DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION
ACTIVITY REPORT: Self Initiated Inspection

N079551939

FACILITY: Viant Medical Inc.		**SRN / ID:** N0795
LOCATION: 520 Watson SW, GRAND RAPIDS		**DISTRICT:** Grand Rapids
CITY: GRAND RAPIDS		**COUNTY:** KENT
CONTACT: Tom Campbell , Manufacturing Engineer		**ACTIVITY DATE:** 01/02/2020
STAFF: April Lazzaro	**COMPLIANCE STATUS:** Compliance	**SOURCE CLASS:** MINOR
SUBJECT: Unannounced, self-initiated inspection.		
RESOLVED COMPLAINTS:		

Staff, April Lazzaro arrived at the facility to conduct an unannounced inspection. I met with Tom Campbell, Sterilization Engineer. Mr. Campbell and I sat down to discuss the purpose of the inspection which is to determine compliance with Stipulation for Entry of Final Order by Consent (Consent Order) AQD No. 2019-26, Permit to Install (PTI) No. 605-89B, the National Emissions Standards for Hazardous Air Pollutants (NESHAP) 40 CFR Part 63 Subpart O for Ethylene Oxide Emissions Standards for Sterilization Facilities and the Michigan Air Pollution Control Rules.

FACILITY DESCRIPTION

Viant Medical, Inc. is a global services provider to the medical device industry and the Grand Rapids facility conducts manufacturing and sterilization utilizing ethylene oxide (EtO). The stationary source consists of two buildings, one located at 520 Watson Avenue SW and one located at 620 Watson Avenue SW. Both buildings were included in this compliance inspection.

The building at 520 Watson contains medical device manufacturing, wherein the building at 620 Watson contains the ethylene oxide sterilization equipment. The facility PTI covers five sterilization chambers controlled by two acid scrubbers operated in series. The NESHAP, Subpart O, requires implementation of monitoring parameters established during emissions stack testing, as well as emissions standards.

To formally resolve prior violations, Viant Medical, Inc. signed Consent Order No. 2019-26 on November 22, 2019 and it became effective on November 26, 2019. The Consent Order, in effect, requires that the company cease all sterilization operations at the facility on or before December 31, 2019. It also states that during the month of January 2020, the only EtO use shall be for calibrating the sterilization chambers to demonstrate that medical equipment previously treated with EtO was sterilized in accordance with FDA requirements. Upon completion of this, all containers of EtO will be removed from the facility. Within seven days, the company shall submit notice to AQD Grand Rapids District Supervisor that the sterilization operations have been shut down, and that all containers of EtO have been removed from the facility and that no further orders of EtO will be placed.

COMPLIANCE EVALUATION

<u>620 Watson Avenue SW</u>

Mr. Campbell and I began the inspection at the 620 Watson Avenue SW building, which houses the EtO sterilization equipment. As we walked through the facility, it was clear that there was no sterilization taking place. There were no pallets of devices to sterilize observed inside the building. The sterilization chambers were all shut down with the exception of Chamber C, which still had to undergo the calibration cycles as noted above. As we walked toward the rear of the building, I observed that the aeration rooms were off, and empty except for a few pallets of historical non-production boxes of product. Mr. Campbell indicated that they will be removed from the facility soon. We went into the EtO storage room and saw that there were seven partially full containers of EtO. Mr. Campbell indicated that they plan to have them shipped off site by the end of January. Removal of EtO from the facility will be verified through an additional inspection.

Stack testing conducted on December 6, 2018, measured the pound per hour (pph) emissions of EtO from the scrubber stack, in comparison to the permit limit of 2.0 pph and found the stack emissions from Viant were 0.006 pph for the combined sterilization chamber vent and aeration room vent combined.

This value indicates compliance with the permit limit.

Emissions records were received from Mr. Campbell for the month of November. Due to the holidays, the December records had not yet been finished. This is reasonable due to the holidays and the fact that this inspection was on January 2nd. Reported emissions for the month of November indicated that emissions of EtO were 7.88 pounds. This includes 0.054 pounds of EtO emitted from the scrubber and 7.83 pounds of fugitive emissions. The permit limits EtO emissions to 0.9 tons per 12-month rolling time period as determined at the end of each calendar month. The reported emissions for the time period of December 2018-November 2019 were 143.5 pounds or 0.072 tons. This value indicates compliance with the 12-month rolling limit. The permit also limits the use of EtO to not more than 360,500 pounds per 12-month rolling time period. The reported EtO usage for the time period of December 2018-November 2019 was 104,623 pounds. This value indicates compliance with the material usage limit.

The permittee also provided monitoring data as required by the Malfunction Abatement Plan for the EtO scrubbers. The Chemrox and Deoxx scrubber ethylene glycol levels were below the established value. The highest Chemrox Total EG level (must be 49.9% or less) was 36.1. The highest Deoxx Total EG level (must be 12.0% or less) was 0.046. The highest Chemrox pH (must be less than 1.5) was 0.64, and the highest Deoxx pH (must be less than 1.5) was 0.63. The other parameters recorded were signed off as filed and up to date with a completed date of December 9 and 10, 2019.

The data above was provided during the inspection and marked as confidential. Emissions data and data required by the permit are not confidential. Therefore, the data is identified in this report, and the piece of paper provided and marked confidential will be placed in the confidential file.

