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

B232950089

FACILITY: Par Sterile Products LLC		**SRN / ID:** B2329
LOCATION: 870 PARKDALE RD, ROCHESTER		**DISTRICT:** Southeast Michigan
CITY: ROCHESTER		**COUNTY:** OAKLAND
CONTACT: Annette Sommers , EH&S Manager		**ACTIVITY DATE:** 08/15/2019
STAFF: Shamim Ahammod	**COMPLIANCE STATUS:** Compliance	**SOURCE CLASS:** MAJOR
SUBJECT: Conducted a scheduled inspection of Par Sterile Products, LLC to determine the company's compliance with the requirements of Renewable Operating Permit (ROP) No. MI-ROP-B2329-2016 and Permit to Install (PTI) No. 736-84.		
RESOLVED COMPLAINTS:		

On Thursday, August 15, 2019, Michigan Department of Environment, Great Lakes and Energy-Air Quality Division (EGLE-AQD) staff, I (Shamim Ahammod) conducted a scheduled inspection of Par Sterile Products, LLC (SRN: B2329) located at 870 Parkdale Road, Rochester, Michigan. The purpose of the inspection was to determine the company'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; and the conditions of Renewable Operating Permit (ROP) No. MI-ROP-B2329-2016 and Permit to Install (PTI) No. 736-84.

INSPECTION

I arrived at the facility at 10:20 AM for the scheduled inspection. I entered the front office and signed in and identified myself to a member of the security office staff. This staff member directed me to Ms. Annette Sommers, Sr. Manager, Par Pharmaceutical. I introduced myself to Ms. Sommers, showed her my credentials, provided him my visiting card and stated the purpose of the visit.
Par Sterile Products Staff Annette Sommers, Allison Zombo, EHS Specialist and I, Shamim Ahammod (EGLE Staff) met at a Par Sterile Products conference room and discussed the permit MI-ROP-B2329-2016 and (PTI) No. 736-84.
On May 26, 1988, (PTI) No. 736-84 was issued for Amsidyl manufacturing process. According to Ms. Sommers, Amsidyl manufacturing process is no longer exist in the facility. I will send a request to the permit section to void this permit.
Ms. Sommers provided me the records that require in monitoring/record-keeping section for FG-382-COGEN, FG-IPA-USE, FG-RICE-NSPS4I-EMERGENCY GENERATOR, FG-CI-RICE-MACT4Z<500HP, FG-RULE290, EU-38-BOILER-3, and EU-38-BOILER-4 of MI-ROP-B2329-2016.

After that, we visited the plant to see the overall operations and equipment at the facility. The Par Pharmaceutical staff showed me the EU-LAB-DIESEL-GENERATOR, EU-B38 -DIESEL-GENERATOR. I verified the non-resettable hour meter for both diesel generators (EU-LAB-DIESEL-GENERATOR, EU-B38 -DIESEL-GENERATOR). Then I visited the Boiler-3 (EU-38-BOILER-3) and Boiler-4 ((EU-38-BOILER-34). I checked the nameplate capacity of each boiler. Then I visited the turbine (EU-TURBINE) and boiler 5 (EU-DUCTBURNER).

SOURCE DESCRIPTION

Par Sterile Products LLC makes pharmaceutical products including injectable pharmaceutical. Due to the nature of pharmaceutical/drug products and manufacturing processes, a highly reliable electric power source is needed. The enhanced electric power supply reliability is accomplished by installing and operating a cogeneration system (cogen) consisting of a gas turbine, a waste heat recovery steam generated and a duct burner. The cogeneration system, which burns only natural gas, is a source of emissions of nitrogen oxides.

Regulatory Analysis

Source-wide conditions

Per special condition (SC) I.1, the facility has source wide individual HAP limit of 9.90 tons per 12-

month rolling period. Per SC I.2, source wide aggregate HAPs emission limits of 24.99 tons per 12-month rolling period. The purpose of these hazardous air pollutants (HAP) emissions limits is to ensure that the permittee remains a synthetic minor source for 40 CFR Part 63 NESHAP (MACT).

Compliance with the source-wide HAP emission limits is demonstrated by recordkeeping requirements set forth in SC VI.1 (monitoring and record-keeping). Ms. Sommers provided source wide each individual HAP and aggregate HAPs records for the 12-month period (attachment 1). These records indicate the highest individual 12-month rolling (Jan.-Dec 2018) emissions were 0.79 tons of Hexene and the highest aggregate HAP emissions were 1.1324 tons. Yearly HAP emissions from fuel-burning equipment were based on maximum rated heat input of the equipment, AP-42 emissions factors, and 8760 hours of operation. Monthly emissions are calculated by dividing the yearly emissions by 12.

