



**Statement of Basis – Title V Permit**  
**McNeil Healthcare, LLC**  
**PFE-TV-2834-44-0507-0596**

The Environmental Quality Board (EQB) is issuing a Title V permit in conformity with Title 40 of the Code of Federal Regulations (40 CFR), Part 70 and with Part VI of the Regulation for the Control of Atmospheric Pollution (RCAP) for **McNeil Healthcare, LLC**. (McNeil). McNeil is located at Road 183 km 19.7 in Las Piedras, Puerto Rico. The EQB received the application for Title V permit on May 14, 2007. On October 29, 2007, the Air Quality Area determined the application was complete.

McNeil manufactures pharmaceutical products. The emission units include manufacturing areas, cleaning of process equipment, tanks, boilers and electric generators. McNeil was subject to RCAP Rule 211 as an Intermediate Synthetic Minor Emission Source. McNeil becomes a major source by installing six generators of 2,000 KW. At the same time, acquires Hershey's facilities which already had a Title V permit and both facilities are consolidated. Therefore, it has the potential to emit more than 100 tons per year of nitrogen oxides (NO<sub>x</sub>), sulfur oxides (SO<sub>x</sub>) and particulate matter (PM<sub>10</sub>) which are criteria air pollutants. This facility is a Minor Emission Source for Hazardous Air Pollutants (HAP) and greenhouse gases (GHGs) expressed as CO<sub>2e</sub>.

The allowable emissions authorized under this permit are mentioned in the table below. The source must annually certify that its actual emissions do not exceed the emissions limits at the time of the permit application and these will be used only for payment purposes.

Criteria Pollutants	Allowable emissions (tons /year)
PM <sub>10</sub>	118.25
SO <sub>2</sub>	450.96
NO <sub>x</sub>	411.52
CO	93.49
VOC	22.34
Lead	0.02
Ozone	0.07
HAP's (combustion)	0.43
methanol	2.67
CO <sub>2e</sub>	55,630.51

Below the emission units, the applicable requirements and the fundamental reasons for the applicable requirements are established.

**Manufacturing Area:** Consists of all the equipment used in the manufacturing processes that emit Particulate Matter (PM). The operations include granulation, compression, coating, ROTO-granulation, packaging and related processes. The emissions are controlled by dust collectors with a 95% or more efficiency for PM removal. The ROTO-granulation unit and Sieving Area have a maximum annual production limit of 3,322 lots per year. Although no federal requirements are applicable to these units, the units are subject to following RCAP limitations.

- PM emission limit: RCAP Rule 409 establishes an emission limit of 0.05 pounds per pound of uncontrolled emissions from any non-process source, shown by a stack test during the first year of the permit using EPA Test Method 5. The current PM emissions must be calculated monthly based in the emission factor of 0.0085 grains/dscf taken in the August 1996 test performance. The emission factor equivalent to the current average concentration will be used in all calculations of PM emissions until new data within the first year of the permit is obtained.

**ROTO-Granulation Unit:** Consists of manufacturing 627 lots per year of pharmaceuticals: Tylenol, Motrin, Pepcid, Inmodium and Benadryl. A solution containing 90% solvent (methanol and acetone) and 10% cellulose is used. VOC emissions are controlled by a thermal oxidizer and an auxiliary filter with 30% efficiency. The thermal oxidizer has a limit of total fuel consumption for liquefied gas (LPG) of 201,982 gallons with a maximum percent of sulfur content of 0.1% per weight for any period of 12 consecutive months. LPG is considered a "clean" fuel because it does not produce visible emissions<sup>1</sup> therefore Visible Emissions Limits are not included. Even though these units are not affected by federal regulations, the units are subject to the following RCAP limitations.

- PM emission limit for fuel burning: RCAP Rule 406 establishes an emission limit of 0.03 lb. of PM per MMBtu of heat input, demonstrated by performing a stack test during the first year of the permit using EPA Test Method 5.

**Process Tanks:** These tanks are installed in the ROTO-Granulation Area. The tanks are used to store a mixture of acetone and methanol. These are equipped by a nitrogen blanketing system. For emissions calculations purposes losses of 1.0% of the total amount of solvent transferred to the tanks are assumed. The maximum use of methanol is 85,237.48 gallons per year. Acetone was excluded from the definition of Volatile Organic Compounds, as established in the amendment of the RCAP of January 19, 2011. The permit requires a monthly log of

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<sup>1</sup> AP-42 (Compilation of Air Pollutant Emission Factors), Section 1.5- Liquefied Petroleum Gas Combustion

the identification and amount of each load of solvent to the tank. Even though these units are not affected by federal regulations, the units are subject to the following RCAP limitations.

- VOC emission limit: RCAP Rule 419 establishes an emission limit of 3 pounds per hour or 15 pounds per day from any article, machine, equipment or any other contrivance without an acceptable control system, program or emissions reduction and prevention mechanism or both, as approved or required by the Board.

