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

B232945933

FACILITY: Par Sterile Products LLC		**SRN / ID:** B2329
LOCATION: 870 PARKDALE RD, ROCHESTER		**DISTRICT:** Southeast Michigan
CITY: ROCHESTER		**COUNTY:** OAKLAND
CONTACT: Annette Sommers ,		**ACTIVITY DATE:** 08/07/2018
STAFF: Kerry Kelly	**COMPLIANCE STATUS:** Compliance	**SOURCE CLASS:** MAJOR
SUBJECT: Evaluate Par Sterile's compliance with their Title V permit as well as State and Federal air quality rules and regulations.		
RESOLVED COMPLAINTS:		

On August 7, 2018, I (Kerry Kelly, MDEQ) conducted an inspection of Par Sterile Products, LLC. (Par Sterile) located at 870 Parkdale Road, Rochester, Michigan 48307-1740. The purpose of the inspection was to determine compliance with the Federal Clean Air Act; Article II, Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994, PA 451; Michigan Department of Environmental Quality, Air Quality Division (MDEQ-AQD) administrative rules and Renewable Operating Permit (ROP) Number MI-ROP-B2329-2016.

During the inspection the following Par Sterile Products staff assisted me:
Ms. Annette M. Sommers, Senior Manager, Training and EHS
Mr. Edgardo Santiago, Stationary Engineer

Par Sterile Products, LLC is an integrated specialty healthcare company that acquires, develops, manufactures and distributes sterile injectable products predominantly to hospitals and clinicians. The facility is located on the eastern border of Oakland County and is surrounded on the west and east by commercial/industrial facilities, residential properties to the north, and Bloomer Park to the south.

MI-ROP-B2329-2016
SOURCE-WIDE CONDITIONS
MI-ROP-B2329-2016 contains a synthetic minor opt-out limit for hazardous air pollutants (HAP). A facility-wide individual HAP limit of 9.9 tons per 12-month rolling time period and the facility-wide aggregate HAP emission limit of 24.9 tons per 12-month rolling time period is established in the Source-wide Conditions.

Compliance with the source-wide HAP emission limits is demonstrated by recordkeeping requirements set forth in Special Condition (SC) VI.1 of MI-ROP-B2329-2016. Records of the facility-wide HAP emissions between June 2017 through May 2018 were provided by Ms. Sommers (Attachment 1). These records indicate the highest individual 12-month rolling HAP emissions were 0.79 tons per year of Hexane and the highest aggregate HAP emissions were 1.1 tons. According to Ms. Sommers, HAP emissions calculations are based on worst-case scenario monthly HAP emissions for each emission unit. A copy of the HAP emission calculation basis was provided by Ms. Sommers (Attachment 2). Yearly HAP emissions from fuel burning equipment were based on maximum rated heat input of the equipment, AP-42 emission factors, and 8760 hours of operation. Monthly emissions are calculated by dividing the yearly emissions by 12.

STAND-ALONE BOILERS
The two permitted boilers at Par Sterile are used as back-up for the co-generation heat recovery boiler that provides steam for heating, cooling, and sterilization.

Permit conditions for the boilers are included in the following tables in the ROP: EU-38-BOILER-3 and EU-38-BOILER-4.

EU-38-BOILER-3
During the inspection I verified EU-38-BOILER-3 is a Wickes boiler manufactured in 1960. The boiler is heated with a Peabody burner and has a maximum pressure of 650 lbs/square inch. According to Ms. Sommers, Par Sterile only uses natural gas in this boiler. I did not see the heat input capacity nor the fuel firing capabilities of the Peabody burner. It is stated in the ROP that the burner has a heat input capacity of 48 million Btu/hour and is capable of firing natural gas or fuel oil.

