



COMMONWEALTH OF  
**PUERTO RICO**  
Environmental Quality Board

FINAL TITLE V OPERATING PERMIT  
AIR QUALITY AREA  
ENVIRONMENTAL QUALITY BOARD



Permit Number:	PFE-TV-2833-09-1096-0011-B
Application Receipt Date:	October 31, 1996 <sup>1</sup>
Final or Effective Issue Date:	April 15, 2016
Expiration Date:	April 15, 2021

In accordance to the provisions of Part VI of the Regulation for Atmospheric Pollution Control (RCAP) and the provisions of the Code of Federal Regulations (CFR), Title 40, Part 70

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**ABBOTT HEALTHCARE (PUERTO RICO) LTD.  
BARCELONETA, PUERTO RICO**

hereinafter referred to as “the permittee” or **Abbott**, is authorized to operate a stationary source of air pollutants consisting of the emission units described in this permit. Until such time as this permit expires, is modified or revoked, the permittee may emit air pollutants as a result of those processes and activities directly related to and associated with the emission sources, according to the requirements, limitations and conditions of this permit, until the expiration date or until it is modified or revoked.

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

<sup>1</sup> The initial application covered all sources that today belong to AbbVie Ltd. After separating the two companies, on January 2, 2013 an application was submitted with all sections for Abbott Healthcare, eliminating sources belonging to Abbvie Ltd.

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Section I - General Information

A. Facility Information

Company Name: Abbott Healthcare (Puerto Rico) Ltd.

Postal Address: PO Box 5050  
Barceloneta, PR 00617

Facility Location: Road No. 2 km 58.2 Cruce Dávila  
Barceloneta, PR 00617

Responsible Officer: Otto E. Aldahondo Delgado  
Site Director - AHL  
otto.aldahondo@abbott.com

Contact Person: Otto E. Aldahondo Delgado  
Site Director - AHL  
otto.aldahondo@abbott.com

Phone: 787-846-3500, ext. 5001

Fax: 787-846-8468

SIC Primary Code: 2833, 2834



B. Process Overview

Abbott Laboratories (Abbott) is a global, science-based healthcare company, with diversified market offerings in diagnostic, medical devices, nutritionals and generic pharmaceuticals.

Abbott Healthcare (Puerto Rico) Ltd. (AHL) and Abbott Diagnostics International Ltd. (ADI) are subsidiaries of Abbott. Both conduct their operations in portions of the north and south of a property of 284 acres located on Road No. 2, km 58.2 in Barceloneta.

Previously Abbott operations covered the operations of what is now known today as Abbvie, Ltd. In January 2013, Abbott was separated between two independent healthcare companies: a

diversified medical products corporation, which retained the Abbott name, and a new research-based company that owns the proprietary pharmaceutical business, named Abbvie. In Puerto Rico, Abbott will be the parent company of Abbott Healthcare (AHL), formerly known as APL (South Chemical Plant) and Abbott Diagnostics (ADI). This Title V permit covers AHL and ADI, as both are under Abbott's common control.

Emission sources include chemical synthesis of pharmaceuticals (EU-1), in which two pharmaceutical drugs are currently being manufactured: Clarithromycin and Feno-Acid Fibrate, loading, unloading and storage of chemicals in storage tanks (EU-14), solvent recovery operations (EU-18) and guide wires manufacturing (EU-25). Abbott uses a regenerative thermal oxidizer (RTO) and an enclosed flame vapor combustion device (EFVCD) to control emissions at the facility. It also uses a caustic scrubber at the output of the thermal oxidizer to control SO<sub>2</sub> and acid gases emissions. As part of the agreements between Abbott and Abbvie, the latter provides utility services to AHL and ADI, which include water, steam, and electricity, among other supplies.

Currently Abbott potential emissions are below the threshold to consider it a major source. However, the Clarithromycin process is subject to regulations in 40 CFR Part 63 Subpart GGG (Pharmaceutical Production MACT), as determined by the EPA on October 22, 2013. Therefore, under Rule 601(A)(3), Abbott is covered by the Title V permit program.

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Section II - Emission Units Description and Control Equipment

The emission units regulated by this permit are the following:

Emission Unit	Description	Control Equipment
EU-1	Chemical Synthesis of Pharmaceutical  Bulk Pharmaceuticals products are produced using batch chemical processing techniques. Several unit processes are typically used such as: reactions, distillation, crystallization, separation, drying and grinding. Although the equipment has the capability to manufacture different pharmaceutical products, they are currently engaged in the manufacture of two products: <i>Clarithromycin and Feno Acid Fibrate.</i>	DF-100/SC-103 or DF-200  DC-791 DC-792 DC-793 DC-794 DC-795
EU-14	Loading, Unloading and Storage of Chemicals (RTO)	DF-100/SC-103 or DF-200
EU-18	Solvent Recovery Operations (S.F.)	DF-100/SC-103 or DF-200
EU-25	Manufacturing of Guide Wires	Dust Collector

Section III - General Permit Conditions

1. **Sanctions and Penalties:** Abbott 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, Abbott 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 Abbott 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, Abbott 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:** Abbott 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.

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7. **Compliance Certification:** As specified under Rule 602(c)(2)(ix)(C) of the RCAP, Abbott shall submit each year a compliance certification. This certification must be submitted to both the EQB and the Environmental Protection Agency (EPA)<sup>2</sup> no later than April 1<sup>st</sup>, covering the previous calendar year, after the permit effective date. 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

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<sup>2</sup> The certification to the EQB shall be mailed to: Manager, Air Quality Area, P.O. Box 11488, San Juan, P.R. 00910. The certification to the EPA shall be mailed to: Chief, Enforcement and Superfund Branch, CEPD, US EPA-Region II, City View Plaza - Suite 7000, #48 Rd. 165 Km 1.2 Guaynabo, P.R. 00968-8069.

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.

10. **Objectionable Odors:** As specified under Rule 420 of the RCAP, Abbott 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. If objectionable odors are detectable beyond Abbott 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]
11. **Permit Renewal Applications:** As established under Rule 602 (a)(1)(iv) of the RCAP, Abbott 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.
12. **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 Abbott 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.
13. **Recordkeeping Requirement:** As established under Rule 603(a)(4)(ii) of the RCAP, Abbott 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.
14. **Semiannual Monitoring Reports/Samplings:** 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. 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 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<sup>st</sup> of the same year and the report covering the period from July through December shall be submitted no later than April 1<sup>st</sup> of the following year. The first semiannual report shall cover the period starting from the effective date of the permit. Once the guidelines are developed by the Board, the permittee must use them to complete these reports.

15. **Deviations Reporting due to Emergencies<sup>3</sup>:** 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 **Abbott** wishes to assert the affirmative defense authorized under Rule 603 (e) of the RCAP. If **Abbott** 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, 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.

16. **Deviation Reporting (Hazardous Air Pollutants):** The source (except sources affected by the Pharmaceutical Production MACT and included in Abbott's SSMP which shall comply with the provisions of the 40 CFR §63.6(e) specifically) 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

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<sup>3</sup> Except sources affected by the 40 CFR part 63, subpart GGG (Pharmaceutical Production MACT) and included in Abbott's Startup, Shutdown and Malfunction Plan which shall comply with the provisions of the 40 CFR §63.6(e) specifically.

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.

17. **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.
18. **Permit Noncompliance:** According to Rule 603(a)(7)(i) of the RCAP, Abbott 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.
19. **Defense not Allowed:** As specified under Rule 603(a)(7)(ii) of the RCAP, Abbott 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.
20. **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 Abbott 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.
21. **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.
22. **Obligation to Furnish Information:** As specified under Rule 603(a)(7)(v) of the RCAP, Abbott 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, Abbott shall also furnish to the EQB copies of documents related to this permit.

23. **Change in Operating Scenario:** As specified under Rule 603(a)(10)(i) 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.
24. **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.
25. **Administrative Permit Amendments and Permit Modifications:** As specified under Rule 606 of the RCAP, the permit shall not be amended nor modified unless **Abbott** complies with the requirements for administrative permit amendments and permit modifications as described in the RCAP.
26. **Source Modifications without a permit revision:** According to Rule 607 of the RCAP, Abbott may perform:
- a. Source changes
    - i. Permitted sources may make Section 502(b)(10) changes without requiring a permit revision, if the changes are not modifications under any provision of Title I of the Act and the changes do not exceed the emissions allowable under the permit (whether expressed therein as a rate of emissions or in terms of total emissions).
      - (1) For each such change, the facility must provide the Administrator and the Board with written notification in advance of the proposed changes, which shall be seven (7) days. The written notification shall include a brief description of the change within the permitted facility, the date on which the change will occur, any change in emissions, and any permit term or condition that is no longer applicable as a result of the change. The source, the Board, and EPA shall attach each such notice to their copy of the relevant permit.
      - (2) The permit shield described in paragraph (d) of Rule 603 shall not apply to any change made pursuant to section (a)(1) of Rule 607.

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- ii. Permitted sources may trade increases and decreases in emissions in the permitted facility for the same pollutant, where the permit provides for such emissions trades without requiring a permit revision and based on the 7-day notice prescribed in section (a)(2) of Rule 607. This provision is available in those cases where the permit does not already provide for such emissions trading.
- (1) Under paragraph (a)(2) of Rule 607, the written notification required shall include such information as may be required by the provision in the Puerto Rico State Implementation Plan (PR-SIP) authorizing the emissions trade, including when the proposed change will occur, a description of each such change, any change in emissions, the permit requirements with which the source will comply using the emissions trading provisions of the PR-SIP, and the pollutants emitted subject to the emissions trade. The notice shall also refer to the provisions with which the source will comply in the PR-SIP and that provide for the emissions trade.
- (2) The permit shield described in paragraph (d) of Rule 603 shall not extend to any change made under section (a)(2) of Rule 607. Compliance with the permit requirements that the source will meet using the emissions trade shall be determined according to requirements of the applicable implementation plan authorizing the emissions trade.
- iii. If a permit applicant requests it, the Board shall issue permits that contain terms and conditions (including all terms required under sections (a) and (c) of Rule 603 to determine compliance) allowing for the trading of emissions increases and decreases in the permitted facility solely for the purpose of complying with a federally-enforceable emissions cap. Such a cap must be established in the permit independent of otherwise applicable requirements. The permit applicant shall include in its application proposed replicable procedures and permit terms that ensure the emissions trades are quantifiable and enforceable. The Board shall not be required to include in the emissions trading provisions any emissions units for which emissions are not quantifiable or for which there are no replicable procedures to enforce the emissions trades. The permit shall also require compliance with all applicable requirements.
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- (1) Under section (a)(3) of Rule 607, the written notification required shall state when the change will occur and shall describe the changes in emissions that will result and how these increases and decreases in emissions will comply with the terms and conditions of the permit.
  - (2) The permit shield described in paragraph (d) of Rule 603 may extend to terms and conditions that allow such increases and decreases in emissions.
- b. Off-Permit Changes. The Board may allow changes that are not addressed or prohibited by the permit and/or State Law.
- i. A permitted facility may make changes without obtaining a permit revision if such changes are not addressed or prohibited by the permit, other than those described in paragraph (c) of Rule 607.
- (1) Each such change shall meet all applicable requirements and shall not violate any existing permit term or condition.
  - (2) Sources must provide contemporaneous written notice to the Board and EPA of each such change, except for changes that qualify as insignificant under paragraph (c)(1) of Rule 602. Such written notice shall describe each such change, including the date, any change in emissions, pollutants emitted and any applicable requirement that would apply because of the change.
  - (3) The change shall not qualify for the shield under paragraph (d) of Rule 603.
  - (4) The permittee shall keep a record describing changes made at the source that result in emissions of a regulated air pollutant subject to an applicable requirement, but not otherwise regulated under the permit, and the emissions resulting from those changes.
- c. A permitted facility cannot make changes without a permit revision if such changes are modifications under any provision of Title I of the Act

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27. a. The permittee may make changes under section 502(b)(10) of the Act without requiring a permit revision if such changes:
- (1) are not modifications under any provision of Title I of the Act,
  - (2) the changes do not exceed the emissions allowable under the permit
  - (3) do not result in the emission of any pollutant not previously emitted,
  - (4) do not violate any applicable requirement or contravene federally enforceable terms and permit conditions such as monitoring (including test methods), recordkeeping, reporting and compliance certification requirements, are not changes under Title I of the Act to an emission limit, a work practice or a voluntary emission cap.
- b. Rule 203 of the RCAP is required for any construction or modification of an emission source, unless it is exempt under Rule 206 of the RCAP. For purposes of part II of the RCAP, a modification is defined as any physical change in, change in the method of operation or a change in type of fuel used of an existing stationary source, that would result in a net increase in that stationary source's potential to emit any air pollutant (subject to any standard), or which results in the emission of any pollutant (subject to an standard) not previously emitted. A physical change shall not include routine maintenance, repair and the replacement of any equipment having the same capacity, equal efficiency or greater environmental benefit to be used for the same purpose.
- c. The written notification addressed in condition 42(a)(1)(i) refers to changes covered under condition 42(a)(1).
- d. Any emission trading as provided in condition 42(a)(2) above will not be authorized if the facility does not provide the reference to the PR-SIP provisions authorizing such emissions trading.
- e. If the permittee requests so, the Board may allow the emission trading in the facility solely for the purpose of complying with a federally-enforceable emissions cap. The application shall be based in replicable procedures and shall include permit terms that ensure the emission trades are quantifiable, replicable and enforceable.
- f. Off- permit changes will not be exempt from complying with the requirements and procedures of Rule 203 of the RCAP, if applicable.

