

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

B361071764

<b>FACILITY:</b> Pharmacia & Upjohn Co LLC, a subsidiary of Pfizer		<b>SRN / ID:</b> B3610
<b>LOCATION:</b> 7000 Portage Road, KALAMAZOO		<b>DISTRICT:</b> Kalamazoo
<b>CITY:</b> KALAMAZOO		<b>COUNTY:</b> KALAMAZOO
<b>CONTACT:</b> Jeff Robey , Senior Specialist EH & S		<b>ACTIVITY DATE:</b> 04/18/2024
<b>STAFF:</b> Michael Cox	<b>COMPLIANCE STATUS:</b> Compliance	<b>SOURCE CLASS:</b> MEGASITE
<b>SUBJECT:</b> Announced Scheduled Inspection Part 1 of 3 (PCE)		
<b>RESOLVED COMPLAINTS:</b>		

At approximately 8:00 A.M. on April 18, 2024, Air Quality Division (AQD) staff Michael Cox (MTC) conducted an announced on-site inspection of Pfizer located at 7000 Portage Road, Kalamazoo, Michigan. The purpose of this inspection was to determine compliance with Section 1 of the facility's renewable operating permit (ROP) MI-ROP-B3610-2021a and Permit to Install (PTI) No. 49-20. This inspection is year one (1) of the three-year inspection cycle. Accompanying AQD staff on the inspection was Mr. Jeff Robey, Environmental Health and Safety Manager and Ms. Bridget Grau, the Environmental Health and Safety Specialist. Records for this inspection were reviewed for the time period of January 1, 2021, through April 18, 2024, on-site. Prior to arriving on site MTC observed the perimeter of the facility for any visible emissions and odors. No odors or visible emissions other than steam plumes were noted on-site.

### Facility Description

This 1,300-acre facility manufactures active pharmaceutical ingredients (APIs), drug products (DP) and medical devices. The facility consists of manufacturing operations, pilot plant and lab operations, waste handling operations, and storage tank farms. Processes that occur at the facility include, but are not limited to, fermentation, mixing, blending, drying, and solids handling.

### Regulatory Analysis

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Pfizer is a major source for nitrogen oxides (NO<sub>x</sub>), particulate matter (PM), volatile organic compounds (VOCs), lead (Pb), carbon monoxide (CO), sulfur oxides (SO<sub>x</sub>), and hazardous air pollutants (HAP). Pfizer is currently operating under MI-ROP-B3610-2021A, PTI No.49-20, PTI No.135-20A, PTI No.167-20A, PTI No. 30-21B, PTI No.4-22, PTI No.103-22, PTI No.23-23, PTI No.43-23, and PTI No.102-23A. The facility is subject to National Emission Standards for Hazardous Air Pollutants (NESHAP) 40 CFR 63, Subpart ZZZZ - National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines, 40 CFR 63 Subpart DDDDD—National Emission Standards for Hazardous Air Pollutants for Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters, 40 CFR 63 Subpart GGG—National Emission Standards for Pharmaceuticals Production, 40 CFR 63 Subpart H—National Emission Standards for Organic Hazardous Air Pollutants for

**Equipment Leaks, 40 CFR 63 Subpart I—National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks, 40 CFR 63 Subpart MMM—National Emission Standards for Hazardous Air Pollutants for Pesticide Active Ingredient Production, New Source Performance Standards (NSPS) 40 CFR 60 Subpart Kb—Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984, 40 CFR 60 Subpart III—Standards of Performance for Stationary Compression Ignition Internal Combustion Engines, 40 CFR 60Subpart JJJJ—Standards of Performance for Stationary Spark Ignition Internal Combustion Engines.**

