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

N510946834

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| **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:** 11/01/2018 |
| **STAFF:** Samantha Braman | **COMPLIANCE STATUS:** Compliance | **SOURCE CLASS:** SM OPT OUT |
| **SUBJECT:** Unannounced, scheduled inspection for compliance with PTI 24-94B. | | |
| **RESOLVED COMPLAINTS:** | | |

**Facility Contacts**:
Duane Rayl, EHS Engineer; 517-546-5400, ext. 1365; drayl@centurionmp.com
Ron Woosley, Sterilization Manager; 517-292-8201; rwoosley@centurionmp.com
Rod Severn, 517-552-7601, rsevern@centurionmp.com

**MDEQ AQD Personnel:**
Samantha Braman, 517-282-1373, bramans1@michigan.gov
April Lazzaro, 616-558-1092, lazzaroa@michigan.gov

**Facility Description:**
This facility was named Tri-State Hospital Supply Corporation but was changed in 2007/8 to align the name with its main products. Currently, the facility produces packaged surgical kits, IV start kits, IV see through breathable bandages, and individual bandages which are then sterilized using Ethylene Oxide (EtO, CAS 75218) for the medical field. The kits are sterile until opened and sold to hospitals and medical facilities.

The facility is located in a small industrial area in the city of Howell. Thompson Lake is located less than 0.25 miles to the north and to the north and east of the facility are residential areas. Centurion employs approx. 145 individuals and operates 24 hours per day Monday-Friday with an occasional Saturday and rarely Sundays. No safety equipment is required for inspection purposes; to enter sterile environments, donning of sterile suits is required.

**Applicable Regulations:**
-PTI 24-94B for 3 Vacudyne EtO Sterilizers, 666 cubic feet each
-40CFR63 Subpart O- Ethylene Oxide Emissions Standards for Sterilization Facilities
DEQ received delegation for Part O in 2004 and in 2014
-R336.1291 for EU-LABELPRINT
-R336.1286(2)(f) for EU-SHRINKWRAP

**Permit Discussion**
PTI 24-94 was issued on 3/30/94 and Subpart O was promulgated 12/6/94. A change in Subpart O required control to be applied to the Aeriation Room Vent (ARV) and the Chamber Exhaust Vent (CEV). Tri-State Hospital Supply Corporation thus installed dry bed scrubbers to control the ARV and the CEV's. On 6/4/01, Tri-State Hospital Supply Corporation performed a stack test that was observed by MDEQ AQD on the emissions from the dry bed scrubbers. The installation of the scrubbers, covered under a PTI exemption and therefore, was not incorporated into a PTI 24-94 at that time.

On 2009, Tri-State Hospital Supply Corporation submitted a PTI application in effort to amend the current permit and include Subpart O requirements and remove the scrubber control equipment on the CEV; this PTI application was numbered 24-94A. The PTI application 24-94A was later voided after it was found that control of the CEV was required.

Permit 24-94 was voided 8/17/2017 and Permit 24-94B was issued 6/1/2017 to address the concerns noted after the 2017 AQD inspection.
The following changes were made:
a. change "flare" to thermal oxidizer
b. denote that control is applied to all chamber exhaust vents

**Concerns Noted:**
1) April noted signs of thermal wear on the outside of the thermal oxidizer flare.
-recommend having an independent inspection done on the thermal oxidizer
2) Malfunction Abatement Plan for EtO Sterilizer is missing Sterilization Operator section as required in Permit 24-94B, SC 3.1.
-recommend revising to include a "Responsibility" section and send revised MAP to AQD. *(Has now been received as of 12/10/18)*
3) Initial stack test completed in 2001.
-Condition in PTI 24-94B gives AQD the ability to request testing in the future.

**Previous Inspections:**
8/13/2014- Dan McGeen, no concerns noted
3/15/2013- Dan McGeen, no concerns noted
6/2/2011- Brad Myott, no concerns noted
4/5/2017- Nathan Hude, concerns noted and addressed with permit revision in August 2017.

