

GOVERNMENT OF PUERTO RICO

DEPARTMENT OF NATURAL AND ENVIRONMENTAL RESOURCES

16 MAR 2020

REVISED TITLE V OPERATING PERMIT AIR QUALITY AREA



Permit Number:	PFE-TV-3841-64-0510-0335
Application Receipt Date:	May 18, 2010
Final or Effective Issue Date:	June 28, 2016
Revision Date due to Resolution R-19-07-11:	March 5, 2020
Expiration Date:	June 28, 2021

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

FENWAL INTERNATIONAL, INC. SAN GERMÁN, PUERTO RICO

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

The conditions of the 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.

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Urb. San José Industrial Park, 1375 Ave. Ponce de León, San Juan, PR 00926-2604
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Section I - General Information

A. Facility Information

Company Name:	Fenwal International, Inc.
Postal address:	P.O. Box 5200
City:	San Germán
State:	Puerto Rico
Zip Code:	00683
Name of Facility:	Fenwal International, Inc.
Location of the Facility:	Road PR-122 Km. 0.5 San Germán, Puerto Rico
Responsible Official:	Eric Santiago General Manager
Phone:	787-892-7000 Extension 1700
Fax:	787-264-0808
Contact Person of the Facility:	Joann Molina Environmental, Health and Safety Coordinator
Phone:	787-892-7000 Extension 1750
Fax:	787-264-0808
SIC Primary Code:	3841

B. Process Description

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Fenwal International, Inc. is a company that manufactures a variety of medical devices for the collection and separation of blood components. It is located on State Road PR-122 Km 0.5 in San Germán. This facility manufactures a variety of

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products for the automated and manual collection, filtration, separation, storage and transfusion of blood and its components.

The unit EU-1 is an internal combustion engine for a fire pump to control fire that is used when there is a fire related emergency. The EU-2, EU-3, EU-8 and EU-9 units are internal combustion engines from emergency power generators.

Four emission units are used in the manufacturing process; EU-4, EU-5, EU-6 and EU-7. The device assembly unit (EU-4) consists of five machines for units assembling, labeling and integrity testing. Methylene chloride and isopropyl alcohol are used in this unit. The EU-4 unit also includes EU-4A, Umbilicus overmolding process (Etching Process). The unit EU-5 includes solvent dispatching process. The unit EU-6 is the Plaletccl/Alyx/Amicus manufacturing process, fugitive emissions are methyl ethyl ketone and cyclohexanone. The emissions of EU-7 are from cleaning processes of the equipment, working areas and clean rooms. The cleaning is carried out with isopropyl alcohol.

Fenwal International, Inc. is a major source of hazardous air pollutants because it has the potential to emit more than 10 tons per year of methylene chloride.

Section II - Description of the Emission Units

The emission units regulated by this permit are as follows:

Emission Unit	Description	Control Equipment
EU-1 Internal combustion engine (Fire pump)	It is used to provide power to the water pump for fire suppression or protection. Engine power: 251 hp Uses diesel fuel at a rate of 13 gals/hr. Displacement: 1.30 L/ cylinder	None
EU-2 Internal Combustion Engine (Emergency Power Generator)	Engine power: 1,818 hp Use diesel fuel at a rate of 87 gal/hr. Displacement: 4.32 L/ cylinder	None
EU-3 Internal combustion engine (Emergency Power Generator 1,000 kW)	Engine power: 1,341 hp Use diesel fuel at a rate of 72 gal/hr. Displacement: 32.10 L Model year: 2011 <i>EPA Certified: Tier 2 Emission Levels</i>	None

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Emission Unit	Description	Control Equipment
EU-4 Device Assembly	Consists of five machines for assembling units, labeling, and integrity testing. The maximum consumption is 504 gal/year of methylene chloride and 457 gal/year of isopropyl alcohol.	Does not require ¹
EU-5 Umbilicus Etching and Solvent dispatching	Consists in the manual application of the solvent methylene chloride, to an umbilicus tube. This is intended to create a layer in the tube before the molding stage of this component. The maximum consumption of methylene chloride is 2,010 gals/year and 775 gals/year of isopropyl alcohol in this unit that are dispensed for consumption on EU-4 and EU-7 units.	Does not require ¹
EU-6- Manufacturing: Alyx/Amicus	These fugitive emissions are from methylethylketone and cyclohexanone. A maximum of 61 gals/year of methylethylketone and 361 gals/year of cyclohexanone is used in this manufacturing.	Does not require ¹
EU-7 Fugitive emissions of VOC from equipment cleaning	These emissions are from the process of cleaning equipment, working areas and clean rooms. A maximum of 318 gallons per year of isopropyl alcohol is used in this area.	Does not require ¹
EU-8 Internal Combustion Engines	EU-8a Engine: 9 hp Model <i>Briggs and Stratton</i> GN503100AC EU-8b Engine: 3 hp Model Ryobi RYi200TA EU-8c Engine: 6.5 hp Model UST 3500W	None
EU-9 Internal combustion engine (Emergency Power Generator 20 kW)	Engine power: 33 hp Use diesel fuel at a rate of 1.70 gal/hr Displacement: 2.2 L <i>EPA Certified: Tier 4 Emission Levels</i>	None

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¹ It does not exceed the thresholds of RCAP Rule 419.

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Section III - General Conditions of the Permit

1. **Sanctions and Penalties:** The permittee will keep a copy of this permit at the facility at all times. It will be available for inspection by the technical staff of the Department of Natural and Environmental Resources (hereinafter DRNA and Board or JCA where the Regulation for the Control of Atmospheric Pollution (RCAP) is cited)².
2. **Right of Entry:** As specified under Rules 103 and 603(c)(2) of the RCAP, the permittee shall allow the EQB 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's premises where an emission source is located or where emission 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 fuels and emissions monitoring; 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 and the applicable requirements.
3. **Sworn Statement:** All reports required pursuant Rule 103(D) of the RCAP (i.e., semiannual monitoring reports and annual compliance certification) shall be submitted together with a sworn statement or affidavit by the Responsible Official or a duly authorized representative. Such sworn

²In accordance with the Reorganization Plan of the Department of Natural and Environmental Resources of 2018, Law 171 of August 2, 2018, Section 28, is transferred to the Department of Natural and Environmental Resources, for execution by the Secretary, the powers and functions previously delegated to the Environmental Quality Board, its President and / or its Governing Board through Act 416-2004, as amended, known as, "Law on Environmental Public Policy." This is why, wherever the permit is established by JCA, Board, Environmental Quality Board or agency, it will be understood that it is currently referring to the Department of Natural and Environmental Resources (DRNA).

