

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

B232969220

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: 08/02/2023
STAFF: Noshin Khan	COMPLIANCE STATUS: Non Compliance	SOURCE CLASS: SM OPT OUT
SUBJECT: scheduled, on-site inspection		
RESOLVED COMPLAINTS:		

On Wednesday, August 2, 2023, I, Noshin Khan, Michigan Department of Environment, Great Lakes, and Energy-Air Quality Division (EGLE-AQD) staff, performed a scheduled, on-site inspection of PAR Sterile Products, LLC located at 870 Parkdale Road, Rochester, Michigan 48307 (SRN: B2329). The purpose of the inspection was to determine the facility's compliance status with the requirements of the federal Clean Air Act; Article II, Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 Public Act 451, as amended (Act 451); the AQD administrative rules, and the conditions of Permit to Install (PTI) Number 73-21. I also observed testing on the facility's non-certified natural gas fired spark ignition reciprocating internal combustion engine (RICE) for compliance with the emission limits specified in 40 CFR Part 60, Subpart JJJJ.

I arrived on site at about 9AM and met with Annette Sommers, Director of Global EHS Workforce Development. We discussed the facility's operations before Annette led me on a walkthrough of the site. The facility produces branded and generic injectable drugs. PAR purchases water based active pharmaceutical ingredients (API's) and packages the solutions in glass vials ranging in size from 1 to 50 milliliters. According to Annette the facility will soon begin preparing syringes, as well. API's are dispensed in downdraft, HEPA-filtered rooms. Emergency generators on site ensure that positive pressure in these rooms can be maintained in case of a power outage. According to Annette, the only process generating VOCs is from use of IPA wipes and spray used as surface wipe down during production. The facility operates three shifts, five days a week, and has 450 employees. Annette described the site as spanning 88 acres with four main buildings: Building 100, an administrative building (Building 8), inspection/packaging (referred to as "IPOC"), and the laboratories (referred to as "QTLDC").

Below, I discuss observations during the walkthrough as they apply to the conditions in the permit.

PTI 73-21

FGEMERGENS

The conditions of this flexible group apply to two diesel-fired emergency generators, EULABDIESELGEN and EUDIESELGEN.

EULABDIESELGEN is described in the permit as being rated at 755 HP/500 kW, and I observed that the nameplate on the generator matches this rating in compliance with Special Condition (S.C.) IV.2. During the inspection I also observed that the generator had a non-resettable hour meter, in compliance with S.C. IV.1, which read 189.0 hours. I also observed EUDIESELGEN and noted that the rating of 1744 HP/1300 kW on its nameplate matches the description in the permit, in compliance with S.C. IV.3. In accordance with S.C. IV.1, this unit also had a non-resettable hour meter which read 133.8 hours.

These units are subject to the following emission limits, per S.C. I.1-I.3 and 40 CFR 60.4205(a) (Subpart IIII):

Non-methane hydrocarbons (NMHC) and NOx: 6.4 g/kW-hr

CO: 3.5 g/kW-hr

PM: 0.20 g/kW-hr

In accordance with S.C. VI.2, Annette provided copies of the USEPA Certificate of Conformity for both generators showing that both units are certified engines with respect to the emission standards in 40 CFR Part 60.

S.C. II.1 requires that only diesel fuel with a maximum sulfur content of 15 ppm (0.0015 percent) by weight and a minimum Cetane index of 40 or a maximum aromatic content of 35% by volume shall be burned in each engine. In compliance with S.C. VI.5, Annette provided a copy of the SDS for the fuel burned in the generators, with the product name "Marathon Petroleum No.2 Ultra Low Sulfur Diesel." The composition information indicates that the fuel contains a trace amount of sulfur (<0.0015%) and up to 5% of aromatics, indicating compliance with this requirement.

S.C. III.1 limits the operation of each engine (including necessary maintenance and readiness testing) to 500 hours per year based on a 12-month rolling time period. S.C. III.2 limits operation of each engine to 100 hours per calendar year for the purpose of necessary maintenance checks and readiness testing. S.C. III.3 limits the operation of each engine to 50 hours per calendar year for non-emergency situations.

Annette provided a log of the operating hours for each generator in compliance with S.C. VI.4. In calendar year 2022, EUDIESELGEN operated for 12 non-emergency hours and 0 emergency hours. EULABDIESELGEN operated for 15.6 non-emergency hours and 0 emergency hours. Based on the records provided the generators operate in compliance with S.C. III.1-III.3.

Per S.C. III.4, certified engines should be operated and maintained according to the manufacturer's emission-related written instructions. Annette provided maintenance records in accordance with S.C. VI.3 which indicate that EULABDIESELGEN was scheduled for annual maintenance on August 28, 2023, and EUDIESELGEN was scheduled for annual maintenance on August 31, 2023. Based on my observations during the inspection and the records provided, the facility operates the generators according to the manufacturer's instructions.

FG-IPA-USE

The conditions of this flexible group apply to all processes using IPA for cleaning and disinfecting process equipment and removing labels from containers. During the inspection, I observed the enclosed rooms where API dispensing is performed. To prevent contamination, entry into the enclosed area is not allowed without proper PPE and clearance.

S.C. I.1 sets an IPA emission limit of 24 tons per year (tpy) based on a 12-month rolling time period determined at the end of each calendar month. In accordance with S.C. VI.2, Annette provided calculations of IPA use in tons per calendar month and 12-month rolling total per month. The monthly IPA emissions are 0.9084 tons. This is calculated from a constant number of IPA spray cans and IPA wipe containers purchased each month. The resulting 12-month rolling IPA emissions are 10.9 tpy, which is below the limit.