**Previous Violations:**
None found on record

**Recent Complaints (within 2 years):**
None found on record

**Number of Violations Found During this Inspection:**
None

**MAERS Reporting**
Category III facility

Although the PTE of the facility is greater than 10 tons per year (tpy) EtO, restrictions in the permit with control ensure emissions well under 10 tpy. The facility is classified as a Category III facility, subject to NESHAP Subpart O.

**MAERS Emission Unit List**
EUAERATION – An EtO aeration room and the associated product transfer corridor. The corridor is vented to the aeration room. The aeration room is controlled by a dry bed scrubber. Installed June 1997.
EUETOC – One (1) EtO sterilization chamber (C), manufactured by Vacudyne. The sterilization chamber vent is controlled by a Thermal Oxidizer. The chamber exhaust vent is controlled by a dry bed scrubber. Installed May 1994.
EUETOD – One (1) EtO sterilization chamber (D), manufactured by Vacudyne. The sterilization chamber vent is controlled by a Thermal Oxidizer. The chamber exhaust vent is controlled by a dry bed scrubber. Installed May 1994.
EUETOG – One (1) EtO sterilization chamber (G), manufactured by Vacudyne. The sterilization chamber vent is controlled by a Thermal Oxidizer. The chamber exhaust vent is controlled by a dry bed scrubber. Installed May 1994.

This facility has other exempt equipment. This includes the following:
EU-PACKAGE, exemption R336.1286(2)(d)
EU-SHRINKWRAP, exemption R336.1286(2)(f)
EU-EMERGEN, exemption R336.1285(2)(g)
EU-LABELPRINT, exemption R336.1291

**Inspection Summary**
This was a scheduled yet uncoordinated inspection. April Lazzaro and I arrived at the facility just before 9am on 11/1. I did not notice any visible emissions or odors while in the parking lot or while walking into the building. Duane greeted us shortly after arriving and we provided them with our business cards along with an explanation for our visit. We sat down in a conference room and discussed the inspection process. We walked through the entire facility.

A. Lazzaro and I left the facility at approximately 12:20pm.

EU-PACKAGE
This area has viewing windows of a sterile area where bandages and kits were packaged. The packaging was completed using packaging with adhesive already applied or by using heat to seal plastic. The kits contained various products such as a kit for starting IV's, the IV breathable bandage, etc. One package was created using plastic sheeting with a thermal press and vacuum to shape the plastic to desired specifications. This process is covered under permit exemption R336.1286(2)(d) and has no to very little air emissions which are released to the general in plant environment.

EUAERATION, EUETOC, EUETOD, EUETOG
Once the components are packaged, they are further taken to be sterilized which is covered under PTI 24-94B and Subpart O. The product is staged in a room called the "Pre-Conditioning Room". In the preconditioning room, the part is pre-treated for 18 hours in a temperature and moisture-controlled atmosphere. From there the product is loaded into one of the three sterilization chambers

The chamber is sealed and the EtO is injected; the product is surrounded and sanitized by the EtO. All the packaging is designed to allow air or EtO to enter and escape. EtO is very volatile with a boiling point of 51°F (point at which liquid turns to gas). The EtO is kept in the chamber by sealed pressure.

Once the EtO sterilizes the products, the EtO is vented using "nitrogen washes" to purge the EtO followed by "air washes" to purge the nitrogen through a vent called the Sterilization Chamber Vent (SCV) which is then routed to the "John Zinc thermal oxidizer" where the EtO is incinerated.

Once the purging and air washing is complete, the door is opened and the Chamber Exhaust Vent (CEV) is activated. This vent uses a fan to vent air to the dry scrubber system for 30 minutes to control any remaining EtO. After the venting, the product is then moved across the corridor to the Aeriation Room. This room and the corridor are under negative pressure where the exhaust is continuously vented to and treated by the same scrubber system as the CEV. The Aeriation Room Vent and the Chamber Exhaust Vent are controlled by the scrubber which is monitored by a Gas Chromatograph as required in the NESHAP.

