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

N510926401

FACILITY: Centurion Medical Products		SRN / ID: N5109
LOCATION: 301 Catrell Dr., HOWELL		DISTRICT: Lansing
CITY: HOWELL		COUNTY: LIVINGSTON
CONTACT: Duane Rayl , EHS Engineer		ACTIVITY DATE: 08/13/2014
STAFF: Daniel McGeen	COMPLIANCE STATUS: Compliance	SOURCE CLASS: MINOR
SUBJECT: Scheduled inspection.		
RESOLVED COMPLAINTS:		

On 8/13/2014, the Department of Environmental Quality (DEQ), Air Quality Division (AQD), conducted a scheduled inspection of Centurion Medical Products.

Environmental contacts:

Duane Rayl, EHS Engineer; 517-546-5400, ext. 1365; drayl@centurionmp.com

Rod Woosley, Sterilization Manager; 517-292-8201; rwoosley@centurionmp.com

Summary of plant operations:

Centurion assembles and packages custom procedural packs, which are ready-to-use kits containing medical supplies, made to order for medical facilities across the nation. The assembled kits are sterilized by the use of ethylene oxide (EO) gas, before they are ready to be shipped.

Regulatory Applicability:

This facility has a Permit to Install, No. 24-94, for their EO sterilizers. Because they have control devices for their sterilizer processes, the facility's potential to emit of hazardous air pollutants (HAPs) is less than 10 tons per year, making them a minor source for HAPs. Therefore, they are not required to obtain a Renewable Operating Permit. However, this facility is subject to the National Emissions Standards for Hazardous Air Pollutants (NESHAP) 40 CFR Part 63, Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities. This regulation is also known as the Ethylene Oxide MACT (Maximum Achievable Control Technology Standards). Under the MACT, they are classified as an area source, rather than a major source. They fall into a MACT category of sources which use more than 10 TPY of ethylene oxide, though what they actually emit is less than 10 TPY.

Emission units:

Emission unit ID	Emission unit description	Control device required by Permit to Install No. 24-94	Control requirements under 40 CFR 63, Subpart O for source using more than 10 tons of ethylene oxide per year	Compliance status
EU-1-SCV	Three 666 cubic feet Vacudyne ethylene oxide sterilizers, which exhaust through sterilization chamber vent (SCV)	John Zink thermal oxidizing flare*, natural gas-fired	99% emission reduction	Compliance
EU-2-CEV	Chamber exhaust vent (CEV) or backvent emissions from the three ethylene oxide sterilizers	DR490 Advanced Air Technologies Dry Bed Scrubber	No control	Compliance
EU-1-ARV	Aeration Room Vent (ARV) emissions from off-gassing of sterilized products	DR490 Advanced Air technologies Dry Bed Scrubber	1 ppm maximum outlet concentration of ethylene oxide, or 99% minimum emission reduction, whichever is less strict	Compliance

***Centurion staff have expressed concern that use of the term "flare" is not technically accurate, and may be misleading.**

MAERS and fee status:

This facility submits an annual Michigan Air Emissions Reporting System (MAERS) report each year. They are classified as a Category III facility, because of the EO sterilizer, and pay a Category III fee each year. Their MAERS report for 2012 contains a document summaring their facility emissions for 2012, which is attached for reference.

Location:

This facility is located in an industrial area, within the City of Howell. To the northwest is a factory, and to the north and northeast are commercial or industrial facilities. Railroad tracks are to the south. To the southwest is a recycling facility. South of that are commercial establishments, along Grand River Avenue. Immediately east of the plant is a residential area.

Recent history:

In 2009, this facility applied to revise their PTI No. 24-94, to remove what was believed, at the time, to be an unnecessary control device for the chamber exhaust vent. Ultimately, they decided not to revise the PTI, because it was discovered that there was an error in the modeling their consultant had prepared, and the control device (the DR490 Advanced Air Dry Bed Scrubber) was needed, after all.

An e-mail from Ms. Virgina Galinsky of the U.S. Environmental Protection Agency (EPA) Region V to AQD, dated 7/29/2013, expressed concern over what appeared on the surface to be exceedances of the 1 ppm ethylene oxide (EO) gas limit for aeration room vent emissions. Ms. Galinsky had been reviewing recordkeeping which Centurion Medical staff had supplied her, to fulfill an EPA. AQD staff reviewed Subpart O, and determined that the source is allowed to comply with either the 1 ppm emission limit, or an emission reduction requirement of 99%, minimum, whichever was less strict. Past emission testing, on 6/4/2001, had shown the emission reduction efficiency to be 99.95%.

