ESTADO LIBRE ASOCIADO DE
PUERTO RICO
ENVIRONMENTAL QUALITY BOARD

TITLE V OPERATING PERMIT
AIR QUALITY AREA
ENVIRONMENTAL QUALITY BOARD

Permit Number:	PFE-TV-2834-44-0507-0596
Application Receipt Date:	May 14, 2007
Final or Effective Issue Date:	September 15, 2016
Expiration Date:	September 15, 2021

In conformity with the provisions of Part VI of the Regulation for Atmospheric Pollution Control (RCAP) and the provisions of the Code of Federal Regulations (CFR), Volume 40, Part 70 we authorize:

McNEIL HEALTHCARE, LLC
LAS PIEDRAS, PUERTO RICO

hereinafter **McNeil** or **the permittee**, is authorized to operate a stationary source of air pollutants emissions consisting of the units and conditions described in this permit. Until this permit expires, is modified or revoked, McNeil shall be able to emit atmospheric pollutants as a result of those processes and activities directly related and associated with the emission sources, in compliance with the requirements, limitations and conditions of this permit, until its expiration date or until such is modified or revoked.

The conditions in this permit shall be enforceable by the federal and state government. Those requirements that are enforceable only by the state government shall be identified as such in the permit. A copy of the permit shall be kept in the aforementioned facility at all times.

Cruz A. Matos Environmental Sciences Building
Urb. San José Industrial Park, 1375 Ponce de León Ave., San Juan, PR 00926-2604
Postal Address: PO Box 11488, San Juan, PR 00910
Ph. 787-767-8181, Fax 787-756-5906
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Section I - General Information

A. Facility Information

Facility Name:	McNeil Healthcare, LLC
Postal Address	P.O. Box 2009
City:	Las Piedras
State:	Puerto Rico
Postal Code:	00771-2009
Company Name:	Johnson & Johnson
Plant Location:	Road 183 Km 19.7 Las Piedras, Puerto Rico
Responsible Officer:	Debbie Vázquez Castillo Vice-President & General Manager
Contact Person:	Anabel Ortiz Senior EHS Specialist
Phone:	(787) 733-1000
Fax:	(787) 716-5027
SIC Primary Code:	2834

B. Process Description

McNeil Healthcare, LLC. is located at Road 183 km 19.7 in Las Piedras and manufactures pharmaceutical products.

The emission units included are: manufacturing areas, cleaning of process equipment, tanks, boilers and electricity generators. Some of these units are subject by the federal regulation for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP).

The manufacturing area consists of all the equipment used in manufacturing processes that emit particulate matter. These operations include granulation, compression, coating, roto-granulation, packaging and related processes. Emissions are controlled by the collectors at 95% or more of efficiency for the removal of particulate matter.

ROTO granulator unit consists of batch processing of pharmaceuticals in aqueous base. Emissions of volatile organic compounds (VOC) are controlled by a thermal oxidizer and an auxiliary filter with 30% efficiency.

Processes tanks are located in the area of ROTO Granulation. These tanks are used to store a mixture of acetone and methanol. These are equipped by a nitrogen blanketing system.

In the cleaning operations of the equipment, isopropyl alcohol 70% and 99%, *Quick Solve* solvent and thinner are used. The emissions of these operations are fugitive.

McNeil uses 5 steam boilers, identified as B-1, B-2, B-3, B-4, and B-5, which burn diesel fuel with a maximum sulfur content of 0.5 percent by weight. The use of biodiesel fuel is permitted as an alternate scenario for these boilers. The units identified as B-4 and B-5 are subject to the New Source Performance Standards contained in 40 CFR Part 60, Subpart Dc. In addition, the 5 boilers are subject to the National Emission Standards for Hazardous Air Pollutants for Industrial, Commercial and Institutional Boilers Area Sources under 40 CFR Part 63, Subpart JJJJJJ.

There are three boilers in Building 3 to generate steam identified as SB-001, SB-004 and SB-005 and one electric generator for emergencies *Wartsila*. These units are authorized to burn residual #6 fuel or lighter grade fuel with a maximum sulfur content of 2% by weight. In addition, the three boilers are subject to the National Emission Standards for Hazardous Air Pollutants for Industrial, Commercial and Institutional Boilers Area Sources under 40 CFR Part 63 Subpart JJJJJJ.

McNeil uses internal combustion engines for 13 electric generators and 3 for emergency fire pumps, which burn diesel fuel with a maximum sulfur content limit of 0.5% by weight. All engines are subject to the National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines of Maximum Achievable Control Technology (RICE MACT) under 40 CFR Part 63, Subpart ZZZZ. The permit specifies those engines affected by the requirements of 40 CFR Part 60 Subpart IIII: New Source Performance Standards for Stationary Compression Ignition Internal Combustion Engines.

The ICENG PE-1 unit, include portable units such as welding machines, pressure washing machines, transfer pumps, compressors and electric generators, burn diesel fuel with a maximum sulfur content of 0.5 percent by weight.

McNeil is a major source for atmospheric pollutants because it has the potential to emit SO_2, NO_x and PM_{10} in excess of 100 tons per year. McNeil is a minor source of hazardous air pollutants and greenhouse gases (GHGs) expressed as CO_2e.

Section II - Emission Units Description

The emission units regulated by this permit are the following:

Emission Units	Description	Control Equipment
PHARMFG	**Pharmaceutical Products Manufacturing Area** It consists of all equipment used in pharmaceutical manufacturing that emits particulate matter (PM). The processes are not necessarily restricted to a particular equipment. Emissions of particulate matter are controlled by dust collectors with an efficiency of 95% or greater.	DC-1, DC-2, DC-3, DC-4, DC-6, DC-7-DC-27, DC-30, DC-35 (See descriptions in Appendices II and III)
EQUIPCLN-1	**Process Equipment Cleaning**	None
GLATTS	**Six fluidized bed dryers and granulators**	None
Chewables	**Weight and material transfer rooms**	DC-5, EF-211, Vacuum system (Discharge volume 175 SCFM) • Efficiency- 95% (See descriptions in Appendices II and III)
Process Tanks	Emission units representing the VOC process tanks installed in the ROTOR area. Units SPT-1 and SPT-2 have a storage capacity of 250 gallons each. SFT-unit 1 has a capacity of 35 gallons. These tanks are used to prepare mixtures of acetone and methanol. A maximum of 85,237.48 gallons per year of methanol are processed. Tanks are equipped with a nitrogen blanketing system.	None

Emission Units	Description	Control Equipment
ROTOR	ROTO-Granulation Unit. The unit is used in the manufacture of 627 annual batches of pharmaceutical products: Tylenol, Motrin, Pepcid, Imodium and Benadryl. A solution containing 90% solvent (methanol and acetone) and 10% cellulose is used.	Thermal Oxidizer TOS1/TO-1 Design efficiency for methanol and acetone removal-99.91% • Discharge volume: 5,000 SCFM for gas flow • Auxiliary fuel: propane • Fuel Consumption: 35.4 gallons per year • Sulfur Percentage: 0.1% (See descriptions in Appendices II and III)
Cleaning of Roto-Granulation Equipment	Cleaning of processes equipment. Fugitive emissions	None
ROTOR-Granulation Room and Sieving Area	3,322 batches per year of pharmaceutical products are handled. Rooms are equipped with a dust collection system for particulate matter.	DC-31 (See descriptions in Appendices II and III)
PHARMFG 2	Continuous operation of packaging for pharmaceuticals. The pharmaceutical area is controlled by a particulate control unit.	DC-33 (See descriptions in Appendices II and III)
B-1	Boiler with a heat input rate of 6.3 MMBtu/hr. Burns diesel fuel at a rate of 45 gallons per hour with a maximum sulfur content of 0.5% by weight. It can be used biodiesel B(20) as established in the alternate operating scenario.	None
B-2	Boiler with a heat input rate of 6.3 MMBtu/hr. Burns diesel fuel at a rate of 45 gallons per hour with a maximum sulfur content of 0.5% by weight. It can be used biodiesel B(20) as established in the alternate operating scenario.	None

Emission Units	Description	Control Equipment
B-3	Boiler with a heat input rate of 6.3 MMBtu/hr. Burns diesel fuel at a rate of 45 gallons per hour with a maximum sulfur content of 0.5% by weight. It can be used biodiesel B(20) as established in the alternate operating scenario.	None
B-4	Boiler with a heat input rate of 16.8 MMBtu/hr. Burns diesel fuel at a rate of 120 gallons per hour with a maximum sulfur content of 0.5% by weight. It can be used biodiesel B(20) as established in the alternate operating scenario.	None
B-5	Boiler with a heat input rate of 25.13 MMBtu/hr. Burns diesel fuel at a rate of 179.5 gallons per hour with a maximum sulfur content of 0.5% by weight. It can be used biodiesel B(20) as established in the alternate operating scenario.	None
SB-001	Boiler with a heat input rate of 28.8 MMBtu/hr. The unit is limited to consume 691,320 gallons of diesel per year with a maximum sulfur content of 2.0% by weight.	None
SB-004	Boiler with a heat input rate of 8.4 MMBtu/hr. The unit is limited to consume 375,290 gallons of diesel per year with a maximum sulfur content of 2.0% by weight.	None
SB-005	Boiler with a heat input rate of 6.7 MMBtu/hr. The unit is limited to consume 316,030 gallons of diesel per year with a maximum sulfur content of 2.0% by weight.	None
ICENG PE-1	Internal combustion portable units with capacity of 10 hp to 200 hp. Include portable units such as welding, pressure washing machines, transfer pumps, compressors or electricity generators. These portable units consume up to 5,624 gallons of diesel fuel per year.	None

Emission Units	Description	Control Equipment
INENGS EG-1	Internal combustion engine for emergency electricity Generator, *Cummins* Brand, Model DQKC, engine with a capacity of 2,680 hp. Diesel fuel consumed at a rate of 135 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-2	Internal combustion engine for emergency electricity generator, *Cummins* Brand, Model DQKC, engine with a capacity of 2,680 hp. Diesel fuel consumed at a rate of 135 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-3	Internal combustion engine for emergency electricity generator, *Cummins* Brand, Model DQKC, engine with a capacity of 2,680 hp. Diesel fuel consumed at a rate of 135 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-4	Internal combustion engine for emergency electricity generator, *Cummins* Brand, Model DQKC, engine with a capacity of 2,680 hp. Diesel fuel consumed at a rate of 135 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-5	Internal combustion engine for emergency electricity generator, *Cummins* Brand, Model DQKC, engine with a capacity of 2,680 hp. Diesel fuel consumed at a rate of 135 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-6	Internal combustion engine for emergency electricity generator, *Cummins* Brand, Model DQKC, engine with a capacity of 2,680 hp. Diesel fuel consumed at a rate of 135 gallons per hour with a maximum sulfur content of 0.5% by weight.	None

Emission Units	Description	Control Equipment
INENGS EG-7	Internal combustion engine for emergency electricity generator, with engine capacity of 470 hp (350 kW). Consumes diesel fuel at a rate of 23.7 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-8	Internal combustion engine for an emergency electricity generator, with engine capacity of 1,135 hp. Consumes diesel fuel at a rate of 58.5 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-9	Internal combustion engine for and emergency electricity generator, with engine capacity of 200 hp (150 kW). Consumes diesel fuel at a rate of 10.1 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-10	Internal combustion engine for emergency electricity generator, with engine capacity of 100 hp. Consumes diesel fuel at a rate of 5.1 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-11	Internal combustion engine for emergency electricity generator, with engine capacity of 277 hp (750 kW). Consumes diesel fuel at a rate of 11.3 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-12	Internal combustion engine for an emergency electricity generator, with engine capable of 1,300 hp (970 kW). Consumes diesel fuel at a rate of 65 gallons per hour with a maximum sulfur content of 0.5% by weight.	None

Emission Units	Description	Control Equipment
EG-03	Internal combustion engine for emergency electricity generator *Wartsila* with a capacity of 20.4 MMBtu/hr. The generator is limited to consume 787,600 gallons annually of residual oil #6 or lighter oil with a maximum sulfur content of 2.0% by weight.	None
EG-2H	Internal combustion engine for an emergency electricity generator with capacity of 1,040 kW. Consumes residual oil #6 or lighter oil at a rate of 81.0 gallons per hour with a maximum sulfur content of 0.3% by weight.	None
FIRE 1	Internal combustion engine for a pump with a capacity of 187 hp. Consumes diesel fuel at a rate of 9.4 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
FIRE 2	Internal combustion engine for a pump with a capacity of 187 hp. Consumes diesel fuel at a rate of 9.4 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
FP-002	Internal combustion engine for a pump with a capacity of 157 hp. Consumes diesel fuel at a rate of 8.8 gallons per hour with a maximum sulfur content of 0.5% by weight.	None

Section III – General Permit Conditions

1. **Sanctions and Penalties:** The permittee must comply with all terms, conditions, requirements, limitations and restrictions established in this permit. Any violation to the terms of this permit is subject to administrative, civil or criminal measures, as established in Section 16 of the Environmental Public Policy Act (Law No. 416 of September 22, 2004, as amended).

