



GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF
ENVIRONMENT, GREAT LAKES, AND ENERGY
LANSING DISTRICT OFFICE



LIESL EICHLER CLARK
DIRECTOR

April 22, 2021

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Mr. Andy Szakal
Centurion Medical Products
301 Catrell Drive
Howell, Michigan 48843

SRN: N5109, Livingston County

Dear Mr. Szakal:

VIOLATION NOTICE

On April 19, 2021, the Department of Environment, Great Lakes, and Energy (EGLE), Air Quality Division (AQD), conducted a review of the results from the TO-15 SUMMA canister method air sampling conducted March 29 and 30, 2021 on and around Centurion Medical Product's (Centurion) property located at 301 Catrell Dr., Howell, Michigan. These results were received by EGLE on April 14 and 21, 2021. The purpose of this data review was to determine Centurion's compliance with the requirements of the federal Clean Air Act; Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (Act 451); the Air Pollution Control Rules.

During the inspection, staff observed the following:

Process Description	Rule/Permit Condition Violated	Comments
Ethylene Oxide Sterilization Process	Rule 901(a)	Rule 901a states "A person shall not cause or permit the emission of an air contaminant that causes injurious effects to human health or safety, animal life, plant life of significant economic value, or property."

The sampling results identified elevated concentrations of ethylene oxide in the air around Centurion. These elevated concentrations along with a subsequent modeling study, indicate the requirements of rule 901(a) have not been met.

The TO-15 SUMMA canister ethylene oxide sampling results are enclosed as part of this notice.

Please initiate actions necessary to correct the cited violation and submit a written response by May 13, 2021, (which coincides with 21 calendar days from the date of this letter). The written response should include: the dates the violation occurred; an explanation of the causes and duration of the violation; whether the violation is ongoing; a summary of the actions that have been taken and are proposed to be taken to correct the violation and the dates by which these actions will take place; and what steps are being taken to prevent a reoccurrence.

Along with your response to the violation above, please submit the following additional information:

1. A demonstration that the containment room (EUCONTAINMENT) emission unit, installed in May 1997, is exempt from the requirements of Rule 201 or submit a PTI application for the process.

Be advised, Rule 201 of the administrative rules promulgated under Act 451 requires that an air use permit to install (PTI) be obtained prior to installation, construction, operation, reconstruction, relocation, or alteration of any process or process equipment which may be a source of an air contaminant.

However, certain processes and process equipment may be exempt from obtaining a PTI. Rule 278 establishes requirements of eligibility for exemptions listed in Rules 280 through 291. To be eligible for a listed exemption, the owner or operator of an exempt process or exempt process equipment must be able to provide information demonstrating the applicability of the exemption. Pursuant to Rule 278(a), this demonstration should be provided within 30 days of a written request by the AQD and should include the following information:

- A description of the exempt process or process equipment, including the date of installation.
 - The specific exemption being used by the process or process equipment.
 - An analysis demonstrating that Rule 278 does not apply to the process or process equipment.
2. Information related to the existing ethylene oxide monitoring system used for NESHAP Subpart O and permit compliance.

Centurion is subject to the federal regulations found in 40 CFR Part 63, National Emissions Standards for Hazardous Air Pollutants (NESHAP) Subpart O- Ethylene Oxide Emissions standards for Sterilization Facilities, the requirements for which have been incorporated into Permit to Install No. 24-94B. In the semi-annual emissions report received by the AQD on January 29, 2021, Centurion identifies the use of a SRI 8610C gas chromatograph monitoring system to

measure emissions of ethylene oxide from EUAERATION and FGETOCHAMBERS.

Include the following information in your response:

- Documentation on how Centurion maintains the gas chromatograph (GC) consistent with the requirements of performance specification (PS) 8 or 9 in 40 CFR Part 60, Appendix B, to measure ethylene oxide. (40 CFR 63.364(e) and EUAERATION SC IV.2 and FGETOCHAMBERS SC IV.5)
 - Identification of the PS used for the continuous emissions monitoring system (CEMs), including all procedures for calibrating, maintaining and operating the CEMs. (40 CFR Part 60, Appendix B)
 - Measurements to demonstrate how the location of the CEMs meets Method 1. (40 CFR Part 60, Appendix A)
 - Monthly multi-point calibration results of the GC (and any other multi-point calibration conducted after routine maintenance or repair) for the previous 5 years.
 - Records of routine maintenance and repair of the GC for the previous 3 years.
 - Instructions by which the daily calibration of the CEMs are conducted and submit the daily CEMs calibration results for the time frame of November 2020 - April 16, 2021.
 - Hourly ethylene oxide concentration in parts per million and daily 24-hour average concentration in parts per million on a daily basis for the time period of November 2020-April 16, 2021.
3. Pressure drop readings of the aeration room for the time frame of October 1, 2020 - April 6, 2021

The AQD sent an information request to Centurion dated March 31, 2021. A conference call was held on April 6, 2021, to discuss the request and clarify the AQD expectations of the formal response. In that call, the AQD requested information on pressure drop readings of the aeration room for the time frame of October 1, 2020-April 6, 2021. The information provided by Centurion in the formal response did not include the pressure drop readings as requested. Please submit those as part of the formal response to this Violation Notice.

Please submit the written response to EGLE, AQD, Lansing District, at 525 West Allegan Street, P.O. Box 30242, Lansing, Michigan 48909 and submit a copy to Ms. Jenine Camilleri, Enforcement Unit Supervisor at EGLE, AQD, P.O. Box 30260, Lansing, Michigan 48909-7760.

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If Centurion Medical Products believes the above observations or statements are inaccurate or do not constitute violations of the applicable legal requirements cited, please provide appropriate factual information to explain your position. Thank you for your attention to resolving the violation cited above. If you have any questions regarding the violation or the actions necessary to bring this facility into compliance, please contact me at the number listed below.

Sincerely,



Samantha Davis
Environmental Quality Analyst
Air Quality Division
517-282-1373

Enclosure
cc: Mr. Jasper Titus, Centurion Medical Products
Ms. Mary Ann Dolehanty, EGLE
Dr. Eduardo Olague, EGLE
Ms. Jenine Camilleri, EGLE
Mr. Christopher Ethridge, EGLE
Mr. Brad Myott, EGLE