

DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION
ACTIVITY REPORT: Scheduled Inspection

B2329

Sched.

FY 2016 Insp

B232936172

FACILITY: Par Sterile Products LLC	SRN / ID: B2329
LOCATION: 870 PARKDALE RD, ROCHESTER	DISTRICT: Southeast Michigan
CITY: ROCHESTER	COUNTY: OAKLAND
CONTACT: Annette Sommers	ACTIVITY DATE: 08/17/2016
STAFF: Iranna Konanahalli	COMPLIANCE STATUS: Compliance
SUBJECT: FY 2016 Major ROP CMS level-2 scheduled annual inspection of Par Sterile Products, LLC. ("Par")	SOURCE CLASS: MAJOR
RESOLVED COMPLAINTS:	

B2329 - SAR - 2016 08 17

Par Sterile Products, LLC (B2329)
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Rochester, Michigan 48307-1740

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Name / ownership changes: Parke Davis, Sterile Products Division → Warner-Lambert
→ Parkedale Pharmaceuticals, Inc. → Parkedale Pharmaceuticals, Inc., a subsidiary of
King Pharmaceuticals, Inc. → JHP Pharmaceuticals, LLC. → Par Sterile Products, LLC

SIC Code = 2834. NAICS Code = 325411

ROP Renewal Application No. 201600011 dated Jan 06, 2016

Renewable Operating Permit Number: MI-ROP-B2329-2012b. Synthetic Minor for HAPs
via source-wide HAP limits in the ROP.

Name change: JHP Pharmaceuticals (MI-ROP-B2329-2012 dated June 5, 2012) → Par
Sterile Operations, LLC (MI-ROP-B2329-2012a dated March 28, 2014), incorrect name →
Par Sterile Products, LLC, (MI-ROP-B2329-2012b)

Name confusion: Correct name (2014) is Par Sterile Products, LLC (incorrect names:
Par Sterile Operations, LLC, Par Pharmaceuticals, LLC)

ROP revisions: MI-ROP-B2329-2007a (ownership change) dated February 14, 2008 →
MI-ROP-B2329-2007b (Turbine and Ductburner NOx limit change) dated December 10,
2008 →, MI-ROP-B2329-2012 (renewal) → MI-ROP-B2329-2012a (name change) → MI-
ROP-B2329-2012b (name change)

2012 ROP renewal: MI-ROP-2329-2012 approved on June 6, 2012. FG-100-ETO is
removed as 3 EO sterilizers, 4 freeze dryers and Deoxx scrubber are all removed as of
July 2011. All conditions pertaining to sulfur in fuel are removed from the ROP, FG-382-
CoGen since the turbine is not capable of burning diesel as result of a turbine retrofit.

Not subject to: NESHAP / MACT O: 40 CFR, Part 63, Subpart O, National Emission
Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization

and Fumigation Operations (Final Rule: Federal Register / Vol. 59, No. 233 /Tuesday, December 6, 1994 / Rules and Regulations. Effective July 2011, all EO processes (Sterilizers and Freeze Dryers and the control equipment known as Deoxx scrubber) are removed.

May not be subject to: Area NESHAP / MACT 6V, 40 CFR Part 63, National Emission Standards for Hazardous Air Pollutants for Chemical Manufacturing Area Sources, Page 56008 Federal Register / Vol. 74, No. 208 / Thursday, October 29, 2009 / Rules and Regulations / Final Rule. The Area NESHAP / MACT 6V is for the control of hazardous air pollutants for nine area source categories including Pharmaceutical Production. AQD has decided not to take delegation of these standards and therefore no attempt has been made evaluate Par's compliance with NESHAP / MACT 6V. Per Nov 4, 2013, e-mail from Ms. Sommers, Par does not meet the criteria and hence not subject to Area NESHAP / MACT 6V.

May be not subject to: Area Source (Par is synthetic minor) NESHAP / MACT 3G, Subpart GGG, Hazardous Air Pollutants for Source, Categories: Pharmaceuticals Production, Page 50280 Federal Register / Vol. 63, No. 182 / Monday, September 21, 1998 / Rules and Regulations / Final Rule. The NESHAP / MACT 3G is for existing and new facilities that manufacture pharmaceutical products. AQD has decided not to take delegation of these standards and therefore no attempt has been made evaluate Par's compliance with NESHAP / MACT 3G. See Page 25666 Federal Register / Vol. 70, No. 92 / Friday, May 13, 2005 / Rules and Regulations / Direct final rule; amendments/ for amendments. According to Ms. Sommers, Par does not use solvents and coatings listed in the MACT and therefore may be exempt from the MACT 3G.

May be subject to: Area source NESHAP / MACT ZZZZ / RICE MACT, Standards of Performance for Stationary Spark Ignition Internal Combustion Engines and National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines / Final rule (Page 3568, Federal Register / Vol. 73, No. 13 / Friday, January 18, 2008 / Rules and Regulations / Final rule; Page 51570 Federal Register / Vol. 75, No. 161 / Friday, August 20, 2010 / Rules and Regulations / Final rule; Page 12863 Federal Register / Vol. 76, No. 46 / Wednesday, March 9, 2011 / Rules and Regulations / Direct final rule; amendments for August 20, 2010, final rule; etc.). AQD has decided not to take delegation of these standards and therefore no attempt has been made evaluate Par's compliance with NESHAP / MACT 4Z.