Ms. Sommers stated that Par Sterile has not used fuel oil in EU-38-BOILER-3 in the past four years and provided a document stating the fuel oil tank was removed October 21, 2016 (Attachment 3). Nearly all conditions for EU-38-BOILER-3 pertain to fuel oil sulfur specifications and limitations. These conditions were not

evaluated since Par Sterile appears to no longer be using fuel oil. Ms. Sommers did provide records of the hours of operation and the fuel usage for EU-38-BOILER-3 between June 2017 through May 2018 (Attachment 4) as required in SC VI.1 and 3. These records indicate that fuel oil was not used in EU-38-BOILER-3 between June 2017 through May 2018.

EU-38-BOILER-4

I inspected the nameplate for EU-38-BOILER-4. According to the nameplate, the unit is a Cleaver Brooks boiler capable of firing natural gas and nos. 2 and 6 fuel oil. The rated heat input capacity stated on the nameplate for this boiler is 24,780 MBtu/hour (24.780 million Btu/hour). According to Ms. Sommers, Par Sterile only uses natural gas in this boiler.

As with EU-38-BOILER-3, Ms. Sommers stated that Par Sterile has not used fuel oil in EU-38-BOILER-4 in the past four years and provided a document stating the fuel oil tank was removed October 21, 2016 (Attachment 3). Nearly all conditions for EU-38-BOILER-4 pertain to fuel oil sulfur specifications and limitations. These conditions were not evaluated since Par Sterile appears to no longer be using fuel oil. Ms. Sommers did provide records of the hours of operation and the fuel usage for EU-38-BOILER-4 between June 2017 through May 2018 (Attachment 5) as required in SC VI.1 and 3. These records indicate that fuel oil was not used in EU-38-BOILER-3 between June 2017 through May 2018.

CO-GENERATION UNIT

FG382-COGEN

FG382-COGEN consists of a natural gas-fired turbine (EU-TURBINE) and a waste heat recovery steam generator (EU-DUCTBURNER). The waste heat boiler has an upstream duct burner rated at 20.9 MMBtu per hour. The waste heat boiler, including duct burner, is also known as Boiler No. 5.

The electricity generated from EU-TURBINE is used to provide power, in conjunction with DTE, to critical operations at the facility such as the septic and sterile areas. Steam from Boiler No. 5 is used for heating, cooling, and sterilization.

Par Sterile is participating in Solar Turbine's Engine Exchange Program for EU-TURBINE. The Engine Exchange Program involves replacing a currently operating gas turbine engine with a like-kind gas turbine using new or factory refurbished parts. The refurbished gas turbine engine is tested and certified to operate under current manufacturer standards.

On July 27, 2016, AQD received a letter from Ms. Sommers stating that a like-for-like exchange was performed on July 13, 2016. The exchange was performed as preventive maintenance. A stack test was required for the new engine by February 28, 2017. Records of the replacement turbine engine specifications, model, and serial number from the manufacturer are on file at the AQD SEMI District Office. These records indicate EU-TURBINE is a Centaur T-40 model gas turbine manufactured by Solar Turbines with a rated horsepower of 4700. I examined EU-TURBINE during the inspection and verified it is a Solar Turbines Incorporated Centaur Gas Turbine. I was unable to read the model and serial number printed on the nameplate during the inspection.

Emissions from FG382-COGEN are limited to the following in the ROP:

Pollutant	Limit
NOx	0.50 lb/MMBtu
NOx	121 tpy

Emissions from EU-TURBINE are limited to the following in the ROP:

Pollutant	Limit
NOx	167 ppm
SO_2	0.30 lb/MMBtu
SO_2	56.5 tpy

Compliance with the NOx and SO2 emission limits, according to the ROP, is demonstrated through testing and monitoring and recordkeeping requirements in SC V.1, SC VI. 4, and SC VI.5.

Testing on EU-TURBINE was conducted February 22, 2017 to demonstrate compliance with SC V.1. SC V.1. requires EU-TURBINE be tested with 360 days of ROP issuance or turbine engine exchange, but not later than the first February 28 following ROP issuance or engine replacement. The February deadline, according to Mr. Iranna Konanahalli, DEQ, Environmental Engineer, was established because Par Sterile typically only operates EU-DUCTBURNER in the winter months. If testing was permitted past the February immediately following ROP issuance or engine exchange, according to Mr. Konanahalli, Par Sterile could contend they are not able to test in the summer months and would need an extension on the 360 day testing requirement.