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**EUEBLR 43-7-S1:**

**This emission unit consists of a 120,000 lbs steam/hr natural gas boiler with No. 2 fuel oil as backup. No. 2 fuel oil has only been burned for testing purposes for less than 5 minutes during the 2022 calendar year. No. 2 fuel oil vendor certifications are kept on-site and were available for review. The vendor certifications indicate that the No.2 fuel oil is Ultra Low Sulphur diesel fuel, which is 0.0015 weight percent sulfur. This unit was not running at the time of inspection and was stated to be down for approximately 2 weeks for annual preventative maintenance.**

**EUEBLR43-8-S1:**

**This emission unit consists of a 120,000 lbs steam/hr natural gas boiler with No. 5 fuel oil as backup. They have not used No. 5 fuel during the time period covered by this inspection. No. 5 fuel oil is not kept on site. This unit was not running at the time of inspection.**

**EUEBLR43-9-S1:**

**This emission unit consists of a 120,000 lbs steam/hr natural gas boiler with maximum heat input capacity of 144.7 MMBTU/hr for natural gas and 138.3 MMBTU/hr for No. 2 fuel oil. This emission unit is equipped with low NOx burners and flue gas recirculation as control equipment, and only natural gas may be burned in this unit. It has a continuously operating oxygen trim system and a continuous emissions monitoring system (CEMS) that records NOx emissions. At the time of inspection, the NOx CEMS read 22.4 ppm at 3.16% O<sub>2</sub>. The unit was operating at 40,599 lbs steam/hr during the inspection. NOx is limited to 0.20 lb/MMBTU on a thirty-day average. The facility is keeping these records, and the highest value observed was 0.045 lb/MMBTU. NOx emissions are also limited to 32.0 TPY on a 12-month rolling period. Records are being kept as required. The highest 12-consecutive NOx emission occurred during the 12-month rolling periods ending in October, November, and December 2022, when 6.1 tons of NOx was emitted. This emission unit is also limited to using 1,614,170 gallons of No. 2 fuel oil per 12-month rolling time period. These records are being kept as required and were noted to be under the limit. The facility is also keeping track of how much natural gas and #2 fuel oil they are using and when. The facility is keeping records of the number of hours they use fuel oil and the capacity factors for natural gas and fuel oil. No. 2 fuel oil vendor certifications are**

kept on-site and were available for review. The vendor certifications indicate that the No.2 fuel oil is Ultra Low Sulphur Diesel Fuel, which is 0.0015 weight percent sulfur.

#### **EUB51GENERATOR-S1:**

This emission unit consists of a diesel-fired reciprocating engine with a max capacity of 1.25MW. It is used only as an emergency generator, and it is not subject to MACT or NSPS. During the facility walk through the non-resettable hour meter read 393.6 hours. Diesel fuel vendor certifications are kept on-site and were available for review. The vendor certifications indicate that the Diesel fuel is Ultra Low Sulphur Diesel Fuel, which is 0.0015 weight percent sulfur. The facility is keeping track of the date, duration, and description of malfunctions and corrective maintenance for this emission unit. This unit also has a NOx emissions limit of 12.9 TPY on a 12-month rolling timescale. Records indicate that they are under this limit. The emission unit is also under the operating hours limit of 500 hours per 12-month rolling time period, with the highest 12-consecutive month rolling time period occurring in December 2021 when the emission unit operated for 25.5 hours for maintenance and readiness testing.