Par's one Cummins (known as EU-LAB-DIESEL-GENERATOR : Installed in October 2013, Cummins Model DFEK, 500kW, 755 HP) of two (2: Cummins and Caterpillar) emergency generators is subject to: NSPS IIII or 4I, New Source Standards of Performance for Stationary Compression Ignition Internal Combustion Engines, 39154 Federal Register / Vol. 71, No. 132 / Tuesday, July 11, 2006 / Rules and Regulations / Final Rule; Page 48072 Federal Register / Vol. 79, No. 158 / Friday, August 15, 2014 / Rules and Regulations / Notice of final decision on reconsideration. One (Caterpillar) of two generators (Cummins EU-LAB-DIESEL-GENERATOR & Caterpillar Model XQ225 EU-B38-DIESEL-GENERATOR) is not subject to NSPS 4I based upon manufacture date (before April 1, 2006). Powerhouse Generator Caterpillar Model XQ225, 225kW, 316 HP, is used to start gas fired turbine.

May not be subject to (Par is HAP synthetic minor): NESHAP / MACT 4Y, Subpart

YYYY, National Emission Standards for Hazardous Air Pollutants for Stationary Combustion Turbines, Page 10512 Federal Register / Vol. 69, No. 44 / Friday, March 5, 2004 / Rules and Regulations / Final Rule. US EPA has adopted a final emission standard requiring control of formaldehyde emissions for all new or reconstructed stationary combustion turbines in the four lean premix and diffusion flame subcategories. The final rule applies to you if you own or operate a stationary combustion turbine which is located at a major source of HAP emissions. Par is a HAP Synthetic Minor Source.

Subject to: NSPS: 40 CFR, Part 60, Subpart GG, New Source Performance Standards for Stationary Gas Turbines (40 CFR, Part 60, Subpart GG, Final Rule, Amendments, Federal Register / Volume 69, No. 130 / Thursday, July 8, 2004 / Rules and Regulations). The original regulations were promulgated on September 10, 1979 (44 FR 52798). The NSPS GG amendments made changes to monitoring, testing, recordkeeping requirements.

Par's one (Cummins: manufactured in Feb 05, 2013) of two (2: 1 of 3 generators removed) emergency generators is subject to: NSPS IIII or 4I, New Source Standards of Performance for Stationary Compression Ignition Internal Combustion Engines, 39154 Federal Register / Vol. 71, No. 132 / Tuesday, July 11, 2006 / Rules and Regulations / Final Rule. One (CAT: cold-start engine for the gas turbine) of two generators are not subject to NSPS 4I based upon manufacture date (before April 2006). Upon removing one of three generators / RICE engines, there are two RICE engines: one cold-start RICE engine for natural gas only fired electricity generating gas turbine with duct-burner (CoGen) for steam generation (process and space heating) and one laboratory CI RICE (Diesel) emergency generator.

2014 Void PTI Nos.: 458-79, 905-79, 402-80, 1025-80, 31-81, 220-81, 570-81, 523-84, 736-84, 281-88A, 1109-91 voided on July 3, 2014

On June 29 and August 17, 2016, I conducted a Major ROP CMS level-2 scheduled annual inspection of Par Sterile Products, LLC. ("Par"), formerly the plant owned by King Pharmaceuticals, Inc. (now Pfizer), located at 870 Parkdale Road, Rochester, Michigan 48307-1740. The inspection was conducted to determine compliance with the Federal Clean Air Act; Article II, Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994, PA 451; Michigan Department of Environmental Quality, Air Quality Division (MDEQ-AQD) administrative rules and Renewable Operating Permit Number MI-ROP-B2329-2012b.

During the inspection, Ms. Annette M. Sommers (Phone: 248-656-5370; Fax: 248-650-6480; Cell: 586-531-5700; E-mail: annette.sommers@JHPPHARMA.com / Sommers, Annette), CIH, CSP, Manager, Industrial Health and Safety, assisted me. Mr. Edgardo Santiago (Phone: 248-656-5312), Stationary Engineer, also assisted.

Mr. Don Vigneu (Phone: 248-656-5312), Stationary Engineer, and Mr. John Kozaruk (Phone: 248-656-5312), Stationary Engineer were not present.

Par Sterile Products, LLC (in 2014 name change: JHP Pharmaceuticals → Par Sterile Products occurred), an investment company, or a private equity firm, is an integrated specialty healthcare company that acquires, develops, manufactures and distributes sterile injectable products predominantly to hospitals and clinicians. JHP

Pharmaceuticals was formed in 2007 in conjunction with the acquisition of selected specialty pharmaceutical products from King Pharmaceuticals (now Pfizer). JHP's (Par) high quality manufacturing facility provides contract manufacturing services to pharmaceutical and biopharmaceutical companies. Par (formerly JHP) is headquartered in Parsippany, New Jersey with its manufacturing facility located in Rochester, Michigan.