2. **Right of Entry**: As specified under Rules 103 and 603(c)(2) of the RCAP, the permittee shall allow the Board or an authorized representative, upon presentation of credentials and other documents as may be required by law, to perform the following activities:

a. Enter upon the permittee premises where an emission source is located or where emissions related activities are conducted, or where records must be kept under the conditions of this permit, under the RCAP, or under the Clean Air Act;

b. Have access to and copy, at reasonable times, any records that must be kept under the conditions of the permit, under the RCAP, or under the Clean Air Act;

c. Inspect and examine any facility, equipment (including monitoring and air pollution control equipment), practices or operations (including QA/QC methods) regulated or required under this permit; as well as sampling emissions of air quality and fuels; and

d. As authorized by the Clean Air Act and the RCAP, to sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with the permit or other applicable requirements.

3. **Sworn Statement or Affidavit:** All reports required pursuant Rule 103(D) of the RCAP (i.e., semiannual monitoring reports and annual compliance certification) should be submitted together with a sworn statement or affidavit by the Responsible Official or a duly authorized representative. Such sworn statement or affidavit shall attest to the truth, correctness and completeness of such records and reports.

4. **Data Availability:** As specified under Rule 104 of the RCAP, all emission data obtained by or submitted to the EQB, including data reported pursuant to Rule 103 of the RCAP, as well as that obtained in any other way, shall be available for public inspection and may also be made available to the public in any additional manner that the EQB may deem appropriate.

5. **Emergency Plan:** As specified under Rule 107 of the RCAP, the permittee shall have available an Emergency Plan which must be consistent with adequate safety practices, and provides for the reduction or retention of the emissions from the plant during periods classified by the EQB as air pollution alerts, warnings or emergencies. These plans shall identify the emission sources, include the reduction to be accomplished for each source, and the means by which such reduction will be accomplished. These plans will be available for any authorized representative of the EQB at any time.

6. **Air Pollution Control Equipment :** The permittee shall comply with Rule 108 of the RCAP, as follows:

a. All air pollution control equipment or control measures shall provide for continuous compliance with applicable rules and regulations. Such equipment or measures shall be installed, maintained, and operated according to those conditions imposed by this Title V permit, within the specified operating limitations of the manufacturer.

b. The collected material from air pollution control equipment shall be disposed in accordance with applicable rules and regulations. The removal, manipulation,

transportation, storage, treatment or disposal will be done in such or manner that shall not to produce environmental degradation, and in accordance with applicable rules and regulations.

c. The Board may require, when deemed appropriate to safeguard the health and welfare of human beings, the installation and maintenance of additional, complete and separate air pollution control equipment of a capacity equal to the capacity of the primary control equipment. Furthermore, the Board may require that such additional air pollution control equipment be operated continuously and conjunctionally with the primary air pollution control equipment.

d. All air pollution control equipment shall be operated at all times while the source being controlled is in operation.

e. In the case of a shutdown of air pollution control equipment for the necessary scheduled maintenance, the intent to shutdown such equipment shall be reported to the Board at least three days prior to the planned shutdown. Such prior notice shall include, but is not limited to the following:

i. Identification of the specific source to be taken out of service with its location and permit number.

ii. The expected length of time that the air pollution control equipment will be out of service.

iii. The nature and quantity of emissions of air pollutants likely to be permitted during the shutdown period.

iv. Measures such as the use of off-shift labor and equipment that will be taken to minimize the length of the shutdown period.

v. The reasons why it will be impossible or impractical to shutdown the operating source during the maintenance period.

f. The permittee shall, to the extent possible, maintain and operate at all times, including periods of start-up, shutdown and malfunction, any affected source and the associated air pollution control equipment, in a manner consistent with the original manufacturers design specifications and in compliance with applicable rules and regulations and permit conditions.

g. The permittee shall keep copies of monthly calibrations and inspections reports of the control equipment such as dust collectors. The permittee shall keep records of all incidents control equipment shutdown if the process continues its operation. All the records shall be available to EQB personnel.

7. **Compliance Certification:** As specified under Rule 602(c)(2)(ix)(C) of the RCAP, the permittee shall submit each year a compliance certification. This certification must be submitted to both the EQB and the Environmental Protection Agency (EPA)[1] no later than **April 1st of each year**, covering the previous calendar year. The compliance certification shall include, but is not limited to, the information required under Rule 603(c) of the RCAP as follows:

   a. The identification of each term or condition of the permit that is the basis of the certification; and

   b. The compliance status. Each deviation shall be identified and taken into account in the compliance certification; and

   c. A statement indicating whether the compliance was continuous or intermittent; and

   d. The methods or other means used for determining the compliance status with each term and condition, currently and over the reporting period consistent with sections (a)(3)-(5) of Rule 603 of the RCAP; and

   e. Identification of possible exceptions to compliance, any periods which compliance is required and in which an excursion or exceedance as defined under 40 CFR Part 64 (CAM) occurred; and

   f. Such other facts as the Board may require to determine the compliance status of a source.

8. **Regulation Compliance:** As specified under Rule 115 of the RCAP, any violation to the RCAP, or to any other applicable rule or regulation, shall be grounds for the Board to suspend, modify, or revoke any relevant permit, approval, variance or other authorization issued by the Board.

9. **Location Approval:** As specified under Rule 201 of the RCAP, nothing in this permit shall be interpreted as authorizing the location or construction of a major stationary source, or the modification of a major stationary source, or a major modification of a significant source, without obtaining first a location approval from the Board and without first demonstrating compliance with the National Ambient Air Quality Standards (NAAQS). This permit does not allow the construction of new minor sources without the required permit under Rule 203 of the RCAP.

[1] The certification to the EQB shall be mailed to: Manager, Air Quality Area, P.O. Box 11488, San Juan, PR, 00910. The certification to the EPA shall be mailed to: U.S. Environmental Protection Agency, 48 Carr. 165 Suite 7000, Guaynabo, P.R. 00968-8073.

10. **Open Burning:** Pursuant to Rule 402 of the RCAP, the permittee shall not cause or permit the open burning of refuse in their premises except as established under paragraph (E) of such rule which authorizes to conduct training or research of firefighting techniques, as previously approved by the Board.

11. **Objectionable Odors:** As specified under Rule 420 of the RCAP, the permittee shall not cause or permit emissions to the atmosphere of any matter which produces an *objectionable* odor that can be perceived in an area other than that designated for industrial purposes. [This condition is enforceable only by the State]

12. **Permit Renewal Applications:** As established under Rule 602 (a)(1)(iv) of the RCAP, the permittee shall submit a permit renewal application applications for permit renewal shall be submitted at least 12 months prior to the date of permit expiration. A responsible official must certify all required applications consistent with paragraph (c)(3) of Rule 602 of the RCAP.

13. **Permit Duration:** As specified under Rule 603 of the RCAP, the following terms will apply during the duration of this permit:

    a. Expiration: This authorization shall have a fixed term of 5 years since the effective date. The expiration date will be automatically extended until the Board approves or denies a renewal application (Rule 605(c)(4)(ii) of the RCAP) but only in those cases where the permittee submits a complete renewal application at least twelve (12) months before the expiration date. [Rules 603 (a)(2), 605 (c)(2), and 605(c)(4) of the RCAP]

    b. Permit Shield: As specified under Rule 605 (c)(4)(i) of the RCAP, the permit shield may be extended until the time the permit is renewed if a timely and complete renewal application is submitted.

    c. In case that this permit is subject to any challenge by third parties, the permit shall remain in effect until the time it is revoked by a court of law with jurisdiction in the matter.

14. **Recordkeeping Requirement:** As established under Rule 603(a)(4)(ii) of the RCAP, the permittee shall retain records of all required monitoring data and support information for a period of 5 years from the date of the monitoring sample, measurement, report, or application. The permittee shall keep available in the facility, copies of all records of required monitoring information including the following :

    i . Date, place - as defined in the permit-and time of sampling;
    ii . Date analyzes were performed;
    iii . The company or entity that performed the analyzes;
    iv . Analytical methods or techniques used;
    v . The results of these analyzes; and
    vi. The operating conditions at the time of sampling or measurement.

15. **Semiannual Monitoring Reports/Samplings[2]:** As established under Rule 603(a)(5)(i) of the RCAP, the permittee shall submit reports to the EQB of all required monitoring every 6 months, or more frequently if required by the Board or any other underlying applicable requirement. All instances of deviations from permit requirements must be clearly identified in such reports. All required reports must be certified by a responsible official as established under Rule 602(c)(3) of the RCAP. The report covering the period from January through June shall be submitted no later than October 1 of the same year and the report covering the period from July through December shall be submitted no later than April 1 of the following year. Once the guidelines are developed by the Board, the permittee must use them to complete these reports.

16. **Deviations Reporting due to Emergencies:** According to Rule 603(a)(5)(ii)(a) of the RCAP, any deviation resulting from an upset (such as sudden malfunction or break-down) or emergency conditions, as defined in Rule 603(e) of the RCAP, must be reported within the next 2 working days from the time the emission limits are exceeded due to the emergency, if the permittee wishes to assert the affirmative defense authorized under Rule 603 (e) of the RCAP. If the permittee raises the emergency defense upon an enforcement action, the permittee shall demonstrate that such deviation happens due to an emergency and that the Board was adequately notified. If such emergency deviation last for more than 24 hours, the affected units may be operated until the end of the cycle or 48 hours, whichever occurs first. The Board may only extend the operation of an emission source in excess of 48 hours, if the source demonstrates to the Board's satisfaction that the National Air Quality Standards have not been exceeded and that there is no risk to the public health.

17. **Deviation Reporting (Hazardous Air Pollutants):** The source shall act as specified in its Emergency Response Plan (established in Rule 107(C) of the RCAP), when such Plan has shown no significant impact on an area other than those that have been designated for industrial purposes or will cease operations immediately if there is a significant impact on an area other than those that have been designated for industrial purposes (state-only enforceable condition). In accordance with Rule 603(a)(5)(ii)(b) of the RCAP, the Board shall be notified within the next 24 hours if a deviation that results in the release of emissions of hazardous air pollutants for more than an hour in excess of the applicable limit occurs. For the discharge of any regulated air pollutant that continues for more than 2 hours in excess of the applicable limit, the permittee shall notify the Board within 24 hours of the deviation. The permittee shall submit to the Board, within 7 days of the deviation, a detailed written report which includes probable causes, time and duration of the deviation, remedial action taken and the steps you are following to prevent recurrence.

18. **Severability Clause:** As specified under Rule 603(a)(6) of the RCAP, the clauses in this permit are severable. In the event of a successful challenge to any portion of the permit in an administrative or judicial forum, or in the event any of its clauses is held to be invalid, all other portions of the permit shall remain valid and effective, including those related to

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[2] These reports include two major elements. The first element is the summary of all monitoring / periodical sampling
required in this permit. The second element requires that all deviations from permit conditions are clearly identified, summarized and reported to the Board.

emission limits, terms and conditions, be they specific or general, as well as monitoring, record keeping and reporting requirements.

19. **Permit Noncompliance:** According to Rule 603(a)(7)(i) of the RCAP, the permittee must comply with all conditions of the permit. Permit noncompliance constitutes a violation of the RCAP and will be grounds for taking the appropriate enforcement action, impose sanctions, revoke, terminate, modify, and/or reissue the permit, or to deny a permit renewal application.

20. **Defense not Allowed:** As specified under Rule 603(a)(7)(ii) of the RCAP, the permittee shall not allege as a defense in an enforcement action, that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

21. **Permit Modification and Revocation:** As specified under Rule 603(a)(7)(iii) of the RCAP, the permit may be modified, revoked, reopened, reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit condition.

22. **Property Rights:** As specified under Rule 603(a)(7)(iv) of the RCAP, this permit does not convey any property rights of any sort, nor does it grant any exclusive privilege.

23. **Obligation to Furnish Information:** As specified under Rule 603(a)(7)(v) of the RCAP, the permittee shall furnish to the EQB, within a reasonable time, any information that the EQB may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit or to determine compliance with the permit. Upon request, the permittee shall also furnish to the EQB copies of documents related to this permit.

24. **Changes in Operating Scenarios:** As specified in Rule 603(a)(10) of the RCAP , the permittee shall record in a logbook, contemporaneously with making a change from one operating scenario to another, the scenario under which it is operating. This logbook must be kept at the facility at all times.

25. **Prohibition on Default Issuance:** As specified under Rule 605(d) of the RCAP, it shall never be considered that a permit has been issued by default as a result of the EQB's failure to take final action on a permit application within 18 months. The EQB's failure to issue a final permit within 18 months should be treated as a final action solely for the purpose of obtaining judicial review in a state court.

26. **Administrative Permit Amendments and Permit Modifications:** As specified under Rule 606 of the RCAP, the permit shall not be amended nor modified unless the permittee complies with the requirements for administrative permit amendments and permit modifications as described in the RCAP.