28. **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 **Abbott**, 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.
29. **Changes in Name or Responsible Official:** This permit is issued to **Abbott Healthcare (Puerto Rico) Ltd.** 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.
30. **Changes in Ownership:** This permit is issued to **Abbott Healthcare (Puerto Rico) Ltd.** 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.

31. **Renovation Work/ Demolition:** Abbott 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.
32. **Plan de Manejo de Riesgo:** If during the effectiveness of this permit, Abbott 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 effectiveness of this permit, Abbott 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.
33. **General Duty:** Abbott 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.
34. **Requirements for Refrigerants (Climatologic and Stratospheric Ozone Protection):**
  - a. In the event that Abbott 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, Abbott 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 §82.166.
  - c. **Service on Motor Vehicles:** If Abbott 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), Abbott 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 the air-tight sealed refrigeration system used as refrigerated cargo or system used on passenger buses using HCFC-22 refrigerant.

35. **Labeling of Products Using Ozone-Depleting Substances:** Abbott 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.
36. **Roof Surface Coating:** Abbott 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 is a state-only enforceable requirement]
37. **Open Burning:** Pursuant to Rule 402 of the RCAP, Abbott 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.
38. **Fugitive Emissions:** Compliance with Rule 404 of the RCAP:
- a. Abbott shall use 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. Abbott 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 and nuisance or violate any regulations, the Board may order that building or 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 should not create occupational health hazards.

39. **Compliance Clause:** Under no circumstances does compliance with this permit exempt **Abbott** from complying with all other applicable state or federal laws, regulations, permits, administrative orders or applicable court orders.
40. **Emissions Calculations:** **Abbott** shall submit, on or before **April 1<sup>st</sup>** 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 purpose and the responsible official must certify all the information submitted as true, correct and representative of the permitted activity.
41. **Annual Fee:** As specified under Rule 610 of the RCAP, **Abbott** 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.
42. **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.
43. **Reports:** 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.
44. **Reservation of Rights:** Except as expressly provided in this Title V permit:
- 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 permit, including but not limited to the right to seek injunctive relief, and imposition of statutory penalties and/or fines.
  - Nothing herein shall be construed to limit the rights of EPA or the Board to undertake any criminal enforcement activity against **Abbott** or any person.
  - Nothing herein shall be construed to limit the authority of EPA or the Board 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 **Abbott'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 - Emissions Limits

The emissions described in the following table represent the allowable emission limits at the time of the permit application. According to Resolution RI-06-02<sup>4</sup>, the emissions calculations will be based on **Abbott's** actual emissions, however calculations based on the facility's allowable emissions will be accepted. If **Abbott** decides to perform the calculations based on allowable emissions, **Abbott** shall pay the same charge per ton as the facilities that decide to do calculations based on their actual emissions. Also, when **Abbott** 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 Rule 610(a) of the RCAP.

Pollutants	Emissions <sup>5</sup> (ton/year)
PM	33.171
SO <sub>2</sub>	8.256
NO <sub>x</sub>	3.938
CO	1.511
VOC	47.395
HAP (Includes Acetonitrile and Methyl Bromide)	6.332
CO <sub>2e</sub>	4,215.38

<sup>4</sup>EQB Resolution - Payment procedure for Title V operating charges and Title V permit renewal charges, issued on March 20, 2006.

<sup>5</sup> Includes fugitive and Abbott Diagnostics emissions.

Section V - Specific Permit Conditions

A. Requirements for each emission unit: Authorized equipment for each emission unit are included in Appendix II of this permit.

1. EU-1 Chemical Synthesis of Pharmaceuticals

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
Production limit	Clarithromycin	225	lots / year	Records	Quarterly	Logbook	Semiannual
	Feno Acid	517					
Clarithromycin emission limits	PM	0.13	ton/year	Records	Quarterly	Logbook	Semiannual
	VOC	0.61					
	HAP	0.016					
Wastewater Discharge Limit	Water Discharge	3,040.3	kg /mixtures run	Records	Quarterly	Logbook	Semiannual
Rule 419 of the RCAP	VOC	3	lb/hr	Emission calculations	N/A	Keep records with the emission calculations	N/A
		15	lb/day				
Emission limit for non-process sources Rule 409 of the RCAP	PM	0.05	output lbs/input lbs-hr	Pressure drop	Weekly	Logbook	Semiannual
95		%					
40 CFR Part 63 Subpart GGG	See Section V.B. of the permit	---	---	---	---	---	---

a. Clarithromycin and Feno Acid Production Limit (PFE-09-0193-0057-I-II-C)

- i. Clarithromycin process production is limited to 225 lots per year (equivalent to 206 metric tons per year).
- ii. Feno-Acid production will not exceed 517 lots/year in existing equipment and 714 lots/year in new equipment.

- iii. Abbott shall prepare and maintain records containing the quarterly amount (on an annual rotating basis) of manufactured lots. The logs shall indicate the number of lots manufactured on existing equipment and the lots manufactured in new equipment. These will be available no later than 30 days from the last day of the period of the previous 4 quarters. The logs must be available at all times for inspection by the technical personnel of the Board.
- b. Clarithromycin production emission limits (PFE-09-0193-0057-I-II-C)
- i. Emissions of particulate matter for the production of Clarithromycin shall not exceed 0.13 ton/year.
  - ii. Emissions of volatile organic compounds (VOC) for the production of Clarithromycin shall not exceed 0.61 ton/year including production, equipment cleaning, tank farm and solvent recovery.
  - iii. Emissions of hazardous atmospheric pollutants (HAP) for the production of Clarithromycin shall not exceed 0.016 ton/year including production, equipment cleaning, tank farm and solvent recovery.
  - iv. The permittee shall prepare an annual report showing that emissions from the production of Clarithromycin do not exceed 0.13 tons per year of particulate matter, 0.61 tons per year of VOC and 0.016 tons per year of HAP. The report must be certified by a licensed professional engineer authorized to practice in Puerto Rico. The report must be available at all times for inspection by the technical personnel of the Board.
  - v. A summary of the report shall be included along with the semiannual report required in the general condition III.14.
- c. Limits for the steam stripper (PFE-09-0193-0057-I-II-C)
- i. The steam stripper shall be inspected, operated and maintained according to the manufacturer's recommendations.
  - ii. The discharge of wastewater containing acetonitrile in the steam stripper for the Clarithromycin manufacturing process shall not exceed 3,040.3 kg per wastewater mix run.

- iii. Abbott shall prepare and maintain records containing the quarterly amount (on an annual rotating basis) of discharge required by the previous condition. The logs must be available at all times for inspection by the technical personnel of the EQB.
- d. Rule 419 of the RCAP [state-only enforceable]
  - i. According to Rule 419 of the RCAP, Abbott will not cause or permit the emission of 3 pounds in any one hour or 15 pounds in any one day of VOC from any article, machine, equipment or any other contrivance unless it is provided with an control system, pollution prevention and reductions mechanism or programs or both, as approved or required by the Board.
  - ii. Abbott shall operate control equipment at all times while emissions in excess of the threshold set by Rule 419 of the RCAP are being generated or can be generated during manufacturing processes, except as specified in conditions 15 and 16 of Section III of this permit.
- e. Control Equipment
  - i. Under normal operating scenario, emissions from this emission unit will be controlled by a regenerative thermal oxidizer and a gas scrubber. These equipment will meet the conditions set out in Section V.A.4. of this permit. As an alternate scenario, Abbott may use the EFVCS, according to the conditions contained in Section VI of this permit. If affected by the 40 CFR Part 63 Subpart GGG, it shall also meet the conditions of section V.B of this permit.
  - ii. Emissions of particulate matter will be controlled by dust collectors.
- f. Rule 409 of the RCAP – Non-Process Sources Limit
  - i. According to Rule 409 of the RCAP, Abbott shall not cause or permit the emission of particulate matter in any one hour in excess of 0.05 pounds per pound of uncontrolled emissions from any non-process source.
  - ii. Abbott shall demonstrate compliance with this condition keeping the pressure drop collectors as recommended by the manufacturer and the following:
    - (1) Calibrate every six months the pressure drop meter of the dust collectors included in this permit. Abbott shall prepare and maintain a log of the date, time, methodology and results of the calibrations. The logs must be available at all times for inspection by the technical personnel of the Board.

- (2) Verify weekly the readings of the pressure drop meters during the operation of each dust collector to ensure that these are working within the range established by the manufacturer to ensure the required control efficiency.
- (3) Shall prepare a Preventive Maintenance Program to ensure proper operation of the dust collectors. The program must be available for review by the Board. At any time the Board may request the program to be revised if it is determined not suitable. Following a request for review, Abbott will have 60 days to submit the revised maintenance program to the Air Quality Area for approval.
- (4) Abbott shall inspect the dust collectors according to the Preventive Maintenance Program to ensure they work properly and to observe changes that may indicate potential malfunction.
- (5) Abbott shall keep a logbook with the results of the dust collector's inspections including the following information:
  - (A) Time and date of inspection
  - (B) Inspection Results
  - (C) If a problem is found:
    - (i) Nature of the problem
    - (ii) Corrective measures

g. The process of Clarithromycin is subject to regulations in 40 CFR Part 63 Subpart GGG (Pharmaceutical Production MACT). The conditions applicable to this regulation are in section V.B. of this permit.

2. EU-14 – Loading, Unloading and Storage of Chemicals

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
Stationary Tanks	N/A	N/A	N/A	Design or control equipment	N/A	Maintenance, repairs	Semiannual
40 CFR Part 63 Subpart GGG	See condition V.B. of this permit	---	---	---	---	---	---

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a. Stationary Tanks – Rule 417 of the RCAP

- i. Abbott shall not place, store, or hold in any stationary tank, reservoir, or other container of more than 151,412 liters (40,000 gallons) capacity of any volatile organic compounds unless such tank, reservoir, or other container is a pressure tank capable of maintaining working pressures sufficient, under normal operating conditions, to control vapor or gas loss to the atmosphere, or unless it is designed and equipped with one of the following vapor loss control devices:
- (1) A floating roof, consisting of a pontoon type, double deck type roof or internal floating cover, which will rest on the surface of the liquid contents to be equipped with a closure seal or seals to close the space between the roof edge and tank wall. This control equipment shall not be permitted if the volatile organic compounds have a vapor pressure of 568 millimeters Hg or 11.0 pounds per square inch absolute or greater, under normal storage conditions. All tank gauging or sampling devices shall be gastight to prevent leakage when sampling. [Rule 417(A) of the RCAP].
  - (2) A vapor recovery system, consisting of a vapor gathering system capable of collecting volatile organic compounds, vapors, and gases discharged, and a vapor disposal system capable of processing such volatile organic vapors and gases to control their emission to the atmosphere. All tank gauging and sampling devices must be gastight, except when gauging or sampling is taking place. [Rule 417(B) of the RCAP].
- ii. Compliance with condition (i) is exempted for the following:
- (1) Storage tanks that are used for storage of any liquid having no photochemical reactivity (including those compounds listed under the definition of VOC) and/or having an absolute vapor pressure less than 0.75 psia, and
  - (2) tanks that treat waste water permitted under the Clean Water Act and exempted by RCRA or CERCLA rules.
- iii. Exemptions based on vapor pressure shall be demonstrated with calculations using Antoine's equation and average temperature of the liquid surface.

b. Control Equipment

i. Emissions from this emission unit will be controlled by a thermal oxidizer and a gas scrubber. These equipment will meet the conditions set out in Section V.A.4. of this permit. If subject to 40 CFR Part 63 Subpart GGG, it shall also meet the conditions of section V.B of this permit.

c. Abbott shall maintain records which indicate the type of material and amount stored in each tank. The logs must be available at all times for inspection by the technical personnel of the EQB.

d. Tanks subject to 40 CFR Part 63 Subpart GGG, will also meet the applicable conditions included in section V.B. of this permit.

