

## Puite, Tammie (EGLE)

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**From:** Lindgren, Jodi (EGLE)  
**Sent:** Tuesday, August 31, 2021 11:47 AM  
**To:** Puite, Tammie (EGLE)  
**Subject:** Fwd: Munson Medical Center Response to VN  
**Attachments:** Munson Medical - Response to VN-08-31-21.pdf; Munson - Air Permit Exemption Evaluation - 08-27-21.pdf

Jodi Lindgren  
Environmental Quality Analyst  
Air Quality Division / Cadillac District Office  
Michigan Department of Environment, Great Lakes, and Energy  
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**From:** Beatty, Tom <TBEATTY@mhc.net>  
**Sent:** Tuesday, August 31, 2021 11:14:36 AM  
**To:** Lindgren, Jodi (EGLE) <LindgrenJ2@michigan.gov>  
**Cc:** Nixon, Shane (EGLE) <NIXONS@michigan.gov>; Dolehanty, Mary Ann (EGLE) <DOLEHANTYM@michigan.gov>; Camilleri, Jenine (EGLE) <CamilleriJ@michigan.gov>; Ethridge, Christopher (EGLE) <ETHRIDGEC@michigan.gov>; Olaguer, Jay (EGLE) <OlaguerJ@michigan.gov>; Richardson, Robert <rrichardson@mhc.net>; Roe, Rachel <RROE02@mhc.net>; Mark Horne <mark.horne@enviro-partners.com>  
**Subject:** Munson Medical Center Response to VN

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Hi Jodi,

Please find our response to the Violation Notice. The original signed letter and exemption evaluation is being mailed to your attention at the Cadillac District Office, and a hard copy is being mailed to Jenine Camilleri in Lansing.

Thank you,

Tom Beatty, P.E.  
Sr. Mechanical / Electrical Engineer  
Munson Medical Center  
1105 Sixth St., Traverse City MI 49684  
Ph: 231-935-2499  
Cell: 231-649-8950

August 31, 2021

Jodi Lindgren  
Environmental Quality Analyst, Air Quality Division  
Michigan Department of Environment, Great Lakes, and Energy  
Cadillac District  
120 West Chapin Street  
Cadillac, MI 49601

Subject: Response to Violation Notice Dated August 10, 2021

Reference: Munson Medical Center  
1105 6<sup>th</sup> Street, Traverse City, MI 49684  
SRN: D5884

Dear Ms. Lindgren:

Munson Medical Center is in receipt of the Violation Notice issued by EGLE dated August 10, 2021. In reviewing the state and federal regulations that apply to this situation, it is our assessment that Munson Medical Center is exempt from the permitting requirements set forth in the Violation Notice, as further described in this letter.

Munson Medical Center installed its ethylene oxide sterilization unit and abator (EtO Sterilizer System) in December 2019. An EtO Sterilizer System requires either a Michigan Rule 201 air permit, or the EtO Sterilizer System must meet an exemption from the requirement to hold an air permit. Munson Medical Center has determined that it meets the requirements for an exemption under Rule 336.1291(2)(c) and is not excluded from exemption under Rule 336.1278.

On August 11, 2021 Munson Medical Center submitted an Initial Notification of Compliance Status (INOCs) for this system to EPA and EGLE. In the INOCs we certified that the sterilizer is equipped with an air pollution control device that is properly maintained and operated at all times the sterilizer process is in operation. Utilization of this highly efficient control device reduces the emissions of ethylene oxide to a level that qualifies the sterilization system for an exemption from the requirement for an air permit.