Per Mr. Charles T. Blocksidge's letter dated September 21, 2007, AQD transferred ownership (Rule 336.1219) of all process equipment, except two diesel-fuel fired reciprocating engine generators, from King Pharmaceuticals to JHP Pharmaceuticals. Mr. Blocksidge (202-772—5834) is an attorney with Blank Rome, LLP, Counselors at Law, Washington D.C. The two generators (FG-DIESEL-GENERATORS) are located at 1200 Parkedale, where King continues to operate penicillin process. JHP purchased only 870 Parkedale portion of King's facility. King purchased 1200 Parkedale facility from Baxter/Hyland Immuno, Inc. (B8907). In January 2011, Pfizer purchased King.

BOILER Nos. 1 and 2

Boiler Nos. 1 and 2 have been physically removed and are not part of the ROP (MI-ROP-B2329-2012a).

MI-ROP-B2329-2012a, EU-38-BOILER-3

Boiler No. 3 is a 48 million BTU per hour, natural gas fired boiler with a steam production capacity of 40,000 pounds per hour (DV383A). As it was installed before 1967, the boiler is grandfathered in connection with Rule 336.1201 (Permit-to-Install).

Natural gas usage and steam production records are kept via Powerplant Report (power plant excel spreadsheet). 6.73 million standard cubic feet (6,728 million BTU) of natural gas was used during 12-month period (MI-ROP-B2329-2012a, EU-38-Boiler-3 VI). Some fuel oil (1,269 gallons = 173.9 million BTU) was used in December 2008 due to emergency malfunction of the gas regulator. Fuel oil contained 0.3 percent sulfur; this is equivalent to 0.3 pounds of sulfur dioxide per million BTU (EU-38-BOILER-3, I.1 limit: 1.7 lbs. /MMBTU; Based upon a heating value of 140,000 BTU per gallon of fuel oil, the SO₂ emission limit is equivalent to a sulfur content of 1.68 [1.7]% by weight.) . Fuel oil has not been used since CY 2001 other than this emergency use.

The emission calculations are performed. Par has kept fuel oil tanks empty since 2009. Par wants to keep diesel capability.

Sulfur dioxide emissions are 0.002 tons (4.04 pounds) of SO₂ per 12-month.

All data pertain to CY 2015 period.

MI-ROP-B2329-2012a, EU-38-BOILER-4. CLEAVER-BROOKS BOILER NO. 4

Cleaver-Brooks Boiler No. 4 (Water Tube Steam Boiler Model: Delta 34-E) with 604 square feet economizer is a 25 million BTU per hour natural gas/No. 2 fuel oil (backup) fired boiler with a steam (125 psig) capacity of 21,000 pounds per hour (DV381A). The Boiler # 4, which was covered by PTI No. 231-79, was installed on July 31, 1979 (before June 9, 1989: not subject to NSPS Dc).

Natural gas usage and steam production records are kept via Powerplant Report (power plant excel spreadsheet). 10.84 million standard cubic feet (10,843 million BTU) of natural gas was used during 12-month period (MI-ROP-B2329-2012a, EU-38-Boiler-4 VI). Some fuel oil (2,405 gallons = 330 million BTU) was used in December 2000. Fuel oil contained 0.05 percent sulfur; this is equivalent to 0.05 pounds of sulfur dioxide per million BTU (MI-ROP-B2329-2012a, EU-38-Boiler-4, I.1 limit: 1.10 lbs./MMBTU; based upon a heating value of 140,000 BTU per gallon of fuel oil, the SO₂ emission limit is equivalent to a sulfur content of 1.08 [1.1]% by weight). Fuel oil has not been used since CY 2001.

The emission calculations are performed. Par has kept fuel oil tanks empty since 2009. Par wants keep diesel capability.

Sulfur dioxide emissions are 0.00325 tons of SO₂ per 12-month.

All data pertain to CY 2015 period.

MI-ROP-B2329-2007b FG-100-ETO (3 EO sterilizers and 4 freeze dryers) – removed Jul 2011.

Based upon August 29, 2011, inspection, all EO processes are removed. Deoxx Scrubber system is dismantled and the piping systems were removed in July 2011. Deoxx scrubber pit is filled with concrete per Sept 2012 inspection.

EO processes (freeze dryers and sterilizers) including Deoxx scrubber are removed from the ROP during the June 2012 renewal (MI-ROP-B2329-2012).

Based upon FY 2012 and 2014 inspection, all freeze dryers and sterilizers use steam.

MI-ROP-B2329-2012a, FG382-COGEN. COGENERATION TURBINE AND WASTE HEAT BOILER WITH DUCT BURNER

FG-382-COGEN: The cogeneration system consists of a turbine (EU-TURBINE), which drives a generator to generate electricity. A waste heat recovery steam generator (EU-DUCTBURNER) recovers energy from the turbine exhaust (hot combustion products). The waste heat boiler has an upstream duct burner rated at 20.9 million BTU per hour. Waste heat boiler, including duct burner, is also known as Boiler No. 5.

The original cogeneration system equipment (Solar T-4500) was installed in 1985 (PTI No. 619-85) and was upgraded / modified (Solar T-4700) in 1992. The Cogen process was covered by PTI No. 463-92 dated August 20, 1992 (ROP No. 199700020 F-1.2) and was amended as PTI No. 90-04 dated September 8, 2004 to include changes in monitoring, recordkeeping, testing, etc. due to amendments to the original NSPS GG (40 CFR, Part 60, Subpart GG, Final Rule, Amendments, Federal Register / Vol. 69, No. 130 / Thursday, July 8, 2004 / Rules and Regulations). The original standards were promulgated on September 10, 1979 (44 FR 52798).