#### **FGBLR43-10&11-S1:**

This flexible group consists of two new 120,000 lb steam/hr boilers with 143.2 MMBTU/hr heat input capacity for natural gas and 138.5 MMBTU/hr for #2 fuel oil. Natural gas is used as the primary fuel, with #2 fuel oil being used as backup. These boilers are equipped with low NOx burners and flue gas recirculation for NOx control and utilize CEMS to monitor NOx emissions. At the time of inspection, Boiler 10 and Boiler 11 were operating. Boiler 10 was operating at 42,161 lbs steam/hr, and the NOx CEMS read 22.0 ppm at 3.10% O<sub>2</sub>. Boiler 11 was operating at 65,201 lbs steam/hr, and the NOx CEMS read 22.9 ppm at 3.14% O<sub>2</sub>. NOx is limited to 0.20 lb/MMBTU on a thirty-day average. The facility is keeping these records, and the highest value observed for Boiler 10 was 0.042 lb/MMBTU in February 2021. The highest value observed for Boiler 11 was 0.028 in April 2021. NOx emissions are also limited the unit to 33.6 TPY on a 12-month rolling timescale. The facility is keeping these records as required. The highest 12-consecutive month rolling NOx emission for Boiler 10 occurred during the 12-month period ending in July 2022, when 6.0 tons of NOx was emitted. The highest 12-consecutive month rolling NOx emission for Boiler 11 occurred during the 12-month period ending in July 2023, when 7.1 tons of NOx was emitted. This flexible group is limited to using no more than 2,527,380 gallons (combined) of #2 fuel oil per year before July 1, 2021, and 3,839,580 gallons per year after June 30, 2021, based on a 12-month rolling timescale. The facility is keeping these records as required and are under these limits. They are also keeping track of how much natural gas and #2 fuel oil they are using and when. Records the number of hours they use fuel oil and the capacity factors for natural gas and fuel oil are being kept as required. They also have records to show that the fuel oil contains less than 0.0015 weight percent sulfur.

#### **FGB43OILTANKS-S1:**

This flexible group consists of three 20,000-gallon No.2 oil storage tanks providing fuel to FGBLR43-10&11-S1 and EUEBLR43-9-S1. I observed these tanks during the inspection. The facility is keeping records of the tank specifications on-site as required.

**FGBOILERMACT-EXISTING AND NEW GAS 1-S1:**

This flexible group consists of the requirements for new and existing boilers and process heaters that are designed to burn gas 1 subcategory fuel with a heat input capacity of 10 MMBTU/hr or greater at major sources of HAP emissions per 40 CFR Part 63, Subpart DDDDD (Boiler MACT). Units designed to burn gas 1 subcategory fuels include boilers or process heaters that burn only natural gas, refinery gas, and/or Other Gas 1 fuels. Units that burn liquid fuel for testing or maintenance purposes for less than a total of 48 hours per year, or that burn liquid fuel during periods of curtailment or supply interruptions are included in this definition.

The affected boilers of this subpart are EUEBLR43-7-S1, EUEBLR43-8-S1, EUEBLR43-9-S1, EUEBLR43-10-S1, and EUEBLR43-11-S1. The facility has conducted initial tune-ups on the affected boilers as required and is operated the affected boilers in accordance with good air pollution control practices for minimizing emissions. The Subpart DDDDD tune-up report was last submitted on February 4, 2022. It should be noted that tune-ups are on a 5-year schedule. The facility is submitting reports in accordance with Subpart DDDDD and MI-ROP-B3610-2021A as required.

**FGBOILERMACT-EXISTING AND NEW SMALL UNITS-S1**

This flexible group consists of the requirements for all existing boilers and process heaters with a heat input capacity of <10 MMBTU/hr for major sources of HAP emissions per 40 CFR Part 63, Subpart DDDDD (Boiler MACT). These boilers or process heaters are designed to burn solid, liquid, or gaseous fuels.

The facility has conducted initial tune-ups on the affected boilers and process heaters as required and is operating the affected boilers and process heaters in accordance with good air pollution control practices for minimizing emissions. The Subpart DDDDD tune-up report was last submitted on February 4, 2022. It should be noted that tune-ups are on a 5-year schedule. The facility is submitting reports in accordance with Subpart DDDDD and MI-ROP-B3610-2021A as required.

**FGCOLDCLEANER-S1:**

This flexible group consists of any cold cleaner that is grandfathered or exempt from Rule 201 pursuant to Rule 278, Rule 278a and Rule 281(2)(h) or Rule 285(2)(r)(iv). Existing cold cleaners were placed into operation prior to July 1, 1979. New cold cleaners were placed into operation on or after July 1, 1979.