Enclosed is an Exemption Evaluation that has been prepared by Environmental Partners, Inc. in accordance with Rule 278a. The Exemption Evaluation addresses the elements of Rules 278, 278a, and 291. The Exemption Evaluation concludes that the EtO Sterilizer System at Munson Medical Center satisfies the requirements for an exemption under Rule 291(c), because potential emissions of ethylene oxide do not exceed 0.006 tons per year. Moreover, the EtO Sterilizer System does not fall under any of the activities that are excluded from exemption under Rule 278. Finally, this letter and its attachments meet the scope of permit exemptions set forth in Rule 278a. Therefore, Munson Medical Center's EtO Sterilizer System is exempt from the requirement to hold a Rule 201 permit to Install (PTI).

We will continue to operate under the exemption as described herein and will assume that the Violation Notice is resolved unless EGLE AQD advises us otherwise.

If there are any questions, please contact me at (231) 935-3704, or Tom Beatty, P.E., Mechanical/Electrical Engineer, Munson Medical Center, at (231) 935-2499.

Sincerely,  
MUNSON MEDICAL CENTER



Robert Richardson  
Vice President, Facilities

cc: Shane Nixon, Supervisor, Michigan EGLE Air Quality Division, Cadillac District  
Jenine Camilleri, Michigan EGLE Air Quality Division Enforcement Unit  
Mary Ann Dolehanty, Michigan EGLE Air Quality Division Director  
Christopher Ethridge, Michigan EGLE Air Quality Division Field Operations  
Eduardo Olaguer, EGLE Air Quality Division Assistant Director  
Tom Beatty, P.E., Munson Medical Center  
James Fegan, Munson Medical Center  
Mark Horne, P.E., Environmental Partners, Inc.



305 Hoover Blvd, Suite 200  
Holland, Michigan 49423

August 27, 2021

Tom Beatty, P.E.  
Sr. Mechanical/Electrical Engineer  
Munson Medical Center  
1105 Sixth Street  
Traverse City, Michigan 49684

Subject: Air Permitting Exemption Evaluation – Ethylene Oxide Sterilizer and Abator System

Dear Mr. Beatty:

As requested, Environmental Partners, Inc. has performed an air permitting and exemption evaluation for the Munson Medical Center (MMC) hospital facility located at 1105 Sixth Street, Traverse City, Michigan. The purpose of this evaluation is to determine whether the ethylene oxide sterilizer and abator system (EtO Sterilizer System) located at this facility require a Permit to Install pursuant to Rule 201 of the Michigan Air Pollution Control Rules, or whether this system is exempt from the requirement to obtain a Permit to Install under Rules 278 through 291. This evaluation also serves to satisfy the requirements of Michigan Rule 278a.

### **Description of the Ethylene Oxide Sterilizer and Abator**

Munson Medical Center installed an Andersen Products EO Gas 4 Sterilizer and Abator in December 2019. This system is used approximately 2 to 3 times per week to sterilize medical devices that cannot be subjected to conventional high temperature sterilization techniques. Items to be sterilized are placed in a 45 liter bag inside of the sterilization unit and processed for a period of 3.5 hours. The exhaust from the sterilization unit is directed through the abator where 99% of the ethylene oxide (EtO) is removed.

### **Applicable Rules**

#### **Federal Rules - NESHAP**

Sources that emit hazardous air pollutants (HAPs) are regulated under the National Emission Standards for Hazardous Air Pollutants (NESHAPs). A major HAP source is a stationary source that emits or has the potential to emit 10 tons per year (tpy) or more of any individual HAP, or 25 tpy or more of all HAPs combined. An area source is a stationary source that is not a major source. It is our understanding that Munson Medical Center (MMC) is an area source of HAPs.

40 CFR 63 Subpart O contains the Ethylene Oxide Emission Standards for Sterilization Facilities at major HAP sources. However, MMC is not a major HAP source. Further, under 40 CFR 63.360(e) of the applicability section of this standard it states, "This 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." Since MMC is not a major HAP source, and since hospitals are specifically excluded within this standard, we conclude that the requirements of 40 CFR 63 Subpart O do not apply to the EtO Sterilizer System at MMC.