The results of the emissions testing conducted on February 22, 2017, according to the test report, are as follows:

Turbine Operating Load (%)	Average NOx Concentration (ppm @ 15% O_2)	Average NOx Emission Rate (lb/MMBtu)
100 (duct burner off)	117.0	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

The test report results indicate NOx emissions from FG382-COGEN are less than the 0.50 lb/MMBtu limit and the NOx emissions from EU-TURBINE are less than the 167 ppm limit.

Par Sterile is required to submit operating parameters established during testing that will be monitored to demonstrate EU-TURBINE is maintaining continuous compliance with the NOx emission limits. According to the EPA's Compilation of Air Emissions Factors (AP-42), the principal mechanism of nitrogen oxide formation in turbines firing gas is thermal NOx, which arises from the thermal dissociation and subsequent reaction of nitrogen (N2) and oxygen (O2) molecules in the combustion air. AP-42 also states that maximum reduction of thermal NOX can be achieved by control of both the combustion temperature and the stoichiometry. On May 19, 2017, Ms. Sommers submitted operating parameters, established during the February 22, 2017 stack test. The turbine engine temperature range submitted by Ms. Sommers was 930 -1163 degrees Fahrenheit. During the inspection, I observed that the turbine engine temperature was being monitored, as required in the ROP. The engine temperature during the inspection was 979 degrees Fahrenheit, which is within the range provided by Ms. Sommers. According to Mr. Santiago, the turbine engine will start shutting down (stop producing megawatts) at 1200 Fahrenheit.

SO2 emissions testing is not required for FG382-COGEN and EU-TURBINE because Par Sterile is only permitted to fire sweet natural gas in FG382-COGEN and EU-TURBINE with sulfur content of 20 grains per 100 standard cubic feet. Verification that the natural gas has less than 20 grains/dry standard cubic foot is required in SC VI.2. Ms. Sommers provided a statement from the natural gas provider for Consumers (Constellation) which certifies the maximum total sulfur content of the natural gas is 20 grains/100 standard cubic foot or less (Attachment 6).

Daily and monthly records of hours of operation, natural gas usage, power production, and steam production are required for FG-382-COGEN in SC VI.1. Ms. Sommers provided these records (Attachment 7).

Monthly and 12-month rolling NOx and SO2 emissions, as required in SC VI. 4 and 5, were provided by Ms. Sommers (Attachment 8). The NOx emissions reported are based on a conservative emission factor of 22.97 lb of NOx per hour. The records provided by Ms. Sommers indicate the12-month rolling total NOx emissions between June 2017 through May 2018 were 97.91 tons, which is below the 121 ton per year limit. The 12-month rolling total SO2 emissions reported for June 2017 through May 2018 were 0.07 tons.

DISINFECTING

FG-IPA-USE

Par Sterile employees use isopropyl alcohol (IPA) throughout the pharmaceutical plant for cleaning and disinfecting the process equipment and for removing labels from containers.

MI-ROP-B2329 -2016 limits IPA emissions plantwide to 24 tons per year. According to purchase records provided by Ms. Sommers (Attachment 9), Par Sterile orders 231.5 gallons of IPA each month. Ms. Sommers stated all of the IPA that is ordered each month is either used or discarded by the end of the month. The IPA emissions each month, therefore, are equivalent to the amount of IPA purchased. Calculations and records of the IPA emissions per month and 12-month rolling indicate 1188.2 lbs (0.59 tons) of IPA is emitted each month and 7.13 tons are emitted each year (Attachment 10).