27. **Permit Reopening:** As specified under Rule 608(a)(1), this permit shall be reopened and revised under the following circumstances:

a. Whenever additional applicable requirements under any law or regulation become applicable to the permittee, when the remaining permit term is of 3 or more years. Such reopening shall be completed 18 months after promulgation of said applicable requirement. No such reopening is required if the effective date of the requirement is later than the date on which the permit is due to expire, unless the original permit or any of its terms and conditions have been extended pursuant to Rule 605(c)(4)(i) or Rule 605(c)(4)(ii) of the RCAP.

b. Whenever the EQB or the EPA determines that the permit contains a material mistake or that inaccurate statements were made in establishing the emission standards or other terms or conditions of the permit.

c. Whenever the EQB or the EPA determines that the permit must be revised or revoked to assure compliance with the applicable requirements.

28. **Changes in Name or Responsible Official:** This permit is issued to **McNeil Healthcare, LLC.** In the event that the company and/or facility change its name, the responsible official must submit an administrative amendment to this permit to reflect the change in name. If the event that the responsible official changes, the new responsible official must submit no later than 30 days after the change, an administrative amendment including a sworn statement in which he/she accepts and promises to comply with all the conditions of this permit.

29. **Changes in Ownership**: This permit is issued to **McNeil Healthcare, LLC.** In the event that the company and/or facility is transferred to a different owner or change operational control and the Board determines that no other change in the permit is necessary, the new responsible official must submit an administrative amendment. The administrative amendment shall include a sworn statement in which the new responsible official accepts and promises to comply with all the conditions of this permit, and a written agreement containing a specific date for transfer of permit responsibility, coverage, and liability between the current and new permittee. This is not applicable if the Board determines that changes to the permit are necessary.

30. **Renovation Work/ Demolition:** The permittee shall comply with the provisions set forth in 40 CFR §61.145 and §61.150, and Rule 422 of the RCAP, and Regulations for the Processing of General Permits (General Permit for the Handling of Asbestos Containing Materials) when doing renovation or demolition activities of asbestos containing materials at the facility.

31. **Compliance Clause**: Under no circumstances does compliance with this permit exempt the permittee from complying with all other applicable state or federal laws, regulations, permits, administrative orders or applicable court orders.

32. **Requirements for Refrigerants (Climatologic and Stratospheric Ozone Protection):**

a. In the event that the permittee has equipment or appliances, including air conditioning units, which use Class I or II refrigerants as defined in 40 CFR part 82, subpart A, Appendices A and B, the permittee shall take the necessary measures to ensure that all maintenance, service or repair services performed are done so according to the practices, certification and personnel requirements, disposition requirements, and recycling and/or recovery equipment certification requirements specified under 40 CFR part 82, subpart F.

b. Owners/ operators of appliances normally containing 50 or more pounds of refrigerant[3] must keep records of refrigerant purchased and added to such appliances pursuant to 40 CFR §82.166.

c. Service on Motor Vehicles: If the permittee performs a service on motor (fleet) vehicles when this service involves ozone-depleting substance refrigerant (or regulated substitute substance) in the motor vehicle air conditioner (MVAC), the permittee is subject to all the applicable requirements as specified in 40 CFR part 82, subpart B, Servicing of Motor Vehicle Air Conditioners. The term motor vehicle as used in subpart B does not include a vehicle in which final assembly of the vehicle has not been completed. The term MVAC as used in subpart B does not include the air-tight sealed refrigeration system used as refrigerated cargo or system used on passenger buses using HCFC-22 refrigerant.

33. **Labeling of Products Using Ozone-Depleting Substances**: The permittee shall comply with the standards for labeling of products using ozone-depleting substances pursuant to 40 CFR part 82, subpart E.

a. All containers in which a class I or class II substance is stored or transported, all products containing a class I substance, and all products directly manufactured with a class I substance must bear the required warning statement if it is being introduced into interstate commerce pursuant to 40 CFR §82.106.

b. The placement of the required warning statement must comply with the requirements pursuant to 40 CFR §82.108.

c. The form of the label bearing the required warning statement must comply with the requirements pursuant to 40 CFR §82.110.

d. No person may modify, remove, or interfere with the required warning statement except as described in 40 CFR §82.112.

34. **Risk Management Plan (RMP):** If during the effectiveness of this permit, the permittee is subject to the 40 CFR part 68, the permittee shall submit a Risk Management Plan according with the compliance schedule in the 40 CFR part 68.10. If during the

[3] As defined in the 40 CFR 82.152.

effectiveness of this permit, the permittee is subject to the 40 CFR part 68, the permittee shall submit a compliance certification with the requirements of part 68 as part of the annual compliance certification required under 40 CFR part 70, including the recordkeeping and the Risk Management Plan.

35. **General Duty:** The permittee has the general obligation of identifying hazards which may result from accidental releases of any controlled substance under section 112(r) of the Clean Air Act or any other extremely hazardous substance in a process, using appropriate hazard assessment techniques, designing, maintaining, and operating a safe facility and minimizing the consequences of accidental releases if they occur as required in section 112(r)(1) of the Act and Rule 107(D) of the RCAP.

36. **Roof Surface Coating:** Pursuant to Rule 424 of the RCAP, McNeil shall not cause or permit the roof surface coating by applying hot tar or any other coating material containing organic compounds without previous notification to the Board. The use of used oil or hazardous waste for roof surface coating is prohibited. This rule will not apply to activities where tar or sealing material is applied without heat and such material is asbestos-free. [State enforceable only]

37. **Ozone Generating Machines:**

a. The operation of each ozone generator machine[4] identified as insignificant activity is limited to 240 hours per year.

b. The permittee shall keep a monthly record of hours and days of operation of each machine. This record shall be available at all times for inspection by EQB and EPA.

38. **Fugitive Emissions:** Compliance with Rule 404 of the RCAP:

a. The permittee shall use, as much as possible, water or suitable chemicals for chemical stabilization and the control of dust in the demolition of a building or structures, construction operations, quarrying operations, the grading of roads, or the clearing of lands.

b. The permittee shall not cause or permit the discharge of visible emissions of fugitive dust beyond the boundary line of the property on which the emissions originate.

39. **Emissions Calculations**: The permittee shall submit, on or before **April 1st of each year,** the actual or permissible emissions calculations for the previous natural year. The emissions calculations shall be submitted on the forms prepared by the Board for this

[4] Emission discharge volume = 8.5 grams / hr

purpose and the responsible official must certify all the information submitted as true, correct and representative of the permitted activity.

40. **Annual Fee:** As specified under Rule 610 of the RCAP, the permittee must submit an annual payment based on the emissions calculations for each regulated pollutant. The payment will be based on their actual emissions at a rate of $37.00 per ton, unless the Board decides otherwise as permitted under Rule 610(b)(2)(iv) of the RCAP. This payment for the previous year must be made on or before **June 30 of each year.**

41. **New or Amended Regulation:** Whether a federal or state regulation is promulgated or amended and the facility is affected by it, the owner or operator shall comply with the requirements of the new or amended regulation.

42. **Reports:** Unless a permit condition establishes otherwise, any requirement of information submittal to the Board shall be addressed to: Manager, Air Quality Area, PO Box 11488, San Juan, P.R. 00910.

43. **Reservation of Rights:** Except as expressly provided in this Title V permit:

a. Nothing herein shall prevent Board or the EPA from taking administrative enforcement measures or seeking legal or equitable relief to enforce the terms of the Title V permits, including but not limited to the right to seek injunctive relief, and imposition of statutory penalties and/or fines.

b. Nothing herein shall be construed to limit the rights of the Board or the EPA to undertake any criminal enforcement activity against the permittee or any person.

c. Nothing herein shall be construed to limit the authority the Board or the EPA to undertake any actions in response to conditions that present an imminent and substantial endangerment to public health or welfare, or the environment

d. Nothing herein shall be construed to limit the permittee's rights to administrative hearing and judicial appeal of termination/ revocation/ disputes over modification/ denial actions in accordance with regulations and the Environmental Public Policy Act.

Section IV - Allowable Emissions

The emissions described in the following table represent the allowable emissions at the time of the permit application and will be used for payment purposes only. According to Resolution RI-06-02[5], the emissions calculations will be based on actual emissions of **McNeil**, however calculations based on allowable emissions of the installation will be accepted. If **McNeil** going to perform the calculations based on allowable emissions, **McNeil** shall pay the same charge

[5]EQB Resolution - Payment procedure for Title V operating charges and Title V permit renewal charges, issued on March 20, 2006.

per ton as the facilities that decide to do the calculations based on actual emissions. Also, when **McNeil** requests a modification, administrative change or minor modification to its Title V permit, the source will pay only those charges related with any emission increase (if any) per ton, based on the change and not based on the previous total charges in accordance with RCAP Rule 610(a).

Pollutant	Emissions Cap (ton/year)
PM	118.25
SO_2	450.96
NO_X	411.52
CO	93.49
VOC	22.34
Pb	0.02
Ozone	0.07
HAP (methanol)	2.67
HAP (combustion)	0.43
CO_2e	55,630.51

Section V - Specific Permit Conditions

A. Normal Operating Scenario

The tables presented below contain a summary of the applicable requirements and test methods required to demonstrate compliance with the emission units identified in Section II of this permit.

1. PHARMFG, CHEWABLES, ROTO-GRANULATION ROOM and SIEVING AREA, GLATTS, PHARMFG 2

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
Production limit	Annual production of Tylenol, Motrin, Pepcid Imodium and Benadryl (Sieving Room)	3,322	lots per year	Records	Monthly	Logbook	Semiannual
Particulate Matter emission limit for non-process sources	PM	≤0.05	lbs/lbs of uncontrolled emissions	Emission calculations using emission factor 0.0085 grains/dscf Stack test using method 5 of Appendix A of 40 CFR Part 60, during the first year of duration of the permit	Monthly During the first year of duration of the Permit	Record of the readings of pressure drops and calibrations	Semiannual Sixty days (60) after the Stack test.

a. Production limit:

(i) Production is limited to a maximum of 3,322 lots per year (Tylenol, Motrin, Pepcid, Imodium and Benadryl). Shall keep a monthly record with the following information about lots processed in the Sieving Room:

a. Product name and its components,
b. Lot size,
c. Start date and
d. Date completed.

b. Particulate Matter emission limit for non-process sources:

(i) McNeil shall not cause the emission of particulate matter at any time in excess of 0.05 pounds per pound of uncontrolled emissions from any non-process source. [Rule 409(B) of the RCAP]

(ii) Actual emissions of particulate matter of the emission units will be calculated monthly based on the emission factor of particulate matter **and the actual performance rate of the production data.** The emission factor equivalent to the

actual average concentration[6] will be used in all calculations of PM emissions until new data is obtained from the next within the first year of the permit. [PFE-44-0900-1690-I-C]

(iii) McNeil shall perform a performance test using Method 5 of 40 CFR Part 60, Appendix A during the first year of the permit to demonstrate compliance and determine a new emission factor for these units.

(iv) McNeil shall submit a performance test protocol at least 30 days prior to the start date of the test for Board approval. This protocol must include the information described in Rule 106(C) of the RCAP.

(v) McNeil shall provide written notification to the Board 15 days prior to the test to afford the Board the opportunity to have an observer present. [RCAP Rule 106 (D)]

(vi) McNeil shall submit two copies of the test results report within 60 days after the performance tests. This report shall include the information required under RCAP Rule 106(E).

(vii) During the test, the source must be operated at its maximum rated capacity or based on representative performance of the affected facility; understanding that, after proving compliance with any applicable emission limit, the Board may restrict the operation of the source at the capacity reached during the performance test. [RCAP Rule 106 (F)]

(viii) Pursuant to Rule 603(A)(4)(ii) of the RCAP, the permit holder must keep records of all required sampling data and support information for five (5) years from the date of the sampling, measurement, report or sampling application.

c. Pressure Drop in Dust Collectors

(i) McNeil shall calibrate pressure drop monitors indicators once per year in dust collectors and vacuum systems, and maintain the results and records of calibrations available at all times at the facility for review. It may not exceed a period of 12 months between calibrations. [PFE-44-0900-1690-I-C]

(ii) McNeil shall keep a weekly log where the pressure drop is recorded for every dust collection system for optimum particulate removal according to the pressure drop parameters recommended by the manufacturer. [PFE-44-0900-1690-I-C]

[6]PM emission factor of 0.0085 granules/dscf based in the performance test performed on August 1996.

2. EQUIPCLN-1 AND CLEANING AREA, ROTOR AND SIEVING AREA

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
VOC Emission Cap	COV	3 15	Pounds per hour Pounds per day	Emission calculations	Semiannual	Documents of emission calculations	Semiannual

a. VOC Emission Limit

(i) Pursuant to Rule 419 of the RCAP, McNeil shall not permit the emission of 3 pounds per hour or 15 pounds per day of VOC from any article, machine, equipment or any other contrivance unless it is provided with an acceptable control system, program or emissions reduction and prevention mechanism or both, as approved or required by the Board. [State-only enforceable condition].

b. Solvents Limit

(i) The use of solvents for equipment cleaning should be limited as stablished in the table below.