3. EU-18 Solvent Recovery Operations

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
Ethanol Recovery Limit	Ethanol Mixture	1.65E6	gal/year	Record	Quarterly	Logbook	Semiannual
Rule 419 of the RCAP	VOC	3	pounds/hr	Emission calculations	N/A	Keep records with the emission calculations	N/A
		15	pounds/day				
40 CFR Part 63 Subpart GGG	See section V.B. of the permit	---	---	---	---	---	---

Ethanol Recovery Limit [PFE-09-1195-1423-I-C]

i. Abbott shall process a maximum of 1.65E6 gallons per year on the equipment for the recovery of ethanol.

ii. Abbott shall maintain a quarterly record with the amount of ethanol processed, based on a rolling period of 12 months. The logs must be available at all times for inspection by the technical personnel of the EQB.

b. RCAP Rule 419 [state-only enforceable]

i. According to RCAP Rule 419, Abbott will not permit the emission of 3 pounds per hour or 15 pounds per day of VOC in any article, machine, equipment or any other device without an acceptable control system, program or emissions reduction and prevention mechanism or both, as approved or required by the Board.

ii. Abbott will operate the control equipment at all times while emissions are or can be generated during the manufacturing processes in excess of the threshold established by RCAP Rule 419, except as specified under conditions 15 and 16 of Section III of this permit.

c. Control Equipment

i. Emissions from this emission unit will be controlled by a regenerative thermal oxidizer and a gas scrubber. These equipment shall meet the conditions set out in Section V.A.5 of this permit.

d. For those equipment included in this emission unit which are subject to 40 CFR Part 63 Subpart GGG, shall meet the applicable requirements included in section V.B. of this permit.

4. Operating Conditions for Thermal Oxidizer/Gas Scrubber

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
Visible Emissions Limit	Visible Emissions	20	Percentage 6-minutes average	Method 9	Once during the first year of the permit.	With each reading	60 days from each reading  Semiannual
				Visible Emissions	Weekly		
Fuel Consumption Limit	LPG consumption	247,982	gal/year	Flowmeter	Continuous	Record with the monthly fuel consumption	Semiannual
	Diesel consumption	157,680	gal/year				
Sulfur content limit in the fuel	Sulfur Content	0.5 (diesel) 0.003 (LPG)	percentage per weight	Fuel supplier certification	With each fuel receipt	Record with each receipt of fuel sulfur content	Monthly
Control equipment for SO <sub>2</sub> and halogens	Efficiency	SO <sub>2</sub>	95%	Design Evaluation	N/A	Keep copy of the design evaluation	N/A
		Acid Gases	90% <sup>6</sup>				

<sup>6</sup> According to section 63.1252(g) of 40 CFR, a device for reducing the halogens from a combustion control equipment must reduce global emissions of hydrogen halides and halogens by 95%. (For those sources subject to 40 CFR Part 63 Subpart GGG)

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
Thermal Oxidizer Operating Parameters	Combustion temperature	1800	°F	Temperature sensor	Continuous	Log with temperature readings	Semiannual
	Chambers Volume	347.6	ft <sup>3</sup>	Design Evaluation	N/A	Keep copy of the design evaluation	N/A
	Maximum Volumetric Capacity	1,200	cfm	Design Evaluation		Keep copy of the design evaluation	N/A
Thermal Oxidizer Operating Parameters	Residence time	2.26	seconds	Design Evaluation	N/A	Keep copy of the design evaluation	N/A
Gas Scrubber Operating Parameters	Minimum flow of the solution	15	gpm	Flowmeter	Continuous (Every -1-hour)	Hourly records	Semiannual
	pH	9.0	pH	pH Meter	Continuous (Every -1-hour)	Hourly records	Semiannual

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 a. Visible Emissions Limit

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- (i) Abbott shall not exceed the opacity limit of 20% for each unit in a 6-minutes average. 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 interval. [RCAP Rule 403(A)]
  - (ii) Abbott shall hire an independent opacity reader, certified in a school endorsed by the EPA to make one opacity reading on each thermal oxidizer/gas scrubber'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 of the opacity reading.
  - (iii) Abbott 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) Abbott shall notify in writing to the Board at least fifteen (15) days prior to 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 initial sampling results report under Method 9 within 60 days after the tests. This report shall contain the information required under RCAP Rule 106(E).
- (vi) Abbott shall conduct weekly visual opacity inspections of the thermal oxidizer during daylight hours in the chimney stack of the equipment using a Visible Emissions Reader certified by a program endorsed by the EPA or the Board. When the certified reader establishes that the opacity limit under RCAP Rule 403 is being exceeded, Abbott shall verify that the equipment causing the visible emissions is operating in accordance with the manufacturer's specifications and permit conditions. If the unit is not working properly, shall take immediate corrective actions in order to eliminate the excess opacity and shall document the steps taken to correct any deficiencies.
- 1) Weekly visible emission test shall be conducted in accordance with Method 9 of 40 CFR Part 60, Appendix A, for a minimum of 6 minutes, and in accordance with the following requirements:
- a) Abbott shall conduct weekly opacity readings for at least 8 consecutive weeks. If no emissions above the established provisions are observed, then -
- b) Abbott may take the opacity readings once every two weeks for a period of 8 consecutive weeks. If emissions above the limits established in Rule 403 of the RCAP are observed, Abbott shall revert to weekly the frequency of readings (according to subparagraph (a) above) If emissions above the provisions of Rule 203 of the RCAP are not observed, then-
- c) The opacity readings may be performed once per month. If emissions above the provisions of Rule 403 of the RCAP are observed, shall revert the frequency of readings to weekly (according to subparagraph (a) above).
- (d) If the facility reverts to a weekly frequency at any time, the frequency of tests will advance in accordance from the initial frequency. This means that, upon completion of step (a), may proceed to step (b) and subsequently to step (c), if emissions above the provisions of Rule 403 of the RCAP are not observed, and so forth successively.
- (2) All visible emissions readings shall be recorded in accordance with Method 9. Shall prepare and maintain a record indicating the dates and results of the.

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readings, such readings record must be available in the facility at all times for Board personnel to review.

- (3) If the unit is not in operation on the day that corresponds to taking a reading, or the conditions of Method 9 are not met, the permittee shall document such in the readings record, and inform it in the visible emissions summary to be submitted to the Board with the semiannual report required in this permit.
- (vii) The permittee must submit a summary of the visible emissions readings along with the semi-annual reports required in this permit. This report shall include a summary of the results of the readings with their beginning and ending time, and the date when the reading of visible emissions was performed. The report shall also include the total number of visible emission readings made in that period for units subject to this requirement. The permittee shall retain a copy of the visible emission readings including date and time of the reading for at least five years, pursuant to Rule 603 (A) (4) (ii) of the RCAP.
- (viii) The Board reserves the right to require additional visible emissions readings in order to demonstrate compliance with the opacity limit.

 c. Fuel Consumption Limit (PFE-09-0193-0057-I-II-C)

- i. The maximum consumption of LPG fuel to be oxidized in the thermal oxidizer shall not exceed 247,982 gallons per year. If Abbott wants to substitute LPG fuel with diesel in the thermal oxidizer, it may oxidize a maximum of 157,680 gallons of diesel per year, provided Abbott complies with the following:
    - (1) For each gallon of diesel that is oxidized in the thermal oxidizer, 1.57 gallons of LPG will be subtracted from the total of 247,982 gallons of LPG. The result will be the limit of LPG fuel that the facility is allowed to burn in the thermal oxidizer.
    - (2) Shall keep a logbook to record the type and consumption of fuel oxidized monthly, and its sulfur content in weight percent for the thermal oxidizer. This record shall be kept on a 12 month rolling basis. Such record must be available at all times for inspection by the technical personnel of the Board.
    - (3) Shall keep a daily record of the date and time when switching from LPG fuel to diesel fuel.
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ii. The thermal oxidizer must be provided with a diesel flow meter and LPG fuel flow meter at the input to the thermal oxidizer, so that fuel consumption can be verified. Flowmeters shall be calibrated every six months to ensure that the fuel consumption limit is not exceeded. Flowmeters will be operated according to the manufacturer's recommendations. Abbott shall keep calibration documents or logs available in the facility at all times for Board staff review or submission to the Board when required.

c. Fuel sulfur content limit

i. The thermal oxidizer will use a fuel with a maximum sulfur content of 0.5% by weight for diesel and 0.003% by weight for LPG fuel. (PFE-09-0193-0057-I-II-C)

ii. Abbott shall keep a copy of the fuel supplier certification whenever fuel is delivered in the facility. Such certificates shall indicate the fuel sulfur content to demonstrate its compliance with the above condition.

iii. Abbott shall submit a report every six months indicating the monthly fuel consumption, hours of operation and daily fuel sulfur content in weight percent. This report will be sent to the Data Validation and Mathematical Modeling Division of the Air Quality Area of the EQB no later than the next 15 days from the end of each period of six calendar months. A copy of this report must be available at the facility for inspection by the technical personnel of the EQB.

vi. Abbott must submit a summary with the information contained in these reports in the semiannual report required under general condition III.14.

d. Thermal Oxidizer Operating Parameters

i. The thermal oxidizer shall operate under the following operational parameters, according to report submitted on July 23, 2012:

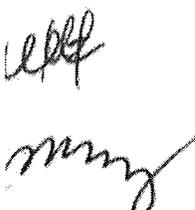
Parameter	Value
Temperature of the combustion chamber	$\geq 1800^{\circ}\text{F}$ (24 hours average)
Chambers Volume	347.6 ft <sup>3</sup>
Maximum Volumetric Load	1,200 cfm

Parameter	Value
Residence time	2.26 seconds (24 hours average)

- ii. Shall maintain a temperature of 1800°F or higher in the thermal oxidizer, based on an average of 24 hours (midnight to midnight). The minimum residence time in the combustion chamber will be 2.26 seconds, based on an average of 24 hours (midnight to midnight).
- iii. The thermal oxidizer shall be provided with a temperature sensor. Abbott must maintain a continuous record indicating the temperatures of the combustion chambers. This record must be kept in the facility at all times for review by the Board personnel or to submit to the Board when required.

e. Gas Scrubber Operating Parameters

- i. The gas scrubber shall operate under the following operational parameters, according to report submitted on July 23, 2012:



Parameter	Value
pH of the caustic solution	≥9.0 (24 hours average)
Minimum flow	15 gpm

- ii. The gas scrubber shall be provided with a pH meter in the caustic solution. Abbott shall keep a record per hour indicating the pH of the solution. This record shall be available at all times for review by the Board technical personnel or to submit to the Board when required.
- iii. The gas scrubber shall be provided with a flowmeter. The flowmeter must be certified by the manufacturer and shall have an accuracy within ± 10% of the design flow. Shall keep a record per hour<sup>7</sup> indicating the average flow for each hour in the scrubber.

<sup>7</sup>Except when controlling emissions subject to 40 CFR Part 63 Subpart GGG, Section 63.1558(b)(1)(ii) of 40 CFR requires that the flow rate is measured and recorded every 15 minutes.

This record shall be available all times for review by the Boards' technical personnel or to be submitted to the Board when required.

- f. Shall maintain and implement a Preventive Maintenance Plan for the thermal oxidizer/gas scrubber. Shall maintain a record of the maintenance performed on the thermal oxidizer and the gas scrubber. This record must be kept in the facility at all times for review by the Boards' technical personnel to submit to the Board when required.
  - g. Abbott shall keep a copy of the control equipment design evaluation, available at all times for inspection by the technical personnel of the EQB.
  - h. The thermal oxidizer and the gas scrubber shall comply with the monitoring requirements included in section V.B. of this permit, when controlling emission sources subject to the requirements of 40 CFR Part 63, Subpart GGG. In case of conflict between the requirements of this section and the requirements included in section V.B. of this permit, the more stringent requirement shall prevail.
- B. Compliance with 40 CFR Part 63, Subpart GGG (National Emission Standards for Pharmaceuticals Production, EU-1 and EU-14)

Applicability [40 CFR §63.1250]

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1. The emission units EU-1 and EU-14 are subject to the national emission standards for hazardous air pollutants for pharmaceutical production included in 40 CFR Part 63 Subpart GGG. Abbott shall comply with the requirements of this subpart and with the applicable requirements of the 40 CFR Part 63 Subpart A, as provided in Table 1 of 40 CFR Subpart GGG.

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According to 40 CFR §63.1250(g)(1), the emission limits in Subpart GGG apply at all times, except that the provisions in §63.1255 of Subpart GGG shall not apply during periods of nonoperation of the PMPU (or specific portion thereof) in which the lines are drained and depressurized resulting in the cessation of the emissions to which §63.1255 of subpart GGG applies.

3. Abbott shall not shutdown items of equipment that are required or utilized for compliance with the emission limitations of subpart GGG during times when emissions (or where applicable, wastewater streams or residuals) are being routed to such items of equipment, if the shutdown would contravene emissions limitations applicable to such items of equipment. This statement does not apply if Abbott must shut down the equipment to avoid damage to a pharmaceutical manufacturing process unit (PMPU) or portion thereof, according to 40 CFR Section 63.1250(g)(2).