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statement 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 Board, 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 Board 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 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 shall be available for inspection, as required by representatives of EQB at any times.
6. **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 Board and the U.S. Environmental Protection Agency (EPA)³ no later than the 1st of April 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 considered in the compliance certification; and
 - c. Whether compliance was continuous or intermittent; and
 - d. The methods or other means used for determining the compliance status of the source, with each term and condition, currently and over the reporting period, consistent with Rule 603 (a)(3) – (5) of the RCAP; and

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³ 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.

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- 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 the source.
7. **Regulation Compliance:** As specified under Rule 115 of the RCAP, any violation to said Regulation, or to any other applicable rule or regulation, shall be grounds for the EQB to suspend, modify, or revoke any relevant permit, approval, variance or other authorization issued by the EQB.
8. **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.
9. **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 *objectionable* odors that can be perceived in an area other than that designated for industrial purposes. If objectionable odors are detectable beyond property perimeter, and complaints are received, the permittee shall investigate and take measures to minimize and/or eliminate the objectionable odors, if necessary. [This condition is enforceable only by the State].
10. **Permit Renewal Applications:** As specified under the Rule 602(a)(1)(iv) of the RCAP, the permittee's 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.
11. **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 five (5) years. 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

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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 it is renewed if a timely and complete renewal application is submitted.
 - (c) In the 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.
12. **Recordkeeping Requirement:** As specified under Rule 603(a)(4)(ii) of the RCAP, the permittee shall retain all required monitoring data and supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application.
13. **Semiannual Monitoring Reports/Samplings⁴:** As specified under Rule 603(a)(5)(i) of the RCAP, the permittee shall submit the Board, the reports of all required monitoring, every six months or more frequently if required by the EQB or any other underlying applicable requirement. All instances of deviations from permit requirements must be clearly identified in such reports. These reports cover two major elements. The first element is the summary of all periodic monitoring / sampling required in this permit. The second element requires that all deviations from permit conditions are clearly identified, summarized and reported to the Board. All required reports must be certified by a responsible official as established under Rule 602(c)(3) of the RCAP. The report that covers the period from January to June shall be submitted no later than October 1st of the same year, and the report covering the period from July to December shall be submitted no later than April 1st of the next year. Once the guidelines are developed by the Board, the permittee must use them to complete these reports.
14. **Deviations Reporting due to Emergencies:** As specified under 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

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⁴These reports cover two major elements. The first element is the summary of all the periodic monitoring / sampling required in this permit. The second element requires that all deviations from the permit conditions be clearly identified, summarized and reported to the Board.

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such emergency deviation last for more than 24 hours, the affected units may be operated until the end of the cycle or 48 hours, what 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.

15. **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, he shall notify the Board within the next 24 hours if a deviation that results in the release of emissions of hazardous air pollutants for more than occurs an hour in excess of the applicable limit. 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.
16. **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 emission limits, terms and conditions, be they specific or general, as well as monitoring, record keeping and reporting requirements.
17. **Permit Noncompliance:** As specified under 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 Regulation 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.
18. **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.

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19. **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.
20. **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.
21. **Obligation to Furnish Information:** As specified under Rule 603(a)(7)(v) of the RCAP, the permittee shall furnish to EQB, within a reasonable time, any information that the Board 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 EQB copies of documents related to this permit.
22. **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.
23. **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.
24. **Permit Reopenings:** As specified under Rule 608(a)(1) of the RCAP, 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

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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.

25. **Changes in Name or Responsible Official:** This permit is issued to **Fenwal International, Inc.** In the event that the company and/or installation 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.
26. **Changes in Ownership:** This permit is issued to **Fenwal International, Inc.** In the event that the company and/or installation is transferred to a different owner or change operational control and the EQB 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.
27. **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.
28. **Risk Management Plan:** 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 §68.10. If during the 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.

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29. **General Duty Requirements:** 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.
30. **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 must keep records of refrigerant purchased and added to such appliances pursuant to 40 CFR §82.166.
31. **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.

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32. **Roof Surface Coating:** This is a state-only requirement. The permittee 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.
33. **Open Burning:** As specified under the Rule 402 of the RCAP, the permittee shall not cause or permit the open burning of refuse in their premises except as established under Rule 402 (E) of the RCAP to conduct training or research of firefighting techniques, as previously approved by the Board. [Condition enforceable only by the State.]
34. **Fugitive Emissions:** As established in 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 land.
 - 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.
 - c) When air pollutants escape from a building or equipment and cause a nuisance or violate any regulations, the Board may order that the building or the equipment in which processing, handling and storage are done, be tightly closed and/or ventilated so that all emissions from the building or equipment are controlled to remove or destroy such air pollutants before being discharged to the open air. The implementation of this measure shall not create occupational health hazards.
35. **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.
36. **Emissions Calculations:** The permittee shall submit, on the first day of April 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 EQB for this purpose and the responsible official must certify all the information submitted as true, correct and representative of the permitted activity. The emission calculations should include but not be limited to emissions of PM/PM₁₀, NO_x, VOC, CO, Pb, SO₂, HAP's and CO_{2e}.