Arrival:

As I approached the facility just before 9;00 AM, I could not see any visible emissions from the facility, nor detect any odors. Weather conditions were sunny, moderately humid, and 61 degrees F, with winds about 10 miles per hour out of the west northwest.

The time and date for this inspection were arranged in advance, as Centurion Medical's environmental staff are headquartered in Williamston, and needed to travel out to the site. Upon arrival, I met with their main environmental contact, Mr. Duane Rayl, EHS Engineer, as well as Mr. Rod Severn, Plant Manager, Mr. Ron Woosley, Sterilization Manager. These three individuals comprise the facility's Sterilization Team. I was also met by Mr. Kelley Kuehne, engineer, who was the previous environmental contact. He did not attend the meeting or the inspection, but indicated he would be able to join us at any time, if needed. I provided a copy of the DEQ brochure *Environmental Inspections: Rights and Responsibilities*.

Pre-inspection meeting:

We discussed the eight instances identified by Ms. Galinsky, of what had initially appeared to be 1 ppm exceedances for the aeration room vent (ARV), following control by the DR490 Dry Bed Scrubber. Subpart O allows for a facility to comply with either the 1 ppm EO limit, or 99% minimum emission reduction efficiency, whichever is less stringent. Centurion Medical staff explained that they do not believe the ARV ever exceeded 1 ppm, because the emissions which were measured were for the combined exhaust stream from the ARV and the chamber exhaust vent (CEV) stream, which has no emission limit set under the NESHAP.

Centurion Medical staff check the gas chromatograph (GC) emissions data after a day has completed. If a reading meets or exceeds 0.8 ppm, they review when back venting of the CEV was done, in relation to the ARV. The concentration of gas in the back vent and also in the ARV is then determined, to see what amount each contributed to the reading of 0.8 ppm or greater. The average concentration of EO gas in the CEV prior to back venting is about 85 ppm. This average is shown on an attached CEV testing document they provided. It was prepared for them by their consultant, Atlantic Environmental. Another

attached document shows a post scrubber reading of 1.2453089 ppm, on 3/8/2013. Of this, they determined that the ARV contribution was 0.6 ppm, well below the 1 ppm limit in Subpart O.

I indicated that because 13 years have passed since the Dry Bed Scrubber was last stack tested in 2001, AQD would like to encourage them to do a new stack test on the unit. They explained that this would be somewhat expensive, but they would do it, if required. They felt that their 2001 stack test should still be valid, because it was conducted under more of a maximum emissions scenario. Ordinarily, they run with about 420 milligrams of EO in the sterilizer chambers. However, during the stack test, they ran with considerably more than that. They could not recall the exact amount offhand, and suggested I check the stack test report which the AQD has on file for the 8/17/1999 testing.

Note: after the inspection, I reviewed the 1999 stack test report by NTH. The executive summary shows that during three test runs, with their three sterilization chambers each being used in one run apiece, the EO concentration in the chambers was:

Chamber G: 853 ppm

Chamber C: 1,775 ppm

Chamber D: 1,024 ppm

However, the above data is in ppm, not in milligrams, and I was unable to locate a chamber ETO value in milligrams in the test report, or its supporting data. The destruction efficiency from the test was rated as 99.985%.

They explained that they also run the John Zink Thermal Oxidizer unit at a temperature considerably higher than the minimum. The flare baseline temperature during its 1999 stack test was 1,185 degrees F, identified in the stack test report.. Per my request, they gave me a copy of a circular strip chart from a representative recent date, 8/11/2014 (attached for reference). It shows the operating temperature to be over 1,400 degrees F, when the unit is running.

Inspection:

Their EO is stored in the form of drums. Each 300 lb drum contains 400 lbs of liquid EO. The drums are placed on a scale to be weighed. Taking the weight of the EO is the first method of measurement they use to verify that they are using the correct amount of the gas, whenever they operate a sterilizer. The second method is verifying the pressure within a sterilizer chamber, and they raise the chamber pressure from 11.5 to 19 inches of mercury. There are two scales for weighing drums. Both were most recently calibrated on 7/23/2014, and are due to be calibrated again on 1/23/2015.

To help explain the sterilization process, I was provided with a flow chart (attached for reference). There are three main steps to the sterilization process:

1.) Medical kits to be sterilized are first placed in the preconditioning room, where they use temperature and humidity control to put any microoganisms into an active state, so they are more vulnerable when they are exposed to EO. The preconditioning is not regulated by the MACT.