Emission Units:

1. EU-TURBINE (Solar Centaur T-4700 42.18 million BTU per hour natural gas turbine)

2. EU-DUCTBURNER (Nooter waste heat recovery steam generator with duct burner, aka Boiler No. 5)

EU-TURBINE: Solar Centaur T-4700 model (nominal 4700 HP, manufactured by Caterpillar Solar Turbines, Inc.), of capacity 42.18 million BTU per hour heat input, natural gas turbine. The cogeneration system consists of a simple cycle, dual fired gas turbine which drives a generator capable of producing 2.8 megawatts of power. The generator is operated in parallel with local utility. Exhaust gases from the turbine are diverted to a waste heat boiler (aka Boiler No. 5) where plant steam is produced. No. 2 fuel oil has been removed effective August 15, 2010 and removed from the ROP (MI-ROP-B2329-2012) effective June 5, 2012.

EU-DUCTBURNER: Nooter waste heat recovery steam generator (aka Boiler No. 5) recovers energy from turbine exhaust to produce 19,830 pounds per hour of steam for plant use. This steam generator also has a natural gas fired *only* duct burner rated at 20.9 million BTU per hour that increases steam output to 41,200 pounds per hour. The duct burner is also known as Boiler No. 5.

FG-382-COGEN, I: Based upon February 20, 2013, stack test, nitrogen oxides emission rates for turbine are: 139.2 at 85% load, 139.4 at 80% load, 122.5 at 100% load and 136.3 at 90% load parts per million, corrected to 15 percent oxygen (MI-ROP-B2329-2012, FG-382-COGEN, I.1 limit: 167 ppm). Based upon the February 20, 2013 stack test, nitrogen oxides emission rates for turbine are: 0.49 at 85% load, 0.50 at 80% load, 0.44 at 100% load and 0.49 at 90% load, pounds of NOx per million BTU (Turbine limit in pounds per MM BTU never existed and Ductburner limit of 0.12 pounds per MM BTU was removed during the PTI and ROP modification [PTI No. 90-04 → PTI No. 90-04A dated July 11, 2008, MI-ROP-B2329-2007a → MI-ROP-B2329-2007b]). Based upon the February 20, 2013 stack test, CogGen (combined Ductburner and Turbine) emissions are 0.34 pounds of NOx per million BTU (MI-ROP-B2329-2012, FG-382-COGEN, I.2 limit 0.50). Fuel oil capability has been removed from CoGen system (MI-ROP-B2329-2012, FG-382-COGEN, I.4 & I.5 Limits: 0.30 lbs SO₂ / MM BTU 56.5 tons of SO₂ per year).

The turbine was retrofitted on August 15, 2011 such that it can no longer burn fuel oil. One 25,000-gallon diesel tank still exists but is empty. The tank could supply fuel oil to the boilers (Nos. 3 & 4).

All conditions pertaining to sulfur are removed from the ROP during the June 2012 ROP renewal (MI-ROP-B2329-2012, FG-382-COGEN) as Par is restricted to burn only natural gas (FG-382-COGEN, III.1: pipeline quality sweet natural gas only)

Per CY 2015 records, 23.65 pounds of NOx per hour (26 pounds per hour hourly limit was removed during PTI No. 90-04 review) and 98.92 (less than FG-382-COGEN, I.3 limit 121 tpy, revised from 115 by PTI No. 90-04; 98.73 tons for turbine plus 0.20 tons for ductburner) tons per 12-month rolling period. However, duct burner accounted for negligible emissions of nitrogen oxides (0.2 tpy Vs 99 tpy; i.e. less than 1 percent of the total for cogen-duct-burner system). Sulfur dioxide emission rates are 0.0006 (less than FG-382-COGEN, I.4 limit 0.3) pounds per million BTU, 0.03 (limit of 12.9 pounds per hour removed during MI-ROP-B2329-2007a to MI-ROP-B2329-2007b modification)

pounds per hour, 0.01 tons per month, 0.07 (less than FG-382-COGEN, I.5 limit 56.5) tons per year (12-month rolling) and 0.13 (<150) parts per million by volume. Low sulfur dioxide emissions are due to the fact that fuel oil has not been used for several years; Par used only natural gas and oil capability has been removed (FG-382-COGEN, III.1 limit: only NG).

FG-382-COGEN, III: Fuel oil capability has been removed.