4. According to Section 63.1250(g)(3) of the 40 CFR, at all times, Abbott must operate and maintain any affected source subject to the requirements of subpart GGG, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require Abbott to make any further efforts to reduce emissions if levels required by the standards have been achieved. Determination of whether such operation and maintenance procedures are being used will be based on information available to the Board, which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operations and maintenance records, and inspection of the source.
5. According to section 63.1250(g)(4) of 40 CFR, in response to an action to enforce the standards set forth in subpart GGG, Abbott may assert an affirmative defense to claim for civil penalties for exceedances of such standards that are caused by malfunction, as defined at 40 CFR §63.2. Appropriate penalties may be assessed, however, if Abbott fails to meet the burden of proving all the requirements in the affirmative defense, as provided in 40 CFR §63.1250(g)(4).
  - a. According to §63.1250(g)(4)(ii), if Abbott experiences an exceedance of its emission limits during a malfunction, Abbott shall notify the EQB by telephone or fax as soon as possible, but no later than 2 business days after the initial occurrence of the malfunction, if it wishes to avail itself of an affirmative defense to civil penalties for that malfunction. If seeking to assert an affirmative defense, Abbott shall also submit a written report to the EQB within 45 days of the initial occurrence of the exceedance of the standard in subpart GGG to demonstrate, with all necessary supporting documentation, that it has met the requirements set forth in §63.1250(g)(4)(i). Abbott may seek an extension of this deadline for up to 30 additional days by submitting a written request to the EQB before the expiration of the 45 day period. Until a request for an extension has been approved by the EQB, Abbott is subject to the requirement to submit such report within 45 days of the initial occurrence of the exceedance.

Standards: General [40 CFR §63.1252]

6. Opening of a safety device - As provided in 40 CFR §63.1252(a), Abbott can open a safety device, as defined in §63.1251, at any time conditions require it to do so to avoid unsafe conditions.
7. Closed-vent systems - According to 40 CFR Section 63.1252(b), closed vent systems that contain bypass lines that could divert a vent stream away from a control device used to comply with the requirements in §63.1253, 63.1254 and 63.1256, shall comply with the requirements of Table 4 to Subpart GGG and the following requirements in §63.1252(b)(1) and (2) of 40

CFR. Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and pressure relief valves needed for safety purposes are not subject to this requirements.

- a. Shall install, calibrate, maintain, and operate a flow indicator that determines whether vent stream flow is present at least once every 15 minutes. Records shall be maintained as specified in § 63.1259(i)(6)(i). The flow indicator shall be installed at the entrance to any bypass line that could divert the vent stream away from the control device to the atmosphere; or
- b. Shall secure the bypass line valve in the closed position with a car seal or lock and key type configuration. A visual inspection of the seal or closure mechanism shall be performed at least once every month to ensure that the valve is maintained in the closed position and the vent stream is not diverted through the bypass line. Records shall be maintained as specified in 40 CFR §63.1259(i)(6)(i).

8. Heat exchange systems - Except as provided in 40 CFR §63.1252(c)(2), heat exchange systems that cool process equipment or materials used in pharmaceutical manufacturing operations shall comply with the requirements in 40 CFR § 63.104, except that the monitoring frequency shall be no less than quarterly. For identifying leaking equipment, the owner or operator of heat exchange systems on equipment which meet current good manufacturing practice (cGMP) requirements of 21 CFR Part 211 may elect to use the physical integrity of the reactor as the surrogate indicator of heat exchange system leaks around the reactor.

9. Control requirements for certain liquid streams in open systems within a PMPU [40 CFR §63.1252 (f)] - Abbott shall comply with the provisions of Table 5 of Subpart GGG, for each item of equipment meeting all the criteria specified in paragraphs (f)(2) through (4) and either paragraph (f)(5)(i) or (ii) of 40 CFR §63.1252:

- a. The item of equipment is of a type identified in Table 5 to 40 CFR Subpart GGG. [40 CFR §63.1252 (f)(2)]
- b. The item of equipment is part of a PMPU, as defined in 40 CFR §63.1251. [40 CFR §63.1252(f)(3)]
- c. The item of equipment is controlled less stringently than in Table 5 of this subpart and the item of equipment is not otherwise exempt from controls by the provisions of Subpart GGG or Subpart A and; [40 CFR §63.1252 (f)(4)]

d. The item of equipment:

- i. Is a drain, drain hub, manhole, lift station, trench, pipe, or oil/water separator that conveys water with an annual average concentration greater than or equal to 1,300 ppmw of partially soluble HAP compounds; or an annual average concentration greater than or equal to 5,200 ppmw of partially soluble and/or soluble HAP compounds. The annual average concentration shall be determined according to the procedures in 40 CFR § 63.1257(e)(1)(ii). [40 CFR §63.1252(f)(5)(i)]
- ii. Is a tank that receives one or more streams that contain water with an annual average concentration greater than or equal to 1,300 ppmw of partially soluble HAP compounds, or greater than or equal to 5,200 ppmw of total partially soluble and/or soluble HAP compounds. The owner or operator shall determine the average concentration of the stream at the inlet to the tank and according to the procedures in 40 CFR §63.1257(e)(1)(ii). [40 CFR §63.1252(f)(5)(ii)]

10. Control requirements for halogenated vent streams that are controlled by combustion devices – In compliance with the section §63.1252(g) of the 40 CFR, the halogenated vent streams treated with a combustion device to comply with the provisions of §63.1253 (storage tanks, EU-14) and 63.1254 (process vents, EU-1) shall be ducted to a halogen reduction device such as, but not limited to, a scrubber, before it is discharged to the atmosphere. The scrubber must reduce overall emissions of hydrogen halides and halogens by 95%<sup>8</sup>.

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Standards: Storage Tanks, EU-14 [40 CFR §63.1253]

11. Abbott must meet the standards for storage tanks included in §63.1256(b)(1) of the 40 CFR, as provided in that section. As primary compliance strategy, storage tanks will be equipped with a closed vent system with a control device<sup>9</sup> that reduces total HAP emissions from the equipment input by 90 percent by weight or greater.<sup>10</sup> Compliance with these provisions

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<sup>8</sup>The PFE-09-0193-0057-I-II-C permit establishes an efficiency for the scrubber of 90% for HCl, HF and HBr<sub>2</sub>. However Abbott must meet a minimum efficiency of 95% when controlling emission sources subject to 40 CFR Part 63 Subpart GGG.

<sup>9</sup>According to its compliance strategy, Abbott will use a closed ventilation system connected to a thermal oxidizer/scrubber to control emissions from storage tanks. As an alternate scenario, tank emissions will be controlled connecting the closed vent system to an EFVCS (See Section V.B. of this permit).

<sup>10</sup>The PFE-09-0193-0057-I-II-C permit requires a minimum efficiency of 99% for VOCs and HAPs.

shall be determined in accordance with the procedures of Section 63.1257(c) of the 40 CFR and monitoring requirements of Section 63.1258 of the 40 CFR.

12. Planned Routine Maintenance – The specifications and requirements in the above condition for control devices do not apply during periods of planned routine maintenance. Periods of planned routine maintenance of the control devices during which the control device does not meet the specifications of the above condition shall not exceed 240 hours in any 365 day period. Abbott may submit an application to the Administrator requesting an extension of this time limit to a total of 360 hours in any 365 days period. The application must explain why the extension is needed; it must specify that no material will be added to the storage tank between the time the 240-hour limit is exceeded and the control device is again operational, and it must be submitted at least 60 days before the 240-hour limit will be exceeded. [40 CFR §63.1253(e)]

Standards: Process vents, EU-1 [40 CFR §63.1254]

13. For each process, Abbott must comply with the requirements in Section 63.1254(a) of the 40 CFR. Compliance with these provisions shall be demonstrated in accordance with the procedures of Section 63.1257(d) of the 40 CFR and the monitoring requirements of Section 63.1258 of the 40 CFR. According to its primary compliance strategy, Abbott will comply with the process vents provisions included in Section 63.1254(a)(1) of the 40 CFR. Uncontrolled HAP emissions from process vents should be reduced by 93% or more.<sup>11</sup> Notification of changes in the method of compliance shall be reported in accordance with the procedures in 40 CFR §63.1260(h).

14. One or more vents within a process could be controlled using the EFVCS, in compliance with §63.1254(a)(1)(ii)(B). The flare will comply with the requirements of §63.11(b) of the 40 CFR.

Standards: Equipment Leaks [40 CFR §63.1255]

15. General Equipment Leaks Requirements [40 CFR §63.1255(a)]
- a. The provisions of 40 CFR §63.1255 apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems required by 40 CFR Part 63, Subpart GGG that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year within a

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<sup>11</sup>According to the permit PFE-09-0193-0057-I-II-C, the thermal oxidizer will have a 99% removal efficiency for VOC and HAPs.

source subject to the provisions of 40 CFR Part 63, Subpart GGG. [40 CFR §63.1255(a)(1)]

- b. The provisions in section 63.1(a)(3), Subpart A of part 63 do not alter the provisions of paragraph (a)(2) of section 63.1255. [40 CFR §63.1255(a)(4)]
- c. Lines and equipment not containing process fluids are not subject to the provisions of 40 CFR Section 63.1255. Utilities, and other non-process lines, such as heating and cooling systems which do not combine their materials with those in the processes they serve, are not considered to be part of a process. [40 CFR §63.1255(a)(5)]
- d. The provisions of this section do not apply to bench-scale<sup>12</sup> processes, regardless of whether the processes are located at the same plant site as a process subject to the provisions of 40 CFR Part 63, Subpart GGG. [40 CFR §63.1255(a)(6)]
- e. The equipment to which section 63.1255 applies shall be identified so that it can be distinguished readily from equipment that is not subject to section 40 CFR 63.1255. Identification of the equipment does not require physical tagging of the equipment. For example, the equipment may be identified on a plant site plan, in log entries, or by designation of process boundaries by some form of weatherproof identification. If changes are made to the affected source subject to the leak detection requirements, equipment identification for each type of component shall be updated, if needed, within 90 calendar days or by the next Periodic Report following the end of the monitoring period for that component, whichever is later.[40 CFR §63.1255(a)(7)]
- f. Equipment that is in vacuum service is excluded from the requirements of 40 CFR Section 63.1255. [40 CFR §63.1255(a)(8)]
- g. Equipment that is in organic HAP service, but is in such service less than 300 hours per calendar year, is excluded from the requirements section 63.1255 if it is identified as required in paragraph (g)(9) of section 63.1255. [40 CFR §63.1255(a)(9)]
- h. In accordance with 40 CFR §63.1255 (a)(10), when each leak is detected by visual, audible, or olfactory means, or by monitoring as described in § 63.180(b) or (c), the following requirements apply:

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<sup>12</sup>*Bench-scale* refers to a batch process (other than a research and development facility) which can be located on top of a lab bench. This bench-scale equipment typically includes a reagent supply vessel, a small reactor and associated equipment for separation, recovery and containment of product. These processes are capable of producing only small amounts of product.

- i. A weatherproof and readily visible identification, marked with the equipment identification number, shall be attached to the leaking equipment. [40 CFR §63.1255(a)(10)(i)]
  - ii. The identification on a valve in light liquid or gas/vapor service may be removed after it has been monitored as specified in paragraph (e)(7)(iii) of section 63.1255, and no leak has been detected during the follow-up monitoring. [40CFR §63.1255 (a)(10)(ii)]
  - iii. The identification on equipment, except on a valve in light liquid or gas/vapor service, may be removed after it has been repaired. [40CFR §63.1255 (a)(10)(iii)]
- i. Except as provided in paragraph (a)(11)(i) of Section 63.1255, all terms in Subpart GGG that define a period of time for completion of required tasks (e.g., weekly, monthly, quarterly, annual) refer to the standard calendar periods unless specified otherwise in the section or paragraph that imposes the requirement. [40 CFR §63.1255(a)(11)]
- i. If the initial compliance date does not coincide with the beginning of the standard calendar period, Abbott may elect to utilize a period beginning on the compliance date, or may elect to comply in accordance with the provisions of paragraph (a)(11)(ii) or (iii) of 40 CFR Section 63.1255. [40 CFR §63.1255(a)(11)(i)]
  - ii. Time periods specified in Subpart GGG for completion of required tasks may be changed by mutual agreement between Abbott and the Administrator, as specified in subpart A of Part 63. For each time period that is changed by agreement, the revised period shall remain in effect until it is changed. A new request is not necessary for each recurring period. [40 CFR §63.1255(a)(11)(ii)]
  - iii. Except as provided in paragraph (a)(11)(i) or (ii) of section 63.1255, where the period specified for compliance is a standard calendar period, if the initial compliance date does not coincide with the beginning of the calendar period, compliance shall be required according to the schedule specified in paragraph (a)(11)(iii)(A) or (B) of section 63.1255, as appropriate. [40 CFR §63.1255(a)(11)(ii)]
    - (A) Compliance shall be required before the end of the standard calendar period within which the initial compliance date occurs if there remain at least 3 days for tasks that must be performed weekly, at least 2

weeks for tasks that must be performed monthly, at least 1 month for tasks that must be performed each quarter, or at least 3 months for tasks that must be performed annually; or [40CFR §63.1255(a)(11)(iii)(A)]

