air Toxics (EAT). The canisters will be cleaned and individually certified by EAT. The laboratory will verify the integrity of each canister by conducting a pressure/vacuum check prior to shipping. The flow controllers will also be individually certified by the laboratory.

Sampling personnel are trained and experienced in collecting canister samples, following chain-of-custody procedures, and shipping canisters to EAT. Sampling personnel will follow EAT's Guide to Air Sampling, which includes guidance for integrated sampling with canisters and flow controllers.

To allow sampling at breathing zone height (approximately 5-6 feet), Ramboll will secure the canisters to utility poles, light posts, or fences with a cable or chain. Prior to the first sampling event, Ramboll will obtain approval from the local municipality or other responsible third party with jurisdiction (e.g., utility) to deploy canisters at off-site sampling locations.

At each sampling location, the brass cap will be removed from the canister and the 24-hour mass flow controller will be attached and tightened with a 9/16" wrench. The canister draws in air through an inlet once the manual valve is opened. Prior to sampling, each canister should undergo a leak check. Field personnel will place the brass cap on the end of the flow controller to create an air-tight sampling train, and quickly open and close the canister valve. If the pressure gauge needle continues to drop, the sampling train is not airtight. The connections should be refitted and/or tightened until the needle is steady after quickly opening and closing the canister valve. Field personnel will record the initial canister pressure and start time. After approximately 24 hours from the sample collection start time, field personnel will record the end time and final canister pressure, close the canister valve, remove the mass flow controller, re-cap the canister, and prepare the canister for shipment. Signage will be placed near the canisters to prevent facility personnel from accidentally dislodging the canister, or placing equipment that could block the inlet.

A label will be attached to each canister that will contain the sample identification, the collection start and end dates and times, and the initial and final canister pressures. The sample identification will include a unique location code and end date of sample collection. All canisters will be shipped to the laboratory on the last day of each sampling round. A custody seal will be taped over the opening of the shipping container. A chain-of-custody form, which documents the history of each sample from collection to analysis, will be included within each shipping container. The form lists the sample identifier, matrix, date and time collected and the requested analysis. The chain also includes the name of the field personnel who collected the sample and the date and name of all sample transfers until acceptance at the laboratory.

For each sample, the following information will be recorded in a field book:

- Sample location at the facility (marked on a facility layout)
- Canister sample ID
- Mass flow controller ID
- Sample collection start date and time
- Sample collection end date and time
- Initial and final canister pressures

the duration of the sampling campaign. If facility operations or safety consideration require moving the locations after the first month, Ramboll will make note of the modification.

2.2 Schedule

At each location, one sample will be collected in a SUMMA® canister over a 24-hour period. Each SUMMA® canister will be equipped with a mass flow controller, which regulates the amount of air entering the canister at a relatively constant rate.

To ensure schedule consistency and to allow sufficient time to review laboratory results prior to the next round of sampling, Ramboll will conduct sampling during the same week in a given month (e.g., first full week of every month). The final proposed schedule will depend on when the work plan is approved, but monthly sampling will continue for two months after the sterilization process is eliminated (e.g., two sampling rounds after the last sterilization batch) as requested by MDEQ. The exact day of the week for each sampling round may depend on forecasted weather conditions (e.g., avoiding days with high winds or heavy precipitation). Ramboll will coordinate the exact sampling date with facility personnel to ensure that measured concentrations are representative of typical operating conditions. A tentative schedule is provided below:

Table 2: Proposed Sampling Schedule for 2019-2020

Sampling Round	Month	Comment
1	June 2019	Assumes work plan approval in early May
2	July 2019	
3	August 2019	
4	September 2019	
5	October 2019	
6	November 2019	
7	December 2019	End of sterilization process
8	January 2020	
9	February 2020	

Ramboll requires at least 3 weeks of lead time following work plan approval to arrange for the preparation and shipment of individually certified canisters, purchase additional sampling-related equipment, obtain required third-party approval for proposed off-site locations, and schedule the first on-site sampling event.

For each round of sampling, Ramboll anticipates the following schedule:

Table 3: Schedule for Each Sampling Round

Timing	Activity
1 week prior to sampling period	Ramboll contacts Viant personnel to determine if there are any unusual events (e.g., maintenance shutdown) for the planned sampling event; if yes, re-schedule the sampling event. Ramboll confirms canister delivery order with analytical laboratory.
Week 1 - Sampling	Ramboll collects samples over a 24-hour period and ships canisters back to the laboratory.

