



December 7, 2022

EGLE AQD Warren District
27700 Donald Court
Warren, MI 48092

RE: Update to Notice of Violation Response - Par Sterile Products

Dear District Supervisor:

I am providing an update to Par Sterile Products (Par's) response to the Notice of Violation issued to Par as the result of the inspection conducted by the Department of Environment, Great Lakes and Energy (EGLE), Air Quality Division on 16SEP2022. Par submitted the original response to EGLE on 29OCT2022. The corrective actions have not changed; however, completion dates for the corrective actions are extended. The corrective actions are updated below.

The Notice of Violation was issued when 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 corrective actions 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 15FEB2023 (formerly 15DEC2022). Date is adjusted to meet vendor emission testing schedule. Testing is confirmed for 04JAN2023, and testing protocol is submitted to EGLE.
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 15FEB2023 along with emissions testing results.
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 15FEB2023.