(B) In all other cases, compliance shall be required before the end of the first full standard calendar period after the period within which the initial compliance date occurs. [40 CFR §63.1255 (a)(11)(iii)(B)]

iv. In all instances where a provision of subpart GGG requires completion of a task during each of multiple successive periods, Abbott may perform the required task at any time during each period, provided the task is conducted at a reasonable interval after completion of the task during the previous period. [40 CFR §63.1255 (a)(11)(iv)]

j. In all cases where the provisions subpart GGG require an owner or operator to repair leaks by a specified time after the leak is detected, it is a violation of 40 CFR Section 63.1255 to fail to take action to repair the leaks within the specified time. If action is taken to repair the leaks within the specified time, failure of that action to successfully repair the leak is not a violation of 40 CFR Section 63.1255. However, if the repairs are unsuccessful, a leak is detected and the owner or operator shall take further action as required by applicable provisions under Section 63.1255 of the 40 CFR. [40 CFR §63.1255(a)(12)]

16. References [40 CFR §63.1255(b)]

a. The owner or operator of a source subject to section 63.1255 shall comply with the provisions of subpart H of part 63, as specified in paragraphs (b)(2) through (4) of Section 63.1255. The term "process unit" as used in Subpart H of Part 63 shall be considered to be defined the same as "group of processes" for sources subject to Subpart GGG. The term "fuel gas system," as used in Subpart H of Part 63, shall not apply for the purposes of Subpart GGG. [40 CFR §63.1255(b)(1)]

b. Sections 63.160, 63.161, 63.162, 63.163, 63.167, 63.168, 63.170, 63.173, 63.175, 63.176, 63.181 and 63.182 shall not apply for purposes of Subpart GGG. Abbott shall comply with the provisions specified in paragraphs (b)(2)(i) through (viii) of section 63.1255. [40 CFR §63.1255(b)(2)]

i. Sections 63.160 and 63.162 shall not apply; however, Abbott shall comply with paragraph (a) of Section 63.1255 of the 40 CFR. [40 CFR §63.1255(b)(2)(i)]

- ii. Section 63.161 shall not apply; however, Abbott shall comply with Section 63.1251 of the 40 CFR. [40 CFR §63.1255(b)(2)(ii)]
  - iii. Sections 63.163 and 63.173 shall not apply; however, Abbott shall comply with paragraph (c) of Section 63.1255 of the 40 CFR. [40 CFR §63.1255(b)(2)(iii)]
  - iv. Section 63.167 shall not apply; however, Abbott shall comply with paragraph (d) of Section 63.1255 of the 40 CFR. [40 CFR §63.1255(b)(2)(iv)]
  - v. Section 63.168 shall not apply; however, Abbott shall comply with paragraph (e) of Section 63.1255 of the 40 CFR. [40 CFR §63.1255(b)(2)(v)]
  - vi. Section 63.170 shall not apply; however, Abbott shall comply with Section 63.1254 of the 40 CFR. [40 CFR §63.1255(b)(2)(vi)]
  - vii. Section 63.181 shall not apply; however, Abbott shall comply with paragraph (g) of Section 63.1255 of the 40 CFR. [40 CFR §63.1255(b)(2)(vii)]
  - viii. Section 63.182 shall not apply; however, Abbott shall comply with paragraph (h) of Section 63.1255 of the 40 CFR. [40 CFR §63.1255(b)(2)(viii)]
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- c. Abbott shall comply with 40 CFR Sections 63.164, 63.165, 63.166, 63.169, 63.177 and 63.179 of the 40 CFR in their entirety, except where this sections reference other sections of Subpart H of Part 63, the references shall mean the sections specified in paragraphs (b)(2) and (4) of Section 63.1255 of the 40 CFR. Section 60.164 of the 40 CFR applies to compressors. Section 63.165 of the 40 CFR applies to pressure relief equipment in gas/vapor service. 40 CFR Section 63.166 applies to sampling connection systems. Section 63.169 of the 40 CFR applies to pumps, valves, connectors and agitators in heavy liquid service; instrumentation systems and pressure relief equipment in liquid service. Section 63.177 of the 40 CFR applies to general alternative means of emissions limitation. Section 40 CFR 63.179 applies to alternative means of emissions limitation for enclosed-vented process units. [40 CFR §63.1255(b)(3)]
  - d. Abbott shall comply with Sections 63.171, 63.172, 63.174, 63.178 and 63.180 of the 40 CFR, except as specified in paragraphs (b)(4)(i) to (vi) of Section 63.1255 of the 40 CFR. [40 CFR §63.1255(b)(4)]
    - i. Section 63.171 shall apply; except §63.171(a) of the 40 CFR shall not apply. Instead, delay of repair of equipment for which leaks have been detected is

allowed if one of the conditions in the following paragraphs (d)(i)(A) through (B) exists:

- (A) The repair is technically infeasible without a process shutdown. Repair of this equipment shall occur by the end of next scheduled process shutdown. [40 CFR §63.1255(b)(4)(i)(A)]
- (B) Abbott determines that repair personnel would be exposed to an immediate danger if attempting to repair without a process shutdown. Repair of this equipment shall occur by the end of next scheduled process shutdown. [40 CFR §63.1255(b)(4)(i)(B)]

ii. Section 63.172 of the 40 CFR shall apply for closed-vent systems used to comply with 40 CFR Section 63.1255, and for control devices used to comply with Section 63.1255 of the 40 CFR only, except:

- (A) Section 63.172(k) and (l) shall not apply. Abbott shall instead comply with paragraph (f) of Section 63.1255 of the 40 CFR. [40 CFR §63.1255(b)(4)(ii)(A)]
- (B) Abbott may, instead of complying with the provisions of §63.172(f) of the 40 CFR, design a closed-vent system to operate at a pressure below atmospheric pressure. The system shall be equipped with at least one pressure gage or other pressure measuring equipment that can be read from a readily accessible location to verify that negative pressure is being maintained in the closed-vent system when the associated control equipment is operating. [40 CFR §63.1255(b)(4)(ii)(B)]
- (C) The requirements apply at all times, except as specified in §63.1250(g) of the 40 CFR. Abbott may not comply with the planned routine maintenance provisions under Section 63.1252(h) of the 40 CFR. [40 CFR §63.1255(b)(4)(ii)(C)]

iii. Section 63.174 of the 40 CFR shall apply, except:

- (A) Sections 63.174(f), (g) and (h) shall not apply. Instead of §63.174(f), (g) and (h), Abbott shall comply with paragraph (f) of Section 63.1255. Section 63.174(b)(3) shall not apply. Instead of §63.174(b)(3), Abbott shall comply with paragraphs (b)(4)(iii)(B) through (F) of section 63.1255. [40 CFR §63.1255(b)(4)(iii)(A)]

- (B) If the percent leaking connectors in a group of processes was greater than or equal to 0.5% during the initial monitoring period, monitoring shall be performed once per year until the percent leaking connectors is less than 0.5%. [40 CFR §63.1255(b)(4)(iii)(B)]
- (C) If the percent leaking connectors in the group of processes was less than 0.5 percent, but equal to or greater than 0.25 percent, during the initial or last required monitoring period, Abbott may elect to monitor once every 4 years. An owner or operator may comply with the requirements of paragraph (b)(4)(iii)(C) of Section 63.1255, by monitoring at least 40% of the connectors in the first 2 years and the remainder of the connectors within the next 2 years. The percent leaking connectors will be calculated for the total of all required monitoring performed during the 4-year period. [40 CFR §63.1255 (b) (4) (iii) (C)]
- (D) Except as provided in paragraph (b)(4)(iii)(B) of section 63.1255, if leaking connectors comprise at least 0.5 percent but less than 1.0 percent of the connectors during the last monitoring period, Abbott shall monitor at least once every 2 years for the next monitoring period. At the end of that 2-year monitoring period, if the percent leaking connectors is greater than or equal to 0.5%, Abbott shall monitor once per year until the percent leaking connectors is less than 0.5%. If at the end of a monitoring period, the percent leaking connectors is less than 0.5 percent, Abbott shall monitor in accordance with paragraph (b)(4)(iii)(C) or (F) of section 63.1255, as appropriate. [40 CFR §63.1255(b)(4)(iii)(D)]
- (E) If Abbott determines that 1% or more of the connectors in a group of processes are leaking, Abbott shall monitor the connectors once a year. Abbott may elect to use the provisions of paragraphs (b)(4)(iii)(C), (D) or (F) of section 63.1255 of the 40 CFR, as appropriate, after a monitoring period in which less than 1 percent of the connectors are determined to be leaking. [40 CFR §63.1255(b)(4)(iii)(E)]
- (F) Abbott may elect to perform monitoring once every 8 years if the percent leaking connectors in the group of processes was less than 0.25% during the initial or last required monitoring period. Abbott shall monitor at least 50 percent of the connectors in the first 4 years



and the remainder of the connectors within the next 4 years. If the percent leaking connectors in the first 4 years is equal to or greater than 0.35 percent, the monitoring program shall revert at that time to the appropriate monitoring frequency specified in paragraph (b)(4)(iii)(C), (D), or (E) of section 63.1255. [40 CFR §63.1255(b)(4)(iii)(F)]

- iv. Section 63.178 of the 40 CFR shall apply, except:
- (A) Section 63.178(b), requirements for pressure testing, may be applied to all processes (not just batch processes) and to supply lines between storage and processing areas. [40 CFR §63.1255(b)(4)(iv)(A)]
  - (B) For pumps, the phrase “at the frequencies specified in Table 1 of this subpart” in § 63.178(c)(3)(iii) shall mean “quarterly” for the purposes of Subpart GGG. [40 CFR §63.1255(b)(4)(iv)(B)]
- v. Section 63.180 shall apply except § 63.180(b)(4)(ii)(A) through (C) shall not apply. Instead, calibration gases shall be a mixture of methane and air at a concentration of approximately, but less than, 10,000 parts per million methane for agitators; 2,000 parts per million for pumps; and 500 parts per million for all other equipment, except as provided in § 63.180(b)(4)(iii). [40 CFR §63.1255(b)(4)(v)]
- vi. When sections 63.171, 63.172, 63.174, 63.178, and 63.180 reference other sections in subpart H part 63, the references shall mean those sections specified in paragraphs (b)(2) and (b)(4)(i) through (v) of section 63.1255, as applicable. [40 CFR §63.1255(b)(4)(vi)]

17. Standards for pumps in light liquid service and agitators in gas/vapor service and in light liquid service [40 CFR §63.1255(c)]
- a. The provisions of Section 63.1255 of the 40 CFR apply to each pump that is in light organic HAP liquid service, and to each agitator in organic HAP gas/vapor service or in light organic HAP liquid service. [40 CFR §63.1255(c)(1)]
  - b. i. Monitoring. Each pump and agitator subject to this section shall be monitored quarterly to detect leaks by the method specified in § 63.180(b) except as provided in §63.177, §63.178, paragraph (f) of Section 63.1255, and paragraphs (c)(5) through (9) of Section 63.1255 of the 40 CFR. [40 CFR §63.1255(c)(2)(i)]

- ii. Leak definition. In accordance with 40 CFR §63.6625, the instrument reading, as determined by the method specified in §63.180(b), that defines a leak is:
  - (A) For agitators, an instrument reading of 10,000 parts per million or greater. [40 CFR §63.1255(c)(2)(ii)(A)]
  - (B) For pumps, an instrument reading of 2,000 parts per million or greater. [40 CFR §63.1255(c)(2)(ii)(B)]
  
- iii. Visual inspections - Each pump and agitator shall be checked by visual inspection each calendar week for indications of liquids dripping from the pump or agitator seal. If there are indications of liquids dripping from the pump or agitator seal at the time of the weekly inspection, Abbott shall follow the procedure specified in either paragraph (c)(2)(iii)(A) or (B) of Section 63.1255 of the 40 CFR prior to the next weekly inspection: [40 CFR §63.1255(C)(2)(iii)]
  - (A) Abbott shall monitor the pump or agitator by the method specified in §63.180(b). If the instrument reading indicates a leak as specified in §63.1255(c)(2)(ii), a leak is detected. [40 CFR §63.1255(c)(2)(iii)(A)]
  - (B) Abbott shall eliminate the visual indications of liquids dripping. [40 CFR §63.1255(c)(2)(iii)(B)]
  
- c. Repair provisions. [40 CFR §63.1255(c)(3)]
  - i. When a leak is detected pursuant to paragraphs (c)(2)(i), (c)(2)(ii)(A), (c)(5)(iv)(A) or (c)(5)(vi)(B) of section 63.1255, it shall be repaired as soon as practicable, but not later than 15 calendar days after it is detected, except as provided in paragraph (b)(4)(i) of section 63.1255. [40 CFR §63.1255(c)(3)(i)]
  
  - ii. According to 40 CFR §63.1255(c)(3)(ii), a first attempt at repair shall be made no later than 5 calendar days after the leak is detected. First attempts at repair include, but are not limited to, the following practices where practicable:
    - (A) Tightening of packing gland nuts. [40 CFR §63.1255(c)(3)(ii)(A)]
    - (B) Ensuring that the seal flush is operating at design pressure and temperature. [40 CFR §63.1255(c)(3)(ii)(B)]

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- d. Calculation of percent leakers [40 CFR §63.1255(c)(4)]
- i. Abbott shall decide no later than the end of the first monitoring period what groups of processes will be developed. Once Abbott has decided, all subsequent percent calculations shall be made on the same basis. [40 CFR §63.1255(c)(4)(i)]
  - ii. If, calculated on a 1-year rolling average, the greater of either 10 percent or three of the pumps in a group of processes leak, Abbott shall monitor each pump once per month, until the calculated 1-year rolling average value drops below 10 percent or three pumps, as applicable. [40 CFR §63.1255(c)(4)(ii)]
  - iii. The number of pumps in a group of processes shall be the sum of all the pumps in organic HAP service, except that pumps found leaking in a continuous process within 1 quarter after startup of the pump shall not count in the percent leaking pumps calculation for that one monitoring period only. [40 CFR §63.1255(c)(4)(iii)]

- iv. In accordance with 40 CFR §63.1255(c)(4)(iv), percent leaking pumps shall be determined by the following equation:

$$\%P_L = [(P_L - P_S) / (P_T - P_S)] \times 100, \text{ where}$$

$\% P_L$  = percent leaking pumps.