Solvent	Solvent used (gallons per year)
Isopropyl Alcohol (70%)	770
Quick Solve Solvent	330
Isopropyl Alcohol (99%)	825
Thinner	260

(ii) The permittee shall keep a monthly record indicating the date and solvent amount used. The records must be available at all times for inspection by personnel of the EQB and EPA. [PFE-44-0900-1690-I-C, PFE-44-0304-0008-I-C, PFE-SM-2834-44-0402-0544]

(iii) McNeil shall keep copy of all updated Safety Data Sheets (SDS) for all used solvents in the cleaning processes of the laundry rooms (EQUIPCLN) for a five years period. These must be available when the technical personnel of the Board and EPA requests them. [PFE-RH-44-0304-0008-II-C]

(iv) McNeil shall prepare and maintain a monthly record for each used solvent in the cleaning processes (EQUIPCLN) indicating the date, amount used and the following: [PFE-RH-44-0304-0008-II-C]

a. Solvent type
b. Daily volume used for each cleaning method in gallons per year
c. Specific gravity or density

d. Percentage per volume
e. VOC pounds or tons emitted

3. PROCESS TANKS:

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
[RCAP Rule 419]	VOC	3 15	Pounds per hour Pounds per day	Emission calculations	Semiannual	Emission calculations documents	Semiannual

a. VOC Emission Limit

(i) Pursuant to Rule 419 of the RCAP, the permittee shall not permit the emission of 3 pounds per hour or 15 pounds per day of VOC from any article, machine, equipment or any other contrivance unless it is provided with an acceptable control system, program or emissions reduction and prevention mechanism or both, as approved or required by the Board. [State-only enforceable condition].

b. Load limit of the tanks:

(i) McNeil shall keep a monthly record with the identity and quantity (gallons) of each load for each solvent storage tank. This record shall be available at all times for inspection by the Board's technical personnel. [PFE-44-0900-1690-I-II-C]

(ii) The permittee shall not exceed the maximum annual storage for each tank according to the following table: [Cumulative increase, PFE-44-0900-1690-I-II-C]

Solvent[7]	Maximum annual load (gallons per year)
Methanol	85,237.48

4. ROTOR: Rotogranulation Unit

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
Production limit	Annual production of pharmaceutical products: Tylenol, Motrin, Pepcid Imodium and Benadryl	627	lots per year	Records	Monthly	Record	Semiannual

[7] Loss of 1.0% is presumed for the total transfer of solvent, using as reference the minimum loss value according to AP-42 Section 6.4.1.

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
Sulfur content limit in the fuel	Sulfur Content	≤0.1	Percentage per weight	Fuel supplier's analysis	Each time the fuel is received	Monthly record of Sulfur Percentage	Monthly
Operating Parameters	Temperature Residence time	1,440 1.46	°Fahrenheit seconds	n/a	24 hours	Records (graphs)	Semiannual
Fuel consumption limit	Auxiliary propane gas fuel consumption	201,982	gallons/year	Flowmeter	Calculate monthly consumption	Fuel consumption monthly record	Monthly

a. Production limit:

(i) The production will be limited to a maximum of 627 lots per year *(Tylenol, Motrin, Pepcid Imodium and Benadryl).* The permittee shall keep a monthly record of the following information about the processed lots in the ROTOR area:

a. Name of the product and its components,
b. Lot size,
c. Start date and
d. End date

b. Operating Limits

(i) Controlled methanol emissions per batch shall be calculated assuming uncontrolled emissions from process vents directed to the thermal oxidizer will be reduced up to 99.91% if the thermal oxidizer reaches a minimum temperature of 1440°F and a residence time of 1.46 seconds.[8] [PFE-44-0900-1690-I-C]

(ii) The graphs where the temperatures of the combustion chamber and the outlet of the chimney of the thermal oxidizer are recorded per 24 hours, shall be available at all times for review by EQB and EPA technical personnel. [PFE-44-0900-1690-I-C]

(iii) Methanol emissions from the manufacture of 627 lots in the Roto-Granulation Unit shall be controlled at all times by the thermal oxidizer. [PFE-44-0900-1690-I-C]

(iv) The Board reserves the right to require additional efficiency tests of the thermal oxidizer in order to demonstrate compliance with the air pollutants emission limits. [PFE-44-0900-1690-I-C]

[8]Operating parameters established according to performance tests conducted on August 19, 2003.

c. Fuel Consumption Limit:

(i) The maximum consumption of propane gas as auxiliary fuel in the thermal oxidizer is limited to 201,982 gallons per year based on a 12-month rolling period. The maximum sulfur content not exceeding 0.1% by weight. [PFE-44-0900-1690-I-C]

(ii) The permittee must keep a record on a monthly basis on a 12 months rolling period indicating the amount of auxiliary fuel consumed by the thermal oxidizer and its sulfur content in weight percent. This must be available at all times for inspection by EQB and EPA personnel. [PFE-44-0900-1690-I-C]

(iii) The thermal oxidizer shall be provided with a fuel flow meter. The flowmeter shall be calibrated every 6 months and the records or documents of the calibrations shall be available at all times for review by technical personnel of EQB and EPA. [PFE-44-0900-1690-I-C]

6. Boilers B-1, B-2, B-3, B-4 and B-5

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
Opacity Limit (RCAP Rule 403)	Opacity	20	6-minutes average percentage	Method 9	Once during the first year of the permit	With each reading	60 from the performance test
Particulate Matter Emission Limit	PM	0.3	Pounds per million Btu	Stack test using Method 5 of Appendix A of 40 CFR Part 60, during the first year of duration of the permit	Once during the first year of the permit	Keep a copy of the final report for a period of five years from the date of the report [Rule 603 (A)(4)(ii)]	60 days after the performance test
Sulfur content limit in the fuel (RCAP Rule 410)	Sulfur Content	≤0.5	Percentage per weight	Fuel supplier's analysis	Each time the fuel is received	Sulfur Percentage Monthly Record	Monthly
Fuel consumption limit	#2 Fuel Consumption B-1, B-2 and B-3 B-4 B-5	 67,500 1,000,000 1,400,000	gallons/year	Flowmeter	Calculate monthly consumption	Fuel Consumption Daily Record	Monthly

a. Particulate Matter Emission Limit for Fuel Burning:

(i) The permittee shall not cause or permit the emission, from any fuel burning equipment burning liquid fuel, or particulate matter in excess of 0.3 pound per million Btu of heat input. [Rule 406 of the RCAP]

(ii) McNeil shall perform a performance stack test during the first year of the permit using Method 5 in 40 CFR Part 60, Appendix A to demonstrate compliance with the previous condition.

(iii) A stack test protocol shall be submitted at least 30 days prior to the test for approval by EQB. This protocol shall contain the information described in Rule 106(C) of the RCAP.

(iv) McNeil shall provide the EQB at least 15 days of prior written notification of any sampling, to afford the EQB an opportunity to have an observer present [Rule 106(D) of the RCAP]

(v) McNeil shall submit two copies of the test report results within 60 days after the performance of the emission tests. This report shall include the information required by Rule 106(E) of the RCAP.

(vi) During the test, the source shall be operated at its maximum capacity or based on representative performance of the affected facility; understanding that after providing compliance with any applicable emission limit, the Board may restrict the operation of the source to the capacity reached during the performance test. [Rule 106(F) of the RCAP]

(vii) According to Rule 603(A)(4)(ii) of the RCAP, the permittee shall retain the records of all required sampling data and support information for a period of five (5) years from the date of the monitoring sample, measurement, report or application.

b. Visible Emissions Limit:

(i) McNeil shall not exceed the 20% six-minute average opacity limit for each unit. However, according to RCAP Rule 403(A), the permittee may discharge visible emissions of an opacity up to 60% for a period of no more than 4 minutes in any consecutive 30 minutes. [RCAP Rule 403(A)]

(ii) McNeil shall hire an independent opacity reader, certified by an EPA accredited school or by the Board to perform one (1) opacity reading on each boiler's stack during the first year of the permit using Method 9 described in Appendix A of 40 CFR Part 60. The equipment shall be operating at the time the opacity readings are performed.

(iii) McNeil shall submit to the Board at least thirty (30) days prior to the initial opacity reading a copy of the format to be used to record the visible emissions readings.

(iv) McNeil shall notify to the Board in writing at least fifteen (15) days prior the initial reading using Method 9, to allow the Board the opportunity to have an observer present. [RCAP Rule 106(D)]

(v) The permittee shall submit two (2) copies of the report of the results of the initial sampling using Method 9 within 60 days of completing the tests. This report shall include the information required by Rule 106(E) of the RCAP. The requirements of subsequent readings shall be submitted in the readings summary to be filed together with the semiannual report required under this permit.

(vi) The Board reserves the right to require additional visible emissions readings in order to demonstrate compliance with the opacity limit.

c. Fuel Consumption Limit:

(i) Boilers B-1, B-2 and B-3 may consume more than 67,500 gallons of diesel fuel per year provided that the total of fuel burned by all boilers does not exceed 2,467,500 gallons per year. [PFE-44-0301-0531-II-C]

(ii) The diesel fuel consumption in the boiler B-4 shall not exceed 1,000,000 gallons per year. [PFE-44-0301-0531-II-C]

(iii) The diesel fuel consumption in the boiler B-5 shall not exceed 1,400,000 gallons of per year. [PFE-44-0301-0531-II-C]

(iv) The total diesel fuel consumption for all boilers (B-1, B-2, B-3, B-4 and B-5) shall not exceed 2,467,500 gallons of per year. [PFE-44-0301-0531-II-C]

(v) McNeil shall keep a daily register of fuel consumption and sulfur content in percent by weight for emission units B-1, B-2, B-3, B-4 and B-5. The percentage of sulfur and cumulative fuel consumption shall be keep on a monthly basis in a rolling 12-month period. The records must be available at all times for inspection by the Board and EPA technical personnel. [PFE-44-0301-0531-II-C].

(vi) McNeil must install and operate flow meters in each boiler. The fuel flow meters shall be calibrated every six months. McNeil shall prepare and maintain records indicating the date, time, methodology used and results of the calibrations. The records shall be available at all times for inspection by the Board and EPA technical personnel. [PFE-44-0301-0531-II-C].

(vii) McNeil shall retain the results and methodology used of the calibration of flow meters for the combustion unit for at least five years, pursuant to RCAP Rule 603(a)(4)(ii).

(viii) McNeil shall submit annually, with the annual compliance certification, a copy of reports of monthly fuel consumption for the reporting year.

d. SO_2 Emission Limit:

(i) The sulfur content in the fuel burned in the boilers B-1, B-2 and B-3, shall not exceed 0.5 percent by weight. [PFE-44-0301-0531-II-C].

(ii) McNeil shall retain a certified copy by the supplier indicating the sulfur content in the fuel burned in the boilers B-1, B-2 and B-3, to demonstrate compliance with the sulfur emission limit. McNeil shall obtain an analysis of sulfur content[9] certified as correct with each receipt of fuel at the facility. The certification shall include the following information:

1. Name of the fuel supplier

2. Statement from the diesel supplier indicating that it complies with the specifications of fuel number 1 or 2, as defined by the American Society for Testing and Materials ASTM D-396-78 (Standard Specification for Fuel Oils).

3. Fuel sulfur content or maximum sulfur content.

(iii) McNeil shall retain all records of all required monitoring data and support information for a period of 5 years from the date of the monitoring sample, measurement, report or application. This includes a record of the sampling results and fuel sulfur content in fuels burned in compliance with RCAP Rule 603(a)(4)(ii).

(iv) McNeil shall submit to the Board a monthly report indicating the daily fuel consumption and sulfur content by weight for the fuel consumed in each unit. This report shall be submitted to the Board no later than the next 15 days following the month for which the report is representative. The report shall be addressed to the Chief of the Validation and Data Management Division and shall be keep available at any time at the facility for inspection by technical staff of EPA and the Board. [RCAP Rule 410]

(v) McNeil shall submit, with each annual compliance certification, a summary of the reports for that year indicating the sulfur content by weight for the fuels consumed monthly.

e. New Sources Performance Standards for Stationary Sources for Industrial, Commercial and Institutional Steam Generating Units under Subpart Dc Part 60 Title 40 of the Code of Federal Regulations (40 CFR) - (B-4 and B-5)

(i) Boilers B-4 and B-5 shall comply with all applicable requirements of the New Source Performance Standards under **40 CFR Part 60, Subpart Dc.** The permittee shall demonstrate compliance with, but not limited to, the following:

a. 40 CFR section 60.42c(d) provides that the permittee shall be limited to combust diesel with a maximum sulfur content of 0.5% by weight.