1. INTRODUCTION

The Viant Medical ("Viant") facility located at 520 Watson Street Southwest in Grand Rapids, Michigan (the "facility" or the "site") conducts ethylene oxide ("EtO") sterilization of medical equipment.

Per a March 22, 2019 settlement communication letter, Michigan Department of Environmental Quality (MDEQ) Air Quality Division (AQD) has requested that Viant conduct air monitoring for EtO within the facility and in the area around the facility, in order to demonstrate the effectiveness of Viant's measures to reduce EtO fugitive emissions. Ramboll proposes conducting air sampling at selected locations within or near the property boundaries during a 24-hour period on a monthly basis ending 60 days after the sterilization process is eliminated.

2. MONITORING DESIGN

2.1 Sampling Locations

Ramboll's proposed sampling locations are informed by the results of prior EtO sampling conducted by MDEQ and Grand Valley State University (GVSU). MDEQ conducted sampling within and near the Viant property in November 2018 and GVSU conducted sampling inside campus buildings north and east of the Viant property in February and March 2019. While EtO was measured at detectable concentrations within and near Viant's western, northern, and southern property boundaries, EtO concentrations at off-site locations further from the property boundary are generally non-detect or just above the detection limit. Accordingly, in order to collect samples with sufficient detectable results to serve its intended purpose, Ramboll's sampling plan consists of locations within or near the Viant property boundary. The selection of locations is constrained by security concerns, potential tampering, and access limitations associated with off-site locations, in addition to the desire to obtain measurable results, as Ramboll expects that concentrations at distances further from the facility would fall below the detection limit.

Ramboll will collect air samples at the following five locations (see also Appendix 1):

Table 1: Proposed Sampling Locations

Location ID	Indoor/Outdoor	On-Site	Location
IA	Indoor	Yes	Inside Scrubber Room
1	Outdoor	Yes	South of building in parking lot
2	Outdoor	Yes	West of building, along western property boundary
3	Outdoor	No	Northwest of building along Watson Street Southwest
4	Outdoor	Yes	North of building, northern corner of parking lot

With the exception of the Scrubber Room sample, samples will be collected outdoors in the parking lot or along a nearby street. The outdoor locations are in the direction of the residential community and the GVSU campus buildings to the north and south. Because of the locations' proximity to utility poles or fences, they can be secured for the duration of the sampling period. For the Scrubber Room location, Ramboll will coordinate with Viant representatives to ensure that appropriate personal protective equipment (PPE) procedures are identified prior to the first sampling event and followed before entering the room. Viant representatives will be present to ensure that monitoring locations do not interfere with ongoing operations or pose safety concerns. Ramboll personnel will take photographs of the final sample configuration.

A layout of the facility and initial proposed sample locations are provided as Appendix 1. The final sample locations may be adjusted in the field as needed. It is anticipated that once the sampling locations have been established in the first month of sampling, the locations will remain the same for

