DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION
ACTIVITY REPORT: On-site Inspection

B232959847

FACILITY: Par Sterile Products LLC		**SRN / ID:** B2329
LOCATION: 870 PARKDALE RD, ROCHESTER		**DISTRICT:** Warren
CITY: ROCHESTER		**COUNTY:** OAKLAND
CONTACT: Annette Sommers , Associate Director EH&S, Workforce Dev.		**ACTIVITY DATE:** 08/03/2021
STAFF: Rem Pinga	**COMPLIANCE STATUS:** Compliance	**SOURCE CLASS:** MAJOR
SUBJECT: Scheduled On-site Inspection		
RESOLVED COMPLAINTS:		

On August 3, 2021, I conducted a scheduled on-site inspection at Par Sterile Products, LLC, located at 870 Parkdale Road, Rochester, Michigan 48307. The purpose of the inspection was to determine the facility's compliance 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 Quality Division (AQD) Administrative Rules and the facility's Renewable Operating Permit (ROP) No. MI-ROP-B2329-2016. Prior to the walk-through inspection, I met and conducted a pre-inspection meeting with Annette Sommers, Senior Training and EHS Manager, and Allison Zombo, EHS Specialist. Ms. Sommers and Ms. Zombo accompanied me during the walk-through inspection.

To comply with the COVID-19 Emergency AQD Field Inspection Guidance Update (June 2020), the inspection was announced and scheduled. I entered the facility wearing face mask, face shield, safety glasses, hard hat, and safety shoes. My temperature was checked and I filled the facility's Covid-19 Safety Questionnaire at the entrance Guardhouse. Following AQD guidance, all recordkeeping information were obtained through email instead of obtaining printed copies during inspection.

Par Sterile Products, LLC is a subsidiary of Par Pharmaceutical, an Endo international company based in Dublin, Ireland. Par Pharmaceutical is headquartered in Chestnut Ridge, New York and specializes in modified-released oral solid dosage forms as well as non-oral dosage forms, such as nasal sprays, injectables, inhalers, patches, and other alternative drug delivery platforms. Par Sterile Products develops, manufactures, and markets a broad portfolio of branded and generic aseptic injectable products. The sterile manufacturing facility produces high quality products such as Adrenalin Injection, Adrenalin Chloride Solution, Aplisol, Argatroban Injection, Ephedrine Sulfate Injection, Ketalar, etc. Ms. Sommers mentioned that the facility production processes operate 2 shifts per day, from 0700 hours through 2400 hours, and 7 days a week. The cleaning and maintenance crews work after midnight.

The facility is currently considered a Title V major source and operates under Renewable Operating Permit (ROP) No. MI-ROP-B2329-2016. Several emission units covered under the ROP were either uninstalled or rendered

inoperable thus Par Sterile Products, LLC (Par Sterile) applied for a synthetic minor (Opt-out) permit to install (PTI). PTI Application No. APP-2021-0131 is currently in-house and being processed by AQD Permit Section. The facility's ROP is also expiring December 6, 2021. An ROP renewal application was due June 6, 2021. To comply with this requirement, the facility submitted an ROP application, ROP Renewal Application No. 202100093, on June 2, 2021. AQD staff conducted a review process on the application and determined the application complete on June 10, 2021. Par Sterile obtained an application shield on June 10, 2021. ROP No. MI-ROP-B2329-2016 remains enforceable until the renewal ROP is issued, or the facility obtains an opt-out/synthetic minor PTI. ROP No. MI-ROP-B2329-2016 also contains facility-wide single Hazardous Air Pollutant (HAP) and combined/aggregate HAPs emission rates restrictions, under "SOURCE-WIDE CONDITIONS", supported by monthly 12-month rolling total emission rates recordkeeping requirements, to demonstrate continued compliance as a synthetic minor source for NESHAP/MACT standards.

The applicable requirements (AR) in the facility's ROP, MI-ROP-B2329-2016, are organized in 2 emission units: EU-38-BOILER-3 and EU-38-BOILER-4; and 5 flexible groups: FG-382-COGEN, FG-IPA-USE, FG-RICE-NSPS4I-EMRGENCY-GENRATOR, FG-CI-RICE-MACT4Z<500HP, and FG-RULE290. It also contains the above-mentioned "SOURCE-WIDE CONDITIONS".

During the walk-through inspection at the Powerhouse building (Building 38), I verified EU-38-BOILER-3, EU-38-BOILER-4, FG-382-COGEN (EU-TURBINE & EU-DUCTBURNER), and FG-CI-RICE-MACT4Z<500HP (EU-B38-DIESEL-GENERATOR) were either dismantled or rendered inoperable.

SOURCE-WIDE CONDITIONS - to ensure that the permittee remains as a synthetic minor source for NESHAP/MACT standards, Par Sterile contained facility-wide single Hazardous Air Pollutant (HAP) and combined/aggregate HAPs emission rates restrictions, supported by monthly 12-month rolling total emission rates recordkeeping requirements. Per ROP No. MI-ROP-B2329-2016, condition (B) SOURCE-WIDE CONDITIONS (I.1), the facility submitted records showing Hexane emitted the highest monthly 12-month rolling total single HAP, from January 2020 through July 2021, at 0.069 tpy and less than the 9.90 tpy permit limit. Per ROP No. MI-ROP- B2329-2016, condition (B) SOURCE-WIDE CONDITIONS (I.2), the highest aggregate HAPs monthly 12-month rolling total emission rate, from January 2020 through July 2021, was reported at 0.0864 tpy and recorded for January 2021. This is less than the 24.9 tpy permit limit.