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[9]As required by RCAP Rule 103(C), all chemical analysis shall be certified as correct by a chemist or chemical engineer licensed to practice the profession in Puerto Rico.

b. Compliance with the fuel sulfur limit under section 60.42c may be determined based on a fuel supplier certification, as described under section 60.48c(f), as applicable. [40 CFR section 60.42c(h)]

c. The sulfur content emission limits apply at all times, including periods of startup, shutdown, and malfunction. [40 CFR 60.42c(i)]

d. The performance test shall consist in the fuel supplier certification, as described in section 60.48c(f), as applicable. [40 CFR section 60.42c(h)]

e. The permittee shall comply with all reporting requirements and applicable maintenance records established in 40 CFR 60.48c.

i. The permittee shall submit a notification of the date of construction or reconstruction and actual startup as provided in section 40 CFR 60.7. This notification shall include the information required in paragraphs (1) through (4) of section 60.48c(a) of 40 CFR.

ii. The permittee shall submit the required fuel consumption reports as established in section 40 CFR 60.42c to the EPA with a copy to the Board.

iii. It shall maintain records and submit reports as required in section 60.48c(d) of 40 CFR, including the following information:

1) Calendar days covered by the reporting period.

2) In addition to the records of fuel supplier certifications, the report shall include a certified statement signed by the official responsible for certifying that the records of fuel supplier certifications submitted represent all of the fuel combusted during the reporting period.

3) In accordance with section 60.48c(d) of 40 CFR the fuel supplier certification shall include;

(a) Name of the fuel supplier

(b) A statement from the fuel supplier that the fuel complies with the specifications under the definition of distillate fuel in section 40 CFR 60.41c, and

(c) The sulfur content or the maximum sulfur content of the fuel.

iv. The permittee shall record and maintain records of the amount of fuel combusted during each month. [40 CFR section 60.48c(g)(2)]

v. All records required under 40 CFR section 60.48c shall be retained for a minimum period of two years. [40 CFR section 60.48c(i)]

vi. The reporting period for the reports required under this Subpart is each six months period. All reports shall be submitted to the EPA, with a copy to the Board, and shall be postmarked by the 30th day following the end of the reporting period. [40 CFR section 60.48c(j)]

7. Boilers SB-001, SB-004 and SB-005

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
Particulate Matter Emission Limit	PM	0.3	Pounds per Million Btu	Stack test using Method 5 of Appendix A, 40 CFR Part 60, during the first year of duration of the permit	Once during the first year of the permit	Keep a copy of the final report for a period of five years from the date of the report [Rule 603 (A)(4)(ii)]	60 days after the performance test
Opacity Limit (RCAP Rule 403)	Opacity	20%	6-minutes average percentage	Method 9	Once during the first year of the permit	With each reading	60 days from the performance test
Sulfur content limit in the fuel (RCAP Rule 410)	Sulfur Content	≤2.0	Percentage per weight	Fuel supplier's analysis	Each time the fuel is received.	Sulfur Percentage Record	Monthly
Fuel consumption limit	#6 fuel or lighter grade consumption	1,478,920	gallons/year	Flowmeter	Calculate monthly consumption	Fuel Consumption Daily Record	Monthly

a. Particulate Matter Emission Limit for Fuel Burning:

(i) The permittee shall not cause or permit the emission, from any fuel burning equipment burning liquid fuel, or particulate matter in excess of 0.3 pounds per million Btu of heat input. [Rule 406 of the RCAP]

(ii) McNeil shall perform a performance stack test during the first year of the permit using Method 5 in 40 CFR Part 60, Appendix A to demonstrate compliance with the previous condition

(iii) A stack test protocol shall be submitted at least 30 days prior to the test for approval by EQB. This protocol shall contain the information described in Rule 106(C) of the RCAP.

(iv) McNeil shall provide the EQB at least 15 days of prior written notification of any sampling, to afford the EQB an opportunity to have an observer present. [Rule 106 (D) of the RCAP]

(v) McNeil shall submit two copies of the test report results within 60 days after the performance of the emission tests. This report shall include the information required by Rule 106(E) of the RCAP.

(vi) During the test, the source shall be operated at its maximum capacity or based on representative performance of the affected facility; understanding that after providing compliance with any applicable emission limit, the Board may restrict the operation of the source to the capacity reached during the performance test. [Rule 106(F) of the RCAP]

(vii) According to Rule 603(A)(4)(ii) of the RCAP, the permittee shall retain the records of all required sampling data and support information for a period of five (5) years from the date of the monitoring sample, measurement, report or application.

b. Visible Emissions Limit:

(i) McNeil shall not exceed the 20% six-minute average opacity limit for each unit. However, according to RCAP Rule 403(A), the permittee may discharge visible emissions of an opacity up to 60% for a period of no more than 4 minutes in any consecutive 30 minutes. [RCAP Rule 403(A)]

(ii) McNeil shall hire an independent opacity reader, certified by an EPA accredited school or by the Board to perform one (1) opacity reading on each boiler's stack during the first year of the permit using Method 9 described in Appendix A of 40 CFR Part 60. The equipment shall be operating at the time the opacity readings are performed.

(iii) McNeil shall submit to the Board at least thirty (30) days prior to the initial opacity reading a copy of the format to be used to record the visible emissions readings.

(iv) McNeil shall notify to the Board in writing at least fifteen (15) days prior the initial reading using Method 9, to allow the Board the opportunity to have an observer present. [RCAP Rule 106(D)]

(v) The permittee shall submit two (2) copies of the report of the results of the initial sampling using Method 9 within 60 days of completing the tests. This report shall include the information required by Rule 106(E) of the RCAP. The requirements of subsequent readings shall be submitted in the readings summary to be filed together with the semiannual report required under this permit.

(vi) The Board reserves the right to require additional visible emissions readings in order to demonstrate compliance with the opacity limit.

c. Fuel Consumption Limit:

(i) McNeil shall not exceed 1,478,920 gallons per year of total No. 6 fuel consumption or lighter grade throughout the plant. [PFE-44-0794-0858-II-C and determination of non-applicability PSD of March 1, 1989 and May 8, 1995]

(ii) Boiler SB-001 consumption shall not exceed 691,322 gallons per year of No. 6 fuel or lighter grade. [PFE-44-0794-0858-II-C and determination of PSD non-applicability of March 1, 1989 and May 8, 1995]

(iii) Boiler SB-004 consumption shall not exceed 375,290 gallons per year of No. 6 fuel or lighter grade. [PFE-44-0794-0858-II-C and determination of PSD non-applicability of March 1, 1989 and May 8, 1995]

(iv) Boiler SB-005 consumption shall not exceed 316,030 gallons per year of No. 6 fuel or lighter grade. [PFE-44-0794-0858-II-C and determination of PSD non-applicability of March 1, 1989 and May 8, 1995]

(v) The simultaneous operation of boilers SB-004 and SB-005 is allowed as long as is not exceeded the total consumption of 691.320 gallons per 12 month rolling period. [PFE-44-0794-0858-II-C and determination of non-applicability PSD]

(vi) SB-001 boiler shall not be operated simultaneously with boiler SB-004 or boiler SB-005 or both. [PFE-44-0794-0858-II-C and determination of PSD non-applicability of March 1, 1989 and May 8, 1995]

(vii) The fuel consumption of any 12 consecutive months will be calculated through the sum of the total monthly consumption in each unit during the previous 11 months. [PFE-44-0794-0858-II-C and determination of non-applicability PSD of March 1, 1989 and May 8, 1995]

(i) McNeil must install and operate flow meters for each boiler. The fuel flow meters shall be calibrated every six months. McNeil shall prepare and maintain records of the date, time, methodology used and results of the calibrations. The records must be available at all times for inspection by Board and EPA technical personnel.

(ii) McNeil shall submit each year, with the annual compliance certification, copies of the reports of boilers monthly fuel consumption for the reporting year.

(iii) McNeil shall retain for at least five years the results and methodology used for the calibration of flow meters for the combustion unit, pursuant to RCAP Rule 603(a)(4)(ii).

d. SO_2 Emission Limit:

(i) The sulfur content in the fuel burned in the three boilers, shall not exceed 2.0 percent by weight. [PFE-44-0794-0858-II-C]

(ii) McNeil shall retain copy of the supplier certification indicating the sulfur content in the fuel to demonstrate compliance with the requirement of keeping daily record of the sulfur content in the fuel burnt. To verify the sulfur content, McNeil shall obtain a certified analysis of sulfur content with each fuel delivery at the facility.

(iii) McNeil shall submit, with each annual compliance certification, a summary of the reports for that year, indicating the sulfur content by weight for the monthly fuels consumed.

(iv) McNeil shall retain all records of required monitoring data and support information for a period of 5 years from the date of the monitoring sample, measurement, report or application. This includes a record of the performance test results and fuel sulfur content in fuels burned in compliance with RCAP Rule 603(a)(4)(ii).

c. **National Emission Standards for Hazardous Air Pollutants for Area Sources: Industrial, Commercial and Institutional Boilers under 40 CFR Part 63, Subpart JJJJJJ**

(i) An affected source is an **existing** source if construction (on-site fabrication, erection, or installation) or reconstruction of the affected source began on **June 4, 2010 or earlier.** The **liquid fuel** includes biodiesel and **biodiesel** is defined in section 63.11237.

1. **EXISTING BOILERS THAT BURN LIQUID FUEL > 5 MMBTU/HR; BOILERS B-1, B-2, B-3, SB-004 and SB-005**

(i) Boilers B-1, B-2, B-3, SB-004 and SB-005 shall comply with all applicable requirements of the National Emission Standards for Hazardous Air Pollutants for Area Sources: Industrial, Commercial and Institutional Boilers under 40 CFR Part 63, Subpart JJJJJJ.

(ii) The permittee must comply each work practice standard, emission reduction measure and management practice specified in Table 2, as applicable to boilers B-1, B-2, B-3, SB-004 and SB-005. [40 CFR Section 63.11201(b)]

(A) An initial tune-up to each boiler B-1, B-2, B-3, SB-004 and SB-005 must be performed as specified in 40 CFR Section 63.11214 and must conduct a *tune-up* biennially to each boiler, as specified in section 40 CFR 63.11223. The permittee must submit a written sworn statement from the responsible official in the Compliance Status Notification Report indicating that the tune-up of each boiler was performed, as specified in 40 CFR section 63.11225.

(B) The boilers B-1, B-2, B-3, SB-004 and SB-005 subject to work practice or management practice standard (Table 2) of a *tune-up* must achieve compliance no later than **March 21, 2014**. [40 CFR Section 63.11196(a)(1)]

(iii) The standards of Subpart JJJJJJ apply at all times when the affected boiler is operating, except during periods of startup and shutdown as defined in Section 63.11237, during which time the permittee must comply only with Table 2 to Subpart JJJJJJ. [Section 63.11201(d) of 40 CFR]

(iv) The permittee shall comply with the **applicable General Compliance Requirements** as described in 40 CFR Section 63.11205.

(v) The permittee shall comply with the **applicable Initial Compliance Requirements** as described in 40 CFR Sections 63.11210, 63.11211, 63.11212, 63.11213 and 63.11214

(vi) The permittee shall comply with the **applicable Notification, Reporting and Recordkeeping Requirements** as described in 40 CFR Section 63.11225.

(vii) The permittee shall comply with the **applicable Continuous Compliance Requirements** as described in 40 CFR Sections 63.11220, 63.11221, 63.11222, 63.11223, 63.11224 and 63.11226.

(viii) The permittee shall comply with the **General Provisions** of Sections 63.1 through section 63.16 as applicable, which are included in Table 8 of 40 CFR Subpart JJJJJJ.

(ix) The permittee shall apply for a construction permit modification if it wishes to use another fuel or fuel mix in the boilers as per requirements of Rule 203 of RCAP.

2. **EXISTING BOILERS WITH A CAPACITY ≥ 10 MMBTU/HR BURNING DIESEL; BOILERS B-4, B-5 AND SB-001**

(i) Boilers B-4, B-5 and SB-001, shall comply with all applicable requirements of the National Emission Standards for Hazardous Air Pollutants for Area Sources: Industrial, Commercial and Institutional Boilers in 40 CFR Part 63, Subpart JJJJJJ.

(ii) The permittee shall comply each work practice standard, emission reduction measure and management practice specified in Table 2, as applicable to boilers B-4, B-5 and SB-001. [40 CFR Section 63.11201(b)]

(A). An initial tune-up to each boiler shall be performed as specified in 40 CFR Section 63.11214 and shall conduct a tune-up biennially to each boiler, as specified in 40 CFR section 63.11223. The permittee shall submit a written sworn statement from the responsible official in the Compliance Status Notification Report indicating that the tune-up of each boiler was performed, as specified in 40 CFR section 63.11225.

(B). The boilers B-4, B-5 and SB-001 subject to work practice or management practice standard (Table 2) of a tune-up must achieve compliance no later than **March 21, 2014.** [40 CFR Section 63.11196(a)(1)]

(C). The permittee shall have an energy assessment (one-time energy assessment) performed by a qualified energy assessor for each boiler B-4, B-5 and SB-001. An energy assessment completed on **or after January 1, 2008** that meets or is amended to meet the energy assessment requirements in Table 2 to 40 CFR Subpart JJJJJJ satisfies this requirement. A facility that operates under an energy management program established by energy management systems compatible with ISO 50001 that includes the affected boilers, also satisfies the energy assessment requirement. The energy assessment must include the elements described in Table 2 to 40 CFR Subpart JJJJJJ.