Based on the information provided and detailed above, it appears as though the scrubbers were properly operating in December.

The most recent stack testing was conducted in December 2018, and the results indicated a removal efficiency of 99.999% and the average EtO concentration during the aeration room test was 0.3 ppm. The NESHAP requires a 99% reduction from the sterilization chamber vent, which was met during testing. The aeration room vent must be controlled to a 1 ppm maximum outlet concentration of 99% emission reduction (whichever is less stringent) which was met during testing.

<u>On-site Follow Up Inspection</u>

On January 23 and 24, 2020 I conducted a follow-up inspection of the building located at 620 Watson Street, SW and found that the facility has discontinued all use of EtO and have emptied the scrubber of all liquid. Additionally, there are no sterilized medical devices in the building. Lastly, the remaining containers of EtO were removed from the facility on January 20, 2020.

<u>520 Watson Avenue SW</u>

The building located at 520 Watson Street SW conducts medical device manufacturing. Activities take place in one of eight clean rooms, where assembly, glue use, ink stamping and solvent use for cleaning occur.

In September of 2018, AQD requested information on activities and emissions occurring at the 520 Watson Street SW building. The information received indicated that the building activities generated 13 tons of Volatile Organic Compound emissions and 0.22 tons of Hazardous Air Pollutant emissions in 2017. A conversation regarding permit exemptions and recordkeeping took place at that time.

During this inspection, the environmental contact, Mr. Jon Hagen, was not available, but I conducted a walk through with Mr. Campbell and Mr. Dan Nanninga. We observed each clean room from the hallway, and I saw a variety of medical device manufacturing activities taking place. On Tuesday January 7, 2020, upon Mr. Hagen's return, I requested emissions recordkeeping for the medical device manufacturing processes to demonstrate compliance with Rule 201 and a permit exemption. I also provided Viant with the email documentation identifying the emissions associated with the activities at 520 Watson Street SW.

I later received an email on January 14th from Mr. Bryan Curry (attached) indicating that he and his stakeholders were working on getting information together and hope to have information for me the following week. Mr. Curry contacted me and stated that Viant is working with an environmental consultant and reevaluating the emissions information previously provided to AQD in September 2018 in order to present the most accurate data.

A Rule 278a letter was sent on to the company by the AQD on January 27, 2020, requesting process descriptions and recordkeeping to demonstrate ongoing compliance as well as a Potential to Emit determination.

The first response to the January 27, 2020 letter Viant Medical, Inc. provided to the AQD was submitted on March 13, 2020 following a request from them for an extension to the original submittal date. Following an extensive internal review, including assistance from Tracey McDonald, Senior Engineer with the AQD State Implementation Plan Development Unit, AQD determined that the methodology utilized to develop the Potential to Emit (PTE) was inadequate. Specifically, AQD determined that because Viant Medical, Inc. chose average utilization factors and average emissions to calculate PTE, it was not acceptable. PTE should be based on the maximum possible emissions based on a 24 hour/day, 7 days/week, 365 days/year basis, not an average. On May 7, 2020 a new submittal and emissions spreadsheet was provided for review. The new methodology and emissions are based on the maximum utilization of each material used in each emission unit, not the average. This method is closer to the AQD expectations than using averages, however it still is a method that takes actual emissions and multiplies them to get annual emissions. This is not really how PTE is calculated typically, however there are some unique characteristics associated with the processes at Viant Medical, Inc., including the fact that they are calculating emissions based on purchase records and allocations. The emissions for the clean rooms that are identified as the emission units are very low, and all but one of the nine emission units have been determined by Viant Medical, Inc. as exempt per Rule 291. One emission unit has been determined by Viant Medical, Inc. to be exempt per Rule 290. Reported emissions are detailed below, and additional information can be found in the full submittal in the AQD files.

Facility Potential to Emit for VOC and HAPs reported by Viant Medical, Inc. are as follows:

Potential VOC Emissions, tons/year										
CR1 R291	CR2 R291	CR3 R291	CR5 R291	CR6 R291	CR7 R291	CR8 R290	Cuff Room R291	MCA R291	Lab Room R291	Facility Total VOC
2.76	3.60	1.66	0.846	0.647	0.168	6.17	2.02	2.30	0.055	20.23

Potential HAP Emissions, tons/year						
CR1	CR2	CR3	CR5	CR6	CR8	Facility Total HAP
0.0524	0.629	3.02E-05	4.53E-06	6.13E-06	0.1514	0.83

Total Facility-Wide PTE for Criteria Pollutants are reported as follows:

Potential Criteria Pollutant Emissions, tons/year							
Source Description	VOC	Total HAPs	CO	NOx	SO2	PM10	PM2.5
Manufacturing Emission Units (CR1-CR8, Cuff Room, MCA)	20.23	0.83	0.00	0.00	0.00	0.00	0.00
Space Heating Equipment	0.07	0.07	1.03	1.23	0.01	0.09	0.09
Emergency	3.80E-	3.80E-	8.18E-	3.80E-	2.51E-	2.20E-	2.20E-

Generators	04	04	05	04	05	03	03
Totals	20.30	0.90	1.03	1.23	0.01	0.10	0.10

COMPLIANCE SUMMARY

Based on the information obtained during the inspection, and the data submittals during the following months, Viant Medical, Inc. was in compliance at the time of the inspection.

NAME April Lazzaro DATE 07/01/2020 SUPERVISOR