EU-38-BOILER-3

EU-38-BOILER-3 is rated at a heat input of 48 million BTU per hour and a steam output capacity of 40,000 pounds per hour. Regarding Rule 336.1201 (Permit-to-Install), Boiler No. 3 is grand-fathered since it was installed before August 15, 1967.

Emission limit

As required in SC I.1 of EU-BOILER-3, SO_2 emission limit from fuel oil is 1.7 lbs/MMBTU. The permittee only uses natural gas as a fuel (attachment 2). Therefore, SC I.1, SC VI.1, and SC VI.4 of EU-BOILER-3 are not applicable for this unit.

Process/operational restrictions

Per SC III.1, the permittee shall burn only pipeline-quality natural gas and fuel oil meeting sulfur specification in SC I.1 of EU-38-BOILER-3. The permittee only uses natural gas as a fuel (attachment 2). Pipeline quality natural gas definition in 40 CFR 60.331(u), "**Natural gas** means a naturally occurring fluid mixture of hydrocarbons (e.g., methane, ethane, or propane) produced in geological formations beneath the Earth's surface that maintains a gaseous state at standard atmospheric temperature and pressure under ordinary conditions. Natural gas contains 20.0 grains or less of total sulfur per 100 standard cubic feet. Equivalents of this in other units are as follows: 0.068 weight percent total sulfur, 680 parts per million by weight (ppm) total sulfur, and 338 parts per million by volume (ppmv) at 20 degrees Celsius total sulfur. Additionally, natural gas must either be composed of at least 70 percent methane by volume or have a gross calorific value between 950 and 1100 British thermal units (Btu) per standard cubic foot. Natural gas does not include the following gaseous fuels: landfill gas, digester gas, refinery gas, sour gas, blast furnace gas, coal-derived gas, producer gas, coke oven gas, or any gaseous fuel produced in a process which might result in highly variable sulfur content or heating value."

As stated in SC III.2 and 40 CFR 60.331(u), the pipeline-quality natural gas shall not have a total sulfur content in excess of 20 grains of sulfur per 100 Standard Cubic Foot (SCF). I reviewed a record which indicates that natural gas consumed by EU-38-BOILER-3 does not contain more than 20 grain of total Sulfur per 100 cubic feet (attachment 2).

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Monitoring/recordkeeping

As specified in SC VI.1, the permittee maintained the records of fuel usage on the 12-month rolling time period from August 2018 to July 2019 (attachment 3). SCVI.2, SC VI.4 and SC VI.5 of EU-38-BOILER-3 are not applicable for this unit because the permittee did not use fuel oil as a fuel in last 12-month (attachment 3). As required in SC VI.3, permittee keeps a monthly log of hours of operation and type of fuel-fired (attachment 4).

EU-38-BOILER-4

EU-38-BOILER-3 is rated at a heat input of 25 million BTU per hour and a steam output capacity of 21,000 pounds per hour. The boiler was installed in 1979.

Emission limit
As required in SC I.1 of EU-BOILER-4, SO_2 emission limit from fuel oil is 1.10 lbs/MMBTU. The permittee only uses natural gas as a fuel (attachment 2). Therefore, SC I.1, SC VI.1, and SC VI.4 of EU-BOILER-4 are not applicable.

Process/operational restrictions
Per SC III.1, the permittee shall not burn any fuel other than pipeline-quality quality sweet natural gas and fuel oil meeting above sulfur specification. The permittee only burns natural gas as a fuel (attachment 2). See the explanation in the Process/Operational Section (SC III.1 of EU-38-BOILER-3).

Monitoring/recordkeeping
As specified in SC VI.1of EU-38-BOILER-4, the permittee maintained the records of fuel usage on the 12-month rolling time period from August 2018 to July 2019 (attachment 5).
SC VI.2, SC VI.4 and SC VI.5 of EU-38-BOILER-4 are not applicable because the permittee did not use fuel oil as a fuel in last 12-month.
As required in SC VI.3 of EU-38-BOILER-4, permittee keeps a monthly log of hours of operation and type of fuel-fired (attachment 4).

FG-382-COGEN
FG-382-COGEN consists of a natural gas-fired turbine (EU-TURBINE) and a waste heat recovery steam generator (EU-DUCTBURNER). The waste heat boiler, including duct burner, is also known as Boiler No. 5.