(D). The boilers B-4, B-5 and SB-001 subject to the energy assessment requirement (Table 2), shall achieve compliance no later than **March 21, 2014.** [Section 63.11196(a)(3) of 40 CFR]

(iii) The standards of Subpart JJJJJJ apply at all times when the affected boiler is operating, except during periods of startup and shutdown as defined in Section 63.11237, during which time the permittee shall comply only with Table 2 to Subpart JJJJJJ. [Section 63.11201(d) of 40 CFR]

(iv) The permittee shall comply with the **applicable General Compliance Requirements** as described in 40 CFR Section 63.11205.

(v) The permittee shall comply with the **applicable Initial Compliance Requirements** as described in 40 CFR Sections 63.11210, 63.11211, 63.11212, 63.11213 and 63.11214

(vi) The permittee shall comply with the **applicable Notification, Reporting and Recordkeeping Requirements** as described in 40 CFR Section 63.11225.

(vii) The permittee shall comply with the **applicable Continuous Compliance Requirements** as described in 40 CFR Sections 63.11220, 63.11221, 63.11222, 63.11223, 63.11224 and 63.11226.

(viii) The permittee shall comply with the **General Provisions** of Sections 63.1 through section 63.16 as applicable, which are included in Table 8 of 40 CFR Subpart JJJJJJ.

(ix) The permittee shall apply for a construction permit modification if it wishes to use another fuel or fuel mix in boilers as per requirements of Rule 203 of RCAP.

8. Internal Combustion Units: INENGS (EG-1, EG-2, EG-3, EG-4, EG-5, EG-6) (2,680 hp); INEGS EG-7 (470 hp), INEGS EG-8 (1,135 hp), INEGS EG-9 (200 hp), INEGS EG-10 (100 hp), INEGS EG-11 (277 hp), INEGS EG-12 (1,300 hp), 2H EG-03 (20.4 MMBtu/hr); EG-2H (1040 kW); FIRE 1 (187 hp); FIRE (187 hp); FP-002 (157 hp).

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
Opacity Limit (RCAP Rule 403)	Opacity	20%	Percent 6-minutes average	Method 9	Once during the first year of permit approval	With each reading	60 days after each reading
Sulfur content limit in the fuel (RCAP Rule 410)	Sulfur Content		Percentage per weight	Fuel supplier's analysis with each delivery	Each time the fuel is received.	Sulfur Percentage Record	Monthly
	INEGS	≤ 0.5					
	EG-2H	≤ 0.3					
	EG-03	≤ 2.0					
	FIRE 1	≤ 0.5					
	FIRE 2	≤ 0.5					
	FP-002	≤ 0.5					
Fuel consumption limit	#2 Fuel Diesel Consumption			Operating Hour meter	Calculate monthly consumption	Fuel Consumption Record	
	(INEGS EG 1-6)	101,250	gallons/year each one			Monthly	Annual
	INENGS 7	11,850	gallons/year				
	INENGS 8	29,250	gallons/year				
	INENGS 9	5,050	gallons/year				
	INENGS 10	2,550	gallons/year				
	INENGS 11	5,650	gallons/year				
	INENGS 12	32,500	gallons/year				
	FIRE 1	4,700	gallons/year				
	FIRE 2	4,700	gallons/year				
	FP-002	883	gallons/year				
	#6 or lighter grade			Flow meter and hour meter		Daily	Monthly
	EG-03	787,600	gallons/year			Monthly	Annual
	EG-2H	4,860	gallons/year				

a. Visible Emissions Limit:

(i) McNeil shall not exceed the 20% six-minute average opacity limit for each unit. However, according to RCAP Rule 403(A), the permittee may discharge visible emissions of an opacity up to 60% for a period of no more than 4 minutes in any consecutive 30 minutes. [RCAP Rule 403(A)]

(ii) McNeil shall hire an independent opacity reader, certified by an EPA accredited school or by the Board to perform one (1) opacity reading on each engine's stack during the first year of the permit using Method 9 described in Appendix A of 40 CFR Part 60. The equipment shall be operating at the time the opacity readings are performed.

(iii) McNeil shall submit to the Board at least thirty (30) days prior to the initial opacity reading a copy of the format to be used to record the visible emissions readings.

(iv) McNeil shall notify to the Board in writing at least fifteen (15) days prior the initial reading using Method 9, to allow the Board the opportunity to have an observer present. [RCAP Rule 106(D)]

(v) The permittee shall submit two (2) copies of the report of the results of the initial sampling using Method 9 within 60 days of completing the tests. This report shall include the information required by Rule 106(E) of the RCAP. The requirements of subsequent readings shall be submitted in the readings summary to be filed together with the semiannual report required under this permit.

(vi) The Board reserves the right to require additional visible emissions readings in order to demonstrate compliance with the opacity limit.

b. Fuel Consumption Emission Limit:

(i) McNeil shall not exceed 750 hours of operation per year at each INENGS unit (EG-1, EG-2, EG-3-EG-4, EG-5, EG-6). [PFE-03-44-0405-0040-II-C]

a. In order to maintain the emergency use category as specified in 40 CFR Part 63 Subpart ZZZZ, the engine is authorized to operate for a maximum of 100 hours per calendar year for any of the combination of the purposes specified in 40 CFR §63.6640(f)(2)(i) through (iii), and up to 50 hours of operation in non-emergency situations, as specified in 40 CFR 63.6640(f)(4). The 50 hours of operation in non-emergency situations are counted as part of the 100 hours per calendar year for maintenance and testing and emergency demand response provided in section 63.6640(f)(2) of the 40 CFR, whereas these 100 hours of operation shall be counted as part of the 750 hours of operation limit.

(ii) McNeil shall not exceed 500 hours of operation per year at each unit: INENGS EG-7, INENGS EG-8, INENGS EG-9, INENGS EG-10, INENGS EG-11, INENGS EG-12, FIRE 1, FIRE 2 and FP-002. [PFE-SM-2834-44-0402-0544] [PFE-RH-44-1204-1838-II-C] [PFE-44-0804-1278-II-C] [PFE-44-0794-0858-II-C]

a. In order to maintain the emergency use category as specified in 40 CFR Part 63 Subpart ZZZZ, the engine is authorized to operate for a maximum of 100 hours per calendar year for any of the combination of the purposes specified in 40 CFR §63.6640(f)(2)(i) through (iii), and up to 50 hours of operation in non-emergency situations, as specified in 40 CFR 63.6640(f)(4). The 50 hours of operation in non-emergency situations are counted as part of the 100 hours per calendar year for maintenance and testing and emergency demand response provided in section 63.6640(f)(2) of the 40 CFR, whereas these 100 hours of operation shall be counted as part of the 500 hours of operation limit.

(iii) McNeil shall not exceed 60 hours of operation per year in unit EG-2H. [PFE-44-0794-0858-II-C and PSD Non-Applicability Determination of March 1, 1989 and May 8, 1995]

a. In order to maintain the emergency use category as specified in 40 CFR Part 63 Subpart ZZZZ, the engine is authorized to operate for a maximum of 60 hours per calendar year for any of the combination of the purposes specified in 40 CFR §63.6640(f)(2)(i) through (iii), and up to 50 hours of operation in non-emergency situations, as specified in 40 CFR 63.6640(f)(4). The 50 hours of operation in non-emergency situations are counted as part of the 60 hours per calendar year for maintenance and testing and emergency demand response provided in section 63.6640(f)(2) of the 40 CFR, whereas these 60 hours of operation shall be counted as part of the 60 hours of operation limit.

(iv) Each INENGS unit (EG-1 through EG-6) shall be provided with an operating hours meter in order to verify the hours of operation and calculate the fuel consumption. [PFE-03-44-0405-0040-II-C]

(v) For each engine, McNeil shall install, maintain and operate a non-resettable hour meter, in order to verify hours of operation and fuel consumption. [40 CFR §63.6625(f)]

(vi) The fuel consumption permitted for each INENGS electricity generator (EG-1 through EG-6) shall not exceed 101,250 gallons per year each. [PFE-03-44-0405-0040-II-C]

(vii) McNeil shall not exceed 787,600 gallons per year of No. 6 fuel or lighter grade consumption in unit EG-03 (*Wartsila)* for any 12 consecutive month period. [PFE-44-0794-0858-II-C and PSD non-applicability Determination of March 1, 1989 and May 8, 1995]

a. In order to maintain the emergency use category as specified in 40 CFR Part 63 Subpart ZZZZ, the engine is authorized to operate for a maximum of 100 hours per calendar year for any of the combination of the purposes specified in 40 CFR §63.6640(f)(2)(i) through (iii), and up to 50 hours of operation in non-emergency situations, as specified in 40 CFR 63.6640(f)(4). The 50 hours of operation in non-emergency situations are counted as part of the 100 hours per calendar year for maintenance and testing and emergency demand response provided in section 63.6640(f)(2) of the 40 CFR.

(viii) McNeil shall install and operate a fuel flow meter in Unit EG-03 *(Wartsila)*. Fuel meter must be calibrated every six (6) months or in accordance with the manufacturer's recommendations, whichever is less. The permittee shall keep calibration results and methodology available at the facility for Board technical personnel review. [PFE-44-0794-0858-II-C and PSD Non-Applicability Determination of March 1, 1989 and May 8, 1995]

(ix) In accordance with Rule 603(A)(4)(ii) of the RCAP, the permittee shall keep the records of all the required sampling data and support information for a five (5) year period beginning on the date of the monitoring sample, measurement, report or application. This includes a record of the monthly and annual fuel consumption reports for each combustion unit. The monthly compliance is determined by adding the total amount of fuel consumed during the preceding eleven (11) months.

c. SO_2 Emission Limit:

(i) The sulfur content in the #2 fuel burned by the INENGS units (EG-1, EG-2, EG-3 EG-4-EG 5 and EG-6) shall not exceed 0.5% by weight. [PFE-03-44-0405-0040-II-C].

(ii) The sulfur content in the #2 fuel burned by the INENGS units (EG-7, EG-8, EG-9, EG-10, EG-11, EG-12) shall not exceed 0.5% by weight. [PFE-SM-2834-44-0402-0544, PFE-RH-44-1204-1838-II-C, PFE-44-0804-1278-II-C and PFE-44-0794-0858-II-C]

(iii) The sulfur content in the #2 fuel burned by FIRE 1, FIRE 2 and FP-002 units shall not exceed 0.5% by weight. [PFE-SM-2834-44-0402-0544, PFE-44-0794-0858-II-C].

(iv) The sulfur content in No. 6 fuel or lighter grade burned by the EG-03 unit (*Wartsila*) shall not exceed 2.0 percent by weight and 0.3% by weight for the EG-2H unit. [PFE-44-0794-0858-II-C and determination of PSD non-applicability of March 1, 1989 and May 8, 1995]

(v) McNeil shall retain copy of the supplier certification indicating the sulfur content in the fuel to demonstrate compliance with the requirement of keeping daily record

of the sulfur content in the fuel burnt. To verify the sulfur content, McNeil shall obtain a certified analysis of sulfur content with each fuel delivery at the facility.

(vi) McNeil shall retain all records of required monitoring data and support information for a period of 5 years from the date of the monitoring sample, measurement, report or application. This includes a record of the performance test results and fuel sulfur content in fuels burned in compliance with RCAP Rule 603(a)(4)(ii).

(vii) McNeil shall submit, with each annual compliance certification, a summary of the reports for that year, indicating the sulfur content by weight for the monthly fuels consumed.

d. National Emission Standards for Hazardous Air Pollutants For Reciprocating Internal Combustion Engines (40 CFR Part 63 Subpart ZZZZ) INENGS (EG-1, EG-2, EG-3, EG-4, EG-5, EG-6)

(i) The engines for the electric generators **for emergencies INENGS (EG-1, EG-2, EG-3, EG-4, EG-5 and EG-6)** are affected by 40 CFR Part 63, Subpart ZZZZ: National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines (RICE NESHAP) for new engines. According to section 63.6590 of Subpart ZZZZ, the engines shall comply with the requirements of Subpart ZZZZ by complying with the requirements of 40 CFR Part 60 Subpart IIII, if applicable. However, the engines are not subject to 40 CFR Part 60, Subpart IIII because they were manufactured in 2005. In case of future amendments to these regulations, the permittee shall verify its applicability and comply with the applicable requirements.

(ii) In the case the internal combustion engines is reconstructed, the permittee shall comply with the applicable requirements of 40 CFR Part 60, Subpart IIII (for CI engines) or JJJJ (for SI engines), as applicable. This could involve stricter limits on the sulfur content in the fuel.