FG-IPA-USE - the purpose of this flexible group is to establish plant wide emission limit and to streamline Isopropyl Alcohol (IPA) use recordkeeping. The permittee uses IPA throughout the pharmaceutical plant for cleaning and disinfecting the process equipment and for removing labels from containers. Per ROP No. MI-ROP- B2329-2016, condition (D) FG

-IPA-USE (I.1), the highest IPA monthly 12-month rolling total emission rate, from June 2020 through July 2021, occurred in July 2021 at 7.9507 tpy and less than the 24.0 tpy permit limit.

FG-RICE-NSPS4I-EMRGENCY-GENRATOR – this flexible group pertains to reciprocating internal combustion engines (RICE) subject to 40 CFR Part 60 Subpart IIII, covering diesel fired engines < 3000 horsepower (hp). The Par Sterile ROP showed EU-LAB-DIESEL-GENERATOR as the emission unit covered by this flexible group. The unit is a Cummins Model DFEK with rating of 500kW, 755 HP, and was installed in October 2013. During walk-through inspection, I observed another diesel emergency generator, a Kohler Model 1250REOZDD, 1300 kW with manufacture date of 11/11/2016. This engine appears to be rated at <3000 hp and covered by this flexible group also. Per ROP No. MI-ROP- B2329-2016, condition (D) FG-RICE-NSPS4I-EMRGENCY-GENRATOR (I), Par Sterile submitted proof that the Cummins and Kohler engines are USEPA certified engines and submitted the USEPA Certificate of Conformity with the Clean Air Act of 1990. Per ROP No. MI-ROP- B2329-2016, condition (D) FG-RICE-NSPS4I-EMRGENCY-GENRATOR (II.1), Par Sterile submitted documentation that the facility burns diesel fuel in the engines with maximum Sulfur content of 15 ppm by weight. Per ROP No. MI-ROP- B2329-2016, condition (D) FG-RICE-NSPS4I-EMRGENCY-GENRATOR (III.1 & 2), Par Sterile keeps monthly hours of emergency and non-emergency hours of operation. The records showed that Kohler's non-emergency hours of operation from June 2020 through July 2021 were 4.1 hours and less than 50 hours. It registered no emergency hours of operation. For the same period, Cummins showed 8.6 hours of non-emergency operating hours and no emergency operating hours. Per ROP No. MI-ROP- B2329-2016, condition (D) FG-RICE-NSPS4I-EMRGENCY-GENRATOR (III.3 & 4), Par Sterile contracts Cummins Sales and Service to conduct engine maintenance according to manufacturer's recommended procedures and emission-related written instructions including tune-ups, oil and filter changes, inspections on hoses, belts, fittings, leaks, etc. Per ROP No. MI-ROP- B2329-2016, condition (D) FG-RICE-NSPS4I-EMRGENCY-GENRATOR (IV.1 & 2), the engines have non-resettable hour meters with readings of 166.6 hours and 111.0 respectively for Cummins and Kohler. The name plates showed 500 kW and 1300 kW for Cummins and Kohler respectively and less than the 2237 kW permit limit.

The Kohler emergency generator's name plate is showing a kW of 1300. I calculated an Hp of 1,742.62 and 4.436 MMBTU/hr. of power output. Assuming 25% efficiency, the power input is estimated at 4 x 4.436 = 17.744 MMBTU/hr. This is greater than the 10 MMBTU/hr. maximum heat input limit in AQD Rule R 336.1285(2)(g), as an applicable requirement to qualify for permit to install (PTI) exemption for internal combustion engines. As such, the engine may require a PTI. I will contact the facility for further clarification on the BTU rating of the engine to determine whether Par Sterile needed to apply for a PTI for the Kohler emergency generator.

FGRULE290 – pertains to any emission unit that emits air contaminants and exempt from AQD Administrative Rule R 336. 1201, permit to install requirements, pursuant to Administrative Rules R 336.1278 and R 336.1290. Par Sterile operates EU-DRUG, EU-BULKA, EU-BULKB, EU-PREP, EU-PACKAGING as emission units under FGRULE290. Submitted records showed Benzyl Alcohol, Ethyl Alcohol, and Delestrogen as compounds emitted under FGRULE290. Benzyl and Ethyl alcohols have 1,000 lb./month emission limit for the PTI exemption requirement. Delestrogen has 10 lb./month emission restriction. For EU-DRUG, EU-PREP, EU-PACKAGING, EU-BULKA and EU-BULKB, the highest Ethyl Alcohol emission occurred in July 2020 at 2.00 lb. while the highest Benzyl Alcohol emission occurred in March 2021 at 0.33 lb., and less than the 1,000 lb. emission limit. Delestrogen was emitted in July 2020 at 0.0024 lb. and in March 2021 at 0.0016 lb. and less than the 10 lb. emission limit.

The company also has a Cummins diesel backup fire pump with manufacture date of 1978, install date of 7/20/1979, and rated at 240 HP. The unit is exempt from permit to install requirements pursuant to Rule 285 (2)(g). The pump is equipped with a non-resettable hour meter to measure hours of operation. The non-resettable hour meter showed 186.49 hours. Par Sterile contracts Cummins Sales and Service to conduct engine maintenance including tune-ups, oil and filter changes, inspections on hoses, belts, fittings, leaks, etc. Per submitted records, the engine runs 30 minutes per week, 2 hours per month and 24 hours per year which is less than 50 hours for non-emergency operating hours.

Overall, I did not find any other non-compliance issues during inspection. However, I need to verify the PTI status of the Kohler engine.

NAME _____ DATE 09/24/2021 SUPERVISOR _____