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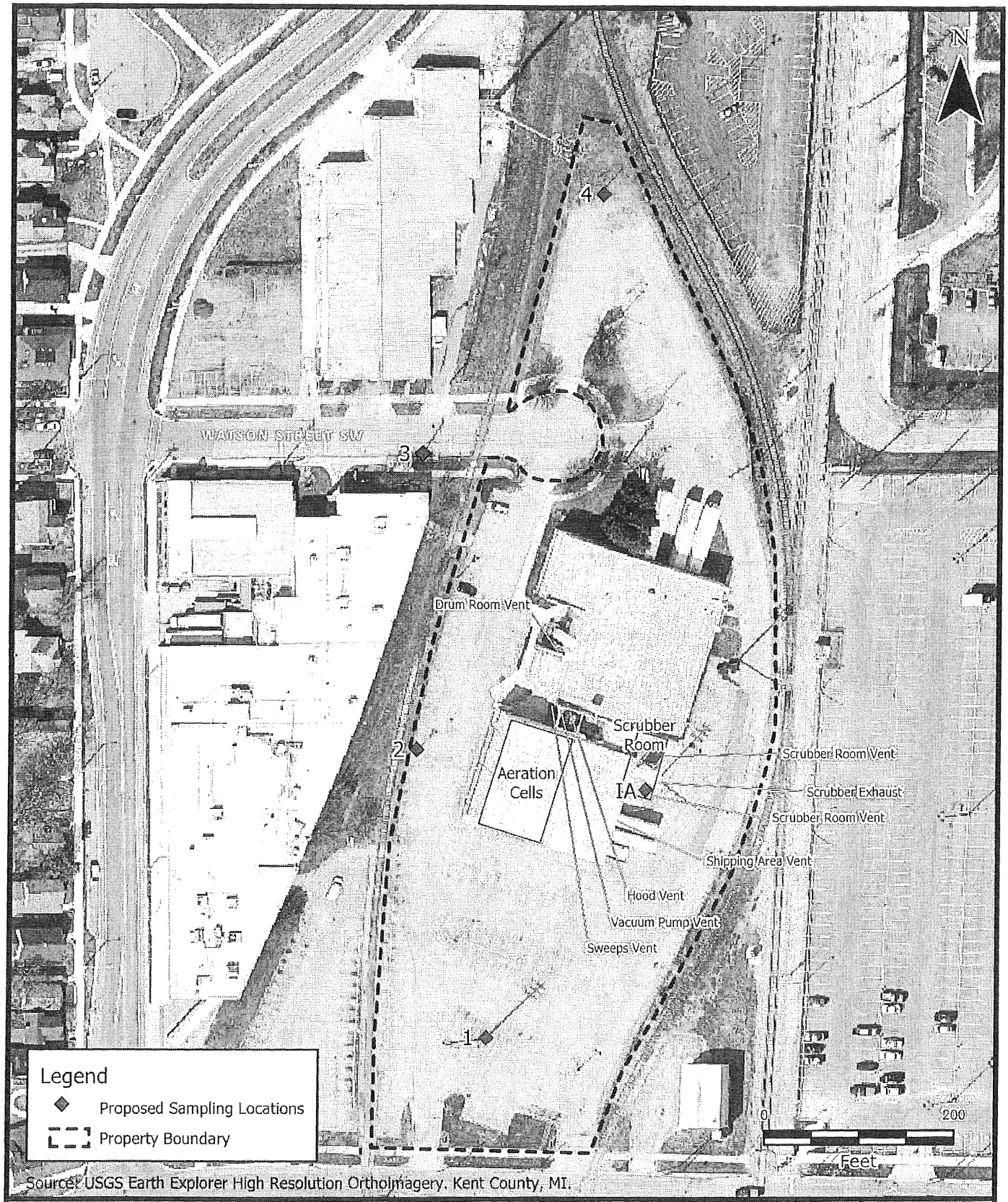
APPENDICES

DRAFT



RAMBOLL

PROPOSED SAMPLING LOCATIONS
VIANT MEDICAL
GRAND RAPIDS, MICHIGAN

FIGURE
1

DRAFTED BY: HA | DATE: 4/16/2019 | PROJECT 1690010876

APPENDIX 2
SUMMARY OF LABORATORY METHOD AND QUALITY CONTROL PROCEDURES

Table 2. Summary of Calibration and QC Procedures for Method TO-15 SIM

QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action
Tuning Criteria	Every 24 hours.	TO-15 Ion Abundance criteria	Correct problem then repeat tune.
Multi-Point Calibration (minimum of 5 points)	Prior to sample analysis.	≤30% RSD.	Correct problem then repeat Initial Calibration Curve.
Initial Calibration Verification and Laboratory Control Sample (ICV and LCS)	After each initial calibration curve, and daily, prior to sample analysis.	70-130%	Check the system and reanalyze the standard. Re-prepare the standard if necessary to determine the source of error. Re-calibrate the instrument if the primary standard is found to be in error.
Continuing Calibration Verification (CCV)	At the start of each day after the BFB Tune check.	≤30%D	. Check the system and reanalyze the standard. Re-prepare the standard if necessary. Re-calibrate the instrument if the criteria cannot be met.
Laboratory Blank	After analysis of standards and prior to sample analysis, or when contamination is present.	Results less than the laboratory reporting limit Table 1.	Inspect the system and re-analyze the blank.
Internal Standard (IS)	As each standard, blank, and sample is being loaded.	Retention time (RT) for blanks and samples must be within ±0.33 min of the RT in the CCV and within ±40% of the area counts of the daily CCV internal standards.	**For blanks:** inspect the system and reanalyze the blank. **For samples:** re-analyze the sample. If the ISs are within limits in the re-analysis, report the second analysis. If ISs are out-of-limits a second time, dilute the sample until ISs are within acceptance limits and narrate.
Laboratory Duplicates - Laboratory Control sample Duplicate (LCSD)	One per analytical batch.	RPD ≤25% for sample concentrations greater than 5 times the reporting limit.	Investigate the cause including canister pressure and flow rates. Re-prepare standard if needed and re-analyze LCSD. If instrument maintenance is required, calibrate as needed.