2.) Products next leave the preconditioning room, and are placed into one of the three EO chambers, C, D, or G. Only one chamber can vent to the thermal oxidizer at a time. Up to 6 pallets of products can go into a given chamber. EO gas is then introduced into the chamber. Different products need to be treated for different amounts of time. The EO is then removed via the SCV, and goes to the thermal oxidizer, to be combusted. The thermal oxidizer must be up a required minimum temperature before EO gas can be routed to it, and it signals when it is ready to operate.

3.) The third step is the aeration process. Because plastic can adsorb EO gas, the sterilized products must off-gas for the proper amount of time, in an Aeration Room. The time needed for aeration differs, depending on the kinds of products which have just been sterilized. 24 hours is the shortest aeration

time required for any of their products. The Aeration Room has a single Aeration Room Vent (ARV) which exhausts to the DR490 scrubber it shares with the backdraft vents to the sterilization chambers. Centurion staff check their products for any residual traces of EO, which is an ISO requirement.

Note: when sterilized products are moved from the sterilization chambers to the Aeration Room, the product transportation corridor between them is vented to the ARV, which is controlled by the dry bed scrubber. The Aeration Room runs constantly. It has its own pressure drop gauge, although this is not a permit requirement.

The three sterilization chambers, C, D, and G, are housed in the sterilizer room. They typically operate 2 shifts, and use each chamber during a shift for 6 loads per day. Sterilization within the chambers takes place at varying levels of negative pressure, or vacuum. Nitrogen is injected into the chamber to purge any remaining air, and steam is added to reach a desired humidity. EO gas is injected into the chamber, followed by a blanket of nitrogen. This is to ensure that no air is in the chamber, as EO gas is highly flammable. This phase is known as the exposure phase.

Near the end of the exposure phase, the chamber receives a signal from the thermal oxidizer that it is ready to receive the gas stream of EO and nitrogen via the SCV. The sterilant gas stream is evacuated to the thermal oxidizer, and the chamber is subjected to a series of nitrogen washes and air washes. Only one chamber at a time exhausts to the oxidizer.

After the evacuation of EO and nitrogen from a chamber, the chamber door can be opened.
This activates a chamber back vent, called a backdraft vent in the PTI, which protects employees by drawing any residual EO out through the CEV, and to the DR490 dry bed scrubber. The MACT once required the CEV to be controlled, but the requirement for control was removed from the MACT in the late 1990s. The PTI requires this control, however.

The plant used 17 tons of EO gas last year. Onsite, they store well below an OSHA threshold of 5,000 lbs of EO gas. The most they have actually stored was 3,200 lbs.

The Aeration Room, where products are allowed to offgas, had a pressure drop of -0.01", water column (w,c,), Emissions are routed to the DR490 Dry Bed Scrubber. It is always running, I was informed. Three beds in the unit act as one complete stage. It was explained that the unit can last from four months, to a year, before the scrubber media must be replaced. There were no visble emissions from the scrubber exhaust stack.

They have recently installed a new gas chromatograph (GC) to be a primary data source for the DR490 Dry Bed Scrubber emissions, while the original GC will serve as backup. The new unit is an SRI 8610C, while the original is a series 8900 unit. A check is made to ensure proper operation each morning, I was told.

The John Zinc Thermal Oxidizer unit was not running, at the moment. There were no visible emissions from its exhaust stack. As mentioned earlier in this report, I was given a copy of a circular strip chart reading, attached for reference, which shows operating temperatures of over 1,400 degrees F, when the unit is used. The temperature scale on the unit is in units of 10, so the apprent values must be multiplied by 10, i.e. 140 X 10 = 1,400 degrees F. The flare has a thermocouple, which is calibrated every 6 months, I was informed.

Sterilization chamber data was as follows:

Chamber G vaporizer temperature: 155 degrees F

Calibrated 7/24/2014, due 1/24/2015

Chamber C vaporizer temperature: 164 degrees F

Calibrated 7/24/2014, due 1/22/2015

Chamber D vaporizer temperature 163 degrees F

Calibrated 7/21/2014, due 1/21/2015

At the plant, they do various daily, monthly, quarterly, semi-annual, and annual inspections, I was told.

A review of the facility's most recent semi-annual emissions report, submitted on 7/11/2014, pursuant to the MACT, shows that there were no violations from 1/1 through 6/30/2014.

Conclusion:

Facility staff were very knowledgeable. The plant was clean, neat, and well organized. It appeared to be in compliance with PTI No. 24-94, and with 40 CFR Part 63, Subpart O, at the time of the inspection. AQD will consider if it is necessary to pursue a new stack test for the DR490 Dry Bed Scrubber.

NAME _____ DATE 9/18/2014 SUPERVISOR M. McCann

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