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37. **Annual Fee:** According to Rule 610 of the RCAP, the permittee shall submit an annual payment based on the emissions calculations for each regulated pollutant. The payment will be based on their actual emissions at 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 calendar year must be made on or before June 30 of each year.
38. **Amendments or New Regulations:** In case a new regulation is established or an existing one is amended (state or federal) and it is determined that it applies to the facility, the permittee shall comply with the provisions of this regulation or amendment by the compliance date or compliance extension of the new or amended regulation.
39. **Reports:** Unless stated otherwise specifically provided in a condition, any requirement of information submittal to the Board shall be addressed to: Manager, Air Quality Area, P.O. Box 11488, San Juan, P.R. 00910.
40. **Reservation of Rights:** Except as expressly provided in this permit:
- a) Nothing herein shall prevent EQB or EPA from taking administrative enforcement measures or seeking legal or equitable relief to enforce the terms of the Title V permit, including but not limited to the right to seek injunctive relief, and imposition of statutory penalties and fines.
 - b) Nothing herein shall be construed to limit the rights of EQB or EPA to undertake any criminal enforcement activity against the permittee or any person.
 - c) Nothing herein shall be construed to limit the authority of EQB or 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 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.

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Section IV - Allowable Emissions

- A. The permissible emissions authorized under this permit are mentioned below. The source shall certify annually that its actual emissions do not exceed the permissible emissions. It should be used for these purposes, the

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same emission factors used and approved in the application for construction permit PFE-64-0112-0060-I-II-C.

Pollutants	Allowable Emissions (tons /year)
PM	0.60
SO ₂	3.2
NO _x	18.2
CO	4.8
VOC	3.0
CO ₂ e	931.19

Hazardous Air Pollutants (HAP's)	Allowable Emissions (tons /year)
Methylene chloride	13.07
Total HAP's	13.10

Section V- Specific Permit Conditions

- A. Normal operating scenario: Internal combustion engines - EU-1 (Fire pump), EU-2 (Generator with engine of 1,818 hp), EU-3 (Generator with engine of 1,341 hp) and EU-9 (Generator with engine of 33 hp).

The following table contains a summary of applicable requirements, as well as the test methods, for emission units EU-1, EU-2, EU-3 and EU-9 identified in Section II of this permit. For other requirements must refer to the permit conditions.

Condition	Parameter	Value	Units	Test Method	Method Frequency	Record Keeping Requirements	Reporting Frequency
Visible emissions Limit	Visible Emissions	20	Percent (6-minute average)	Method 9	Once during the first year of permit approval.	Tests results	Within 60 days after finishing the test.
SO ₂ Emission Limit	Sulfur content in diesel	0.0015	Percent by weight	Fuel supplier certification	With every fuel receipt.	Record with each receipt of fuel sulfur content.	Semiannual
Limit on Hours of Operation	EU-2	500	Hours per year	Non-resettable hour meter	Monthly	Record	Semiannual
	EU-3	500					
	EU-9	100					
	EU-1	200					

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a. VISIBLE EMISSIONS LIMIT:

- (i) The permittee shall not exceed the opacity limit of 20% on 6-minutes average except for units EU-1, EU-2, EU-3 and EU-9. Nevertheless, the permittee may discharge into the atmosphere visible emissions of an opacity up to 60% for a period of no more than four (4) minutes in any consecutive thirty (30) minutes interval. [Rule 403 (A) of the RCAP]
- (ii) The permittee shall contract an independent opacity reader, certified in a school approved by the EPA or EQB, to perform one (1) opacity reading in the stack of the units EU-1, EU-2, EU-3 and EU-9 during the first year of the permit approval using Method 9 established under Appendix A in 40 CFR Part 60. The engines shall be operating at the time of performance of the opacity readings.
- (iii) The permittee shall submit to the Board, a copy of the format to be used to record the readings of visible emissions at least thirty (30) days prior to the reading of the initial opacity reading.
- (iv) The permittee shall notify in writing the Board at least fifteen (15) days of prior of the initial reading of Method 9, to allow the EQB the opportunity to have an observer present. [Rule 106(D) of the RCAP]
- (v) Two (2) copies of the report of the initial reading under Method 9 shall be submitted by the permittee within 60 days after the tests. This report shall contain the information required in Rule 106(E) of the RCAP.

b. SULFUR CONTENT LIMIT:

- (i) The internal combustion engines of the units EU-3 and EU-9 are affected by the 40 CFR, Part 60, Subpart IIII, so the maximum sulfur content in diesel fuel to be burned shall not exceed **0.0015% by weight**. [40 CFR Section 60.4207(b)]
- (ii) The maximum sulfur content in diesel fuel to be oxidized in internal combustion engines of the units EU-1 and EU-2, shall not exceed **0.0015% by weight**. [PFE-64-0112-0060-I-II-C]
- (iii) The permittee shall install, operate and maintain a non-resettable hour meter for each of internal combustion engines EU-1, EU-2, EU-3 and EU-9 so that the hours of operation and fuel consumption can be verified. [PFE-64-0112-0060-I-II-C.]
- (iv) The permittee must keep a monthly record of the hours of operation as recorded in the non-resettable hours meter, the operating reason (operating

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purpose; emergency, non-emergency, maintenance, demand response, etc.), the fuel consumption and daily sulfur content of fuel in weight percent for each internal combustion engine of the units EU-1, EU-2, EU-3 and EU-9. [PFE-64-0112-0060-I-II-C]

- a. Must document how many hours are spent for emergency operation, including what classified the operation as emergency and how many hours are spent the engine for non-emergency operation.
 - b. The registered hour meter will be used to calculate the cumulative fuel consumption on a monthly basis. The calculation of fuel consumption during any consecutive 12 months period shall be calculated by adding the fuel consumption of each month. It shall be available at all times in the facility for review by technical staff of the Board.
- (v) This permit does not authorize the use of alternative fuels and other fuels in the emission sources described in this permit. [PFE-64-0112-0060-I-II-C]
- (vi) Maintain a **monthly** report for all internal combustion engines included in Section V(A) of this permit that indicating the date, hour meter reading and the total hours of operation, **the purpose of engine use**, the monthly consumption fuel and the sulfur content of the fuel in percent by weight of each engine of the units EU-1, EU-2, EU-3 and EU-9 for evaluation and review by technical staff of the Board. The registered hour meter will be used to calculate the cumulative fuel consumption which will remain on a monthly basis over a period of 12 months. The calculation of the fuel consumption during any consecutive 12-month period is calculated by adding the consumption fuel of each month to the total fuel consumption of the previous 11 months. [PFE-64-0112-0060-I-II-C]
- (vii) The permittee shall submit to the Board a **semiannual** report which indicates the hours of operation and purpose thereof, the monthly fuel consumption and fuel sulfur content in percent by weight of **all internal combustion engines** of EU-1, EU-2, EU-3 and EU-9 units. [PFE-64-0112-0060-I-II-C]
- a. The report shall be accompanied by the fuel supplier certification indicating the sulfur content which should be obtained each time the fuel is received. This shall regularly accompany the report as fuel is received at the facility. This report shall be submitted to the attention of the Chief of the Validation and Data Management Division, Air Quality Area.
 - b. The report covering the period from January to June must be submitted no later than October 1st of the same year and the report

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covering the period from July to December must be submitted no later than April 1st of next year.

