



GRETCHEN WHITMER  
GOVERNOR

STATE OF MICHIGAN  
DEPARTMENT OF  
ENVIRONMENT, GREAT LAKES, AND ENERGY  
WARREN DISTRICT OFFICE



LIESL EICHLER CLARK  
DIRECTOR

October 6, 2022

VIA E-MAIL AND U.S. MAIL

Paula Del Papa  
VP Manufacturing Operations  
Par Sterile Products  
870 Parkdale Road  
Rochester, MI 48307

SRN: B2329, Oakland County

Dear Paula Del Papa:

**VIOLATION NOTICE**

On September 16, 2022, the Department of Environment, Great Lakes, and Energy (EGLE), Air Quality Division (AQD), conducted an inspection of Par Sterile Products located at 870 Parkdale Road, Rochester, Michigan. The purpose of this inspection was to determine Par Sterile Products' 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; 40 CFR Part 60 Subpart JJJJ & IIII – Standards of Performance for Stationary Spark Ignition and Compression Ignition Internal Combustion Engines; and Permit to Install No. 73-21.

During the inspection, staff observed the following:

<b>Process Description</b>	<b>Rule/Permit Condition Violated</b>	<b>Comments</b>
Natural gas fired emergency generator (770 HP, Spark Ignition)	40 CFR 60.4243(b)(2)(ii) 40 CFR 60.8(a)	Facility installed and commenced operation of an engine not certified for compliance with 40 CFR Part 60, Subpart JJJJ without conducting the necessary performance testing within 180 days after initial startup.

Please initiate actions necessary to correct the cited violation and submit a written response to this Violation Notice by October 27, 2022 (which coincides with 21 calendar days from the date of this letter). The written response should include: the dates the violation occurred; an explanation of the causes and duration of the violation; whether the violation is ongoing; a summary of the actions that have been taken and are proposed to be taken to correct the violation and the dates by which these actions will take place; and what steps are being taken to prevent a reoccurrence.

Paula Del Papa  
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Please submit the written response to EGLE, AQD, Warren District, at 27700 Donald Court, Warren, MI 48092 and submit a copy to Jenine Camilleri, Enforcement Unit Supervisor at EGLE, AQD, P.O. Box 30260, Lansing, Michigan 48909-7760.

If Par Sterile Products believes the above observations or statements are inaccurate or do not constitute violations of the applicable legal requirements cited, please provide appropriate factual information to explain your position.

Thank you for your attention to resolving the violation cited above and for the cooperation that was extended to me during my inspection of Par Sterile Products. If you have any questions regarding the violation or the actions necessary to bring this facility into compliance, please contact me at the number listed below.

Sincerely,



Adam Bogner  
Environmental Engineer  
Air Quality Division  
586-854-1517

cc: Mary Ann Dolehanty, EGLE  
Annette Switzer, EGLE  
Christopher Ethridge, EGLE  
Brad Myott, EGLE  
Jenine Camilleri, EGLE  
Joyce Zhu, EGLE