Compliance Evaluation

Emission limits per PTI 24-94B are as follows:
Aeration room - controlled by dry bed scrubber:
- 0.044 lb/hr EtO
- 263 lb/yr EtO

Sterilization chambers - controlled by thermal oxidizer for sterilization chamber vents (SCV) and dry bed scrubber for chamber exhaust vents (CEV).
- SCV
  - 0.009 lb/hr EtO
  - 40.1 lb/ yr EtO
- CEV
  - 0.008 lb/hr EtO
  - 12 lb/yr EtO

The permit requires a minimum temperature of 1,185°F. The set point of the unit is currently 1,300°F. The company stated that they turn the unit on 10 minutes prior to the venting of the sterilization chamber to ensure it is up to temperature. A review of the temperature indicates that Centurion was in compliance with the permitted limit.

The company representatives informed us that they check and calibrate the temperature probe on the oxidizer, however they have not looked inside the unit in recent memory. April also noted that the constant heating and cooling of the unit could lead to acid attack. This information further leads AQD to believe that the interior of the unit may not be in good condition. A discussion ensued where Centurion indicated they would make an appointment with the manufacturer to conduct a full inspection. AQD requests that Centurion submit the report received from this maintenance activity upon receipt.

Monitoring/Recordkeeping & Applicable NESHAP Subpart O Requirements:

All records as required in Permit 24-94B were requested to be sent by email and were received on 11/06/18 as requested. Recordkeeping is discussed in more

As defined under paragraph 63.361, Centurion is a "Source using 10 tons" which is a source that uses 10 or more tons of EtO in any consecutive 12-month period after December 6, 1996.

**63.360(a)** states the regulation applies if the company uses more than 1 ton of EtO
**63.360(f)** requires Centurion to obtain a permit, PTI 24-94 satisfies this requirement
**63.360(g)(1)** requires existing sterilization chamber vents compliance by 12/6/98
**63.360(4)** requires existing aeration room vents compliance by 12/6/00
**63.362(a)** states Centurion must comply with Table 1
-As a source >10 ton, the Sterilization Chamber Vent must have an emission reduction of 99%
-As a source >10 ton, the Aeriation Room Vent must have an emission reduction of 99% or a maximum concentration of 1 ppm, whichever is less stringent from each aeriation vent.
-As a source >10 ton, the Chamber Exhaust Vent requires no control
**63.362(b)** states paragraphs c-d of section apply during sterilization operation and emission limitations do not apply during periods of malfunction.
*Compliance- Records were requested via email with a receive by date of 4/17/17 rather than onsite. The records were received on 11/06/18. Based on a stack test conducted on 8/17/99 the Sterilization Chamber Vent is controlled at 99.985% destruction efficiency.*
*The Aeriation Room Vent and the Chamber Exhaust Vent are controlled by the scrubber which is monitored by a Gas Chromatograph. 24hr average emissions for this vent were provided for the periods of 8/6/18-11/02/18 as requested indicating a maximum of 0.11ppm on 10/09/18 which is well below the 1ppm limit.*

**63.363(a)(1) – (b)(1)** requires the determination of control efficiency via testing
*Compliance with this requirement was completed during the 6/4/01 stack test*

**63.363(c)** has standards for determining initial compliance with the regulation for the Aeration Room Vent
*Compliance with this requirement was completed during the 6/4/01 stack test*

**63.363(e)** requires documentation to be submitted on the design and operation of the air pollution control system including recommendations for the parameters to be monitored to determine continuous compliance for any device other than acid water scrubbers or catalytic or thermal oxidizers.
*A thermal oxidizer is used for the SCV, yet a dry packed bed scrubber is used for the CEV control.*