$P_L$  = number of pumps found leaking as determined through periodic monitoring as required in paragraphs (c)(2)(i) and (ii) of section 63.1255.

$P_T$  = total pumps in organic HAP service, including those meeting the criteria in paragraphs (c)(5) and (6) of section 63.1255.

$P_S$  = number of pumps in a continuous process leaking within 1 quarter of startup during the current monitoring period.

- e. Exemptions. In accordance with 40 CFR §63.1255 (c) (5), each pump or agitator equipped with a dual mechanical seal system that includes a barrier fluid system is exempt from the requirements of paragraphs (c)(1) through (c)(4)(iii) of section 63.1255, provided the following requirements are met:

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- i. Each dual mechanical seal system is:
  - (A) Operated with the barrier fluid at a pressure that is at all times greater than the pump/agitator stuffing box pressure; or [40 CFR §63.1255(c)(5)(i)(A)]
  - (B) Equipped with a barrier fluid degassing reservoir that is connected by a closed-vent system to a control device that complies with the requirements of paragraph (b)(4)(ii) of Section 63.1255; or [40 CFR §63.1255(c)(5)(i)(B)]
  - (C) Equipped with a closed-loop system that purges the barrier fluid into a process stream. [40 CFR §63.1255(c)(5)(i)(C)]
- ii. The barrier fluid is not in light liquid service. [40 CFR §63.1255(c)(5)(ii)]
- iii. Each barrier fluid system is equipped with a sensor that will detect failure of the seal system, the barrier fluid system, or both. [40 CFR §63.1255(c)(5)(iii)]
- iv. Each pump/agitator is checked by visual inspection each calendar week for indications of liquids dripping from the pump/agitator seal. If there are indications of liquids dripping from the pump or agitator seal at the time of the weekly inspection, Abbott shall follow the procedures specified in either paragraph (c)(5)(iv)(A) or (B) of section 63.1255 prior to the next required inspection. [40 CFR §63.1255(c)(5)(iv)]
  - (A) Abbott shall monitor the pump or agitator using the method specified in § 63.180(b) to determine if there is a leak of organic HAP in the barrier fluid. If the instrument reading indicates a leak, as specified in paragraph (c)(2)(ii) of section 63.1255, a leak is detected. [40 CFR §63.1255(c)(5)(iv)(A)]
  - (B) Abbott shall eliminate the visual indications of liquids dripping. [40 CFR §63.1255(c)(5)(iv)(B)]
- v. Each sensor as described in paragraph (c)(5)(iii) of section 63.1255 is observed daily or is equipped with an alarm unless the pump is located within the boundary of an unmanned plant site. [40 CFR §63.1255(c)(5)(v)]

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- vi. (A) Abbott determines, based on design considerations and operating experience, criteria applicable to the presence and frequency of drips and to the sensor that indicate failure of the seal system, the barrier fluid system, or both. [40 CFR §63.1255(c)(5)(vi)(A)]
  - (B) If indications of liquids dripping from the pump/agitator seal exceed the criteria established in paragraph (c)(5)(vi)(A) of section 63.1255, or if, based on the criteria established in paragraph (c)(5)(vi)(A) of Section 63.1255, the sensor indicates failure of the seal system, the barrier fluid system, or both, a leak is detected. [40 CFR §63.1255(c)(5)(vi)(B)]
- vii. When a leak is detected pursuant to paragraph (c)(5)(iv)(A) or (B) of Section 63.1255, the leak must be repaired as specified in paragraph (c)(3) of Section 63.1255. [40 CFR §63.1255(c)(5)(vii)]
- f. Any pump/agitator that is designed with no externally actuated shaft penetrating the pump/agitator housing is exempt from the requirements of paragraphs (c)(1) through (3) of 40 CFR Section 63.1255. [40 CFR §63.1255(c)(6)]
- g. Any pump/agitator equipped with a closed-vent system capable of capturing and transporting any leakage from the seal or seals back to the process or to a control device that complies with the requirements of paragraph (b)(4)(ii) of Section 63.1255 is exempt from the requirements of paragraphs (c)(2) through (5) of Section 63.1255. [40 CFR §63.1255(c)(7)]
- h. Any pump/agitator that is located within the boundary of an unmanned plant site is exempt from the weekly visual inspection requirement of paragraphs (c)(2)(iii) and (c)(5)(iv) of Section 63.1255, and the daily requirements of paragraph (c)(5)(v) of Section 63.1255, provided that each pump/agitator is visually inspected as often as practicable and at least monthly. [40 CFR §63.1255(c)(8)]
- i. If more than 90 percent of the pumps in a group of processes meet the criteria in either paragraph (c)(5) or (6) of section 63.1255 of the 40 CFR, the group of processes is exempt from the requirements of paragraph (c)(4) of 40 CFR §63.1255. [40 CFR §63.1255(c)(9)]

18. Standards: Open-ended valves or lines [40 CFR §63.1255(d)]

- a. i. Each open-ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve, except as provided in § 63.177 and paragraphs (d)(4) through (6) of section 63.1255 of the 40 CFR, [40 CFR §63.1255(d)(1)(i)]
- ii. The cap, blind flange, plug, or second valve shall seal the open end at all times except during operations requiring process fluid flow through the open-ended valve or line, or during maintenance or repair. The cap, blind flange, plug, or second valve shall be in place within 1 hour of cessation of operations requiring process fluid flow through the open-ended valve or line or within 1 hour of cessation of maintenance or repair. The owner or operator is not required to keep a record documenting compliance with the 1-hour requirement. [40 CFR §63.1255(d)(1)(ii)]
- b. Each open-ended valve or line equipped with a second valve shall be operated in a manner such that the valve on the process fluid end is closed before the second valve is closed. [40 CFR §63.1255(d)(2)]
- c. When a double block and bleed system is being used, the bleed valve or line may remain open during operations that require venting the line between the block valves but shall comply with paragraph (d)(1) of section 63.1255 at all other times. [40 CFR §63.1255(d)(3)]
- d. Open-ended valves or lines in an emergency shutdown system which are designed to open automatically in the event of a process upset are exempt from the requirements of paragraphs (d)(1) through (d)(3) of section 63.1255. [40 CFR §63.1255(d)(4)]
- e. Open-ended valves or lines containing materials which would autocatalytically polymerize are exempt from the requirements of paragraphs (d)(1) through (d)(3) of section 63.1255. [40 CFR §63.1255(d)(5)]
- f. Open-ended valves or lines containing materials which could cause an explosion, serious overpressure, or other safety hazard if capped or equipped with a double block and bleed system as specified in paragraphs (d)(1) (d)(3) of section 63.1255 are to exempt from the requirements of paragraphs (d)(1) through (d)(3) of section 63.1255. [40 CFR §63.1255(d)(6)]

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19. Standards: Valves in gas/vapor service and in light liquid service [40 CFR §63.1255(e)]
- a. The provisions of section 63.1255 apply to valves that are either in gas organic HAP service or in light liquid organic HAP service. [40 CFR §63.1255(e)(1)]
  - b. For existing and new affected sources, all valves subject to this section shall be monitored, except as provided in paragraph (f) of section 63.125 and in section 63.177, by no later than 1 year after the compliance date. [40 CFR §63.1255(e)(2)]
  - c. Monitoring. According to 40 CFR §63.1255(e)(3), the owner or operator of a source subject to §63.1255 shall monitor all valves, except as provided in paragraph (f) of §63.1255 and in §63.177, at the intervals specified in paragraph (e)(4) of this section and shall comply with all other provisions of this section, except as provided in paragraph (b)(4)(i) of section 63.1255, sections 63.178 and §63.179.
    - i. The valves shall be monitored to detect leaks by the method specified in section 63.180(b). [40 CFR §63.1255(e)(3)(i)]
    - ii. An instrument reading of 500 parts per million or greater defines a leak. [40 CFR §63.1255(e)(3)(ii)]
  - d. Subsequent monitoring frequencies. In accordance with 40 CFR §63.1255(e)(4), after conducting the initial survey required in paragraph (e)(2) of section 63.1255, Abbott shall monitor valves for leaks at the intervals specified below:
    - i. For a group of processes with 2% or greater leaking valves, calculated according to paragraph (e)(6) of section 63.1255, Abbott shall monitor each valve once per month, except as specified in paragraph (e)(9) of §63.1255 of the 40 CFR. [40 CFR §63.1255(e)(4)(i)]
    - ii. For a group of processes with less than 2% leaking valves, Abbott shall monitor each valve once each quarter, except as provided in paragraphs (e)(4)(iii) through (e)(4)(v) of Section 63.1255 of the 40 CFR. [40 CFR §63.1255(e)(4)(ii)]
    - iii. For a group of processes with less than 1 percent leaking valves, Abbott may elect to monitor each valve once every 2 quarters. [40 CFR §63.1255(e)(4)(iii)]

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- iv. For a group of processes with less than 0.5 percent leaking valves, Abbott may elect to monitor each valve once every 4 quarters (every 12 months). [40 CFR §63.1255(e)(4)(iv)]
- v. For a group of processes with less than 0.25% leaking valves, Abbott may elect to monitor each valve once every 2 years. [40 CFR §63.1255(e)(4)(v)]
- e. Calculation of percent leakers. In accordance with 40 CFR §63.1255(e)(5) to a group of processes to which subpart GGG applies, Abbott may choose to subdivide the valves in the applicable groups of processes and apply the provisions of paragraph (e)(4) of section 63.1255 for each subgroup. If Abbott elects to subdivide the valves in the applicable group of processes, then the provisions of paragraphs (e)(5)(i) through (e)(5)(viii) of Section 63.1255 apply.
  - i. The overall performance of total valves in the applicable group of processes must be less than 2% leaking valves, as detected according to paragraphs (e)(3)(i) and (ii) of this section and as calculated according to paragraphs (e)(6)(ii) and (iii) of 40 CFR section 63.1255 of the 40 CFR. [40 CFR §63.1255(e)(5)(i)]
  - ii. The initial assignment or subsequent reassignment of valves to subgroups shall be governed by the provisions of paragraphs (e)(5)(ii) (A) through (C) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(e)(5)(ii)]
    - (A) Abbott shall determine which valves are assigned to each subgroup. Valves with less than 1 year of monitoring data or valves not monitored within the last 12 months must be placed initially into the most frequently monitored subgroup until at least 1 year of monitoring data has been obtained. [40 CFR §63.1255(e)(5)(ii)(A)]
    - (B) Any valve or group of valves can be reassigned from a less frequently monitored subgroup to a more frequently monitored subgroup provided that the valves to be reassigned were monitored during the most recent monitoring period for the less frequently monitored subgroup. The monitoring results must be included with the less frequently monitored subgroup's monitoring event and associated next percent leaking valves calculation for that group. [40 CFR §63.1255 (e)(5)(ii)(B)]

(C) Any valve or group of valves can be reassigned from a more frequently monitored subgroup to a less frequently monitored subgroup provided that the valves to be reassigned have not leaked for the period of the less frequently monitored subgroup (e.g., for the last 12 months, if the valve or group of valves is to be reassigned to a subgroup being monitored annually). Nonrepairable valves may not be reassigned to a less frequently monitored subgroup. [40 CFR §63.1255(e)(5)(ii)(C)]

iii. According to §63.1255(e)(5)(iii) of the 40 CFR, Abbott shall determine every 6 months if the overall performance of total valves in the applicable group of processes is less than 2 percent leaking valves and so indicate the performance in the next periodic report. If the overall performance of total valves in the applicable group of processes is 2% leaking valves or greater, Abbott shall revert to the program required in paragraphs (e)(2) through (e)(4) of section 63.1255 of 40 CFR. The overall performance of total valves in the applicable group of processes shall be calculated as a weighted average of the percent leaking valves of each subgroup according to the following equation:


$$\%V_{LO} = \frac{\sum_{i=1}^n (\%V_{Li} \times V_i)}{\sum_{i=1}^n V_i}$$

where:

$\%V_{LO}$  = overall performance of total valves in the applicable process or group of processes

$\%V_{Li}$  = percent leaking valves in subgroup i, most recent value calculated according to the procedures in paragraphs (e)(6)(ii) and (iii) of Section 63.1255

$V_i$  = number of valves in subgroup i

n = number of subgroups

iv. Records [40 CFR §63.1255(e)(5)(iv)] - In addition to records required by paragraph (g) of section 63.1255 of the 40 CFR, Abbott shall maintain records specified in paragraphs (e)(5)(iv)(A) through (D) of 40 CFR §63.1255.