- (viii) According to Rule 603(a)(4)(ii) of the RCAP, the permittee shall keep all records of required monitoring data and supporting information for a period of five (5) years from the date of the monitoring sample, measurement, report, or application. This includes records of the hours of operations and sulfur content of consumed fuels.

c. LIMITS OF HOURS OF OPERATION:

- (i) The maximum operating hours of the engine for the emergency generator in the emission unit EU-1 is 200 hours per year, according to the permit PFE-64-0112-0060-I II-C. 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 200 hours of operation limit.
- (ii) The maximum operating hours of the engines for the emergency generators in the emission units EU-2 and EU-3 is 500 hours each per year, according to the permit PFE-64-0112-0060-I II-C. 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 for each.
- (iii) The maximum operating hours of the engine for the emergency generator in the emission unit EU-9 is 100 hours per year, according to the permit PFE-64-0112-0060-I II-C. 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-

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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 100 hours of operation limit.

d. Other federal requirements

(i) EU-1: Internal combustion engines of the fire pump (251 hp):

1. The internal combustion engines for the fire pump of 251 hp (EU-1) is subject to 40 CFR Part 63, Subpart ZZZZ: National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Engines Stationary Internal Combustion Engines (RICE NESHAP), as defined in Section 63.6585(a) of 40 CFR. The permittee shall comply with the applicable requirements of this regulation in accordance with, but not limited to, the following requirements:

a) According to Table 2d, subsection 4 of the Subpart ZZZZ shall:

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

1. Sources have the option to utilize an oil analysis program as described in section 63.6625(i) of 40 CFR in order to extend the specified oil change requirements in Table 2d of the Subpart ZZZZ.

ii) Inspect air cleaner 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.

b) The permittee shall:

i) Operate and maintain the engine and after-treatment control device (if any) according to the manufacturer's emission-related written instructions or develop your 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 practice for minimizing emissions. [40 CFR §63.6625(e)]

ii) Install a non-resettable hour meter if one is not already installed. [40 CFR §63.6625(f)]

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- iii) Minimize the engine's time spent at idle during startup and minimize the engine's startup time to a period needed for appropriate and safe loading of the engine, not to exceed 30 minutes. [40 CFR §63.6625(h)]
 - c) In accordance with 40 CFR §63.6605, the permittee shall operate each engine in a manner that minimizes emissions.
 - d) In accordance with 40 CFR §63.6640 must operate and demonstrate compliance with the Work and Management Practices contained in Table 6 to this Subpart.
 - e) **To maintain the emergency engine category, the permittee shall comply with the limitations on use and operation contained in 40 CFR §63.6640(f).** For any engine operation that does not meet these requirements, the engine will not be considered as one of emergency under this subpart and shall comply with all requirements for non-emergency engines.
 - f) It shall maintain applicable records in accordance with the provisions of 40 CFR §63.6655(f).
 - i) The permittee shall keep records of the hours of operation of the engine that is recorded through the non-resettable hour meter.
 - ii) The permittee shall 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 operation.
 - iii) If the engine is used for the purposes specified in §63.6640(f)(2)(ii) or (iii) or §63.6640(f)(4)(ii), the permittee shall keep records of the notification of the emergency situation, and the date, start time, and end time of engine operation for these purposes.
2. In the case that the internal combustion engine unit EU-1 is reconstructed, the permittee shall comply with the applicable requirements of 40 CFR Part 60, Subpart IIII, as applicable.

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(ii) **EU-2: Internal combustion engine of 1,818 hp of an electric generator for emergencies**

1. In the case that the internal combustion engine of unit EU-2 is reconstructed, the permittee shall comply with the applicable requirements of 40 CFR Part 60, Subpart IIII, as applicable.
2. The internal combustion engines for unit EU-2 is subject to 40 CFR Part 63, Subpart ZZZZ: National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Engines Stationary Internal Combustion Engines (RICE NESHAP), as defined in Section 63.6585(a) of 40 CFR. However, it does not have applicable requirements as long as it is considered an emergency engine. **To maintain the emergency engine category, the permittee shall comply with the limitations on use and operation contained in 40 CFR §63.6640(f).** For any engine operation that does not meet these requirements, the engine will not be considered as one of emergency under this subpart and shall comply with all requirements for non-emergency engines.

(iii) **EU-3: Internal combustion engine of 1,341 hp of an electric generator for emergencies**

1. The internal combustion engine unit EU-3 is subject by the regulations described in 40 CFR Part 60 Subpart IIII (Standards of Performance for New Sources for Stationary Compression Ignition Internal Combustion Engines), so the engine must comply with all applicable requirements under this Subpart.
- a) In accordance with section 60.4205(b) of 40 CFR, each engine must comply with the applicable emission standards in Section 60.4202, for all pollutants, for the same model year and maximum engine power. In accordance with 40 CFR sections 89.112, and 89.113, each engine must not exceed Tier 2 emissions and opacity as follows:
 - i. 6.4 g/KW-hr for NMHC + NO_x,
 - ii. 3.5 g/KW-hr for CO, and
 - iii. 0.20 g/KW-hr for PM.
 - iv. Opacity within the limits set out in 40 CFR section 89.113.