GENERATORS

Par Sterile currently has two reciprocating internal combustion engines (RICE): EU-LAB-DIESEL-GENERATOR and EU-B38-DIESEL-GENERATOR. EU-LAB-DIESEL-GENERATOR is used to generate electricity to power lab incubators in the event of a power outage. EU-B38-DIESEL-GENERATOR is run by a program and is used to black-start FG382-COGEN. The requirements for these engines are located in the following flexible groups in the ROP: FG-RICE-NSPS4I-EMRGENCY-GENRATOR and FG-CI-RICE-MACT4Z<500HP.

FG-RICE-NSPS4I-EMRGENCY-GENRATOR

This flexible group includes one 500 kilowatt, diesel-fuel fired, 755 HP emergency engine manufactured by Cummins (EU-LAB-DIESEL-GENERATOR). During the inspection, I inspected the nameplate on the engine and verified the manufacturer, size, and fuel capabilities for this engine were the same as stated in the ROP. This engine is subject to the Standards of Performance for Stationary Compression Ignition Internal Combustion Engines, 40 CFR, Part 60, Subpart IIII.

Emissions from each engine in FG-RICE-NSPS4I-EMRGENCY-GENRATOR are limited to the following in the ROP:

Pollutant	Limit
NMHC + NOx	6.4 g/kW-hr
CO	3.5 g/kW-hr
PM	0.2 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 engines according to the manufacturer's emission-related written instructions. At the time of my inspection, I noted that this engine had a certified engine plate identifying it as a certified Cummins engine belonging to engine family: DCEXL015.AAJ. According to Ms. Sommers, this engine is maintained by the manufacturer and provided copies of maintenance and testing completed as required in SC VI. 3 (Attachment 11).

Per EPA's Engine Family Spreadsheet, (https://www.epa.gov/sites/production/files/2016-09/nrci-cert-ghg-14d.xls), the engines' certificate number is DCEXL015.AAJ and the engine has the following certified emission factors (g/kW-hr2):

Steady State NMHC	Steady State NOx	Steady State NMHC + NOx	Steady State CO	Steady State PM	Steady State CO2
0.10 g/kW-hr	5.64 g/kW-hr	5.37g/kW-hr	0.6 g/kW-hr	0.13 g/kW-hr	652.00 g/kW-hr

The emission factors are in compliance with the Subpart IIII emission limits as well as the emissions limits established in the ROP.

EU-LAB-DIESEL-GENERATOR is required to be equipped with a non-resettable hours meters to track the operating hours of the engine. During the inspection I observed a control/display panel for the engine, but the display was not on at the time and I was, therefore, unable to determine if the control/display panel included an hour meter.

Records of the hours of operation, reason for operation, and number of gallons of fuel used each month for EU-LAB-DIESEL-GENERATOR are required in SC VI.2 and 4. Ms. Sommers provided records of the operating hours, reason for operation, and fuel use for June 2017 through May 2018 for EU-LAB-DIESEL-GENERATOR (Attachment 12). Based on these records, this engine operated 27.9 hours in the 12-month reporting period

which is less than the100 hours permit limit.

According to Ms. Sommers, EU-LAB-DIESEL-GENERATOR does not operate and is not contractually obligated to be available for more than 15 hours per calendar year for the purposes specified in §60.4211(f)(2)(ii) and (iii).

FG-CI-RICE-MACT4Z<500HP
This flexible group consists of one emission unit; EU-B38-DIESEL-GENERATOR. During the inspection, I read the manufacturer, size, and fuel capabilities listed on the nameplate of EU-B38-DIESEL-GENERATOR. Based on the nameplate, EU-B38-DIESEL-GENERATOR is a Caterpillar Model 3306, diesel fuel-fired, 382 HP engine capable of generating 270 kW of electricity.

FG-CI-RICE-MACT4Z<500HP SC III.1 requires the Par Sterile 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 1,000 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 September 18, 2017 (Attachment 13). This document indicates Michigan Cat personnel changed the oil and filter and inspected the air cleaner, hoses, and belts on EU-B38-DIESEL-GENERATOR.