**Cleaning of Process Equipment:** The use of isopropyl alcohol (IPA) 70%, solvent Quicksolve, IPA 99% and thinner is limited to 770; 330, 825, and 260 gallons per year, respectively. The emissions of these operations are fugitive. Even though these units are not affected by federal regulations, the units are subject to the following RCAP limitations:

- VOC emission limit: RCAP Rule 419 establishes an emission limit of 3 lbs. per hour or 15 lbs. per day in any article, machine, equipment or any other contrivance without an acceptable control system, program or emissions reduction and prevention mechanism or both, as approved or required by the Board.

**Boilers:** units B-1, B-2, B-3, B-4 and B-5 with a rate of heat input of 6.3 MMBtu/hr, 6.3 MMBtu/hr, 6.3 MMBtu/hr, 16.8 MMBtu/hr and 25.13 MMBtu/hr, respectively, have a limit for diesel fuel total consumption of 2,467,500 gallons for any period of 12 consecutive months. Since units B-4 and B-5 were built after June 9, 1989 and they have a heat input maximum design capacity of less than 100 MMBtu/hr but greater than 10 MMBtu/hr, they are subject to the Standards of Performance for New Stationary Sources under 40 CFR Part 60, Subpart Dc. Units SB-001, SB-004 and SB-005 with a rate of heat input of 28.8 MMBtu/hr, 8.4 MMBtu/hr and 6.7 MMBtu/hr, respectively, have a fuel consumption limit of No. 6 or lower grade that comes from a PSD Non-Applicability Determination, which is included in the construction permit (PFE-30-0896-0860-I-II-C) and Title V permit. The permit requires daily consumption record keeping and reporting it monthly to the Board. These units are not subject to 40 CFR Part 60, Subpart Dc. Since the boilers in the facility are existing boilers that use *fuel oil*, the requirements of the National Emission Standards for Hazardous Air Pollutants for Industrial, Commercial and Institutional Boilers Area Sources under 40 CFR Part 63, Subpart JJJJJJ are applicable. Specifically, performance adjustments are required every two years and an energy assessment of boilers B-4, B-5 and SB-001. All these requirements were included in the permit. All units are subject to the following RCAP limitations.

- PM emission limit: RCAP Rule 406 establishes an emission limit of 0.03 lb. of PM per MMBtu of heat input, demonstrated by a stack test during the first year of the permit using Test Method 5 of the EPA.

- Sulfur content: Rule 410 of RCAP requires the sulfur content limit in fuel. The distilled fuel used for units B-4 and B-5 shall not have a sulfur content in excess of 0.5% per weight. Fuel No. 6 for units SB-001, SB-004 y SB-005 shall not have a sulfur content in excess of 2.0% per weight. To comply with this requirement, McNeil shall keep a copy of the supplier's certification indicating the sulfur content in the fuel.
- Opacity: As required by Rule 403 of the RCAP, the units shall not discharge visible emissions of opacity of up to 60% in a 6 minutes average. The permit requires an opacity test of each boiler stack during the first year of the permit using EPA Test Method 9 and subsequent weekly opacity inspections using a visible emissions reader certified by a school approved by the EPA or the Board.

**Internal Combustion Engines for Emergencies:** Units identified as INENGS (EG-1, EG-2, EG-3, EG-4, EG-5 and EG-6) with a capacity of 2,680 horsepower each, have a diesel fuel consumption limit of 101,250 gallons per year per each unit. The rest of the units identified as INENGS EG-7, INENGS EG-8, INENGS EG-9, INENGS-10, IENGS-11, INENGS-12, FIRE 1, FIRE 2 and FP-002 have a diesel fuel total consumption of 79,600 gallons per year, which is limited by their respective annual hours of operation. Each unit shall be equipped with an hours meter so that it can check the hours of operation and calculate fuel consumption. Units EG-03 (Warstila) and EG-2H, with a capacity of 20.4 MMBtu/hr and 1,040 kW, have a limit for total fuel consumption for residual oil #6 or lower grade, of 787,600 gallons and 4,860 gallons<sup>2</sup> for each 12 consecutive months period, respectively. In addition, the EG-03 Unit (Wartsila) shall be provided with a fuel flow meter. Although 40 CFR Part 63 Subpart ZZZZ does not limit the yearly operating hours in an emergency, the PREQB construction permits limit yearly operating hours for each engine.

The permit requires monthly fuel consumption record keeping for all the INENGS units and daily for EG-003. Since units INENGS (EG-1, EG-2, EG-3, EG-4, EG-5 and EG-6) were installed in the facility after June 12, 2006, the engines are subject to NESHAP for RICE MACT under 40 CFR Part 63 Subpart ZZZZ. Subpart ZZZZ establishes that these engines comply with the requirements of Subpart ZZZZ by complying with the requirements of 40 CFR Part 60, Subpart IIII, however, none of the engines is subject to 40 CFR, Part 60, Subpart IIII. Units EG-03, INENGS (7-12), FIRE 1, FIRE 2 and FP-002 shall comply with the emissions limits in Table 2d of Subpart ZZZZ of 40 CFR Part 63 applicable to the sources because they are existing Reciprocal Internal Combustion Engines(RICE), located in a Minor Source of HAP. All the units are subject to the following RCAP limitations.