Emission limits
SC I.1 and I.2 of FG-382-CO-GEN limits NOx emission rates from the turbine with and without the duct burner firing. To satisfy the permit limit, the permittee is required to conduct NOx emission test. On February 22, 2017, the permittee conducted NOx emission test on FG-382-CO-GEN while the duct burner was not firing. The results of this test are summarized below.

Turbine Operating Load (%)	Average NOx Concentration (ppmv @15% O_2	Average NOx emission rate (lbs/MMBTU)
100 (duct burner off)	117	0.41
90 (duct burner off)	127.7	0.44
85 (duct burner off)	130.7	0.44
80 (duct burner off)	127.9	0.43
100(duct burner firing)	86.3	0.31
Emission Limit	**167**	**0.50**

SC I.3 of FG-382-CO-GEN, Nitrogen oxides (NOx) emissions limit is 121 tons per year (12-month rolling time period). During the period of August 2018 through July 2019, NOx emissions were 94.43 tons from FG-383-CO-GEN (attachment 6).
SC I.4 of EU-TURBINE, sulfur dioxide (SO_2) emissions limit is 0.30 lb/MMBTU per 24-hour average. During the period of August 2018 through July 2019, SO_2 emissions were 0.03 lb per hour (0.001 lb/MMBTU) in August-2018 from EU-TURBINE (attachment 6).
Calculation for August 2018:
0.03lb/hr*24 hr/1day*31 days/Aug*August natural gas usage/21593 MMBTU = 0.001 lb/MMBTU
SC I.5 of EU-TURBINE, sulfur dioxide (SO_2) emissions limit is 56.5 tons per year (12-month rolling time period). During the period of August 2018 through July 2019, SO_2 emissions were 0.08 tons from EU-TURBINE (attachment 6).

Process/operational restrictions
For the requirement of SC III.1 of FG-382-CO-GEN, see the detailed explanation in Process/Operational Section (SC III.1 of EU-38-BOILER-3).

Testing/Sampling
ROP was issued on December 6, 2016. The permittee was required to conduct NOx emission test on stack test on FG-382-CO-GEN at least once within the 360-day period following issuance of the ROP. Within this period, the permittee conducted NOx emission test on FG-382-CO-GEN on February 22, 2017. For the requirement of SC V.1 of FG-382-CO-GEN, see the detailed explanation in the Emission Limit section (SC I.1 and I.2 of FG-382-CO-GEN).

Monitoring/recordkeeping
SC VI.1.a of FG-383-CO-GEN, the permittee keeps records of daily and monthly hours of operation of EU-TURBINE and EU-DUCTBURNER (attachment 7). SC VI.1.b of FG-383-CO-GEN, see the detailed explanation in SC VI.2.a of FG-383-CO-GEN. SC VI.1.c of FG-383-CO-GEN, the permittee keeps records of daily and monthly natural gas usage at EU-TURBINE, EU-DUCTBURNER, and FG-382-COGEN (attachment 7). SC VI.1.d of FG-383-CO-GEN, the permittee keeps records of daily and monthly power (kilowatt-hours) and steam (lbs) production (attachment 7). SC VI.2.a of FG-383-CO-GEN (Sulfur monitoring), the permittee need not monitor sulfur in fuel because it elected to burn in FG-383- COGEN only pipeline quality sweet natural gas that meets the definition of natural gas in Section 60.331(u).
I reviewed a record which indicates that natural gas consumed by FG-383-CO-GEN does not contain more than 20 grain of total Sulfur per 100 cubic feet (attachment 2) and satisfied the condition set forth in 40 CFR 60.331(u), SC VI.2.a and SC VI.b of FG-383-CO-GEN. See the detailed explanation in the Process/Operational Section (SC III.1 of EU-38-BOILER-3).

SC VI.3.a of FG-383-CO-GEN, the permittee is exempt from fuel nitrogen monitoring because they fire only pipeline quality sweet natural gas as defined in 40 CFR 72.2. SC VI.4 of FG-383-CO-GEN, the permittee keeps records of NOx emissions calculation for the EU-TURBINE in tons per month and tons per 12-month rolling period (attachment 6). SC VI.5 of FG-383-CO-GEN, the permittee keeps records of SO2 emissions calculation in lbs per million BTU, tons per month and tons per 12-month tolling period (attachment 6). SC VI.6 of FG-383-CO-GEN, the permittee maintains records of operating range to demonstrate compliance with emissions limit (attachment 8).

Other requirements
SC IX.1, of FG-383-CO-GEN, see the detailed explanation in SC I.1 and SC I.2 (emission limit) and SC III (Process/operational restrictions).
SC IX.3 of FG-383-CO-GEN, see the detailed explanation in SC III (Process/operational restrictions).
SC IX.5 of FG-383-CO-GEN, see the detailed explanation in SC V.1 (testing/sampling).

