

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

D639445514

|  |                               |                           |
|--|-------------------------------|---------------------------|
| FACILITY: Mid Michigan Medical Center - Gratiot  |                               | SRN / ID: D6394           |
| LOCATION: 300 Warwick Dr, ALMA   |                               | DISTRICT: Lansing         |
| CITY: ALMA   |                               | COUNTY: GRATIOT           |
| CONTACT: Cecil Place , Facilities Supervisor   |                               | ACTIVITY DATE: 08/08/2018 |
| STAFF: Michelle Luplow   | COMPLIANCE STATUS: Compliance | SOURCE CLASS: MINOR       |
| SUBJECT: Scheduled, announced inspection to determine compliance with PTI 299-93 for an EtO sterilizer/abator system, in addition to informing facility contact of the change in EtO screening levels. |                               |                           |
| RESOLVED COMPLAINTS:   |                               |                           |

Inspected by: Michelle Luplow

Personnel Present: Cecil Place, Facilities Supervisor (cecil.place@midmichigan.org)  
Garett Bass, Biomedical Equipment Specialist III (garett.bass@midmichigan.org)

Pertinent Personnel (not onsite):

Steve Kuehne, Facility Operations Manager (steve.kuehne@midmichigan.org)

**Purpose:** Conduct an announced, scheduled compliance inspection by determining compliance with MidMichigan Medical Center's (MMC) Permit to Install (PTI) No. 299-93 for an EO sterilizer with abator system. The facility was inspected in December 2016.

EO sterilizers were also one of the FY17 inspection objectives because the screening levels on ethylene oxide have changed, becoming more stringent.

**Facility Background/Regulatory Overview:** MMC is a hospital. The permitted EO sterilizer is used for sterilizing medical equipment that can't be sterilized at or above 270°F (steam sterilization), such as cameras. EO sterilizers operate at lower temperatures than traditional sterilization equipment.

In addition to the EO sterilizer MMC also has 5 generators and 5 boilers onsite. See Tables 1 and 2 for the lists of generators and boilers. MMC is a true minor source of criteria air pollutants and HAPs.

**RICE MACT ZZZZ Emergency Engines at Area Source of HAP**

MMC has 5 emergency generators (see Table 1), 3 of which are existing emergency engines, according to the 40 Part 63 definition of "existing." Generators 3-5 are existing emergency compression ignition engines, but are not subject to the RICE MACT Subpart ZZZZ at area sources of HAP because these generators are considered "existing insti emergency stationary RICE," as they operate at a medical center.

The MDEQ Air Quality Division currently does not have the delegated authority to enforce the RICE MACT ZZZZ sources; however, a check was conducted to ensure that the engines were still operating/considered emergency per the following definition:

"Emergency engines" are defined as not being operated for more than 100 hours per calendar year for readiness testing and maintenance checks, and may be operated up to 50 hours per calendar year for non-emergency situations (the 50 hours is included in the aforementioned 100 hours per calendar year).

Based on operating hours recorded during the December 2016 inspection and the hours recorded during the current inspection, all 3 engines operated less than 50 hours during that ~2-year time period. Meeting both the maintenance/readiness testing and non-emergency operating hour limits.

MCC is required per their Utility Management Plan (via the Joint Commission under the Federal Center for Medicare/Medicaid) to test-run all their generators on a monthly basis for 1 hour each. Total hours operated for each engine included in Table 1.

C. Place had mentioned that Consumer's wanted MMC to use their generators during certain times of the year to the hospital to eliminate their pull on the grid via a financial incentive. I explained to C. Place via email, that if this contract with Consumer's will result in greater than 15 hours per year of usage, it can no longer be considered an

institutional emergency generator and will become subject to the area source RICE MACT Subpart ZZZZ. With this mind, MMC would be allowed to operate for up to 50 hours per calendar year for non-emergencies, as part of the financial arrangement with Consumer's, as long as they are only supplying power to the hospital itself. Operations greater than 50 hours per year would render the engine a non-emergency engine and would be subject to a separate RICE MACT Subpart ZZZZ requirements.

