DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION
ACTIVITY REPORT: Scheduled Inspection

N079545206

FACILITY: MedPlast 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:** 07/05/2018
STAFF: April Lazzaro	**COMPLIANCE STATUS:** Non Compliance	**SOURCE CLASS:** MINOR
SUBJECT: Unannounced, scheduled inspection.		
RESOLVED COMPLAINTS:		

Staff, April Lazzaro arrived at the facility to conduct an unannounced, scheduled inspection and 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 Permit to Install (PTI) No. 605-89B, and the National Emissions Standards for Hazardous Air Pollutants (NESHAP) 40 CFR Part 63 Subpart O for Ethylene Oxide Emissions Standards for Sterilization Facilities.

FACILITY DESCRIPTION

MedPlast Medical, Inc. is a global services provider to the medical device industry, and the Grand Rapids facility conducts sterilization of medical equipment using ethylene oxide (EtO). 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.

COMPLIANCE EVALUATION

Medical equipment that is packaged in gas permeable cardboard boxes and Tyvek packaging are loaded onto a pallet, and first placed in one of four pre-conditioning rooms. Here, the packaging is exposed to warm moist air that makes microbes and/or spores more permeable to the EtO. Following this, it is placed in one of the sterilization chambers. There are four 8-pallet chambers (A-D) and one cart sterilizer (E). The cart sterilizer is about 1/10th the size of an 8-pallet chamber. Once the pallets are loaded into the chamber and all the air is vacuumed out, a little bit of steam is added, and the chamber is flooded with EtO for an exposure time that varies between 1 and 6 hours. The EtO is kept circulating inside the chamber by fans to ensure distribution. At the end of the cycle time, nitrogen is pumped into the chamber to force out the EtO. All EtO from the sterilization chamber is vented to the scrubbers. Any EtO escaping from the back vent on each chamber is collected and sent through the scrubber system as well. After the sterilization chamber, the pallets are sent to one of the six aeration chambers which are heated to 110-120°F to encourage further removal of EtO from the pallets. All air flow from the aeration chambers is collected and ducted to the scrubber system which is detailed below.

MedPlast has devices to continuously monitor the concentration of EtO in the facility at the parts per million level. This information, along with the known general comfort ventilation fan speed is used to quantify fugitive emissions from the facility.

It is noted that one of the customers products requires a positive pressure cycle, instead of the typical negative pressure cycle. It was during this cycle in 2017 that an excess emissions incident occurred. This was reported pursuant to Rule 912 and the AQD sent a Violation Notice for exceeding the permit limit. Fugitive emissions need to be included in the annual Michigan Air Emissions Reporting System, which the company is currently doing.

MedPlast controls the emissions of EtO through the use of acid-water scrubber systems as detailed below. These scrubbers use sulfuric acid as a catalyst to covert ethylene oxide to ethylene glycol, which is then disposed of properly.

The small acid-water scrubber, also referred to as the Chemrox is located inside the building adjacent to sterilization chamber E. This system is set up to control sterilization chamber back vent exhaust only. The Chemrox exhaust is ducted directly to the large Deoxx scrubber with no bypass. Monitoring parameters for the Chemrox scrubber include measuring the temperature, pH, liquid level and the gallons of flow per minute. Flow at the time of the inspection was 24 gpm and the temperature was 72°F

which is within the appropriate range. All parameters are recorded per the scrubber Operation, Monitoring and Malfunction Plan for Scrubber Operations dated May 2005. Mr. Campbell and I discussed the need to review and possibly update the plan because it has not been done in 13 years. He agreed to go through and update where necessary and resubmit to the AQD.

The Deoxx scrubber (also referred to as Talos) is a large acid-water scrubber that is housed in a room on the southeast side of the facility. The system consists of a main tower flanked by two reactor tanks. The tower is filled with scrubber packing media. When the system reaches the maximum glycol percentage it is recharged by pumping the liquid from the system and replenishing it with new water and acid. Monitoring parameters for the Deoxx scrubber include measuring the temperature, pH, liquid level and the gallons of flow per minute, as well as water loss and packing monitoring. The pH was at 0.5 and the scrubber inlet pressure drop was 0.5" H_2O and the outlet pressure drop were at 0.1" H_2O at the time of the inspection. This is a difference from the 6" H_2O that it was at prior to the replacement of the packing. (the max range is listed as 8.0", so it was still compliant with the established parameters) The packing for this scrubber was replaced in July 2018, during a routine maintenance activity because the facility noticed that a mold was growing on it. The water level is monitored visually and recorded monthly. The system will shut down if the water level is low in the scrubber. The level was above the 95" mark (designated by white tape) and was currently at 100". The flow was currently at 660 gpm and the temperature was 100°F. Due to the acid environment, the pumps and gauges have some noticeable matter accumulation at the connections. Mr. Campbell indicated that the pumps and gages are going to be replaced within the next two years.