**63.363(f)** states that the facility must demonstrate continuous compliance with limits and work practice standards except during periods of startup, shutdown, and malfunction.
**63.364 a)(1)** The owner or operator of a source subject to emissions standards in §63.362 shall comply with the monitoring requirements in §63.8 of subpart A of this part, according to the applicability in Table 1 of §63.360, and in this section.
**63.364(a)(2)** Each owner or operator of an ethylene oxide sterilization facility subject to these emissions standards shall monitor the parameters specified in this section. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.
**63.364(c)** For sterilization facilities complying with §63.363(b) or (c) through the use of catalytic oxidation or thermal oxidation, the owner or operator shall either comply with §63.364(e) or continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion chamber using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required only when the oxidation unit is operated. From 15-minute or shorter period temperature values, a data acquisition system for the temperature monitor shall compute and record a daily average oxidation temperature. Strip chart data shall be converted to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature.
**63.364(c)(4)** The owner or operator shall install, calibrate, operate, and maintain a temperature monitor accurate to within ±5.6 °C (±10 °F) to measure the oxidation temperature. The owner or operator shall verify the accuracy of the temperature monitor twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested. As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards).
*-The temperature calibration records were requested via email rather than onsite. The records were received on 11/06/18 for the period of 7/28/2017-7/23/2018 as requested and indicated that the testing is being completed*

*twice per year as required. The maximum temperature difference identified in these records was below the maximum allowable difference of 10°F.*
*- The daily thermal oxidizer temperature charts were received on 11/06/18 for the period of 10/23-31/18.*

**63.364(d)** For sterilization facilities complying with §63.363(b) or (c) through the use of a control device other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator shall monitor the parameters as approved by the Administrator using the methods and procedures in §63.365(g).
*Records were requested via email rather than onsite. The records were received on 11/06/18 and indicated that a plan was submitted and approved by AQD on 10/29/01. The plan has since been updated to reflect the requirements of PTI 24-94B.*
*Last dry bed scrubber media change was 7/27/18.*

**63.364(e)** Measure and record once per hour the ethylene oxide concentration at the outlet to the atmosphere after any control device according to the procedures specified in §63.365(c)(1). The owner or operator shall compute and record a 24-hour average daily. The owner or operator will install, calibrate, operate, and maintain a monitor consistent with the requirements of performance specification (PS) 8 or 9 in 40 CFR part 60, appendix B, to measure ethylene oxide. The daily calibration requirements of section 7.2 of PS-9 or Section 13.1 of PS-8 are required only on days when ethylene oxide emissions are vented to the control device.
*-Records were requested via email rather than onsite. The records received on 11/06/18 were for monthly GC (Gas Chromatograph) Calibration and were completed 8/31/18, 9/28/18, and 10/26/18. This form indicates the GC model as 8610C.*
*-A request for the daily calibrations was requested via email. The records were received the same day for 8/06/18-11/02/18 and show calibration using a mid-point gas as required by the performance specification. The sheet also includes daily maintenance checks on the device as well.*
*-A request for the hourly average GC readings was requested via email. The records were received the same day for 6/03-09/18.*
*-A request for the daily average GC readings was requested via email. The records were received the same day for 5/01/18-10/31/18.*

**63.365** Details test methods and procedures
*It appears these requirements were all fulfilled during the 8/17/99 test of the thermal oxidizer and the 6/4/01 test of the dry bed scrubbers.*

**63.366** Reporting Requirements
*It appears these requirements were all fulfilled with semiannual reporting; the most recent report received was 7/23/18.*

EU-LABELPRINT
In a separate area of the facility the company does flexographic printing where they print packaging for its products using printing presses and inks. There are 8 presses. They utilize water-based paints with low VOC. All the printing presses are vented internally.

For the ink emissions, Centurion is claiming the use of R336.1291, de minimis.

