

DEPARTMENT OF ENVIRONMENTAL QUALITY  
AIR QUALITY DIVISION  
ACTIVITY REPORT: Other

N510957768

<b>FACILITY:</b> Centurion Medical Products	<b>SRN / ID:</b> N5109
<b>LOCATION:</b> 301 Catrell Dr., HOWELL	<b>DISTRICT:</b> Lansing
<b>CITY:</b> HOWELL	<b>COUNTY:</b> LIVINGSTON
<b>CONTACT:</b> Andy Szakal , Regional EHS Specialist	<b>ACTIVITY DATE:</b> 03/25/2021
<b>STAFF:</b> April Lazzaro	<b>COMPLIANCE STATUS:</b> Compliance
<b>SOURCE CLASS:</b> SM OPT OUT	
<b>SUBJECT:</b> Purpose of this site visit was to determine appropriate locations to deploy summa canisters.	
<b>RESOLVED COMPLAINTS:</b>	

**Air Quality Division (AQD) staff April Lazzaro, Grand Rapids District Office inspector and Amy Robinson, Specialist with the Air Monitoring Unit arrived at the Centurion Medical Products (Centurion) facility at 9:00 AM for a scheduled site visit. We met with Rod Severn, Director of Manufacturing Operations, Ryan Sustic, Quality Control Manager and Andrew Szakal, Regional Environmental Health and Safety Specialist. Centurion is owned by Medline Industries, Inc. AQD staff Samantha Davis joined us virtually during the indoor portions of the site visit.**

**During the opening conference, AQD staff explained to Centurion staff that the purpose of the site visit was to identify the location of the ethylene oxide emitting sources at the facility so that sampling locations could be chosen purposefully. I informed Centurion that I would be taking photos so that AQD management could better understand the facility operations, and that I would provide them with a copy of all photos I took. We discussed that if there were any areas where confidential information was located, I would not photograph those areas. None of the areas where I took photos were identified during the site visit as areas containing confidential information.**

**Also, during the opening conference, I informed Centurion staff that while this was not a compliance inspection, if at any time a violation or concern was identified, it would immediately be discussed with those present.**

**Centurion manufactures medical products consisting of dressings, trays and single-use instruments in areas referred to as Building 1 & 2. Since these areas are not sources of ethylene oxide, they were not included in the site visit.**

**The area referred to as Building 3 is a large warehouse for storage. At times, small amounts of sterilized product may be housed in this area. We did not identify any sterilized product in the warehouse at the time of the site visit.**

**The area referred to as Building 4 contains the ethylene oxide sterilization process. Products spend time in the preconditioning room that is a certain temperature and moisture level to prepare products for the sterilization chamber. Centurion operates three (3) independent ethylene oxide sterilization units. Emissions from the sterilization chamber are routed to a thermal oxidizer. Emissions from the sterilization chamber exhaust vent (also known as the back vent) are routed to a dry bed scrubber.**

**Following the sterilization process, the pallets of packaged products are wheeled across a hallway into the aeration room. In the aeration room, the products are housed for a certain length of time where additional ethylene oxide emissions are captured and routed to the dry bed scrubber. A minimum of 24 hours is used for all**

products in the aeration room. A pressure drop gauge is located in the product corridor that measures the differential pressure between the corridor and the aeration room. The reading at the time of the site visit was -0.02" H<sub>2</sub>O.

Following the time in the aeration chamber, the finished product is typically moved directly into the bed of a freight truck by use of a forklift. However, if the product cycle finishes during the night shift, product will sit in the shipping and receiving dock until the morning when the day shift arrives and can load the product into the freight truck. While there are 5 loading dock doors at the facility, only the two middle doors are used for receipt of incoming supplies and then storage of outgoing sterilized product. The outgoing sterilized product is driven to the distribution center owned by Medline located in Romulus, Michigan. An online search indicated the distribution center is located at 36445 Van Born Rd, Romulus MI, 48174. Finally, one bay is used for "on time" type shipping of products that might be a small order of product that is needed quickly, and the remaining loading dock is not in use.

Building 5 contains warehouse space as well as the print department. At times, small amounts of sterilized product may be housed in this area. We did not identify any sterilized product in the warehouse at the time of the site visit.

The site visit included outdoor observations as well. The purpose of the outdoor observations was to determine if any air handling units or ventilation system exhaust ports are located at the facility. The identification of these is important in the development of the proposed initial phase of summa canister monitoring that the AQD will conduct at the facility to determine ambient concentrations of ethylene oxide.

Observations on the exterior of the building identified some wall fans were present. However, each fan was then observed from the inside of the building and found to be rendered inoperable by the placement of a sheet of wood covering the exhaust point.

While we were outside, I noted three small pipes exiting out the back of Building 4 that houses the sterilization chambers. One of these pipes was ejecting steam, and I asked what it was. I was told that these three pipes eject steam that is "non-contact" and does not originate from inside the sterilization chamber.

I asked about roof access, to determine if any general ventilation systems existed that could vent fugitive ethylene oxide emissions from the facility. I was informed that there is no way to access the roof without a ladder or a lift. To compensate for not being able to access the roof, we learned that the thermal oxidizer was not scheduled to ignite for a couple more hours, so we climbed the side of it to access the observation deck of the unit.

From the vantage point on the thermal oxidizer observation deck, most of the facility roofs were visible. I did not note any functional air handling units. I did however notice a large brown tarp was present on the ductwork that transferred ethylene oxide from the chamber exhaust vents (back vents) to the dry bed scrubber. Since the maintenance manager was out of state, no Centurion staff knew what the purpose was for the tarp. The maintenance manager was contacted, and he stated that the insulation on the exterior of the duct work had deteriorated and lead to a water leak into the building between the ductwork and the fascia. Since I could not

access the roof, further investigation was not possible. I also noted an area that appeared to be a possible gap in the ductwork, as well as some discoloration and possible corrosion in various locations. These items were all discussed with Centurion as a concern the moment they were identified.

Ms. Robinson conducted her external site assessment with the purpose of developing the AQD ethylene oxide summa canister sampling plan. We learned that there was a fence at the back of the property which would allow for canister security since they are often chained in place to eliminate tampering. Additionally, to eliminate interference, Centurion stated that they will eliminate all employee parking at the back of the facility on the day of the sampling. Occasionally, the neighbors conduct open burning. If open burning is to occur during sampling, Centurion staff will notify the AQD immediately.

All of the photos that were taken during the site visit will accompany this report on a CD.

During the site visit, we observed and briefly discussed the in-plant gas chromatography monitoring system that is in place to monitor levels of ethylene oxide in the facility for worker safety. The facility has 8 sample locations in the facility, and the equipment is a Smart Max II Gas Alarm System, with a TIF 8800 combustible gas monitor. It is equipped with a SRI 8610C gas chromatograph that measures the gas concentrations in parts per million. The unit is calibrated daily per manufacturers instructions. It was noted (and photographed) that some of the sample orifice/filters were very dirty. The specific filter replacement schedule for the units was unknown. Each of the in-plant monitors were reading 0.0000 ppm ethylene oxide at the time of the site visit. A schematic indicating the location of the monitors was provided to AQD following the site visit.

During the exit conference, we went over the concerns noted regarding the tarp over the duct work and I informed Centurion that the AQD would likely ask for additional information. Ms. Robinson indicated that she would notify the facility ahead of time of the dates of sampling, but that it would be within the next week or two.

NAME April Lazzaro DATE 04/22/2021 SUPERVISOR B.M.