**NSPS for Compression Ignition Internal Combustion Engines, Subpart IIII**

The two 1500 HP engines are subject to NSPS Subpart IIII for emergency engines <30 l/cyl, model 2007 and later. Upon review of the regulation via EPA's NSPS quiz tool, MMC is subject to the following Subpart IIII sections: 40 CFR 60.4205(b), §60.4202; §60.4207(a), (b), (e); §60.4208(a), (b), (h), (i); §60.4209(a); §60.4211 (a), (c), (f), (g); §60.4206; §60.4214(b). The total cylinder displacement for each engine is 30.5 L, which N. Bovid calculated to be 2.54 L/cyl.

Emergency CI engines <30 l/cyl are required to demonstrate that the engines are certified to meet the emission limits in the NSPS and to maintain the engines via manufacturer's specifications. Based on the "South Coast Air Quality Management District Certified ICE-Emergency Generators list, both engines are NSPS-certified.

Certification of the engines is maintained by maintaining and operating the engines according to manufacturer's emission-related instructions. Attached are examples of inspection checklists from all 5 engines during the weekly checks (conducted by internal staff) and annual inspections conducted by W. W. Williams, who inspect, maintain and operate (for 4 hours) the engines annually. Future compliance will be determined concerning whether these inspections meet manufacturer's maintenance specifications.

Emergency status also must be maintained, similar to the RICE MACT Subpart ZZZZ emergency generator requirements, and considerations must be made on MCC's part by recognizing that if Consumer's has a contract for more than 50 hours per year of operation time on these engines, the generator will no longer be considered an emergency engine and will be subject to new regulations within the NSPS Subpart IIII. Currently the engines are operated as emergency engines: between December 2016 and the current inspection, these two engines were operated less than 45 hours per year each, meeting both the 50 hr non-emergency and 100 hr maintenance/readiness testing operating hour limits.

**Boiler MACT NESHAP Subpart JJJJJJ for area sources of HAPs**

All 5 boilers are exempt from the Boiler MACT NESHAP Subpart JJJJJJ because they are classified as "gas-fired boilers" as defined in 40 CFR 63.11237. To be considered a gas-fired boiler, the boiler must burn gaseous fuels not combined with any solid fuels and burn liquid fuel only during periods of gas curtailment, gas supply interruption, startups, or periodic testing on liquid fuel. The periodic testing of liquid fuel should not exceed a combined total of 48 hours during any calendar year.

On September 13, 2011 MMC (then Gratiot Medical Center) sent a notification to the AQD office for the NESHAP JJJJJJJ Boiler MACT indicating that they were subject to its regulations. However, based on my review of the Boiler MACT JJJJJJ, MMC would not be subject because the boilers meet the regulation's the exemption definition of a "gas-fired boiler."

**NSPS for Small Industrial-Commercial-Institutional Steam Generating Units Subparts Da, Db, Dc**

The 3 Keweenaw boilers are exempt from the NSPS Subparts Da, Db, and Dc because they are smaller than 10 MMBTU/hr. The two Cleaver-Brooks boilers are subject to NSPS subpart Dc because they are less than 100 MMBTU/hr, but greater than or equal to 10 MMBTU/hr, and have the capability of burning fuel oil. The NSPS Dc says that they must meet a 0.5 wt% sulfur content of the fuel oil as an alternative to SO2 emission limit testing. M. Evitts said in the 2015 inspection that the fuel oil sulfur content is 5 ppm (which is 0.005 wt%). Because MMC's fuel oil meets the 0.5 wt% sulfur content limit, it is not subject to the PM limit in NSPS Dc. MMC is subject to all applicable notification and recordkeeping requirements as specified in 40 CFR 60.48c.