EU-SHRINKWRAP
The room containing EU-LABELPRINT also houses a machine used to shrink wrap products using plastic. The products are placed inside plastic sheeting and a heated sealer is used to cut and seal the plastic. Emissions from this process are captured via a hood and vented out the side of the building near the same area as the printer vent. After sealing, the product is sent through an oven that shrinks the plastic wrapper further, this furnace is not externally vented. The sealer is used for 1-3 hours per day, only during day shift. Based on the throughput of this device, the use of R336.1286(2)(f) is appropriate.

EU-EMERGEN
There is also an emergency generator located onsite. Centurion is considered an "Area" source for the purpose of engine federal regulations because although the facilities PTE is > 10tpy EtO, permit restriction keep facility below major source thresholds. This engine is exempt from permitting requirements as the estimated BTU output is 341,214 thus R336.1285 (2) (g) is fitting.

Rating: 100 kW
Fuel Type: Natural Gas (spark ignition)

Production Date of 10/6/2014
Model: SG0100GG189.0R18HPLYE
Serial: 9227289

MAERS:

A discussion was held with Centurion on MAERS reporting, including reporting fugitive emissions. It is important to quantify the fugitive emissions that are being vented out the floor sweep behind the drums, (in the "containment room"). The GC and some flow data can be used to calculate pounds of emissions.
GC monitors are also placed throughout the facility to monitor for employee safety.

DISCUSSION:

At the inspection we asked for the initial correspondence between DEQ and Centurion regarding installation and operation of the dry-bed scrubber. These letters took place from 1997 to late 2001; however, DEQ did not receive delegation over Subpart O until 2004 and then later again in 2014. Although, after reviewing these documents, the NESHAP and PTI 24-94B we have determined that PTI 24-94B does contain the requirements necessary to operate a device other than an acid-water scrubber as outlined in 63.363(e). As stated above 63.363(e)requires documentation to be submitted on the design and operation of the air pollution control system including recommendations for the parameters to be monitored to determine continuous compliance for any device other than acid water scrubbers of catalytic or thermal oxidizers. Appropriate documentation has been submitted and the permit requires a Malfunction Abatement Plan for the dry-bed scrubber which outlines the design and operation, and the permit also gives parameters to be monitored to determine continuous compliance.

Upon review of the daily average GC readings, they did not match up with Section 4.1 in Centurion's MAP, Preventative Maintenance. Section 4.1 states the dry-bed scrubber media will be replaced when the daily GC average readings are consistently exceeding 0.8ppm. The readings leading up to the last media change on 7/27/18 were not reflecting this parameter. The highest GC reading was 0.21ppm. I had a discussion with Duane Rayl and Ron Woosley on 12/21/18 to have them explain to me a little more about this. They informed me the 0.8 ppm parameter is in there to reflect their Arizona plant, as they often have higher ppm readings. I asked what parameters the Howell plant uses to know when to change the media. Duane and Ron said the replacement varies a little but is typically replaced once per year depending on various things such as number of cycles, moisture content and ppm. When the dry-bed media was replaced in July of 2018 it had been about a year since the last replacement. After learning this information, I asked if they could provide me with an updated MAP containing the parameters that the Howell facility used to replace the dry-bed scrubber media.
*UPDATE: Received a draft updated MAP for the dry-bed scrubber that outlines the parameters for which they change out the media on 12/21/18.*

Based on the review of this facility, it appears that Centurion Medical Products is in compliance with all state and federal rules and regulations. An updated Malfunction Abatement Plan (MAP) is also required for compliance with Permit 24-94B, SC 3.1.
*UPDATE: Received an updated MAP for the GC from Duane on 12/10/18 that meets the requirements of PTI 24-94B.*

Copies of all records or reports received are attached to the hard copy of this inspection report and will be filled in the Lansing District Office.

NAME Shannon Brennan DATE 1/3/19 SUPERVISOR B.M.