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- b) The permittee shall obtain a certification from the manufacturer that the engine meets the emission standards specified for the same model year and maximum engine power in 40 CFR 89.112 and 40 CFR 89.113 for all pollutants beginning in model year 2007. [40 CFR 60.4202(a)(2)]
- c) The permittee shall operate and maintain each engine so that it complies with the emission standards required under item b. of this condition of this section during the entire life of the engine. [40 CFR section 60.4206]
- d) In accordance with section 60.4207(b) of 40 CFR, the permittee shall use diesel for each engine that meets the requirements of 40 CFR Section 80.510(b). That is,
 - i. The maximum sulfur content of the fuel shall not exceed 15 ppm or 0.0015% by weight.
 - ii. The fuel shall meet a minimum cetane index of 40 or a maximum aromatic content of 35 volume percent.
- e) The permittee shall comply with the applicable monitoring requirements of 40 CFR Section 60.4209.
- f) The permittee shall demonstrate compliance, purchasing an engine certified to the standards in 40 CFR Section 60.4205(b) and item b. of this condition for the same model year and maximum engine power. The engine must be installed and configured according to the manufacturer's emission-related written specifications, except as permitted by paragraph (g) of section 60.4211. [40 CFR Section 60.4211(c)]
- g) **The permittee shall operate the engine according to the requirements of paragraph (f) of section 60.4211, to be considered an emergency engine under this subpart.** If the engine is not operated according to the requirements of that paragraph (f) of section 60.4211, the engine will not be considered an emergency engine under this subpart and the permittee shall comply with all applicable requirements under the same subpart for non-emergency engines.
- h) The permittee shall comply with the test methods and other procedures of Section 40 CFR 60.4212, as applicable.
- i) The permittee shall comply with the applicable notification requirements, reporting and maintenance of records applicable in 40 CFR section 60.4214.

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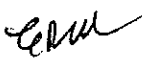
- j) The permittee shall comply with the General Provisions of sections 60.1 through section 60.19 that apply, which are included in Table 8 of 40 CFR Subpart III.
- (iv) **EU-9: Internal combustion engine of 33 hp for an electric generator for emergencies**
1. The internal combustion engine unit EU-9 is subject to 40 CFR Part 63, Subpart ZZZZ (National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Engines Stationary Internal Combustion Engines). In accordance with Section 63.6590(c) of 40 CFR, the engine must meet the requirements of Subpart ZZZZ by meeting the requirements of 40 CFR Part 60 Subpart III.
 - a. The internal combustion engine is subject to 40 CFR Part 60, Subpart III (Standards of Performance for New Sources for Stationary Compression Ignition Internal Combustion Engines).
 - b. You must comply with all applicable requirements under such Subpart.
 - c. In accordance with section 60.4205(b) of 40 CFR, the engine must comply with the applicable emission standards in Section 60.4202(a)(1), for all pollutants, for the same model year and maximum engine power.
 - d. The permittee shall operate and maintain each engine so that it complies with the emission standards required under item c. of this condition of this section during the entire life of the engine. [40 CFR section 60.4206]
 - e. In accordance with section 60.4207(b) of 40 CFR, the permittee shall use diesel for this engine that meets the requirements of 40 CFR Section 80.510(b). That is,
 - i. The maximum sulfur content of the fuel shall not exceed 15 ppm or 0.0015% by weight.
 - ii. The fuel shall meet a minimum cetane index of 40 or a maximum aromatic content of 35 volume percent.
 - f. The permittee shall comply with the applicable monitoring requirements of 40 CFR Section 60.4209.
 - g. The permittee shall demonstrate compliance, purchasing an engine certified to the standards in 40 CFR Section 60.4205(b) and item c. of this condition for the same model year and maximum engine power. The engine must be installed and configured according to the manufacturer's emission-related

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written specifications, except as permitted by paragraph (g) of section 60.4211. [40 CFR Section 60.4211(c)]

- h. **The permittee shall operate the engine according to the requirements of paragraph (f) of section 60.4211, to be considered an emergency engine under this subpart.** If the engine is not operated according to the requirements of that paragraph (f) of section 60.4211, the engine will not be considered an emergency engine under this subpart and the permittee shall comply with all applicable requirements under the same subpart for non-emergency engines.
- i. The permittee shall comply with the test methods and other procedures of Section 40 CFR 60.4212, as applicable.
- j. The permittee shall comply with the applicable notification requirements, reporting and maintenance of records applicable in 40 CFR section 60.4214.
- k. The permittee shall comply with the General Provisions of sections 60.1 through section 60.19 that apply, which are included in Table 8 of 40 CFR Subpart III.
- B. **Normal operating scenario: EU-4 (Device Assembly and Umbilicus overmolding Etching Process), EU-5 (Solvent Dispatching Process), EU-6 (Manufacturing Process-Plaletcell/Amicus and Alyx) and EU-7 (Solvent Mixing Area and Manufacturing Process)**
1. The emission units EU-4, EU-5, EU-6 and EU-7 shall not exceed the consumption indicated in the following table in any period of 12 consecutive months. At the end of each month, the used amount of isopropyl alcohol, methylene chloride, methyl ethyl ketone and cyclohexanone during the period of 12 consecutive months shall be calculated by adding the amount used in that month to the total of the previous 11 months. [PFE-64-0112-0060-I-II-C]



Substance	Maximum Consumption (gallons/year)
Methylene chloride	2,514
Isopropyl alcohol	775
Methyl Ethyl Ketone	61
Cyclohexanone	361