FG-382-COGEN, IV: NA

FG-382-COGEN, V: BT Environmental Consulting, Inc. (BTEC, Inc. – Mr. Randy Tysar, Barry Boulianne, and Jeff Peitzsch) of Royal Oak, Michigan, conducted tests using CEM methods. Mr. Thomas Gasloli and I observed the sampling and CoGen operations. AQD received the January 3, 2013 test protocol. Mr. Gasloli approved the test plan on January 7, 2013, via the letter to Ms. Annette Sommers dated January 7, 2013. AQD received the test report on March 25, 2013. Based upon the February 20, 2013, test, CogGen (combined Ductburner and Turbine) emissions are 0.34 pounds of NOx per million BTU (MI-ROP-B2329-2012, FG-382-COGEN, I.2 limit 0.50). Turbine NOx emissions were (Feb 20, 2013): 0.44 (100% load), 0.49 (90% load), 0.49 (85% load) and 0.50 (80% load) pounds of NOx per MM BTU and 122.5 (100% load), 136.3 (90% load), 139.2 (85% load) and 139.4 (80% load) ppm NOx corrected to 15 percent oxygen (MI-ROP-B2329-2012, FG-382-COGEN, I.1 limit 167 ppm at 15% O₂). The ROP (MI-ROP-B2329-2012) required the tests for nitrogen dioxide and operating range to be completed by February 28, 2013. On February 20, 2013, 21-minute turbine tests were conducted at 4 different load conditions (80, 85, 90, 100 percent loads, 4*3=12 tests). On February 20, 2013, 3 21-minute CoGen (Turbine + Ductburner) test at full load (80% turbine load) were conducted. Based upon the 2013 tests, PAR Sterile Products chose its operation envelope: minimum 80% load (below 80 percent load engine begins interruption), operating temperature in the range of 930 and 1163 degrees Fahrenheit and electricity production in the range of 1.9 and 3.2 megawatts (MW). 2013 test results are similar to 2009 test results.

FG-382-COGEN, VI: Record of operating parameters (known as Powerplant Report) is maintained using a spreadsheet. Because Par fires only pipeline quality natural gas, Par has elected not to monitor sulfur and nitrogen. NOx and SO2 emissions calculations are performed. Performance test was conducted on February 20 (Turbine or Engine and CoGen = Turbine + Ductburner), 2013, to determine an operating range such that the turbine complies with nitrogen oxide emission limits. The turbine (aka engine) is operated in the range of 930-1,163 degrees Fahrenheit. Operating the turbine over the temperature maximum (1,163 degrees Fahrenheit) will cause the turbine trip, which will shut down the gas turbine. The gas turbine is never operated below 800 degrees Fahrenheit. Typical operating turbine engine operating temperature is 1100 degrees Fahrenheit. Combustion air is supplied at 122 psig pressure.

Per CY 2015 records, CoGen operated 8,596 hours per year produced 31,800 megawatts-hour (MW-Hour) of electrical energy, used 292.92 (289 turbine + 3.92 duct-burner) million cubic feet of pipeline quality natural gas and produced 120,169,100 pounds of steam.

Per Feb 2013 NOx stack tests, maximum operating temperature is 1163 °F and max

production is 3.2 MW of electric power.

Low sulfur dioxide emissions are due to the fact that fuel oil has not been used for several years; Par used only natural gas and oil capability is has been removed (FG-382-COGEN, III).

Permit-to-Install No. 90-04 (PTI No. 463-92 → PTI No. 90-04) was approved on September 8, 2004. Nitrogen oxides limit was raised from 110 tpy to 121 tpy based upon 12-month rolling time period to include the duct burner emissions. The PTI also changed monitoring requirements in accordance with NSPS GG amendments of July 8, 2004. In addition, PTI No. 90-04 removed 26 pounds of NOx per hour limit. The requirements of the PTI No. 90-04 were incorporated into the ROP (MI-ROP-B2329-2007). MI-ROP-B2329-2012 added the requirement that only natural gas be fired (FG-382-COGEN, III) and all sulfur requirements (FG-382-COGEN) were removed.

Pipeline quality sweet natural gas means a naturally occurring fluid mixture of hydrocarbons (e.g. methane, ethane, or propane) produced in geological formations beneath the Earth's surface that maintains gaseous state at standard atmospheric temperature and pressure under ordinary conditions. Natural gas contains 20.0 grains or less of total sulfur per 100 standard cubic feet (0.068 weight percent total sulfur or 680 parts per million by weight (ppmw) total sulfur or 338 parts per million by volume (ppmv) at 20 degrees Celsius total sulfur). Additionally, natural gas must either be composed of at least 70 percent methane by volume or have a gross calorific value between 950 and 1,100 British Thermal Units (BTU) per standard cubic feet (SCF). Natural gas does not include the following gaseous fuels: landfill gas, digester gas, refinery gas, sour gas, blast furnace gas, coal-derived gas, producer gas, coke oven gas, or any gaseous fuel produced in a process which might result in highly variable sulfur content or heating value. (40 CFR Part 60, Subpart GG Amended July 8, 2004, Section 60.331(u))

CY 2015 NOx: 98.92 tons per 12-mo for turbine and 0.2 tons per 12-mo for ductburner.

Per CY 2015 records, CoGen operated 8,596 hours per year produced 31,800 megawatts-hour (MW-Hour) of electrical energy, used 292.92 (289 turbine + 3.92 duct-burner) million cubic feet of pipeline quality natural gas and produced 120,169,100 pounds of steam.

COGEN STACK TESTS (FG-382-COGEN, V).