During the pre-inspection file review, it was noted that during the addition of chamber E, the Environmental Protection Agency (EPA) was consulted on the matter of defining new construction of the affected unit and testing. This consultation took place in July 2004. EPA staff stated that it would not be considered "construction or reconstruction", but because the source operating conditions have changed, the prior stack testing was no longer representative of operations. EPA stated that new testing needed to be conducted and the facility should re-establish scrubber operating limits for the continuous parameter monitoring because the previous test may no longer demonstrate compliance. This information was discussed with Mr. Campbell, because I was unable to find evidence that testing was conducted as required. AQD staff involved in the discussion with EPA was unable to recall how the issue was addressed in 2005. Mr. Campbell provided an e-mail that the company sent internally that summarized a meeting with AQD staff that occurred on November 15th, 2004. The email indicates that DEQ agreed that additional testing would not be warranted, if the EtO from the 5 chambers stayed below 412 lbs and below the 3,500 cycles per year they would not exceed any permit limits. While this information may be true, it does not have any bearing as to whether or not NESHAP Subpart O requires testing after an operational change. It does appear as though the EPA was correct, and the NESHAP does require testing following a change, including the addition of a new sterilization chamber as stated in 40 CFR 63.363(a)(2). As such, MedPlast Medical, Inc. Grand Rapids facility shall conduct stack testing of the system prior to November 30, 2018 to demonstrate compliance with the permitted emission limit, and to establish new operational parameters.

A facility evaluation was conducted on emissions of EtO as they relate to permitting of Hazardous Air Pollutants (HAPS) and the major source thresholds of 10 tons of any single HAP emitted. MedPlast utilized 55 tons of EtO at the facility in 2017 which were in large part controlled by the scrubber system as described above. The permit provides limitations, but they are not legally enforceable conditions to limit the potential to emit of this facility pursuant to Rule 336.1205. MedPlast will be asked to provide Potential to Emit calculations and consider facility-wide limitations. The Potential to Emit calculations should include any emissions from the adjacent plant as one stationary source.

PTI No. 605-89B contains emission limits of 2.0 pounds per hour (pph) and 0.9 tons per 12-month rolling time period as determined at the end of the month for EtO emissions from the scrubber stack. Initial compliance testing demonstrated compliance with the 2.0 pph emission limit. Mr. Campbell provided documents that demonstrate compliance with the 12-month rolling emission limit. Emissions of EtO from the stack and fugitive combined for the 12-month rolling time frame ending in June 2018 were 0.59 tons.

Material usage of EtO is limited to not more than 360,500 pounds of EtO per 12-month rolling time period. The 12-month rolling usage for the period ending in June 2018 was 106,619 pounds of EtO.

The malfunction abatement plan will be updated as indicated above, but overall is a thorough and lengthy document that covers all aspects of the requirements.

The permit states that the permittee shall not operate any sterilizer or aeration operations associated with the sterilizers unless the acid-water scrubber is installed, maintained and operated in a satisfactory manner. Satisfactory manner is defined as a combined minimum capture and destruction efficiency of 99.5% by weight for EtO. Based on the known EtO use, the amount of fugitive emissions and the destruction efficiency of the scrubber system the overall control efficiency was able to be calculated. In 2017, the highest overall control efficiency achieved was 99.43% and the lowest overall control efficiency achieved was 97.38%. The facility does not meet the required overall control efficiency which is a violation of PTI No. 605-89B, Special Condition No. 1.5. A Violation Notice will be issued.

The Ethylene Oxide NESHAP also requires that the source reduce ethylene oxide emissions to the atmosphere by at least 99% from each sterilization chamber vent; and a maximum concentration of 1 ppmv or by at least 99%, whichever is less stringent from each aeration room vent. During seven months in 2017, MedPlast Medical, Inc. failed to achieve a 99% reduction of ethylene oxide. This is a violation of 40 CFR 63.362. A Violation Notice will be issued.

In addition to the NESHAP requirement for stack testing due to the new chamber installed in 2005, the permit states that verification of EtO emission rates from the EU-ETOSTERILIZERS, and the control efficiency (combined capture and destruction efficiencies) of the acid water scrubber system, by testing at owner's expense, in accordance with Department requirements, may be required. As such, the AQD is requesting verification of EtO emission rates, including capture and destruction efficiencies of the sterilizing chambers. As indicated, above the MedPlast Medical, Inc. Grand Rapids facility shall conduct stack testing of the system prior to November 30, 2018 to demonstrate compliance with the permitted emission limit, and to establish new operational parameters.

The permittee is keeping recordkeeping for EU-ETOSTERILIZERS as required by the permit and emissions information was being maintained on site and is attached.

The stack was not measured however, Mr. Campbell indicated no changes have been made.

SUMMARY

Based on observations made during the inspection, and a review of records received, MedPlast Medical, Inc. was in non-compliance at the time of the inspection. A Violation Notice will be issued.

NAME  DATE 8-6-18 SUPERVISOR