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2. The permittee shall maintain at the facility, available to EQB personnel, the following record:
 - a. A monthly record of consumption of isopropyl alcohol, methylene chloride, methyl ethyl ketone and cyclohexanone. Also, keep the following information for isopropyl alcohol, methylene chloride, methyl ethyl ketone and cyclohexanone.
 - i. Name of the substance or product and the corresponding Safety Data Sheet (SDS).
 - ii. Amount used in the month and the amount accumulated in the last 12 months. [PFE-64-0112-0060-I-II-C]
3. The permittee shall submit to the Board a semiannual report which summarizes the total amounts of isopropyl alcohol, methylene chloride, methyl ethyl ketone and cyclohexanone consumed in the emission units EU-4, EU-5, EU-6 and EU-7. The report covering the period from January to June shall be submitted no later than October 1st of that year and the record covering the period from July to December must be submitted no later than April 1st of the next year. [PFE-64-0112-0060-I-II-C]
4. The permittee should keep accessible to personnel of this Board for a period of five (5) year, the following documentation and any other evidencing the information contained in the record required in condition 2 above:
 - a. Invoices or delivery orders of isopropyl alcohol, methylene chloride, methyl ethyl ketone and cyclohexanone. [PFE-64-0112-0060-I-II-C]
5. **Emission Limit of Volatile Organic Compounds (VOC): Units EU-4, EU-5, EU-6 and EU-7:** In accordance with Rule 419 of RCAP, the permittee shall not permit the emission of 3 pounds of volatile organic compounds in any one hour, nor more than 15 pounds in any one day, from any article, machine, equipment or any other contrivance unless it is provided with a control system, pollution prevention and reductions mechanism or programs or both, as approved or required by the Board. In accordance with Rule 419(F)(3), this rule will not apply to equipment, activities, or emission units that emit less than 3 pounds/hr or 15 pounds/day of volatile organic compounds. [**Condition enforceable only by the State.**]
 - a. The permittee shall submit to the Board a semiannual report of VOC emissions in each unit of emissions (EU-4, EU-5, EU-6 and EU-7) in pounds per hour and pounds per day to demonstrate the exemption of applicability of the Rule. The report covering the period from January to June shall be submitted no later than October 1st of that year and

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the report covering the period from July to December must be submitted no later than April 1st of the next year.

- b. If the permittee needs to increase the consumption of substances VOC within a unit that may affect these values and the applicability of the Rule 419 of the RCAP or some unit uses VOCs, the permittee shall apply and obtain a review of the construction permit PFE-64-0112-0060-I-II-C, along with a demonstration of compliance or exemption limit VOC for that emission unit before increasing.
6. **Emission limits for methylene chloride:** The permittee shall not exceed 13.07 tons per year (in any period of 12 consecutive months) of methylene chloride. [PFE-64-0112-0060-I-II-C]

C. Normal operating scenario for EU-8: Internal Combustion Engines

(i) EU-8a - Motor Briggs & Stratton de 9 hp

1. This internal combustion engine are subject to 40 CFR Part 63, Subpart ZZZZ: National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Engines Stationary Internal Combustion Engines (RICE NESHAP), as defined in Section 63.6585(a) of 40 CFR, so must meet the following applicable requirements:

	Requirements	Reference
a.	Compliance Date	Section 63.6595(a)(1) of 40 CFR
b.	Operating Limitations	Section 63.6602 of 40 CFR
c.	Monitoring requirements, operation and maintenance	Section 63.6625(e), (h), and (j) of 40 CFR
d.	Continuous Compliance Requirements	Section 63.6640(a) of 40 CFR
e.	Requirements	Table 2c (#7) and 6 (#9) of 40 CFR
f.	Recordkeeping Requirements	Section 63.6655 (a)(2) and (5), (d) and (e)(1) and 63.6660 of 40 CFR.
g.	General Provisions	Table 8 of the Part 63, Subpart ZZZZ of 40 CFR.

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(ii) **EU-8b (Engine Ryobi of 3 hp) and EU-8c (UST 3500W of 6.5 hp)**

- These internal combustion engines are subject to 40 CFR Part 60, Subpart JJJJ: Standards of Performance for Stationary Spark Ignition Internal Combustion Engines, so must meet the following applicable requirements:

	Requirements	Reference
a.	Emission standards	Section 60.4231(a) and 60.4233(a) of 40 CFR
b.	Requirements of fuel	For gasoline: 60.4235 of 40 CFR
c.	Requirements Importing/ Installing	Section 60.4236(a) and (d) of 40 CFR
d.	General Compliance	Section 60.4234 of 40 CFR
e.	Requirements of Notifications, reports and records	Section 60.4245(a) of 40 CFR
f.	General Provisions	Section 60.4246 Table 3 of Parte 60, Subpart ZZZZ of 40 CFR.

Section VI - Insignificant Emission Units

The activities may have suffered changes from the time when it was submitted. However, Fenwal International, Inc. must include the list of insignificant activities that are exempt due to size or production and some of these may require a construction permit under Rule 203 of the RCAP.

Emission Unit ID	Description (Exemption criteria)
Two liquefied petroleum gas (LPG) storage tanks (200 lbs each)	Storage tanks with a capacity of less than 10,000 gallons. Appendix B(3)(ii)(N) of the RCAP
Laboratory equipment used exclusively for chemical and physical analyses.	Rule 206(B)(4) of the RCAP
Three aboveground diesel storage tanks (one tank of 250 gallons and two tanks of 6,000 gallons each)	Storage tanks with a capacity of less than 10,000 gallons. Appendix B(3)(ii)(N) of the RCAP
Comfort cooling towers	Water cooling tower, except for systems including contact process water or water treatment with chromium-based chemicals. Appendix B(3)(xxxiii) of the RCAP

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Emission Unit ID	Description (Exemption criteria)
Laundry operations that service uniforms or other clothing used at the facility. This does not include machines that use PERC.	Appendix B(3)(ii)(G) of the RCAP

Section VII - Permit Shield

- 1- Pursuant to Rule 603(d) of the RCAP, compliance with the conditions of the permit shall be deemed compliance with any applicable requirement at the date the permit is issued, whenever said requirement is specifically identified in the permit. Likewise, it will be considered to be in compliance with any requirement specifically identified as Non Applicable in the permit.

A. Non- applicable requirements

Determination of Non-Applicability	
Code	Reason
National Emission Standards for Hazardous Air Pollutants: Reinforced Plastic Composites Production (40 CFR Part 63, Subpart WWWW)	Does not meet the applicability criteria of this subpart.
National Emission Standards for Hazardous Air Pollutants: Surface Coating of Plastic Parts and Products (40 CFR Part 63, Subpart PPPP)	Does not meet the applicability criteria of this subpart.
National Emission Standards for Hazardous Air Pollutants: Hazardous Organic NESHAP (HON) (40 CFR Part 63, Subparts F, G, H and I)	Does not meet the applicability criteria of this subpart.
Compliance Assurance Monitoring (CAM) (40 CFR Part 64)	The part is not applicable, except for its definition of excursion and leave in section 64.1 of the 40 CFR as cited in Rule 605(c)(5)(iii)(E) of the RCAP.