FG-IPA-USE
The facility's employees use isopropyl alcohol (IPA) throughout the pharmaceutical plant for cleaning and disinfecting the process equipment and for removing labels from containers.

Emission limits
As specified in SC I.1 of FG-IPA-USE, plant-wide IPA emissions limits to 24 tons per year (12-month rolling time period). During the period of August 2018 through July 2019, IPA emissions were 7.13 tons from FG-IPA-USE (attachment 9). As specified in SC VI.1.a of FG-IPA-USE, the permittee maintains the records of IPA used in each calendar month (attachment 9). SC VI.1.b of FG-IPA-USE, the permittee keeps the records of IPA used in every year based upon 12-month rolling time period, as determined at the end of each calendar month (attachment 9).

FG-RICE-NSPS4I-EMERGENCY-GENERATOR
Emission unit: EU-LAB-DIESEL-GENERATOR

Emission limit
Emissions from each engine in FG-RICE-NSPS4I-EMERGENCY-GENERATOR are limited to the following in the ROP: Per SC I.1, NMHC + NOx emission limit is 6.4 g/kW-hr. Per SC I.3, the CO emission limit is 3.5 g/kW-hr. Per SC I.4, the PM emission limit is 0.20 g/kW-hr. Compliance with these emission limits is demonstrated by purchasing an engine certified by the manufacturer to meet the emission limits and by operating the engine according to the manufacturer's emission-related written instructions (attachment 10).

Material limit
SC II.1 of FG-RICE-NSPS4I-EMERGENCY-GENERATOR, the permittee shall burn only diesel fuel in **FG-RICE-NSPS4I-EMERGENCY-GENERATOR (aka: FG60-4I-Engine<3000 hp)** with the maximum sulfur content of 15 ppm (0.0015 percent) by weight. Ms. Sommers provided a record indicating the permittee burns only diesel fuel and the sulfur content is 0.0005% which is below the limit of 0.0015% (attachment 11).

Process/operational restrictions
SC III.1, the operational hours of EU-LAB-DIESEL-GENERATOR was 25.7 hours for maintenance checks and readiness testing and emergency demand response for the period of January through December 2018, which was below the permit limit of 100 hours per the calendar year (attachment 12). **SC III.2,** the non-emergency operational hours of EU-LAB-DIESEL-GENERATOR was 25.7 hours for the period of January through December 2018, which was below the permit limit of 50 hours per the calendar year (attachment 12).

Design/equipment parameters
Per SC IV.1, EU-LAB-DIESEL-GENERATOR is required to be equipped with a non-resettable hours meters to track the operating hours of the engine. At the time of inspection, I observed a non-resettable hours meters was equipped in EU-LAB-DIESEL-GENERATOR. The readings I noted was 152 hours on the display board of EU-LAB-DIESEL-GENERATOR.

SC IV.2, I verified the nameplate of the engine and found the maximum capacity of the engine is 500 KW which is below the permit limit of 2237 KW.

Testing/sampling
SC V.1, the permittee is not required to conduct initial performance testing for each engine in FG-RICE-NSPS4I-EMERGENCY-GENERATOR (aka: FG60-4I-Engine<3000 hp) because engines are certified by the manufactures as required by 40 CFR Part 60, Subpart IIII and the permittee maintained the engines as required in 40 CFR 60.4211. I reviewed the manufacturer's certification documentation that indicating each engine in FG-RICE-NSPS4I-EMERGENCY-GENERATOR (aka: FG60-4I-Engine<3000 hp) meets the applicable emission limitations contained in the federal Standards of Performance for New Stationary Source 40 CFR Part 60, Subpart II (attachment 10).

Monitoring/recordkeeping
SC VI.1, Ms. Sommers provided a maintenance plan and annual maintenance record conducted in EU-LAB-DIESEL-GENERATOR (attachment 13). SC VI.2, at the time of inspection I observed the non-resettable hour meter in EU-LAB-DIESEL-GENERATOR that record operating hours during the emergency and non-emergency service. VI.3, regarding the testing requirement or manufacturer certification, see detailed explanation in Testing/Sampling section (SC V.1 of EU-LAB-DIESEL-GENERATOR). SC VI.4, regarding sulfur content of diesel fuel, see detailed explanation in Material Limit section (SC II.1 of EU-LAB-DIESEL-GENERATOR).