1. September 09, 2001 stack test: Nitrogen oxides emission rates are 113 (<167) parts per million and 22.9 (<26) pounds per hour. Per CY 06 records, 23 pounds of NOx per hour and 97 (96 due to Cogen NG plus 1 due to Duct Burner NG plus 0.0 due to FO) (<121, revised from 115 by PTI No. 90-04) tons per 12-month rolling period (CY 2006). PTI No. 90-04 removed 26 pounds of NOx per hour limit; as incorporated in the ROP (MI-ROP-B2329-2007) the hourly limit was removed.
2. November 27, 2007, stack test: JHP conducted stack test on November 27, 2007, using NTH consultants. JHP failed to meet 0.12 pounds of NOx per MM BTU limit for the duct burner; the tested duct burner emission rate was 0.16 pounds of NOx per MM BTU. The Violation Notice dated February 27, 2008, for failure to

comply with NOx limit of FG-382-COGEN I.1b of MI-ROP-B2329-2007a, which was later revised to MI-ROP-B2329-2007b in order to resolve compliance problem with the duct burner NOx limit (MI-ROP-B2329-2007a: 0.12 lbs/MM BTU). The ROP (MI-ROP-B2329-2007a) required the tests for nitrogen dioxide and operating range to be completed by March 2008. The duct-burner emissions were calculated by indirect method: subtracting NOx emissions due to Turbine from NOx emissions due to CoGen (Turbine + Duct-burner). Revised PTI No. 90-04A approved on July 11, 2008 (incorporated into MI-ROP-B2329b) removed the ductburner NOx limit of 0.12 pounds per MM BTU.

3. February 12 and 13, 2009, stack test: BT Environmental Consulting, Inc. (BTEC, Inc. – Mr. Randy Tysar) of Ferndale, Michigan, conducted tests using CEM methods. Mr. Thomas Maza and I observed the sampling and CoGen operations. Mr. Maza approved the test plan on January 20, 2009. Via e-mail dated January 22, 2009, I modified the operating parameters to be monitored during the sampling. AQD received the test report on March 20, 2009. Based upon the February 12 and 13, 2009, test, CogGen (combined Ductburner and Turbine) emissions are 0.35 pounds of NOx per million BTU (MI-ROP-B2329-2007b I.2 limit 0.50). Turbine NOx emissions were (Feb 12): 0.452 (85% load), 0.471 (80% load), 0.427 (100% load) and 0.452 (90% load) pounds of NOx per MM BTU and 129.5 (85% load), 133.3 (80% load), 117.8 (100% load) and 124.4 (90% load) ppm NOx corrected to 15 percent oxygen (MI-ROP-B2329-2007b I.1 limit 167 ppm at 15% O₂). The ROP (MI-ROP-B2329-2007b) required the tests for nitrogen dioxide and operating range to be completed by February 28, 2009. On February 12, 3 21-minute turbine tests were conducted at 3 different load conditions (80, 85, 90, 100 percent loads, 4*3=12 tests). On February 13, 3 21-minute CoGen (Turbine + Ductburner) test at full load (80% turbine load) were conducted.
4. February 20, 2013, CoGen stack test – MI-ROP-B2329-2012: BT Environmental Consulting, Inc. (BTEC, Inc. – Mr. Randy Tysar, Barry Boulianne, and Jeff Peitzsch) of Royal Oak, Michigan, conducted tests using CEM methods. Mr. Thomas Gasloli and I observed the sampling and CoGen operations. AQD received the January 3, 2013 test protocol. Mr. Gasloli approved the test plan on January 7, 2013, via the letter to Ms. Annette Sommers dated January 7, 2013. AQD received the test report on March 25, 2013. Based upon the February 20, 2013, test, CogGen (combined Ductburner and Turbine) emissions are 0.34 pounds of NOx per million BTU (MI-ROP-B2329-2012, FG-382-COGEN, I.2 limit 0.50). Turbine NOx emissions were (Feb 20, 2013): 0.44 (100% load), 0.49 (90% load), 0.49 (85% load) and 0.50 (80% load) pounds of NOx per MM BTU and 122.5 (100% load), 136.3 (90% load), 139.2 (85% load) and 139.4 (80% load) ppm NOx corrected to 15 percent oxygen (MI-ROP-B2329-2012, FG-382-COGEN, I.1 limit 167 ppm at 15% O₂). The ROP (MI-ROP-B2329-2012) required the tests for nitrogen dioxide and operating range to be completed by February 28, 2013. On February 20, 2013, 21-minute turbine tests were conducted at 4 different load conditions (80, 85, 90, 100 percent loads, 4*3=12 tests). On February 20, 2013, 3 21-minute CoGen (Turbine + Ductburner) test at full load (80% turbine load) were conducted. Based upon the 2013 tests, PAR Sterile Products chose its operation envelope: minimum 80% load (below 80 percent load engine begins interruption), operating temperature in the range of 930 and 1163 degrees Fahrenheit and electricity production in the range of 1.9 and 3.2 megawatts (MW). 2013 test results are similar to 2009 test results.

Engine exchange Program

Par (formerly JHP) is participating in Solar Turbine's engine program. This is a like-for-like engine exchange program. At JHP, one such exchange occurred in June 2010. After about 30,000 operating hours, the engine exchanged for factory overhauled engine, which is different from what JHP had.