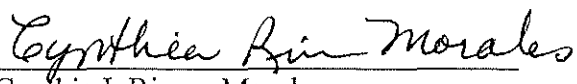
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Section VIII - Permit Approval

Pursuant to the powers granted by the Environmental Public Policy Act, Public Law Number 416 of September 22, 2004, as amended, and after verifying the administrative file and compliance with the Uniform Administrative Procedures Act, Public Law Number 38 of June 30, 2017, as amended, the US Clean Air Act, the Puerto Rico Environmental Public Policy Act, and the Regulations for the Control of Atmospheric Pollution, the Department of Natural and Environmental Resources approves the permit subject to the terms and conditions stated therein.

In San Juan, Puerto Rico, today March 16, 2020.


Cynthia I. Rivera Morales
Acting Secretary

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APPENDIX

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Appendix I - Definitions and Abbreviations

A. Definitions:

1. Act – US Clean Air Act, as amended, 42 U.S. 7401, et seq.
2. Responsible Official – See definition for Responsible Official as established in the Environmental Quality Board Regulations for the Control of Atmospheric Pollution (1995).
3. Regulations - Environmental Quality Board Regulations for the Control of Atmospheric Pollution.
4. Title V - Title V of the U.S. Clean Air Act (42 U.S.C. 7661).

B. Abbreviations

AP-42	Compilation of Air Pollutant Emission Factors
Btu	British thermal unit
CFR	Code of Federal Regulations
CO	Carbon Monoxide
CO _{2e}	Carbon dioxide equivalent
EPA	US Environmental Protection Agency
EQB	Puerto Rico Environmental Quality Board
hp	horsepower
HAP	Hazardous Air Pollutants
Lbs	Pounds
MMBtu	Million Btu
NAAQS	National Ambient Air Quality Standards
NO _x	Nitrogen Oxide
Pb	Lead

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PM	Particulate Matter
PM ₁₀	Particulate matter with a mass median aerodynamic diameter equal to or less than 10 microns.
RCAP	Environmental Quality Board Regulations for the Control of Atmospheric Pollution
RMP	Risk Management Plan
SIC	Standard Industrial Classification
SO _x	Sulfur Oxides
SO ₂	Sulfur Dioxide
VOC	Volatile Organic Compounds

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COMMONWEALTH OF
PUERTO RICO
Environmental Quality Board

Statement of Basis - Title V Permit
Fenwal International, Inc.
PFE-TV-3841-64-0510-0335

The Puerto Rico Environmental Quality Board (EQB) is issuing a Title V permit pursuant to 40 Code of Federal Regulations (CFR) Part 70 and Part VI of the Regulations for the Control of Atmospheric Pollution (RCAP) for Fenwal International, Inc. Fenwal International, Inc. is located in the Road #122 km 0.5 in San Germán, Puerto Rico. EQB received a Title V permit application from on May 18, 2010 which it was amended on July 20, 2012.

Fenwal International, Inc. is a company that manufactures a variety of medical devices for the collection and separation of blood components. In addition, it is dedicated to a variety of products for the automated and manual collection, filtration, separation, storage and transfusion of blood and its components. The facility has internal combustion engines (emergency power generators and a fire pump) (EU-1, EU-2, EU-3, EU-8 and EU-9). Also, Fenwal International, Inc. has manufacturing processes which are four emission units (EU-4, EU-5, EU-6 and EU-7): five machines for assembling, Umbilicus overmolding process and solvent dispatching, Plaletcell/Alyx/Amicus manufacturing process and the solvent mixture area.

This facility is required to obtain a Title V operating permit because it is a major source of hazardous air pollutant (HAPs) as it has the potential to emit methylene chloride in excess of 10 tons per year.

Emission Units

The Emission Units section lists the significant emission units, the associated control equipment, if any, and the type of fuel. This section is a general description of the facility. The emission units are as follows:

UEP
mmf
EU-1: Fire pump: It has an internal combustion engine with a capacity of 251 hp. It consumes diesel at a rate of 13 gallons per hour. Although 40 CFR Part 63 Subpart ZZZZ does not limit the yearly operating hours in an emergency, the PREQB construction permit limit hour operating hours for EU-1 to 200 hours/year. It does not have a control equipment.

sep
EU-2: Electric Generator for Emergencies: It has an internal combustion engine with a capacity of 1,818 hp. It consumes diesel at a rate of 87 gallons per hour. Although 40 CFR Part 63 Subpart ZZZZ does not limit the yearly operating hours in an emergency, the PREQB construction permit limit yearly operating hours for EU-2 to 500 hours/year. It does not have a control equipment.

EU-3: Electric Generator for Emergencies: It has an internal combustion engine with a capacity of 1,341 hp. It consumes diesel at a rate of 72 gallons per hour. Although 40 CFR Part 63 Subpart ZZZZ

does not limit the yearly operating hours in an emergency, the PREQB construction permit limit yearly operating hours for EU-3 to 500 hours/year. It does not have a control equipment.

EU-4: Device Assembly and Umbilicus overmolding-Etching Process (EU-4A). Consists of five machines for assembling units, labeling and integrity testing. Umbilicus overmolding process consists on delaminating the tubes called umbilicus with methylene chloride before proceeding with the overmolding step. The Umbilicus Etching process consists to apply methylene chloride to the ends of the Umbilicus. The sole purpose for doing this is to create a rough surface on the tube ends where the new molded parts can be attached to. Once the umbilicus pass the dry out period it is send to the molding machine to be overmolded on both ends.

It will use 504 gal/year of methylene chloride and 1,374 gal/year of isopropyl alcohol. Between the unit process of EU-4A and EU-5, the consumption of methylene chloride is 2,010 gals/year in this unit.

EU-5: Solvent dispatching process. Between the unit process of EU-4A and EU-5, the consumption of methylene chloride is 2,010 gals/year in this unit.