eurofins | Air Toxics

Method: EPA Method TO-15 Analysis of Ethylene Oxide in Specially Treated Canisters by GC/MS Selective Ion Monitoring

Eurofins Air Toxics SOP #134 Revision 0 Effective Date: October 30, 2018 Methods Manual Summary

Description: This method involves the collection of ethylene oxide in ambient air using specially treated evacuated canisters. Up to 0.5 liters of air is withdrawn from the canister using a mass flow controller and concentrated on a series of traps designed to remove water from the sample stream. The sample is then focused onto a cryogenic-cooled column prior to analysis by GC/MS in the Selected Ion Monitoring (SIM) mode.

The mass spectrometer is set to acquire both SIM and full scan data simultaneously. This generates two separate data files in the analytical software. One file contains full scan data and the other contains SIM data for selected compounds. Ethylene oxide is quantified using the SIM file and the full scan data file is used if needed to assist to aid in confirmation and identification of potential interfering compounds.

The reporting limits and QC acceptance criteria are summarized in Table 1. The summary of calibration and QC procedures are summarized in Table 2.

Table 1. Reporting Limits and QC Acceptance Criteria

Analyte	RL/LOQ (ppbv)	QC Acceptance Criteria			
		ICAL (%RSD)	CCV (%R)	ICV/LCS (%R)	Precision Limits (Max. RPD)
Ethylene Oxide	0.050	≤30%	70 - 130	70 - 130	± 25

Viant Medical, Inc.

RESPONSE TO COMMENTS DOCUMENT

November 26, 2019

Consent Order No. 2019-26

Gretchen Whitmer, Governor
Liesl Eichler Clark, Director

Air Quality Division
Michigan Department of Environment, Great Lakes, And Energy
INTERNET: http://www.michigan.gov/air

Mary Ann Dolehanty, Director
Air Quality Division
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SUMMARY OF COMMENTS

Comment

The civil fine of $110,000 doesn't seem adequate for a company that has been releasing to the neighborhood for 30 years, why is it only $110,000 when the company has over a billion dollars in revenue?

AQD Response

The proposed penalty calculated in this case conforms with the United States Environmental Protection Agency (USEPA) Clean Air Act Stationary Source Civil Penalty Policy (EPA Penalty Policy). The Air Quality Division (AQD) Enforcement staff followed the USEPA penalty policy to calculate the proposed penalty.

The USEPA Penalty Policy takes into account several factors, including, actual or possible harm of the violation, the length of time of the violation, the sensitivity to the environment, importance to the regulatory scheme, and the size of the violator. These factors were considered in calculating the gravity portion of the penalty.

One key component of the USEPA Penalty Policy is the size of the violator and how that can affect the overall amount of the penalty. The USEPA Penalty Policy does consider net worth or assets of the company. However, the penalty cannot be overly weighted based on a company's size. The increase in penalty can only account for 50 percent of the gravity portion of the penalty, which was applied in this case.

Another component of the USEPA Penalty Policy is the length of time the violations occurred. Although the facility has been in operation for 30 years, Viant Medical, Inc., which was previously known as MedPlast Medical, Inc., has only owned and operated this facility since June 2017. The penalty is attributed to the time that the alleged violations occurred, which is when MedPlast and Viant owned the facility, and the initial air quality violations were cited on August 23, 2017.

Finally, there are aggravating or mitigating factors that can also increase or decrease the penalty, such as the degree of cooperation and history of noncompliance. After the initial calculated penalty is offered to the company, AQD staff negotiate with the company to determine the final settlement amount. In this case, factors such as litigation risk (court costs, attorney fees) and the company's willingness to cooperate to resolve the violations along with the company agreeing to shut down the sterilization processes were taken into account in determining the final settlement amount.

