



October 19, 2022

EGLE AQD Warren District
27700 Donald Court
Warren, MI 48092

RE: Notice of Violation Response - Par Sterile Products

Dear District Supervisor:

On 16SEP2022, the Department of Environment, Great Lakes and Energy (EGLE), Air Quality Division, conducted an inspection of Par Sterile Products (Par) located at 870 Parkdale Rd., Rochester, Michigan 48307. The purpose of the inspection was to determine Par's compliance with applicable rules of the Clean Air Act; the Air Pollution Control Rules; Standards of Performance for Stationary Spark Ignition and Compression Ignition Internal Combustion Engines; and Permit to Install No. 73-21. The inspection determined that Par installed and operated a natural gas emergency generator that is non-EPA certified. Par was not able to provide performance testing results required for a non-EPA certified generator per 40 CFR Part 60, Subpart JJJJ.

The emergency generator is a 770 HP generator manufactured by Cummins/Onan in 1996. It is natural gas fired. The generator was onboarded in April 2020. It was installed at Par following the 1996 Cummins installation guidelines. The generator is operated approximately one hour per month by site staff for routine preventative maintenance, and it is operated annually with Cummins service personnel to complete their preventative maintenance protocol.

The following will be completed to address the Notice of Violation:

1. Performance testing will be completed per NSPS JJJJ 60.4230 (a)(4)(iv); 60.4233(e); 60.4243(b)(2)(ii); 60.4244 (testing requirements) to verify compliance with Table 1 emissions. Testing will be scheduled as soon as possible, with results being provided to EGLE no later than 15DEC2022.
2. Performance testing will be scheduled in Par's preventative maintenance system to occur every three years or every 8,760 hours of operation (whichever comes first) to comply with 60.4244. The work order number assigned in the preventative maintenance system will be provided to EGLE for verification by 15DEC2022.
3. Current procedure to evaluate construction projects for environmental compliance will be reviewed. Procedural changes for evaluating impact of onboarded or modified equipment against federal and state air regulations will be provided to EGLE by 15DEC2022.

We believe that you will find the above initial response satisfactory. We remain committed at Par to maintain acceptable regulatory compliance at the facility. We would appreciate an opportunity to supply additional information to resolve any remaining issues that you may have after reviewing this response. Should you have any questions or comments, please contact me at (248) 656-5370 or via email at sommers.annette@endo.com.

Sincerely,

A handwritten signature in cursive script that reads "Annette Sommers".

Annette Sommers
Associate Director, EHS

Cc:

Adam Bognar (EGLE)
Jenine Camilleri (EGLE)
Paula Del Papa (Par)