As an area source of HAPs, the Area Source NESHAP 40 CFR 63 Subpart W National Emission Standards for Hospital Ethylene Oxide Sterilizers applies to the EtO Sterilizer System at MMC. All of the applicability criteria listed under 40 CFR 63.10382(a) are satisfied by the EtO Sterilizer System at MMC. The EtO Sterilizer System is considered a New Source since it was constructed after December 28, 2007.

Under this NESHAP, the EtO Sterilizer System must comply with each of the following:

- One of the three compliance options under 40 CFR 63.10400
- The management practices under 40 CFR 63.10390
- Submittal of an Initial Notification of Compliance Status (40 CFR 63.10430)

As part of the Initial Notice of Compliance Status submitted to EPA on 08/11/21, MMC certified that in accordance with 40 CFR 63.10400(c), the EtO Sterilizer System air pollution control device (APCD) is operated during all sterilization processes, and the APCD is operated in accordance with the manufacturer's recommended procedures. Please note that as described in the definitions under 40 CFR 63.10488, the reference to applicable state or local regulation under 40 CFR 63.10400(c) refers to control requirements rather than permitting requirements.

#### *Federal Enforceability and Potential to Emit*

Limitations on emissions through the use of an air pollution control device must be federally enforceable, as described in the definition of Potential to Emit (40 CFR 52.21(b)(4) under EPA's New Source Review provisions. Under the Clean Air Act, the EtO Sterilizer System at MMC is subject to the requirements of the 40 CFR 63 Subpart W Area Source NESHAP. In conformance with the compliance requirements of the NESHAP, MMC submitted a complete Initial Notice of Compliance Status in which they certified that during all sterilization processes the APCD is operated in accordance with manufacturer recommended practices. We conclude that this certification of compliance with a federally applicable NESHAP places a federally enforceable limitation on the potential emissions of the MMC EtO Sterilizer System.

State Rules – Rule 201 Permit to Install

Pursuant to Michigan Rule 201, a permit to install (PTI) must be obtained prior to the construction, installation or modification of any process or process equipment that emits or may emit any air pollutant regulated under Title I of the Clean Air Act, or any air contaminant as defined under the Michigan Air Pollution Control Rules. However, if the process meets the criteria of one or more of the applicable exemptions under Rules 280 through 291, and the use of that exemption is not excluded pursuant to Rule 278, the requirement to obtain a PTI does not apply.

Since the EtO Sterilizer System described above emits a regulated pollutant (ethylene oxide), the Rule 201 requirement to obtain a PTI may apply. Ethylene oxide is regulated as a VOC, HAP, and a Toxic Air Contaminant (TAC) in the State of Michigan. The Rule 291 “De Minimis” rule was reviewed to determine whether this exemption may apply to the EtO Sterilizer System. In addition, Rule 278 was reviewed to determine whether this system would be excluded from the use of an otherwise applicable exemption.

EtO Sterilizer System Potential Emissions

Based on manufacturer specifications, the EtO Sterilizer System uses 17.6 grams of ethylene oxide over a 3.5 hour time period for each sterilization cycle. Each sterilization cycle in the EtO Sterilizer System requires a minimum 3.5 hours, and the post control emissions of ethylene oxide are 0.17 grams over the sterilization period. Since 3.5 hours is the minimum sterilization cycle time period, it reflects the highest hourly emission rate.

Given that the minimum sterilization cycle time period is 3.5 hours, and the use of the air pollution control device is federally enforceable, the post control potential ethylene oxide emissions from the EtO Sterilizer System are as follows:

$$\frac{0.17 \text{ grams EtO}}{\text{cycle}} \times \frac{\text{lb}}{453.59 \text{ g}} \times \frac{\text{cycle}}{3.5 \text{ hours}} \times \frac{8760 \text{ hours}}{\text{year}} \times \frac{\text{ton}}{2000 \text{ lb}} = \frac{0.000469 \text{ tons EtO}}{\text{year}}$$

As shown above, the potential emissions of ethylene oxide from the EtO Sterilizer System are extremely low, and as a result Rule 291 was reviewed for potential applicability.