**NESHAP Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities**

MMC is not subject to 40 CFR 63 Subpart O because the subpart does not apply to "ethylene oxide sterilization operations at stationary sources such as hospitals, doctors offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals." (40 CFR 63.360(e))

**Table 1. Emergency Generators**

| Engine | Serial # | HP/<br>kW | MMBtu/hr | Fuel | Hours<br>as of<br>8/8/18 | Permit<br>No | Installation<br>Date | Manufacture<br>Date | Federal<br>Regulation |
|--------|----------|-----------|----------|------|--------------------------|--------------|----------------------|---------------------|-----------------------|
|        |          |           |          |      |                          |              |                      |                     |                       |

|                                      |           |          |      |        |       |                        |        |        |   |
|--------------------------------------|-----------|----------|------|--------|-------|------------------------|--------|--------|---|
| Generator #1<br>Cummins QST30-G5     | 37228493  | 1500/800 | 7.84 | Diesel | 357.7 | Exempt Rule 285(2) (g) | 9/2007 | 5/2007 | NSPS Subpart IIII (emergency, <30 L/ cylinder displacement)   |
| Generator #2<br>Cummins QST30-G5     | 37228519  | 1500/800 | 7.84 | Diesel | 363.3 | Exempt Rule 285(2) (g) | 9/2007 | 5/2007 | NSPS Subpart IIII (emergency, <30 L/ cylinder displacement)   |
| Generator #3<br>Cummins QSX15-G9 NR2 | 79017789  | 750/500  | 1.7  | Diesel | 463.2 | Exempt Rule 285(2) (g) | 5/2004 | 8/2003 | Existing Emergency engine, not subject to Area source RICE NESHAP ZZZZ – institutional emergency engine |
| Generator #4<br>Cummins 6BT5.9-G6    | 46329015  | 170/100  | 0.3  | Diesel | 414.0 | Exempt Rule 285(2) (g) | 1/2005 | 9/2003 | Existing Emergency engine, not subject to Area source RICE NESHAP ZZZZ – institutional emergency engine |
| Generator #5<br>Cummins WSG 1068     | 052539493 | 176/100  | 0.3  | Diesel | 373.7 | Exempt Rule 285(2) (g) | 5/2005 | 1/2005 | Existing Emergency engine, not subject to Area source RICE NESHAP ZZZZ – institutional emergency engine |

Table 2. Boilers

| Boiler  | Serial # | BTU/hr    | Fuel              | PTI No.           | Manufacture Date | Federal Regulation   |
|---------|----------|-----------|-------------------|-------------------|------------------|--|
| Kewanee | NB18256  | 6,840,000 | Sweet Natural Gas | Exempt R282(b)(i) | 1954             | Exempt from NSPS Da, Db, Dc; Exempt from Boiler MACT Subpart JJJJJJ (classified as “gas-fired boiler”) |
| Kewanee | NB18257  | 6,840,000 | Sweet Natural Gas | Exempt R282(b)(i) | 1954             | Exempt from NSPS Da, Db, Dc; Exempt from Boiler MACT Subpart JJJJJJ (classified as “gas-fired boiler”) |
| Kewanee | NB21134  | 6,840,000 | Sweet Natural Gas | Exempt R282(b)(i) | 1954             | Exempt from NSPS Da, Db, Dc and from Boiler MACT Subpart JJJJJJ (classified as “gas-fired boiler”)     |

|                                   |          |            |                                 |                    |      |  |
|-----------------------------------|----------|------------|---------------------------------|--------------------|------|--|
| Cleaver Brooks<br>CBI-200-250-150 | OL105029 | 10,206,000 | Sweet Natural Gas & Fuel Oil #2 | Exempt R282(b)(ii) | 2007 | NSPS Subpart Dc; Exempt from Boiler MACT Subpart JJJJJJ (classified as "gas-fired boiler") |
| Cleaver Brooks<br>CBI-200-250-150 | OL105830 | 10,206,000 | Sweet Natural Gas & Fuel Oil #2 | Exempt R282(b)(ii) | 2007 | NSPS Subpart Dc; Exempt from Boiler MACT Subpart JJJJJJ (classified as "gas-fired boiler") |

**Inspection:** This was an announced scheduled compliance inspection. At approximately 8:15 a.m. on August 8, 2018 I met with Cecil Place, MMC's Facilities Supervisor, who was serving as my point of contact while waiting for S. Kuehne to return at the end of August. (When arriving at the hospital, go to the front desk volunteer to call your contact directly to meet you in the lobby). I provided C. Place with a Boiler MACT outreach brochure and a January 2017 PTI Exemptions Handbook.