- (A) Which valves are assigned to each subgroup, [40 CFR §63.1255(e)(5)(iv)(A)]
  - (B) Monitoring results and calculations made for each subgroup for each monitoring period, [40 CFR §63.1255(e)(5)(iv)(B)]
  - (C) Which valves are reassigned and when they were reassigned, and [40 CFR §63.1255(e)(5)(iv)(C)]
  - (D) The results of the semiannual overall performance calculation required in paragraph (e)(5)(iii) of Section 63.1255 of the 40 CFR. [40 CFR §63.1255(e)(5)(iv)(D)]
- v. Abbott shall notify the EQB and EPA no later than 30 days prior to the beginning of the next monitoring period of the decision to subgroup valves. The notification shall identify the participating processes and the valves assigned to each subgroup. [40 CFR §63.1255(e)(5)(v)]
- vi. Semiannual reports. In addition to the information required by paragraph (h)(3) of section, 63.1255, Abbott shall submit in the periodic reports the information specified in paragraphs (e)(5)(vi)(A) and (B) of Section 63.1255 of the 40 CFR. [40 CFR §63.1255(e)(5)(vi)]
- (A) Valve reassignments occurring during the reporting period, and [40 CFR §63.1255(e)(5)(vi)(A)]
  - (B) Results of the semiannual overall performance calculation required by paragraph (e)(5)(iii) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(e)(5)(vi)(B)]
- vii. To determine the monitoring frequency for each subgroup, the calculation procedures of paragraph (e)(6)(iii) of section 63.1255 of the 40 CFR shall be used. [40 CFR §63.1255(e)(5)(vii)]
- viii. Except for the overall performance calculations required by paragraphs (e)(5)(i) and (e)(5)(iii) of section 63.1255 of the 40 CFR, each subgroup shall be treated as if it were a process for the purposes of applying the provisions of section 63.1255. [40 CFR §63.1255(e)(5)(viii)]

f. i. Abbott shall decide no later than the implementation date of Subpart GGG or upon revision of an operating permit how to group the processes. Once Abbott has decided, all subsequent percentage calculations shall be made on the same basis. [40 CFR §63.1255(e)(6)(i)]

ii. According to 40 CFR §63.1255(e)(6)(ii), percent leaking valves for each group of processes or subgroup shall be determined by the following equation:

$$\%V_L = [V_L/V_T] \times 100$$

Where:

$\%V_L$  = percent leaking valves as determined through periodic monitoring required in paragraphs (e)(2) through (4) of section 63.1255 of the 40 CFR.

$V_L$  = number of valves found leaking excluding non-repairable as provided in paragraph (e)(6)(iv)(A) of 40 CFR Section 63.1255 of the 40 CFR.

$V_T$  = total valves monitored in a monitoring period excluding valves monitored as required by paragraph (e)(7)(iii) of section 63.1255 of the 40 CFR.

iii. When determining monitoring frequency for each group of processes or subgroup subject to monthly, quarterly, or semiannual monitoring frequencies, the percent leaking valves shall be the arithmetic average of the percent leaking valves from the last two monitoring periods. When determining monitoring frequency for each group of processes or subgroup subject to annual or biennial (once every 2 years) monitoring frequencies, the percent leaking valves shall be the arithmetic average of the percent leaking valves from the last three monitoring periods. [40 CFR §63.1255(e)(6)(iii)]

iv. (A) Non-repairable valves shall be included in the calculation of percent leaking valves the first time the valve is identified as leaking and non-repairable and as required to comply with paragraph (e)(6)(iv)(B) of section 63.1255 of the 40 CFR. Otherwise, a number of non-repairable valves (identified and included in the percent leaking calculation in a previous period) up to a maximum of 1 percent of the total number of valves in organic HAP service at a process may be excluded from

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calculation of percent leaking valves for subsequent monitoring periods. [40 CFR §63.1255(e)(6)(iv)(A)]

- (B) If the number of non-repairable valves exceeds 1% of the total number of valves in organic HAP service at a process, the number of non-repairable valves exceeding 1% of the total number of valves in organic HAP service shall be included in the calculation of percent leaking valves. [40 CFR §63.1255(e)(6)(iv)(B)]

g. Repair provisions. [40 CFR §63.1255(e)(7)]

- i. When a leak is detected, it shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in paragraph (b)(4)(i) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(e)(7)(i)]

- (A) A first attempt at repair shall be made no later than 5 calendar days after each leak is detected. [40 CFR §63.1255(e)(7)(ii)]

- iii. When a leak is repaired, the valve shall be monitored at least once within the first 3 months after its repair. Days that the valve is not in organic HAP service shall not be considered part of this 3 month period. The monitoring required by this paragraph is in addition to the monitoring required to satisfy the definitions of "repaired"<sup>13</sup> and "first attempt at repair."<sup>14</sup> [40 CFR §63.1255(e)(7)(iii)]

- (A) The monitoring shall be conducted as specified in §63.180(b) and (c) of the 40 CFR as appropriate to determine whether the valve has resumed leaking. [40 CFR §63.1255(e)(7)(iii)(A)]

- (B) Periodic monitoring required by paragraphs (e)(2) through (4) of section 63.1255 of the 40 CFR may be used to satisfy the requirements of paragraph (e)(7)(iii) of section 63.1255 of the 40 CFR, if the timing

<sup>13</sup> Repaired means that the equipment is adjusted, or otherwise altered, to eliminate a leak as defined in the applicable paragraphs of §63.1255 and is, unless specified otherwise in the applicable provisions of §63.1255, monitored according to the specified in Section 63.180(b) and (c) as appropriate, to verify that emission from the equipment are below the applicable leak definition. [40 CFR §63.1251]

<sup>14</sup> First attempt at repair means to take action in order of stopping or reducing leakage of organic material into the atmosphere. [40 CFR §63.1251]

of the monitoring period coincides with the time specified in paragraph (e)(7)(iii) of section 63.1255. Alternatively, other monitoring may be performed to satisfy the requirements of paragraph (e)(7)(iii) of section 63.1255, regardless of whether the timing of the monitoring period for periodic monitoring coincides with the time specified in paragraph (e)(7)(iii) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(e)(7)(iii)(B)]

(C) If a leak is detected by monitoring that is conducted pursuant to paragraph (e)(7)(iii) of section 63.1255, Abbott shall follow the provisions of paragraphs (e)(7)(iii)(C)(1) and (2) of section 63.1255 of the 40 CFR to determine whether that valve must be counted as a leaking valve for purposes of paragraph (e)(6) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(e)(7)(iii)(C)]

(1) If Abbott elects to use periodic monitoring required by paragraphs (e)(2) through (4) of section 63.1255 to satisfy the requirements of paragraph (e)(7)(iii) of section 63.1255, then the valve shall be counted as a leaking valve. [40 CFR §63.1255(e)(7)(iii)(C)(1)]

(2) If Abbott elects to use other monitoring prior to the periodic monitoring required by paragraphs (e)(2) through (4) of section 63.1255 to satisfy the requirements of paragraph (e)(7)(iii) of section 63.1255, then the valve shall be counted as a leaking valve unless it is repaired and shown by periodic monitoring not to be leaking. [40 CFR §63.1255(e)(7)(iii)(C)(2)]

h. According to 40 CFR §63.1255(e)(8), first attempts at repair include, but are not limited to, the following practices where practicable:

- i. Tightening of bonnet bolts,
- ii. Replacement of bonnet bolts,
- iii. Tightening of packing gland nuts, and
- iv. Injection of lubricant into lubricated packing.

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- i. Any equipment located at a plant site with fewer than 250 valves in organic HAP service in the affected source is exempt from the requirements for monthly monitoring specified in paragraph (e)(4)(i) of section 63.1255 of the 40 CFR. Instead, Abbott shall monitor each valve in organic HAP service for leaks once each quarter, or comply with paragraph (e)(4)(iii), (iv), or (v) of section 63.1255 of the 40 CFR, except as provided in paragraph (f) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(e)(9)]

20. Unsafe to monitor/inspect, difficult to monitor/inspect, and inaccessible equipment. [40 CFR §63.1255(f)]

- a. According to 40 CFR §63.1255(f)(1), equipment that is designated as unsafe to monitor, unsafe to inspect, difficult to monitor, difficult to inspect, or inaccessible is exempt from the monitoring requirements as specified in paragraphs (f)(1)(i) through (iv) of section 63.1255 of the 40 CFR provided Abbott meets the requirements specified in paragraph (f)(2), (3), or (4) of section 63.1255 of the 40 CFR, as applicable. All equipment must be assigned to a group of processes. Ceramic or ceramic-lined connectors are subject to the same requirements as inaccessible connectors.

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- i. For pumps and agitators, paragraphs (c)(2), (3), and (4) of section 63.1255 of the 40 CFR do not apply. [40 CFR §63.1255(f)(1)(i)]
- ii. For valves, paragraphs (e)(2) through (7) of section 63.1255 of the 40 CFR do not apply. [40 CFR §63.1255(f)(1)(ii)]
- iii. For connectors, § 63.174(b) through (e) and paragraphs (b)(4)(iii)(B) through (F) of section 63.1255 of the 40 CFR do not apply. [40 CFR §63.1255(f)(1)(iii)]
- iv. For closed-vent systems, § 63.172(f)(1) and (2) and § 63.172(g) of the 40 CFR do not apply. [40 CFR §63.1255(f)(1)(iv)]

b. Equipment that is unsafe to monitor or unsafe to inspect. [40 CFR §63.1255(f)(2)]

- i. Valves, connectors, agitators, and pumps may be designated as unsafe to monitor if Abbott determines that monitoring personnel would be exposed to an immediate danger as a consequence of complying with the monitoring requirements referred to in paragraphs (f)(1)(i) through (iii) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(f)(2)(i)]

- ii. Any part of a closed-vent system may be designated as unsafe to inspect if the owner or operator determines that monitoring personnel would be exposed to an immediate danger as a consequence of complying with the monitoring requirements referred to in paragraph (f)(1)(iv) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(f)(2)(ii)]
  - iii. The owner or operator of equipment that is designated as unsafe to monitor must have a written plan that requires monitoring of the equipment as frequently as practicable during safe to monitor times, but not more frequently than the periodic monitoring schedule otherwise applicable to the group of processes in which the equipment is located. [40 CFR §63.1255(f)(2)(iii)]
  - iv. For any parts of a closed-vent system designated as unsafe to inspect, Abbott must have a written plan that requires inspection of the closed-vent systems as frequently as practicable during safe to inspect times, but not more frequently than annually. [40 CFR §63.1255(f)(2)(iv)]
- c. Equipment that is difficult to monitor or difficult to inspect. [40 CFR §63.1255(f)(3)]
- i. A valve, agitator, or pump may be designated as difficult to monitor if Abbott determines that the valve, agitator, or pump cannot be monitored without elevating the monitoring personnel more than 2 meters above a support surface, or it is not accessible in a safe manner when it is in organic HAP service. [40 CFR §63.1255(f)(3)(i)]
  - ii. Any part of a closed-vent system may be designated as difficult to inspect if Abbott determines that the equipment cannot be inspected without elevating the monitoring personnel more than 2 meters above a support surface, or it is not accessible in a safe manner when it is in organic HAP service. [40 CFR §63.1255(f)(3)(ii)]
  - iii. At an existing source, any valve, agitator or pump within a group of processes that meets the criteria of paragraph (f)(3)(i) of section 63.1255 may be designated as difficult to monitor, and any parts of a closed-vent system that meet the requirements of paragraph (f)(3)(ii) of section 63.1255 may be designated as difficult to inspect. At a new affected source, Abbott may designate no more than 3 percent of valves as difficult to monitor. [40 CFR §63.1255(f)(3)(iii)]