**Rule 291**

Michigan Rule 291 provides an exemption from the Rule 201 permitting requirements for an emission unit whose potential emissions of air contaminants meet one or more of the annual emission limitations specified under subdivisions (a) through (d) of Rule 291(2), and Table 23 of Rule 291(2). Each of these categories specifies screening level ranges and respective limits on annual potential air contaminant emissions. The Rule 291 air contaminant categories, screening levels, and corresponding potential emission limits are summarized below:

<b>Rule Citation Category</b>	<b>Screening Level (<math>\mu\text{g}/\text{m}^3</math>)</b>	<b>Potential Emissions (tpy)</b>
291(2) Table 23 - VOC	All VOCs irrespective of screening level	5
291(2)(a)	< 2 and $\geq$ 0.04	0.12
291(2)(b)	< 0.04 and $\geq$ 0.005	0.06
291(2)(c)	< 0.005	0.006

An analysis as required by Rule 291(2)(f) is provided below.

The Michigan Air Toxics System toxic screening levels for ethylene oxide (CAS # 75218) are  $0.0002 \mu\text{g}/\text{m}^3$  (IRSL) and  $0.002 \mu\text{g}/\text{m}^3$  (SRSL) on an annual basis. These screening levels fall under the Rule 291(2)(c) category ( $< 0.005 \mu\text{g}/\text{m}^3$ ), for which potential emissions must not exceed 0.006 tons per year in order to be eligible for a permitting exemption under Rule 291.

As described in the section above, the potential emissions of ethylene oxide from the EtO Sterilizer System are 0.000469 tons/yr, which are below the 0.006 tons/yr limitation under Rule 291(2)(c). Therefore the EtO Sterilizer System qualifies for an exemption from the requirement for a Rule 201 air permit as long as it is not excluded from exemption under Rule 278.

**Rule 278 – Exclusion from Exemption**

To ensure that an emission unit is eligible to use an exemption under Rules 280 through 291, it must be demonstrated that it is not excluded from exemption under Rule 278. It is the opinion of Environmental Partners, Inc. that the MMC EtO Sterilizer System is not excluded from the use of the Rule 280 through 291 exemptions since:

- a. It is not subject to the Prevention of Significant Deterioration requirements under 40 CFR 52.21, nor is it subject to the non-attainment new source review requirements under Michigan Air Pollution Rule 220.
- b. Actual emissions are projected to be below the significance levels as defined under Michigan Air Pollution Rule 119.

- c. It is not a new or reconstructed major source of HAPs, as defined under 40 CFR 63.2 and 40 CFR 63.5(b)(3).
- d. It is not subject to the original National Emission Standards for Hazardous Air Pollutants under 40 CFR Part 61.
- e. It is understood that the exemption applies only to the requirement to obtain a Rule 201 permit to install, and any other applicable requirement(s) would continue to apply.

**Conclusion**

Based on the permitting and exemption evaluation described above, it is the opinion of Environmental Partners that the Munson Medical Center EtO Sterilizer System is exempt from the requirement to obtain a Rule 201 Permit to Install since it meets the eligibility criteria of Rule 291, and it is not excluded from the use of an exemption under Rule 278.

The findings and conclusions presented herein represent the opinion of Environmental Partners based upon the information made available to us. To ensure the best possible protection for Munson Medical Center, Environmental Partners recommends that these findings and conclusions be presented to the Michigan Department of Environment, Great Lakes, and Energy (EGLE) Air Quality Division (AQD) Cadillac District for their confirmation and validation of the opinions expressed herein. If there are any questions, please call me at (616) 928-9128.

Sincerely,  
ENVIRONMENTAL PARTNERS, INC.



Mark A. Horne, P.E.  
Principal