PTI No. 299-93 – 3M Steri-Vac Ethylene Oxide (EO) sterilizer with Donaldson catalytic abator

During the 2015 inspection Bob Francisco and I verified that the unit permitted in 1993 is the same unit that is currently present onsite, and I verified that the model and serial numbers for the sterilizer and the catalytic abator system were the same as they had been at the previous inspection: the sterilizer has top (Model 487AGP, Serial # 701517) and bottom aeration chambers. The catalytic abator (Donaldson-3M Model 4614893002, Serial # ETX006550) is a separate unit. Garret Bass said that it takes 12 hours for one batch of equipment to be sterilized, and it takes an additional 3 hours for the unit to treat the sterilizer gas within the abator system prior to exhausting to atmosphere. The abator converts EO to water vapor and CO<sub>2</sub>. One 100-g canister (100% EtO per SDS, attached) is used per batch of equipment to be sterilized. G. Bass, per the manufacturer's manual, said that the sterilizer operates at warm (132 F) and cool (99 F) cycles, and the abator exhaust at normal operating conditions is 460F, with the upper limit reaching to 500 F.

MMC is required to keep the monthly sterilant usage data for at least two years. Darsha Cole, Sterile Processing Supervisor, provided me with over a year's-worth of purchase order records (January 2017 – June 2018) to demonstrate that usage is being tracked (see attached). The purchase records show monthly purchases of sterilant and that each monthly purchase consists of a box of 12 EO canisters. D. Cole stated that they ran 133 load cycles during the 2017 calendar year, and between January and June 2018 ran a total of 40 load cycles.

MMC is also required to ensure that the catalytic abatement system on the sterilizer unit is installed and operating properly. 3M certifies that the abator system will achieve 99.9% efficiency if the catalytic bed is replaced every 3 years, based on 250 sterilization cycles per year. It is my professional judgment that proper maintenance of the abator system ensures proper operation, and therefore maintenance on the abator system was checked to determine compliance with the permit.

Between 1993 (permit issuance) and the 2015 inspection, MMC had not been operating their abator system properly, because the catalyst had never been replaced. In response to this finding, the catalyst was replaced on 4/21/2015. The next catalyst replacement was required by 4/21/2018 (3 years from the date of the previous catalyst change). G. Bass provided me records showing that the catalyst had been replaced by 3M on 4/25/18, and that the next scheduled catalyst replacement is planned for 4/1/2021. G. Bass explained that 3M offers testing of the abator exhaust in lieu of catalyst replacement, but he said that MMC has opted to replace the catalyst every 3 years.

G. Bass said that a 3M contractor also services the sterilizer unit semi-annually, in addition to replacing the abator filter (filters incoming air). Additionally, there are internal services that are also performed on the unit on a quarterly basis, which includes performing leak checks using their leak-check monitor. If there is a leak, an alarm sounds. Larry George, 3M's service technician for the EO unit, said that he replaces/inspects all hoses, fittings, etc.; however, he said they do not check to determine if the catalyst/abator portion of the unit is operating properly. Attached are service records for these activities.

A stack test is required, upon request by the AQD, to verify emission rates from the sterilizer/abator system, to ensure they meet the permitted 0.9 mg/m<sup>3</sup> limit. The AQD has never requested that a stack test for EO

emissions be conducted to determine the control efficiency of the catalytic abatement system thus the emission rate of EO from the stack, and at this time I see no need for MMC to test because they are maintaining the abator according to manufacturer's recommendations.

**Compliance Statement:** At this time MidMichigan Medical Center - Gratiot is in compliance with PTI 299-93.

NAME Michael M. Lopez DATE 8/22/18 SUPERVISOR [Signature]