Comment

Add to the Consent Order some sort of communication between the community and the organization so that as they change processes or introduce chemicals or processes that could be damaging to the community, the community is made aware of the changes. Additionally, provide some sort of assistance or way to organize the neighbors to respond to their concerns.

AQD Response

A consent order includes a plan to bring the company back into compliance. The steps the company needs to take to come back into compliance are outlined in the proposed consent order. Future notifications to the community will occur but this is not something the AQD would require as part of a consent order. In the future, the AQD will notify the community when there is any type of permitting action at this facility or if new violations are identified. This information will be posted on the Viant website and the community will be notified by mail and/or email by way of an Interested Parties list. Those community members that attended the informational meeting and hearing who filled out cards, and anyone who provided comments to the AQD, will be included as part of the Interested Parties list.

Comment

The fines collected for the penalty should go directly to the community. A Supplemental Environmental Project (SEP) or other direct assistance to the community to address continued health concerns should be required in this consent order. This project or assistance should directly benefit the community/neighborhood surrounding the facility.

AQD Response

By law, any penalty amount must be directed to the State's General Fund. The Department of Environment, Great Lakes, and Energy has no authority to require a company to submit and implement a community-based SEP. The submittal of a SEP is at the discretion of the company, and Viant did not submit a community-based SEP for consideration.

Comment

Stop ethylene oxide usage at the facility and the company should close.

AQD Response

Due to the regulation of medical device sterilization by the Federal Food and Drug Administration, use of ethylene oxide at the facility could not be immediately discontinued. The Consent Order requires the company to stop sterilization at the end of the year on or before December 31, 2019, and stop all use of ethylene oxide by January 31, 2020. Additionally, all sources of ethylene oxide are required to be removed from the facility once use of ethylene oxide at the facility is ceased in January 2020. If the company fails to meet these deadlines, stipulated fines up to $10,000 per violation per day will be assessed to the company.

Comment

Make the company remove the storage tank(s).

AQD Response

The AQD contacted the Michigan Department of Licensing and Regulatory Affairs Underground Storage Tank Division to determine if an underground storage tank is present on the Viant property. They did not have any record of underground storage tanks for ethylene oxide being present on the property.

The AQD received information from the company that there are emergency underground containment tanks on the property. These tanks do not store ethylene oxide. The purpose of these tanks is to capture emergency deluge water if there is a leak or fire in the ethylene oxide storage room and the sprinkler system is utilized to flood the ethylene oxide storage area. These tanks are only there for emergency capture and storage of deluge water used for controlling a leak or fire.

Below is a summary of the information provided by the company:

> Viant utilizes a storage room, known as the "drum room," for the storage of ethylene oxide (EtO). Liquid EtO is stored in metal drums in the drum room and dispensed from those drums as needed for use in the sterilization process. In the event of leak or fire, the drum room is equipped with a sprinkler system called the emergency deluge system. The emergency deluge system is designed to suppress a fire and/or dilute a spill of liquid EtO in the drum room by distributing pressurized water from open nozzles in the drum room. The drum room contains a trench drain that discharges to two 6,000 gallon secondary containment tanks located under the facility parking lot to the west of the drum room. The secondary containment tanks are made of concrete and are lined with an epoxy sealant. These tanks are kept empty at all times exclusively for the purpose of secondary containment in the event of an emergency. If the emergency deluge system is activated, up to 12,000 gallons of deluge system water can be captured in the emergency containment tanks, corresponding to about one (1) hour of deluge system flow.
>
> Michigan's storage tank regulations define an "underground storage tank (UST) system" to expressly exclude "an emergency spill or overflow containment UST system that is emptied within 10 days after use." Mich. Admin. Code R 29.2107. Such emergency containment systems are therefore excluded from registration because they are not UST systems. *Id.* R 29.2103 (a).
>
> Based on a review of applicable state rules, the company's emergency deluge and containment tank system meets the exemption in the Michigan regulations because it is an emergency containment system and is used per the company's Chemical Spill Response Procedure, which requires that the secondary containment tanks be emptied within 24 hours.

By: Jeff Rathbun