There are 15 cold cleaners associated with Section 1 of the ROP. The facility has a list of each cold cleaner that contains the specifications for each unit. Each unit has an identifier, date of installation, air/vapor interface area, Reid vapor pressure, and solvent type. The units use either Safety-Kleen Premium Gold or Isopar-L. None of the units are agitated or heated. During the facility tour, I observed six of these cold cleaners, and each had rules posted and the lid closed.

**FGRULE290-S1:**

This flexible group consists of any emission unit that emits air contaminants and is exempt from the requirements of Rule 201 pursuant to Rule 278, Rule 278a and Rule 290. Emission units installed/modified before December 20, 2016, may show compliance with Rule 290 in effect at the time of installation/modification. Section 1

has one emission unit in this flexible group: EUELECTROPOLISH-S1. The facility is keeping the Rule 290 records for the emission unit, which specifies each contaminant emitted, whether it was controlled or uncontrolled, the ITSL/IRSL, and the calculated actual emissions. The records showed that the emission unit was under the required limits for the time period covered by this inspection.

#### **FGRICEMACT-CI-S1:**

This flexible group consists of emergency generators subject to 40 CFR Part 63, Subpart ZZZZ - National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines (RICE), located at a major source of HAP emissions, existing emergency, compression ignition (CI) RICE equal to or less than 500 brake hp. A RICE is existing if the date of installation is before June 12, 2006.

The facility is keeping track of the hours of operation, the purpose of operation, the occurrences of any malfunctions and corrective actions taken, and maintenance records for each unit. These records show that they are under the operating hours limits and are conducting maintenance on the generators as required. During the facility tour, I observed the emergency generators serving Building 51 and Building 38. All the observed generators were noted to have a non-resettable hour meter installed. Diesel fuel vendor certifications are kept on-site and were available for review for the generators that fire diesel fuel. The vendor certifications indicate that the Diesel fuel is Ultra Low Sulphur Diesel Fuel, which is 0.0015 weight percent sulfur.

#### **FGRICE-CI-NSPS-S1:**

These flexible group conditions apply to Stationary Compression Ignition RICE units that meet all the criteria specified in 40 CFR Part 60, Subpart IIII; 40 CFR 60.4200, and meet the definition of Emergency Stationary ICE or Fire Pump Engine in 40 CFR 60.4219

Four fire pumps serving the facility are subject to Subpart IIII. During the facility tour, I observed the fire pump generators in Building 199 East and Building 199 West. The facility is keeping track of the hours of operation for each unit. After a review of the hours of operation records, it was noted that the generators are under the hours of operation limits set forth in this subpart. Diesel fuel vendor certifications are kept on-site and were available for review for the generators that fire diesel fuel. The vendor certifications indicate that the Diesel fuel is Ultra Low Sulphur Diesel Fuel, which is 0.0015 weight percent sulfur.

#### **FGRICE-SI-NSPS-S1:**

This flexible group conditions apply to Stationary Reciprocating Spark Ignition Internal Combustion Engines (ICE) units that meet all the criteria specified in 40 CFR Part 60, Subpart JJJJ; 40 CFR 60.4200, and meet the definition of Emergency Stationary ICE 40 CFR 60.4248.

One propane-fired emergency generator is subject to Subpart JJJJ. The facility is keeping track of the hours of operation, the purpose of operation, the occurrences of any malfunctions and corrective actions taken, and maintenance records for the unit.

The records show that the generator is under the hours of operation limits and are conducting appropriate maintenance to comply with this Subpart.

**Compliance Determination**

Based on the observations made during the inspection and review of the required records and reports, Pfizer appears to be in compliance with Section 1 of MI-ROP-B3610-2021A and PTI No. 49-20, as well as all other State and Federal Air Pollution rules and regulations.

NAME Michael T. Cox

DATE 5/2/2024

SUPERVISOR Monica Brothers