(iii) **ONLY FOR EXISTING EMERGENCY ENGINES (INSTALLED BEFORE JUNE 12, 2006) EG-03 (20.4 MMBtu/hr), INENGS EG-7 (470 hp), INENGS EG-8 (1,135 hp), INENGS EG-9 (200 hp), INENGS EG-10 (100 hp), INENGS EG-11 (277 hp), INENGS EG-12 (1,300 hp), EG-2H (1,040 kW), FIRE 1 (187 hp), FIRE 2 (187 hp), FP-002 (157 hp)**

(A). The engines of the electric generators for emergencies are affected by 40 CFR Part 63, Subpart ZZZZ: National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines (RICE NESHAP), as defined in 40 CFR section 63.6585(a), and therefore must meet the applicable requirements of such regulations by no later than **May 3, 2013**.

(B). According to Table 2d to Subpart ZZZZ, the permittee shall:

i. change oil and filter every 500 hours of operation or annually, whichever comes first;

ii. inspect air filter every 1,000 hours of operation or annually, whichever comes first, and replace as necessary; and

iii. inspect all hoses and belts every 500 hours of operation or annually, whichever comes first, and replace as necessary.

(C). According to 40 CFR §63.6625, the permittee shall:

i. operate and maintain the engine and control device (if any) according to the manufacturer's emission-related written instructions or develop an own maintenance plan which must provide to the extent practicable for the maintenance and operation of the engine in a manner consistent with good air pollution control practices for minimizing emissions.

ii. install a non-resettable hour meter, if one is not already installed.

iii. minimize the engine's time spent at idle during startup and minimize the engine startup time to a period needed for appropriate and safe loading of the engine, not to exceed 30 minutes.

(iv) According to 40 CFR §63.6605, the permittee shall operate the engine in a manner for minimizing emissions.

(v) According to 40 CFR §63.6640, the permittee shall operate and show compliance with the applicable Work or Management Practices contained in Table 6 of the Subpart.

(vi) In order to maintain the emergency engine category, the permittee shall comply with the use and operation limitations contained in the 40 CFR §63.6640(f). For any engine operation that does not meet these requirements, the engine will not be considered an emergency engine under this Subpart and must meet all requirements for non-emergency engine.

(vii) The permittee shall keep the applicable records according to the 40 CFR §63.6655(f).

i. Keep records of the hours of operation of the engine that is recorded through the non-resettable hour meter.

ii. Must document how many hours are spent for emergency operation, including what classified the operation as emergency and how many hours are spent for non-emergency situations.

iii. If the engine is used for the purposes specified in 40 CFR §63.6640(f)(2)(ii) or (iii) or §63.6640(f)(4)(ii), shall keep records of the notification of the emergency situation, and the date, and time and end time of engine operation for these purposes.

(D) The permittee shall comply with the applicable **General Provisions** of sections 63.1 to 63.15 included in Table 8 of Subpart ZZZZ of 40 CFR.

8. ICENG PE-1

a. Portable Internal Combustion Units Requirements [PFE-44-0900-1690-I-II-C]

(i) The maximum consumption of diesel fuel to be oxidized in portable combustion units shall not exceed 5,624 gallons per year.

(ii) Prior to the installation of portable electric generators, McNeil shall determine whether they are affected by the regulations described in 40 CFR Part 60, Subpart IIII.

(iii) Electricity generators included in the portable combustion units must be equipped with an operating hours meter in order to verify the hours of operation and calculate the fuel consumption.

(iv) McNeil shall prepare and maintain a record of all internal combustion portable units prior to installation. The record must include the following information:

a. name of the responsible contractor for each portable unit

b. capacity of each unit and fuel consumption rate

c. technical specifications of each unit

d. purpose to operate each unit

e. description of the place in which the unit is located

(v) McNeil shall prepare and keep a daily record during the operation of portable combustion units containing the following information:

a. identification of each unit

b. dates each unit operated

c. amount of fuel burnt for each unit during the operation period and the sulfur content in diesel in weight percent

d. regarding electricity generators, it must list the hours recorded in the meter. This schedule will be used to calculate the cumulative fuel consumption

e. will add all fuel amounts stated in item (c) during the year. This total shall not exceed the maximum fuel consumption limit allowed

(vi) Records shall be maintained in the facility for evaluation and review by the technical staff of the Board when requested. The Board will use these records to verify when the portable units were operating, to identify where they were operating and to determine if the fuel consumption limit authorized in this permit was exceeded.

(vii) The fuel consumption in each portable units shall be maintained on a daily basis in a rolling period of 365 days. The calculation of fuel consumption during any 365-day period shall be calculated by adding the fuel consumption of each day to the total fuel consumption of the previous 364 days.

(viii) The permittee shall calculate the emissions allowed for portable combustion units using emission factors from AP-42 or Airs Facility Subsystem. The emission calculation shall be based on the cumulative fuel consumption of all units operated during the year.

Section VI - Emission Unit Requirements for Alternate Operating Scenarios

A. For Alternate Operating Scenarios: McNeil is allowed to burn B20[10] biodiesel mixture as an alternative fuel in the B-1, B-2, B-3, B-4 and B-5 units. [PFE-03-44-0704-0061-II-C]. For Alternate Scenarios, McNeil shall comply with the following:

(i) All applicable requirements (sampling, test methods and reporting) of the Normal Operating Scenario appearing in Section V of this permit.

(ii) The fuel to be burned corresponds with a fuel mixture (B20)[11] consisting of diesel (maximum S% of 0.5) and biodiesel (maximum S% of 0.0).

(iii) 1.2%[12] increase in NOx emissions for each unit in the alternate scenario is presumed, until new sampling data is obtained. If biodiesel is used in these units, sampling should be performed to determine the emissions of NOx using diesel and using biodiesel during the first 90 days of biodiesel used in the units.

1. Tests shall be conducted as provided in RCAP Rule 106.

[10]A blend of biodiesel fuel that meets ASTM D6751 specifications with diesel fuel; designated as B20, which represents 20 percent by volume of the biodiesel fuel in the mixture.
[11] Fuel prepared by the manufacturer according to the specifications of ASTM D7467 – 10 and that complies with the EPA registration for Fuel Manufacturers.
[12]According to emission calculations included in the Title V Permit application.

2. If the results exceed the presumption of 1.2% increase, Mc Neil must request a modification to its construction permit PFE-03-44-0704-0061-II-C to reflect the increase in NOx.

Section VII - Recordkeeping Requirements

A. McNeil shall prepare and update on a monthly basis the records of the hours of operation, fuel consumption and sulfur percent for ROTOR, INENGS, FIRE 1 and FIRE 2, FP-002, EG-2H and ICENG PE-1 units.

B. McNeil shall prepare and update on a daily basis fuel consumption records and sulfur percent for the B-1, B-2, B-3, B-4, B-5, SB-1, SB4, SB5 and EG-03 units.

C. The fuel consumption of any 12 consecutive months will be calculated through the sum of the total monthly consumption in each unit during the previous 11 months.

D. McNeil shall have available at the facility at all times copies of the Emergency Plan required under Rule 107 of the RCAP.

E. McNeil shall maintain records of fire control activities related to research or training.

F. McNeil shall maintain records of purchases of refrigerant[13] and refrigerant added to devices or equipment normally containing 50 or more pounds of refrigerant. [40 CFR §82.166]

G. All monitoring records, fuel sampling test results, calibration test results, charts produced by instrumentation, all the reports and logs must be retained for a period of five years after the date they are recorded and shall be available at the request of the EPA or the Board. All rolling averages are calculated on daily basis.

H. McNeil shall write down in a record, contemporaneously with the change from one operating scenario to another authorized under Section VI of this permit, the scenario under which it is operating. McNeil shall keep this record at the facility at all times.

Section VIII - Reporting Requirements

A. Certification of Compliance: According to RCAP Rule 602(c)(2)(ix)(c), McNeil shall submit a compliance certification annually. The compliance certification shall be submitted to both the EQB and the EPA[14] no later than April 1st of each year covering the previous calendar year. The compliance certification must include, but shall not be limited to, the information required in RCAP Rule 603(c).

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[13] As defined in 40 CRF 82.152

[14] JCA certification should be directed to: Manager, Air Quality Area, PO Box 11488, San Juan, PR 00910. The EPA certification should be directed to: U.S. Environmental Protection Agency, 48 Carr. 165 Suite 7000, Guaynabo, P.R. 00968-8073.

B. Emissions Calculations: No later than April 1st of each year, McNeil shall send the calculation of the actual emissions for the previous calendar year. The emissions calculation shall be provided in the forms prepared by the EQB for such purpose and the responsible official will certify that all information submitted is true, correct and representative of the of the permit activity. Emission calculations must include, but not be limited to, emissions PM/PM_{10}, NO_x, COV, CO, Pb, SO_2, HAP's and GHGs expressed as CO_2e.

C. In Accordance with Rule 603(a)(5)(i) of the RCAP, McNeil shall submit biannual reports of the required sampling, on October 1st and April 1st of each year, respectively, or more frequently if required by the underlying applicable requirements or by the Board. All instances of deviations from permit requirements must be clearly identified in such reports. The responsible official must certify all required reports as established under Rule 602(c) (3) of the RCAP.

D. Monthly Fuel Consumption Reports: McNeil must submit a monthly report for units B-1, B-2, B-3, B-4, B-5, SB-001, SB-004, SB-005 and EG-03 on the sulfur content in percent by weight and daily fuel consumption in each unit. This report must be submitted to the Board to the attention of the Chief of the Data Validation and Mathematical Modeling Division during the first 30 days of the next month for which the report is representative.

E. Fuel Consumption Annual Reports: The permittee shall submit annually a report on the sulfur content in weight percent and monthly fuel consumption for ROTOR, INENGS, FIRE 1 and FIRE 2, FP-002, EG-2H and ICENG PE-1 units. This report must be submitted to the Board to the attention of the Chief of the Data Validation and Mathematical Modeling Division during the first 15 days of next year for which the report is representative.

F. McNeil shall submit to the Board copies of all reports required by 40 CFR Part 60, Subpart Dc sent to the EPA.

G. In accordance with RCAP Rule 603 (a)(5)(ii), any deviation resulting from upset conditions (such as a sudden malfunction or unexpected rupture) or from emergency as defined under RCAP Rule 603(e) shall be reported within the next two (2) working days.

H. In accordance with RCAP Rule 603(a)(5)(ii)(b), McNeil shall notify the Board within the next 24 hours of any deviation that results in the release of hazardous air pollutants that continues for more than an hour in excess of the applicable limit. In case of a release of any regulated air pollutant that continues for more than two hours in excess of the applicable limit, the Board will be notified within 24 hours of the deviation. McNeil shall also submit to the Board, within 7 days of the deviation, a detailed written report which includes probable causes, time and duration of the deviation, remedial action taken and the steps they are taking to prevent reoccurrence. [State-only enforceable condition]

I. McNeil shall submit two copies to the Board of the written report of the results of all the emissions sampling within 60 days after completing the performance tests. [RCAP Rule 106(E)]

J. McNeil shall comply with the applicable notification requirements of 40 CFR Part 60 and Part 63, Subpart A by the dates specified.

Section IX - Insignificant Emission Units

McNeil provided the following list of insignificant activities for a better understanding of its operations and the distribution of its equipment. Since there is no requirement to update this list, activities may have changed since the time it was submitted, however McNeil shall include the list of insignificant activities that are exempted because of size or production rate and some may require a construction permit under Rule 203 of RCAP.