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<sup>2</sup> Based on a use limit of 60 hours per year according to PFE-44-0794-0858-II-C and PSD Non-Applicability Determination of March 1, 1989 and May 8, 1995

- Sulfur content: RCAP Rule 410 requires the sulfur content limit in fuel. The distilled fuel used shall not have a sulfur content in excess of 0.5% per weight. The residual oil #6 or lower grade, used shall not have a sulfur content in excess of 2.0% per weight. To comply with this requirement, McNeil shall keep a copy of the supplier's certification indicating the sulfur content in the fuel.
- Opacity: As required by RCAP Rule 403, the units shall not release visible emissions of an opacity greater than 60% in a 6 minute average. The permit requires an opacity test of the chimney stack of each boiler during the first year of the permit using Test Method 9 of the EPA and subsequent weekly visual inspections for opacity using a visible emissions reader certified by a school approved by the EPA or the Board.

**Internal Combustion Portable Units:** Consists of welding machines, pressure washers, transfer pumps, compressors and generators. Portable units have a diesel fuel consumption limit of 5,624 gallons per year. The permit requires registering the monthly fuel consumption and reporting it annually to the Board. Hour meters are required for the portable electric generators.

The stack tests for the combustion units of the former Hershey (SB-001, SB-004 and SB-005) were performed on November 12, 2003. The results were not approved by the EQB. The stack test for EG-003 was not performed because the equipment was inoperative.

The non-applicable requirements to the emission units included in the permit and the basis for the non-applicability are established below:

Code for the Non-Applicability Determination	
Code	Basis
40 CFR Part 63, Subpart GGG	National Emissions Standard for Hazardous Air Pollutants for Pharmaceutical Production. Not applicable to minor sources of hazardous air pollutants (HAP).
40 CFR Part 61, Subpart V	National Emissions Standard for Equipment Leaks. The facility has no components in HAP service.
40 CFR Part 63, Subpart G	National Emission Standards for Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations, and Wastewater. The facility is not a manufacturing site for Synthetic Organic Chemicals.

Code for the Non-Applicability Determination	
Code	Basis
40 CFR Part 63, Subpart H	National Emissions Standard for Organic Hazardous Air Pollutants for Equipment Leaks. Applies to pharmaceutical production processes that use carbon tetrachloride or methyl chloride over 300 hours per year.  The facility does not use carbon tetrachloride or methyl chloride in their pharmaceutical production processes.
40 CFR Part 60, Subpart Kb	It does not apply to tanks greater than or equal to 151 m <sup>3</sup> capacity to store liquid with an actual maximum vapor pressure of less than 3.5 kPa or greater or equal capacity of 75 m <sup>3</sup> but less than 151 m <sup>3</sup> storing liquid with an actual maximum vapor pressure of less than 15 kPa.
40 CFR Part 60 Subpart Dc	Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units  Not applicable to steam generating units (boilers) that were built before June 9, 1989 and with a capacity of less than 10 MMBtu/hr.  Not applicable to emission units identified as B-1, B-2, B-3 and SB-001, because they were built on 1984, 1984, 1986, 1977, respectively. Not applicable to units SB-004 and SB-005 because their capacity is less than 10 MMBtu/hr.
40 CFR Part 63 Subpart DDDDD	National Emission Standards for Hazardous Air Pollutants for Major Sources: Industrial, Commercial and Institutional Boilers  The facility is not a Major Source of HAP.
40 CFR Part 60 Subpart IIII	Standards of Performance for Stationary Compression Ignition Internal Combustion Engines  Not applicable to internal combustion engines except ICENG PE-1, because they were manufactured on or before 2005.
40 CFR Part 63, Subpart JJJJ	Standards of Performance for Stationary Spark Ignition Internal Combustion Engines  There are no spark ignition internal combustion engines authorized in the facility.
Rule 406 of RCAP	Particulate Matter Emission Limit for Fuel Burning Equipment  It does not apply to internal combustion engines of electric generators and fire pumps because they do not meet the definition of Equipment for Fuel Burning Rule 102 of the RCAP.

All the monitoring, recordkeeping and reporting provisions are applicable pursuant to Rule 603 of the RCAP, which requires all these elements shall be included in the Title V permit issued.

As established in Appendix B of the RCAP, McNeil provided a list of activities because of their size and production rate.

The EQB found that the Title V permit for **McNeil Healthcare, LLC.** satisfies the requirements of Part VI of the RCAP.