FGFACILITY

Per S.C. I.1 and I.2, the facility is subject to an individual HAP emission limit of 8.9 tpy and a total HAPs emission limit of 22.4 tpy, both based on a 12-month rolling time period, as determined at the end of each month.

In accordance with S.C. VI.2, Annette provided HAP emission calculations. From January 2022 through July 2023, the highest 12-month rolling aggregate HAPs emissions were 1.98 tons as calculated in July 2023. This is below both limits.

Other Emission Units

The facility's 770 HP/550 kW natural gas fired Cummins emergency generator was undergoing emissions testing during my visit to verify compliance with 40 CFR Part 60, Subpart JJJJ. This generator is located near the main office and dispensing building. During the previous inspection, the facility was unable to provide documentation to certify compliance with Subpart JJJJ and initial testing required by 40 CFR 60 Subpart A had not been performed. A violation was sent to the facility on October 6, 2022 for operation of the generator without conducting the required initial performance test. Since the generator is larger than 500 HP, testing is required every 8,760 hours or 3 years, whichever comes first, to demonstrate compliance. In response to the violation, PAR planned to perform the required testing on December 15, 2022. The test was rescheduled multiple times, first due to scheduling conflicts, then due

to issues with the engine. The generator was unable to operate above 80% load without overheating due to a disconnected cable for the generator spark arrestor module. Later, the unit could not operate above 80% load for a sustained period due to a faulty gas regulator which was replaced on April 06, 2023. However, the replacement regulator was undersized and had to be replaced again on June 28, 2023. PAR then rescheduled testing for August 2, 2023. Annette provided work orders and maintenance logs for the generator for the incidents above. The results of the stack test are discussed later in this report.

The facility has a Cummins diesel backup fire pump, installed in 1979 and rated at 240 HP. I observed this unit during the walkthrough and observed a non-resettable hour meter that read 239.92 hours. In the records provided by Annette, it's indicated that the pump is operated for 30 minutes each week for maintenance and uses 19.48 gallons of fuel per month. This unit is exempt from permit requirements per Rule 285(2)(g).

The facility also has a 150 kW Cummins natural gas fired emergency generator to serve as backup for the computer servers in Building 8. I observed this unit during my walkthrough and observed a non-resettable hour meter that read 58.8 hours. Annette also provided the USEPA Certificate of Conformity showing that the engine is certified with respect to the emissions standards in 40 CFR Subpart 60. These limits are 4.4 g/kW-hr of CO, 2.7 g/kW-hr of NMHOC + NO_x, 2 g/HP-hr of NO_x, 2.7 g/kW-hr of HC + NO_x, 1 g/HP-hr of VOC, and 4 g/HP-hr of CO. This unit is also exempt from permit requirements per Rule 285(2)(g).

In the QTLDC building there are two boilers used for space heating in the labs. I observed the labs during our walkthrough but was unable to see the boilers. Annette sent pictures of the nameplates which show that each has a maximum heat input capacity of 4 MMBtu/hr. These units are exempt from permit requirements per Rule 282(2)(b)(i).

The facility claims permit exemption Rule 290 for its manufacturing activities. The records Annette provided include monthly and 12-month rolling calculations for emissions of the following individual toxic air contaminants: hydrochloric acid, phenol, hexane, formaldehyde, propylene, and manganese.

The highest monthly emissions of each of these compounds from January 2022 through July 2023 are listed below:

Compound	Highest Individual Month Emissions (lbs)
HCL	0.56
Phenol	1.77
Hexane	140
Formaldehyde	155
Propylene	350
Manganese	140

Although the total uncontrolled emissions of air contaminants from manufacturing activities are less than 1,000 lbs/month, formaldehyde and manganese have a 20 lb/month emission limit due to their initial threshold screening levels (ITSL). Based on the calculations provided, these limits have been exceeded and the facility is in violation of Rule 201.

Stack test

After arriving at the facility, I checked in with testing staff from Impact Compliance and Testing around 9:10 AM. Andrew Riley (EGLE-AQD) was also present to observe testing. The first run was finished soon after I checked in—staff informed me that it was performed from 8:10 AM to 9:12 AM. For each run, the test probe was placed in Stack A for 30 minutes and Stack B for 30 minutes for a total run time of 1 hour. Impact staff confirmed that they were operating the generator at a minimum of 90% capacity. After my inspection, I checked in with staff again after Run 2 was complete. Run 2 was performed from 9:30 AM to 10:32 AM.

Below are the preliminary results I recorded during my observations, not corrected to 15% O2:

Run 1

Parameter	Stack A Average	Stack B Average
VOC	5.92	5.71
NOx	410	269
CO	1405	1266
CO2	12.5	12.4
O2	0.05	0.04

Run 2

Parameter	Stack A Average	Stack B Average
VOC	6.06	5.69
NOx	425	317
CO	1370	1290
CO2	12.5	12.4
O2	0.04	0.04

On August 24, 2023, a final test report was submitted with the summarized results below.

Parameter	Run 1	Run 2	Run 3	Three-Test Average
NOx @ 15% O2 (limit 160 ppmvd)	96.3	106	115	106 ppmvd
CO @ 15% O2 (limit 540 ppmvd)	381	377	376	378 ppmvd
VOC @ 15% O2 (limit 86 ppmvd)	1.89	2.03	1.93	1.95 ppmvd

These results indicate compliance with the emission limits in 40 CFR Part 60.

Conclusion

The facility is currently in violation of Rule 201 because it has not met the emission limits in Rule 290 for its manufacturing processes and a violation notice will be issued. The provided emission calculations for formaldehyde and manganese show emissions greater than 20 lbs in a month for each. Based on my observations during the inspection and records review, the facility is in compliance with the other evaluated rules and regulations.

NAME Noshin Khan

DATE 9/27/2023

SUPERVISOR K. Kelly