SC III.5. in the ROP establishes a 100 hour per calendar year limit for maintenance checks, readiness testing, and emergency demand response for EU-B38-DIESEL-GENERATOR. Ms. Sommers provided records of the operating hours and fuel use for June 2017 through May 2018 for EU-B38-DIESEL-GENERATOR (Attachment 14). Based on these records, EU-B38-DIESEL-GENERATOR operated 15.96 hours in the 12-month reporting period which is less than 100 hours. According Ms. Sommers, this engine operated only for testing and maintenance purposes during the reported time period.

Ms. Sommers stated that EU-B38-DIESEL-GENERATOR does not operate and is not contractually obligated to be available for more than 15 hours per calendar year for the purposes specified in §60.4211(f)(2)(ii) and (iii).

EU-B38-DIESEL-GENERATOR is required to be equipped with a non-resettable hours meter to track the operating hours of the engine. During the inspection I observed a control/display panel for the engine, but the display was on at the time and I was unable to determine if the control/display panel included an hour meter as a result.

FGRULE290
Processes included in FGRULE290 include: dispensing solid materials, preparation of drug powder, liquid mixing, and packaging. According to Ms. Sommers, the drug manufacturing process involves weighing dry material, mixing frozen protein or solid active pharmaceutical products with water, and placing the products into vials or bags. Ms. Sommers said no solvents are used in the mixing process.

Ms. Sommers provided a list of the initial threshold screening level (ITSL) for each toxic air contaminate (TAC) emitted from FGRULE290 (Attachment 15). The list names five TACs: ethyl alcohol, benzyl alcohol, isopropyl alcohol, phenol, and estradiol. None of the compounds listed have initial threshold screening levels (IRSL). Ethyl alcohol, benzyl alcohol, isopropyl alcohol, and phenol have ITSLs greater than 2 micrograms per cubic meter are emitted from the process. Estradiol has an ITSL of 0.1 microgram per cubic meter. The ROP limits uncontrolled, non-carcinogenic VOC emissions with ITSLs greater than 2.0 micrograms per cubic meter to 1,000 lbs per month. Ms. Sommers provided records of the monthly and yearly non-carcinogenic VOC emissions from FGRULE290 (Attachment 16). The records state the yearly VOC emissions for FGRULE290 are 6.2 pounds for the time period between June 2017 through May 2018. The highest monthly VOC emission rate during the reported time period was 1.20 pounds in June 2017. Controlled emissions are limited to 500 lbs for TACs with ITSLs greater than 2.0 micrograms per cubic meter and 10 lbs for TACs with ITSLs between 0.04 and 2.0 micrograms per cubic meter. Emission records provided (Attachment 2) indicate the potential yearly phenol emissions were 0.014 lbs. Reported estradiol emissions for June 2017 through May 2018 were zero.

ACTIVE PTI NOT INCLUDED IN ROP
On May 26, 1988, a permit to operate (PTI 736-84) was issued to Parke-Davis (now Par Sterile) for the installation and operation of equipment used to manufacture the anticancer drug Amsidyl. According to the permit application for PTI 736-84, powder is mixed with solvent in a "glove box" controlled by a HEPA filter. PTI 736-84 was never voided and the conditions in the PTI are not included in MI-ROP-B2329-2016. According to Ms. Sommers, Amsidyl is not currently manufactured at the facility and solvents are not used in the current drug

manufacturing process. As stated in the preceding paragraph, current drug manufacturing processes are exempt from the requirements to obtain a permit to install per Rule 290. It appears PTI 736-84 can be voided because the drug manufacturing processes currently at the facility are exempt from the requirement to obtain a permit to install.

CONCLUSION

Based on information collected and belief formed after reasonable inquiry during this inspection, Par Sterile appears to be in compliance with the Federal Clean Air Act; Article II, Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994, PA 451; Michigan Department of Environmental Quality, Air Quality Division (MDEQ-AQD) administrative rules and Renewable Operating Permit (ROP) Number MI-ROP-B2329-2016.

NAME K. Kelly DATE 9/10/18 SUPERVISOR