Emission Unit Identification	Description (Exemption basis)
Tablets and Caps Printing	RCAP Appendix B (3)(ii)(P)
31 ozone generating units	RCAP Appendix B (3)(ii)(P)
1 Methanol Storage Tank - MST-1 of 1,500 gallons	RCAP Appendix B (3)(ii)(N)
1 Acetone Storage Tank - AST-1 of 7,500 gallons	RCAP Appendix B (3)(ii)(N)
1 Acetone Storage Tank - NO -AST-2 of 1,000 gallons	RCAP Appendix B (3)(ii)(N)
Propane Gas Storage Tank of 12,000 gallons	RCAP Appendix B (3)(ii)(P)
Solvent Transfer Pipe	RCAP Appendix B (3)(ii)(P) (Emits less than 1 ton of VOC per year)
Sand blasting operations in closed areas or exteriors, that satisfy the conditions related to particulate and fugitive emissions, localization, application rate, recordkeeping, and registration approval.	RCAP Appendix B (3)(viii)
Laboratories used only for quality control or environmental compliance testing that are associated with manufacturing, production or other business or commercial facilities.	RCAP Appendix B (3)(xxi)
Non routine cleaning of tanks and equipment for purposes of worker entry or in preparation for maintenance or decommissioning (except equipment subject to 40 CFR Part 63 Subpart GGG).	RCAP Appendix B(3)(xxvi)
Steam vents and leaks from boilers and steam distribution systems.	RCAP Appendix B(3)(xxxv)
Sampling Points and systems used exclusively to withdraw materials for testing and analysis including air contaminant detectors and vent lines.	RCAP Appendix B(3)(xxvii)
Office Activities	RCAP Appendix B(3)(ii)(A)
Stationary Water Storage Tanks	RCAP Appendix B(3)(i)(A)
Water treatment equipment, including sewers and sewer manholes if the VOC concentration in the water is less than 3,500 parts per billion by weight	RCAP Appendix B(3)(ii)(L)

Emission Unit Identification	Description (Exemption basis)
Coating Pans (1-19 (DC-8-DC-26))	RCAP Appendix B(3)(ii)(P)
Granulation Area SB-715, P3E-001	RCAP Appendix B(3)(ii)(P)
Building 2, DC-DFT-2-4	RCAP Appendix B(3)(ii)(P)
Diesel Fuel Storage Tank with a capacity of 50,000 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(ii)(P)
Diesel Fuel Storage Tank with a capacity of 30,000 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(ii)(P)
4 Diesel Fuel Storage Tanks with a capacity of 15,000 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(ii)(P)
2 Diesel Fuel Storage Tanks with a capacity of 600 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
8 Diesel Fuel Storage Tanks with a capacity of 500 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
Diesel Fuel Storage Tanks with a capacity of 560 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
Fuel Diesel Storage Tank with a capacity of 285 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
Fuel Diesel Storage Tank with a capacity of 214 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
Diesel Fuel Storage Tank with a capacity of 2,500 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
Fuel Diesel Storage Tank with a capacity of 600 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
Diesel Fuel Storage Tank with a capacity of 6,000 gallons	RCAP Rule 206 (F)(3) and Appendix B(3)(xi)
Diesel Fuel Storage Tank with a capacity of 10,000 gallons	RCAP Appendix B(2)
Fuel Diesel Storage Tank with a capacity of 300 gallons	RCAP Appendix B(3)(ii)(N) and B(3)(xi)
Fuel Diesel Storage Tank with a capacity of 200 gallons	RCAP Appendix B(3)(ii)(N) and B(3)(xi)
Fuel Oil Storage Tank with a capacity of 250,000 gallons	RCAP Appendix B(2)
Fuel Oil Storage Tank with a capacity of 2,000 gallons	RCAP Appendix B(2)
Fuel Oil Storage Tank with a capacity of 400 gallons	RCAP Appendix B(3)(ii)(N) and B(3)(xi)
Cooling Tower	RCAP Rule 206 and Appendix B(3)(xxxiii)
Lunch Room	RCAP Rule 206 and Appendix B(3)(ii)(J)
Cleaning Tray	RCAP Appendix B(3)(ii)(P)
Laundry Room	RCAP Appendix B(3)(ii)(G)
Storage Areas (Class I and Class II)	RCAP Appendix B(2)

Emission Unit Identification	Description (Exemption basis)
Activities in maintenance workshops such as brazing, welding and soldering equipment used as an aid to primary source equipment.	RCAP Appendix B(3)(ii)(E)
Waste Oil Tank with capacity of 2,000 gallons	RCAP Appendix B(3)(ii)(N) and B(3)(xi)
Room Glatt #1, DC-36	RCAP Appendix B(3)(ii)(P)
Room 526, DC-34	RCAP Appendix B(3)(ii)(P)
Mixing Room, DC-32	RCAP Appendix B(3)(ii)(P)
Vacuum System 2901-VAC-001 (Rooms 311, 313, 344 and 360)	RCAP Appendix B(3)(ii)(P) 0.34 ton/yr based in the management ≤ 3,000 kg/day of solid pharmaceutical product controlled by a dust collector with a minimum efficiency of 95%. [PFE-44-0900-1692-I-II-C]

Section X - Permit Shield

In accordance with RCAP Rule 603(D), compliance with permit conditions shall be deemed compliance with any requirement applicable as of the date of permit issuance, but only if such applicable requirement is included and specifically identified in the permit. Likewise, it shall be considered in compliance with any requirement specifically identified in the permit as "Not Applicable".

A. Reasons for Non-Applicability

Code for the Non-Applicability Determination	
Code	Reason
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.
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^3 capacity to store liquid with an actual maximum vapor pressure of less than 3.5 kPa or greater or equal capacity of 75 m^3 but less than 151 m^3 storing liquid with an actual maximum vapor pressure of less than 15 kPa.

Code for the Non-Applicability Determination	
Code	**Reason**
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.

B. The permit shield covers any alternative operating scenario provided it is defined and permitted under the conditions of this permit.

Section XI - Permit Approval

Pursuant to the powers granted to the Environmental Quality Board by the Environmental Public Policy Act, Public Law Number 416 of September 22 of 2004, as amended, and after verifying the administrative file and compliance with the Uniform Administrative Procedures Act, Public Law Number 170 of August 12, 1988, as amended, the US Clean Air Act, the Puerto Rico Environmental Public Policy Act, and the Regulations for the Control of Atmospheric Pollution of Puerto Rico, the Environmental Quality Board approves this permit subject to the terms and conditions stated therein.

In San Juan, Puerto Rico, September 9, 2016.

ENVIRONMENTAL QUALITY BOARD

María de los Ángeles Ortiz
Alternate Member

Rebeca Acosta Pérez
Vice President

Weldin F. Ortiz Franco
President

APPENDIX

Appendix I - Definitions y Abbreviations

A. Definitions:

1. Biodiesel[15]- Fuel comprising monoalkyl esters of long chain fatty acids derived from vegetable oil or animal fat, designated B100, and attaining the ASTM 6751 requirements.

2. Law - Federal Clean Air Act, as amended, *42 U.S.7401, et seq.*

3. Responsible Official - See the definition of Responsible Official as established under the Regulation for Air Pollution Control of the Environmental Quality Board (1995).

4. Regulation - Regulation for the Control of Atmospheric Pollution of the Environmental Quality Board.

5. Title V - Title V of the Federal Clean Act (*42 U.S.C. 7661*).

B. Abbreviations

EPA	Environmental Protection Agency
AP-42	Compilation of Air Pollutant Emission Factors
ASTM	American Society for Testing and Materials
Btu	British Thermal Unit
HAP	Hazardous Air Pollutants
CFR	Code of Federal Regulations
CO	Carbon Monoxide
VOC	Volatile Organic Compounds
HAP	Hazardous Air Pollutants
EQB/Board	Environmental Quality Board of Puerto Rico
Lbs	Pounds
MMBtu	Million Btu

[15] As defined by the ASTM.

NAAQS	National Ambient Air Quality Standards
NO_x	Nitrogen oxides
NSPS	New Source Performance Standards
Pb	Lead
PM	Particulate matter
PM_{10}	Particulate matter with a aerodynamic mass diameter equal to or less than (10) microns
PSD	Prevention of Significant Deterioration
RCAP	Regulation for Air Pollution Control of the Environmental Quality Board
RMP	Risk Management Plan
SIC	Standard Industrial Classification
SO_x	Sulfur Oxide
SO_2	Sulfur dioxide
VHAP	Volatile Hazardous Air Pollutants

C. **Notifications Address**

Permit Compliance and Modifications Notifications

Puerto Rico Environmental Quality Board
Air Quality Area
Box 11488
San Juan, PR 00910

Appendix II- Description of Control Equipment

Emission Point	Id. Control Equipment	Controlled Pollutant	CONTROL EQUIPMENT				Estimate Basis[b]
			Type [a]	Manufacturer/ Model No.	Efficiency %		
					Design	Actual	
F-216	DC-1	PM-10	10 (b) cartridges	Farr/50LL	95	> 95	A
F-217	DC-2	PM-10	10 (b) cartridges	Farr/16D	95	> 95	A
F-218	DC-3	PM-10	10 (b) cartridges	Farr/50LL	95	> 95	A
F-70	DC-4	PM-10	10 (b) cartridges	Torit/AFT 4-16	95	> 95	A
F-145	DC-5	PM-10	10 (b) cartridges	Torit/3DF24	95	>95	E- Manufacturing specifications
F-134	DC-6	PM-10	10 (b) cartridges	Torit/TD-2300	95	> 95	A
F-144	DC-7	PM-10	10 (b) cartridges	Torit/2DF12-002	95	> 95	A
F-133	DC-8	PM-10	10 (b) cartridges	Farr/20L	95	95	A, E
F-135	DC-9	PM-10	10 (b) cartridges	Farr/GS16SQ	95	95	A, E
F-136	DC-10	PM-10	10 (b) cartridges	Farr/GS12SQ	95	95	A, E
F-137	DC-11	PM-10	10 (b) cartridges	Farr/16L	95	95	A, E
F-138	DC-12	PM-10	10 (b) cartridges	Farr/16L	95	95	A, E
F-139	DC-13	PM-10	10 (b) cartridges	Farr/16L	95	95	A, E
F-141	DC-14	PM-10	10 (b) cartridges	Farr/16L	95	95	A, E
F-142	DC-15	PM-10	10 (b) cartridges	Farr/16L	95	95	A, E

Emission Point	Id. Control Equipment	Controlled Pollutant	CONTROL EQUIPMENT				Estimate Basis[b]
			TYPE[a]	Manufacturer/ Model No.	Efficiency %		
F-143	DC-16	PM-10	10 (b) cartridges	Farr/20L	95	95	A, E
F-140	DC-17	PM-10	10 (b) cartridges	Farr/20L	95	95	A, E
F-163	DC-18	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-164	DC-19	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-165	DC-20	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-166	DC-21	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-167	DC-22	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-168	DC-23	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-169	DC-24	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-170	DC-25	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-171	DC-26	PM-10	10 (b) cartridges	Torit/2DF-24	95	95	A, E
F-191	DC-27	PM-10	10 (b) cartridges	Torit/DFT2-16	95	> 95	A
F-161	DC-30	PM-10	10 (b) cartridges	Torit/DFT2-24	95	> 95	A
EF-236	DCP-31	PM-10	10 (b) cartridges	Torit/DFT 3-6	99	>95	A

Emission Point	Id. Control Equipment	Controlled Pollutant	CONTROL EQUIPMENT				Basis the Estimate[b]
			TYPE[a]	Manufacturer/ Model No.	Efficiency %		
TO-1	TO-1	PM-10, methanol, acetone	10	Thermal Oxidizer	>98	99.91	A
EF211	EF-211 Filters 30% and 95% eff	PM-10	10 (b) cartridges		95	> 95	E-Manufacturing specifications
PHARMFG 2	DC-33	PM-10	10(b) cartridges		95	> 95	A
PHARMFG	DC-35	PM-10	10(b) cartridges		95	> 95	A

Control Equipment Codes

10a Filter (*baghouse*)
10b Ohers: Cartridges

Emissions Estimate Method Codes

A. Stack test
B. Material Balance
C. Emission factor
D. Engineering estimate
E-Mfg - Manufacturer's design specifications

Appendix III - Control Equipment Volumetric Flow Rate

Control Equipment	Volumetric Flow Rate (scfm)
DC-1	26,400
DC-2	5,000
DC-3	27,400
DC-4	5,000
DC-6	3,000
DC-7	4,000
DC-27	4,000
DC-30	6,000
[16]GLATT No. 1	7,600
[16]GLATT No. 2	7,600
[16]GLATT No. 3	7,600
[16]GLATT No. 4	7,600
[16]GLATT No. 5	7,600
[16]GLATT No. 6	7,600
DC-5	7,800
EF-211	13,080
Vacuum system	175
DC-8	5,500
DC-9	5,500
DC-10	5,500
DC-11	5,500
DC-12	5,500
DC-13	5,500
DC-14	5,500
DC-15	5,500
DC-16	5,500
DC-17	5,500
DC-18	5,500
DC-19	5,500
DC-20	5,500
DC-21	5,500
DC-22	5,500
DC-23	5,500
DC-24	5,500
DC-25	5,500
DC-26	5,500
DC-31	2,500
DC-33	8,000
DC-35	4,000

[16]The units have their own filter systems. Fugitive emissions.

COMMONWEALTH OF
PUERTO RICO
Environmental Quality Board

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_X), sulfur oxides (SO_X) and particulate matter (PM_{10}) which are criteria air pollutants. This facility is a Minor Emission Source for Hazardous Air Pollutants (HAP) and greenhouse gases (GHGs) expressed as CO_2e.

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_{10}	118.25
SO_2	450.96
NO_x	411.52
CO	93.49
VOC	22.34
Lead	0.02
Ozone	0.07
HAP's (combustion)	0.43
methanol	2.67
CO_{2e}	55,630.51

Cruz A. Matos Environmental Building
Urb. San José Industrial Park, 1375 Ave. Ponce de León, San Juan, PR 00926-2604
P.O. Box 11488, San Juan, PR 00910
Tel. 787-767-8181, Fax 787-767-4861
www.jca.pr.gov

EQB
Environmental Quality Board
Commonwealth of Puerto Rico

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[1] 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 stablished in the amendment of the RCAP of January 19, 2011. The permit requires a monthly log of

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1 *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[2] 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. UnitsEG-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.

[2] 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^3 capacity to store liquid with an actual maximum vapor pressure of less than 3.5 kPa or greater or equal capacity of 75 m^3 but less than 151 m^3 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.