Other requirements
SC IX.1, 40 CFR Part 60, Subparts A and IIII, 40 CFR 60.4200, see detailed explanation in SC V.1 (testing and sampling) and SC I.1 (emission limit).

FG-CI-RICE-MACT4Z<500HP
This flexible group consists of one emission unit: EU-B38-DIESEL-GENERATOR.

Process/operational restrictions
Per III.1, SC III.2 and 40 CFR 63.6602, the permittee requires to maintain EU-B38-DIESEL-GENERATOR in a satisfactory manner. Satisfactory maintenance, according to the ROP, includes changing the oil and filter every 500 hours of operation or annually, whichever comes first, inspecting the air cleaner every 1000 hours of operation or annually, whichever comes first, and replacing as necessary; and inspecting all hoses and belts every 500 hours of operation or annually, whichever comes first, and replace as necessary. Ms. Sommers provided a copy of the preventive maintenance performed on EU-B38-DIESEL-GENERATOR by Michigan CAT on February 11, 2019 (attachment 13).
SC III.5 and 40 CFR 63.6640(f)(2), Ms. Sommers provided records of the operating hours and fuel usage for January through December 2018 for EU-B38-DIESEL-GENERATOR (attachment 14). Based on these records, EU-B38-DIESEL-GENERATOR operated 15.96 hours per the calendar year (2018) for the testing and maintenance purposes which were below the permit limit of 100 hours per calendar year.
SC III.6 and 40 CFR 63.6640(f)(3), for the non-emergency situations, EU-B38-DIESEL-GENERATOR was operated 15.96 hours per the calendar year (2018) which was below the permit limit of 50 hours per calendar year (attachment 14).

Design/equipment parameters
Per SC IV.1 and 40 CFR 63.6625(f), EU-B38-DIESEL-GENERATOR is required to be equipped with a non-resettable hours meters to track the operating hours of the engine. At the time of inspection, I observed a non-resettable hours meters was equipped in EU- B38-DIESEL-GENERATOR. The readings I noted was 7880 hours on the display board of EU-B38-DIESEL-GENERATOR.
Testing/sampling
SC V.1 and 40 CFR 63.6625(i), see the detailed explanation in Process/operational restrictions Section (III.1, SC III.2 of EU-B38-DIESEL-GENERATOR).

Monitoring/recordkeeping
For the requirements of SC VI.1, see the detailed explanation in the Process/Operational restriction section (SC III.1 of EU-B38-DIESEL-GENERATOR). For the requirements of SC VI.2, see the detailed explanation in Process/Operational Section (SC III.5 and SC III.6 of EU-B38-DIESEL-GENERATOR).
Other requirements
SC IX.1, 40 CFR Part 63, Subpart A and Subpart ZZZZ, see the detailed explanation in SC 1 through 6, SC V.1 and SC VI.1-2 of FG-CI-RICE-MACT4Z<500HP.

FG-RULE290
Emission unit: EU-DRUG, EU-BULKBA, EU-BULKB, EU-PREP, and EU-PACKAGING are in FG-RULE290 that emits air contaminants and is exempt from the requirements of Rule 201 pursuant to Rules 278 and 290.
BULK MANUFACTURING
Emission Limit
SC I.1, during the period of August 2018 through July 2019, monthly the non-carcinogenic

uncontrolled VOC emissions from EU-BULK was less than 1 lb which was below the permit limit of 1000 lbs per month (attachment-15a and 15b).
Per SC 2.c, during the period of August 2018 through July 2019, monthly the carcinogenic controlled Cytovene emissions from EU-BULK was 0 lb which was below the permit limit of 10 lbs per month (attachment 15a and 15b).

Monitoring/recordkeeping

SC VI.1.a, the permittee kept records identifying each air contaminant that is emitted (attachment 15b).

SC VI.1.b, the permittee kept records identifying if each air contaminant is controlled or uncontrolled (attachment 15b).
SC VI.1.c, the permittee kept records identifying if each air contaminant is either carcinogenic or non-carcinogenic (attachment 15b).
SC VI.1.d, the permittee kept records identifying if each air contaminant is either ITSL or IRSL (attachment 16.b).
SC VI.1.e, Ms. Sommers provided monthly records identifying and detailing the quality, nature, and quantity of the air contaminant emissions from FGRULE290 (attachment 15.1-b and 16.a-b).

Conclusion

Based on the on-site inspection, reviewing records and discussion with staff, Par Sterile Products, LLC appears to be in compliance with the requirements of ROP No. MI-ROP-B2329-2016.

NAME [signature] DATE 9/9/19 SUPERVISOR SK