Solar overhauls about 800 engines per year and the engines are exchanged with the customers. Every 30,000 (approx) operating hours intervals, engines are overhauled at a factory. Overhaul involves complete disassembly, inspection, rework and reassembly to restore engine to original thermodynamic and mechanical performance. Existing engine core is removed and is replaced with exchange (overhauled) engine core. Overhauled engines are placed in engine exchange fleet.

AQD received July 27, 2016, letter (from Ms. Annette Sommers) stating that like-for-like exchange was performed on July 13, 2016. The exchange occurred as a part of preventive maintenance. This exchange requires a stack test by February 28, 2017. Cost of the engine exchange is \$375,000.00 Vs new engine \$2,500,000.00. Old engine Serial No. and Model No.: OHF10-C7364. New engine Serial No. and Model No.: OHF16-C2055. About once in five years such engine swap occurs.

During the June 2012 ROP renewal permitting issues were handled. AQD required stack testing upon completion of engine exchange.

One diesel generator (Caterpillar Diesel Generator Model 3306B, Serial No. 08JJ00461, Engine Model 3306B, 225 kW is used to start the CoGen turbine. This is black start generator.

MI-ROP-B2329-2012a, FG-IPA-USE

FG-IPA-USE, I: 6.23 (FG-IPA-USE, I.1 limit: 24) tons of Isopropyl Alcohol were used per 12-month period (CY 2015).

FG-IPA-USE, VI: 2,428 gallons of Isopropyl Alcohol were used per 12-month period (CY 2015).

MI-ROP-B2329-2012a, FG-RICE-MACT-EMERGENCY-GENERATORS

Upon closing of sale to JHP Pharmaceutical (now Par Sterile Products), King Pharmaceuticals has retained the diesel generators along with the penicillin process. Pfizer purchased King in Jan 2011

However, one Caterpillar Diesel Generator (1360 kW or 1.36 MW) was present on Par's site for several years. The generator was always idle and was not hooked up to diesel supply. There was no electrical connection. I advised, during FY 2014 inspection, Ms. Sommers it needed permit if it were to be restarted. By December 2015, this Caterpillar 1.36 MW generator was permanently removed and during FY 2016 (August 2016) the generator was not present.

One diesel generator (Caterpillar Diesel Generator Model 3306B, Serial No. 08JJ00461, Engine Model 3306B, 225kW) is used to jump start CoGen turbine. This is known as black start generator.

One Cummins Emergency Diesel Generator (Model No. DFEK-1216951, Serial No. B130452542, Maximum Diesel flow = 424 liters per hour (112 gallons per hour), Build date February 05, 2013, rated 625 KVA, Power Factor = 0.8, 500 kW (0.5 MW), installed October 2013) is present.

Cummins (manufactured in Feb 05, 2013) emergency diesel (Compression Ignition (CI) Reciprocating Internal Combustion Engine (RICE)) generator is subject to: NSPS IIII or 4I, New Source Standards of Performance for Stationary Compression Ignition Internal Combustion Engines, 39154 Federal Register / Vol. 71, No. 132 / Tuesday, July 11, 2006 / Rules and Regulations / Final Rule. One other cold-start engine (CAT) that starts gas turbine (one [idle] of three generators removed) is not subject to NSPS 4I based upon manufacture date (before April 2006).

This NSPS 4I generator will be incorporated into 2016 ROP renewal. At present (CY 2016) there are two RICE engines in all: laboratory generator (Cummins) and powerhouse (CAT) cold-start engine for gas turbine start-up; one Caterpillar 1.36 MW generator was permanently removed (about December 2015).

NSPS 4I testing and US EPA (Ann Arbor) certificate

US EPA (Office of Transportation and Air Quality Regulation, Ann Arbor, MI 48105) has issued a certificate (Certificate of Conformity with 40 CFR, Part 60; Certificate No. DCEXL015.AAJ-014; Issue date: 05/01/2012 for Model Year 2013 and Engine Family DCEXL015.AAJ). This certificate may satisfy NSPS 4I testing requirements.

RICE MACT 4Z: Emergency diesel generators may be subject to RICE MACT 4Z, Area Source NESHAP / MACT ZZZZ, Standards of Performance for Stationary Spark Ignition Internal Combustion Engines and National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines / Final rule (Page 3568, Federal Register / Vol. 73, No. 13 / Friday, January 18, 2008 / Rules and Regulations / Final rule

The ROP requires simple requirements for RICE MACT (MI-ROP-B2329-2012a, FG-RICE-MACT-EMERGENCY-GENERATORS, VI, 1-6).

MI-ROP-B2329-2012a, FGRULE290

These are small processes: Drug and Chemical (6.62 pounds per year VOC – CY 2015), Bulk Manufacturing (7.68 pounds per year. VOC – CY 2015), FDA regulations require that the plant must maintain dust-free and sterile environment.

Heated mixing tank is indefinitely out of service via utility disconnection; the tank is still present.

Drug chemical dispensing. The dispensing facility (Room No. D-317) has been upgraded with a brand new HEPA filter system (CY 2005). Only solid materials are handled and no liquid.

TCA tank cleaning is permanently removed and the area (Room No. 380) has been renovated.

Formaldehyde cleaning operations out of service because it is related to flu vaccine, which is not made anymore.