EU-6: Plaletcell/Alyx/Amicus Manufacturing Process. Pure cyclohexanone and a mixture of equal parts (50/50) of methyl ethyl ketone and cyclohexanone are used in the solvent bonding processes known as the Plaletcell/Amicus/Alyx Process. These solutions are in container which is called Medica Dispenser which is a stainless steel unit designed in such a way that the assembler can enter the plastic tube in the solutions and then remove the solvent for joining plastic parts. The fugitive emissions processes are methyl ethyl ketone and cyclohexanone. It will use 61 gals/year of methyl ethyl ketone and 361 gals/year of cyclohexanone in these manufacturing processes.

EU-7: Solvent mixture area and manufacturing process. The fugitive emissions are cleaning of the equipment, work areas and clean rooms. It will be used 1,577 gal/year of isopropyl alcohol in these areas.

EU-8: Internal combustion engines. The three internal combustion engine consume gasoline at a rate of 2.55 gallons per hour.

- a. EU-8a-Internal combustion engine-generator. Engine power is 9 hp. Briggs and Straton Model GN503100AC
- b. EU-8b- Internal combustion engine-generator. Engine power is 3 hp. Ryobi Model RYi200TA.
- c. EU-8c- Internal combustion engine-generator. Engine power is 6.5 hp. UST Model 3500W.

EU-9: Electric Generator for Emergencies. It has an internal combustion engine with a capacity of 33 hp. It consumes diesel at a rate of 1.70 gallons per hour. It is a Caterpillar, model C2.2. Although

40 CFR Part 63 Subpart ZZZZ does not limit the yearly operating hours in an emergency, the PREQB construction permit limit yearly operating hours for EU-9 to 100 hours/year. It does not have a control equipment.

Allowable Emissions

The permissible emissions described in the following table represents the permissible emissions at the moment of permit application and will be used only for payment purposes. In accordance with Rule 610(a) of the RCAP, when Fenwal International, Inc. applies for a modification, administrative change or minor modification to its Title V permit, the source will pay only for those charges related with any emission increase (if any) per ton, based on the change and not based on the total fees previously paid.

Pollutants	Allowable Emissions (tons /year)
PM	0.60
SO ₂	3.2
NO _x	18.2
CO	4.8
VOC	6.8
CO ₂ e	931.19

Hazardous Air Pollutants (HAP's)	Allowable Emissions (tons/year)
Methylene chloride	13.07
Total HAP's	13.10

According to EQB Resolution RI-06-02¹, emissions calculations should be based on the actual emissions of Fenwal International, Inc.; however, the calculations based on the allowable emissions of the facility will be accepted. If Fenwal International, Inc. decides to perform calculations based on allowable emissions, Fenwal International, Inc. shall pay the same fee per ton as the sources that decide to do the calculations based on actual emissions.

¹EQB Resolutions-Payment procedure for Title V operating fees and for renovation fees of Title V permit issued March 20, 2006.

Applicable Requirements

National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines (RICE NESHAP) - 40 CFR Part 63 Subpart ZZZZ

This subpart applies to any existing, new or reconstructed stationary reciprocating internal combustion engine located in major sources of hazardous air pollutants. Fenwal International, Inc. is a major source of hazardous air pollutants. All the engines are affected by this regulation. The EU-2 has no applicable requirements under this regulation provided that operates as an emergency engine.



Standards of Performance for Stationary Compression Ignition Internal Combustion Engines - 40 CFR Part 60 Subpart IIII

This subpart applies to stationary compression ignition internal combustion engines who the permittee were ordered after July 11, 2005 and manufactured after April 1st, 2006. This subpart applies to EU-3 engine. The EU-3 is affected by emission limits for which require a certification from the manufacturer of the engine.

Standards of Performance for Stationary Spark Ignition Internal Combustion Engines - 40 CFR Part 60 Subpart JJJJ

The internal combustion engines of the two power generators (engine of 3 hp [Ryobi RYi200TA] and engine of 6.5 hp [UST 3500W]) are subject to the National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines contained in 40 CFR Part 63 Subpart ZZZZ. The permittee shall comply with the applicable requirements of the Subpart ZZZZ through the compliance with the applicable requirements of 40 CFR Part 60 Subpart JJJJ.

Emission Limit of Volatile Organic Compounds (VOC): Units EU-4, EU-5, EU-6 and EU-7

 In accordance with Rule 419 of RCAP, the permittee shall not permit the emission of more than 3 pounds of volatile organic compounds at any hour, or more than 15 pounds per day in any article, machine, equipment or any other contrivance unless such equipment is provided with an acceptable control system, programs or mechanism to reduce and prevent emissions or both, as approved or required by the Board. The permittee shall submit to the Board for approval, an acceptable control system for the unit or program to prevent and reduce emissions no later than 60 days from the effective date of the modification of the construction permit PFE- 64-0112-0060-I-II-C issued on March 13, 2014. [Condition is enforceable only by the State.] 

The following requirements do not apply to Fenwal International, Inc.:

- National Emission Standards for Hazardous Air Pollutants: Reinforced Plastic Composites Production (40 CFR Parte 63, Subpart WWW): The facility does not meet applicability criteria of this Subpart.
- National Emission Standards for Hazardous Air Pollutants: Surface Coating of Plastic Parts and Products (40 CFR Parte 63, Subpart PPPP): The facility does not meet applicability criteria of this Subpart.
- National Emission Standards for Hazardous Air Pollutants: Hazardous Organic NESHP (HON) (40 CFR Parte 63, Subparts F, G, H, I of 40 CFR): The facility does not meet applicability criteria of this Subpart.

The frequency of reporting for compliance certification for this source should be annual. Unless specifically stated, all terms and conditions of Title V permit, including provisions designed to limit the potential to emit of the source, are enforceable by EPA and by the citizens, under the Federal Clean Air Act. These terms and conditions are designated as executable only by the state, as indicated by the permit are enforceable only by the EQB.

EQB has determined that this Title V Operating Permit satisfies the requirements under Part VI of the RCAP.

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