Bulk manufacturing area A & B is equipped with HEPA filters for powder and liquid mixing.

Preparation services is equipped with HEPA filters.

Packaging operations is equipped with HEPA filters.

Isopropyl alcohol wipe up: Consolidated into facility-wide IPA use.

Oxycell (cotton ball oxidized) manufacture: out of service and the product, surgical cotton ball, is discontinued due to poor quality cotton raw material.

Ether extraction: discontinued because it is related to flu vaccine.

All particulate emissions are controlled using HEPA filters to maintain clean room per FDA regulations. Upon cleaning the air using HEPA filters, exhaust gases are released to in-plant environment. i.e., plant air is recirculated to maintain clean room. 25 percent of air is purged to outside ambient air. Equal amount of make-up air (equal to purged air) is brought to the clean room upon filtration using a separate HEPA filter system.

ROP Revisions / Renewals:

1. MI-ROP-B2329-2007a dated February 14, 2008: This modification of MI-ROP-B2329-2007 → MI-ROP-B2329-2007a dated March 8, 2007, incorporates ownership transfer from Parkedale Pharmaceuticals, Inc. (a wholly owned subsidiary of King Pharmaceuticals, Inc.) to JHP Pharmaceuticals, LLC. In addition, two diesel fired generators (PTI No. 319-07) were removed from the ROP. Because the generators are located 1200 Parkedale Road, they are retained by King (Pfizer since Jan 2011). 870 Parkedale Road facilities are operated by JHP and all processes at that address are part of JHP's ROP.
2. MI-ROP-B2329-2007a → MI-ROP-B2329-2007b dated December 10, 2008: JHP performed the ROP required sampling and analysis on November 27, 2007 for NOx emissions for the duct burner. The stack test emissions rate was 0.16 pounds of Nitrogen Oxides per million BTU heat input, which exceeded the limit of 0.12 pounds of Nitrogen Oxides per million BTU (MI-ROP-B2329-2007a, FG-382-COGEN I.1.b). PTI No. 90-04A was approved on July 11, 2008. The permit (PTI No. 90-04A dated July 11, 2008) removed the duct burner emission limit for nitrogen oxides (0.12 pounds/ MM BTU) and replaced it with 0.50 pounds of NOx per MM BTU for the entire CoGen System. JHP Pharmaceuticals requested the special conditions from Permit to Install No. 90-04A be incorporated into the ROP. This PTI was issued to remove the NOx limit

from the duct burner. MI-ROP-B2329-2007b that incorporates PTI No. 90-04A was approved on December 10, 2008. The ROP modifications to special conditions for FG-382-COGEN include: replacing the NOx limit for EU-DUCTBURNER with a NOx limit for FG-382-COGEN and clarifying how the emissions shall be determined; changing the averaging time for the NOx limit from 24-hour to Test Protocol since compliance is based on stack testing; removing the SO2 hourly limit; and revising testing and recordkeeping conditions effected by the emission limit changes

3. MI-ROP-B2329-2007b → MI-ROP-B2329-2012 (June 2012 renewal): FG-100-ETO for 3 EO sterilizers and 4 freeze dryers were removed from the ROP since all EO processes including Deoxx Scrubber were removed effective July 2011. Because of August 15, 2010, turbine retrofit such that the turbine (engine) could no longer burn diesel / fuel oil, all conditions pertaining to sulfur in fuel are removed from the ROP, FG-382-CoGen (June 2012 renewal). Besides, CoGen is restricted to burn only pipeline quality natural gas (FG-382-CoGen, III.1 [pipeline quality sweet natural gas only], VI.2 [sulfur monitoring not required if firing only pipeline quality sweet natural gas], VI.3 [nitrogen monitoring not required if firing only pipeline quality sweet natural gas])
4. MI-ROP-B2329-2012 → MI-ROP-B2329-2012a : Name change. There is error in name change. The name change should have been from JHP Pharmaceuticals to Par Sterile Products, LLC. However, by mistake name has been changed to Par Sterile Operations, LLC. On September 9, 2014, I asked Ms. Annette Sommers to change name again to Par Sterile Products, LLC to reflect correct name. There is name confusion: Par Sterile Operations, LLC, Par Sterile Products, LLC, Par Pharmaceuticals, LLC.
5. MI-ROP-B2329-2012a → MI-ROP-B2329-2012b: Name is corrected as Par Sterile Operations, LLC → Par Sterile Products, LLC
6. MI-ROP-B2329-2016 is on 30-day public notice (August 22 – September 21, 2016).

SOURCE-WIDE CONDITIONS

Par is keeping HAP emissions records for the entire facility. Total HAP emissions are less than 2 tpy (CY 2015) tons per year (MI-ROP-B2329-2012, Source-Wide, I. 1 & 2: 9.90 tons of single HAP and 24.90 aggregate HAPs)

Conclusion:

I did not find violation of RO permit conditions during the inspection. Par is NOT subject to NESHAP / MACT O and but subject to RICE MACT 4Z. Par is also subject to NSPS GG & 4I. Par is participating in Solar's Turbine Engine Exchange Program. All EO processes are removed. Aug 2010 turbine retrofit removed diesel capability from the turbine.

NAME J. Sheehan DATE 08/29/2016 SUPERVISOR Joyce