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iv. The owner or operator of valves, agitators, or pumps designated as difficult to monitor must have a written plan that requires monitoring of the equipment at least once per calendar year or on the periodic monitoring schedule otherwise applicable to the group of processes in which the equipment is located, whichever is less frequent. For any part of a closed-vent system designated as difficult to inspect, Abbott must have a written plan that requires inspection of the closed-vent system at least once every 5 years. [40 CFR §63.1255(f)(3)(iv)]

d. Inaccessible, ceramic, or ceramic-lined connectors. [40 CFR §63.1255(f)(4)]

i. In accordance with 40 CFR §63.1255(f)(4)(i), a connector may be designated as inaccessible if it is:

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- (A) Buried;
  - (B) Insulated in a manner that prevents access to the connector by a monitor probe;
  - (C) Obstructed by equipment or piping that prevents access to the connector by a monitor probe;
  - (D) Unable to be reached from a wheeled scissor-lift or hydraulic-type scaffold which would allow access to equipment up to 7.6 meters (25 feet) above the ground; or
  - (E) Not able to be accessed at any time in a safe manner to perform monitoring. Unsafe access includes, but is not limited to, the use of a wheeled scissor-lift on unstable or uneven terrain, the use of a motorized man-lift basket in areas where an ignition potential exists, or access would require near proximity to hazards such as electrical lines, or would risk damage to equipment.

ii. A connector may be designated as inaccessible if it would require elevating the monitoring personnel more than 2 meters above a permanent support surface or would require the erection of scaffold. [40 CFR §63.1255(f)(4)(ii)]

iii. At an existing source, any connector that meets the criteria of paragraph (f)(4)(i) or (ii) of section 63.1255 of the 40 CFR may be designated as

inaccessible. At a new affected source, Abbott may designate no more than 3% of connectors as inaccessible. [40 CFR §63.1255(f)(4)(iii)]

- iv. If any inaccessible, ceramic, or ceramic-lined connector is observed by visual, audible, olfactory, or other means to be leaking, the leak shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in paragraph (b)(4)(i) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(f)(4)(iv)]
- v. Any connector that is inaccessible or that is ceramic or ceramic-lined is exempt from the recordkeeping and reporting requirements of paragraphs (g) and (h) of Section 63.1255. [40 CFR §63.1255(f)(4)(v)]

21. Recordkeeping requirements. [40 CFR §63.1255(g)]

- a. An owner or operator of more than one group of processes subject to the provisions of section 63.1255 of the 40 CFR may comply with the recordkeeping requirements for the groups of processes in one recordkeeping system if the system identifies with each record the program being implemented (e.g., quarterly monitoring) for each type of equipment. All records and information required by section 63.1255 of the 40 CFR shall be maintained in a manner that can be readily accessed at the plant site. This could include physically locating the records at the plant site or accessing the records from a central location by computer at the plant site. [40 CFR §63.1255(g)(1)]

- b. General Recordkeeping. According to 40 CFR §63.1255(g)(2), except as provided in paragraph (g)(5)(i) of section 63.1255 and in paragraph (a)(9) of section 63.1255, the following information pertaining to all equipment subject to the requirements in section 63.1255 shall be recorded:

- i. (A) A list of identification numbers for equipment (except connectors that are subject to paragraph (f)(4) of this section) subject to the requirements of section 63.1255 of the 40 CFR. Except for equipment subject to the recordkeeping requirements in paragraphs (g)(2)(ii) through (viii) of section 63.1255 of the 40 CFR, equipment need not be individually identified if, for a particular type of equipment, all items of that equipment in a designated area or length of pipe subject to the provisions of section 63.1255 of the 40 CFR are identified as a group, and the number of subject items of equipment is indicated. The list for each type of equipment shall be completed no later than the completion of the initial survey required for that component. The

list of identification numbers shall be updated, if needed, to incorporate equipment changes identified during the course of each monitoring period within 90 calendar days, or by the next Periodic Report, following the end of the monitoring period for the type of equipment component monitored, whichever is later. [40 CFR §63.1255(g)(2)(i)(A)]

- (B) A schedule for monitoring connectors subject to the provisions of §63.174(a) of the 40 CFR and valves subject to the provisions of paragraph (e)(4) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(g)(2)(i)(B)]
- (C) Physical tagging of the equipment to indicate that it is in organic HAP service is not required. Equipment subject to the provisions of section 63.1255 may be identified on a plant site plan, in log entries, or by other appropriate methods. [40 CFR §63.1255(g)(2)(i)(C)]

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ii. (A) A list of identification numbers for equipment that Abbott elects to equip with a closed-vent system and control device, under the provisions of paragraph (c)(7) of §63.1255, §63.164(h), or §63.165(c). [40 CFR §63.1255(g)(2)(ii)(A)]

(B) A list of identification numbers for compressors that Abbott elects to designate as operating with an instrument reading of less than 500 parts per million above background, under the provisions of §63.164(i) of the 40 CFR. [40 CFR §63.1255(g)(2)(ii)(B)]

iii. (A) A list of identification numbers for pressure relief devices subject to the provisions in 40 CFR §63.165(a) of the 40 CFR. [40 CFR §63.1255(g)(2)(iii)(A)]

(B) A list of identification numbers for pressure relief devices equipped with rupture disks, under the provisions of §63.165(d) of the 40 CFR [40 CFR §63.1255(g)(2)(iii)(B)]

iv. Identification of instrumentation systems subject to the provisions of section 63.1255. Individual components in an instrumentation system need not be identified. [40 CFR §63.1255(g)(2)(iv)]

- v. According to 40 CFR §63.1255(g)(2)(v), the following information shall be recorded for each dual mechanical seal system:
- (A) Design criteria required by §63.1255(c)(5)(vi)(A) and §63.164(e)(2), and an explanation of the design criteria; and [40 CFR §63.1255(g)(2)(v)(A)]
  - (B) Any changes to these criteria and the reasons for the changes. [40 CFR §63.1255(g)(2)(v)(B)]
- vi. A list of equipment designated as unsafe to monitor/inspect or difficult to monitor/inspect under paragraph (f) of section 63.1255 of the 40 CFR and a copy of the plan for monitoring or inspecting this equipment. [40 CFR §63.1255(g)(2)(vi)]
- vii. A list of connectors removed from and added to the process, as described in §63.174(i)(1) of the 40 CFR, and documentation of the integrity of the weld for any removed connectors, as required in §63.174(j) of the 40 CFR. This is not required unless the net credits for removed connectors is expected to be used. [40 CFR §63.1255(g)(2)(vii)]
- viii. For equipment that Abbott elects to monitor as provided under §63.178(c) of the 40 CFR, a list of equipment added to batch product processes since the last monitoring period required in §63.178(c)(3)(ii) and (iii). This list must be completed for each type of equipment within 90 calendar days, or by the next Periodic Report, following the end of the monitoring period for the type of equipment monitored, whichever is later. Also, if Abbott elects to adjust monitoring frequency by the time in use, as provided in §63.178(c)(3)(iii) of the 40 CFR, records demonstrating the proportion of the time during the calendar year the equipment is in use in a manner subject to the provisions of section 63.1255 are required. Examples of suitable documentation are records of time in use for individual pieces of equipment or average time in use for the process unit. [40 CFR §63.1255(g)(2)(viii)]
- e. Records of visual inspections. For visual inspections of equipment subject to the provisions of paragraphs (c)(2)(iii) and (c)(5)(iv) of section 63.1255, Abbott shall document that the inspection was conducted and the date of the inspection. Abbott shall maintain records as specified in paragraph (g)(4) of section 63.1255 for leaking equipment identified in this inspection, except as provided in paragraph (g)(5) of

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section 63.1255 of the 40 CFR. These records shall be retained for 2 years. [40 CFR §63.1255(g)(3)]

d. Monitoring records. In accordance with 40 CFR §63.1255(g)(4), when each leak is detected as specified in paragraph (c) of section 63.1255 of the 40 CFR and § 63.164, paragraph (e) of section 63.1255 and §63.169, and §63.172 and §63.174, the following information shall be recorded and kept for 5 years (at least 2 years onsite, with the remaining 3 years either onsite or offsite):

i. The instrument and the equipment identification number and the operator name, initials, or identification number. [40 CFR §63.1255(g)(4)(i)]

ii. The date the leak was detected and the date of the first attempt to repair the leak. [40 CFR §63.1255(g)(4)(ii)]

iii. The date of successful repair of the leak. [40 CFR §63.1255(g)(4)(iii)]

iv. The maximum instrument reading measured by Method 21 of 40 CFR Part 60, Appendix A, after the leak is successfully repaired or determined to be non-repairable. [40 CFR §63.1255(g)(4)(iv)]

v. "Repair delayed" and the reason for the delay if a leak is not repaired within 15 calendar days after discovery of the leak. [40 CFR §63.1255(g)(4)(v)]

(A) Abbott may develop a written procedure that identifies the conditions that justify a delay of repair. The written procedures shall be included in a document that is maintained at the plant site. Reasons for delay of repair may be documented by citing the relevant sections of the written procedure. [40 CFR §63.1255(g)(4)(v)(A)]

(B) If delay of repair was caused by depletion of stocked parts, there must be documentation that the spare parts were sufficiently stocked onsite before depletion and the reason for depletion. [40 CFR §63.1255(g)(4)(v)(B)]

vi. If repairs were delayed, dates of process shutdowns that occur while the equipment is unrepaired. [40 CFR §63.1255(g)(4)(vi)]

vii. (A) If the alternative in § 63.174(c)(1)(ii) of the 40 CFR is not in use for the monitoring period, identification, either by list, location (area or

grouping), or tagging of connectors disturbed since the last monitoring period required in §63.174(b), as described in §63.174(c)(1) of the 40 CFR. [40 CFR §63.1255(g)(4)(vii)(A)]

(B) The date and results of follow-up monitoring as required in 40 CFR § 63.174(c)(1)(i) and (c)(2)(ii). If identification of disturbed connectors is made by location, then all connectors within the designated location shall be monitored. [40 CFR §63.1255(g)(4)(vii)(B)]

viii. The date and results of the monitoring required in § 63.178(c)(3)(i) for equipment added to a batch process since the last monitoring period required in §63.178(c)(3)(ii) and (iii) of the 40 CFR. If no leaking equipment is found in this monitoring, Abbott shall record that the inspection was performed. Records of the actual monitoring results are not required. [40 CFR §63.1255(g)(4)(viii)]

ix. Copies of the periodic reports as specified in paragraph (h)(3) of section 63.1255 of the 40 CFR, if records are not maintained on a computerized data base capable of generating summary reports from the records. [40 CFR §63.1255(g)(4)(ix)]

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e. Records of pressure tests. According to the 40 CFR §63.1255(g)(5), the owner or operator who elects to pressure test a process equipment train or supply lines between storage and processing areas to demonstrate compliance with section 63.1255 is exempt from the requirements of paragraphs (g)(2), (3), (4), and (6) of section 63.1255 of the 40 CFR. Instead, the owner or operator shall maintain records of the following information:

i. The identification of each product, or product code, produced during the calendar year. It is not necessary to identify individual items of equipment in the process equipment train. [40 CFR §63.1255(g)(5)(i)]

ii. Physical tagging of the equipment to identify that it is in organic HAP service and subject to the provisions of section 63.1255 of the 40 CFR is not required. Equipment in a process subject to the provisions of section 63.1255 of the 40 CFR may be identified on a plant site plan, in log entries, or by other appropriate methods. [40 CFR §63.1255(g)(5)(ii)]

- iii. The dates of each pressure test required in section 63.178(b) of the 40 CFR, the test pressure, and the pressure drop observed during the test. [40 CFR §63.1255(g)(5)(iii)]
- iv. Records of any visible, audible, or olfactory evidence of fluid loss. [40 CFR §63.1255(g)(5)(iv)]
- v. According to §63.1255(g)(5)(v) of the 40 CFR, when a process equipment train does not pass two consecutive pressure tests, the following information shall be recorded in a log and kept for 2 years:

- (A) The date of each pressure test and the date of each leak repair attempt. [40 CFR §63.1255(g)(5)(v)(A)]
- (B) Repair methods applied in each attempt to repair the leak. [40 CFR §63.1255(g)(5)(v)(B)]
- (C) The reason for the delay of repair. [40 CFR §63.1255(g)(5)(v)(C)]
- (D) The expected date for delivery of the replacement equipment and the actual date of delivery of the replacement equipment. [40 CFR §63.1255(g)(5)(v)(D)]
- (E) The date of successful repair. [40 CFR §63.1255(g)(5)(v)(E)]

  
  
f. Records of compressor and relief device compliance tests. According to 40 CFR §63.1255(g)(6), the dates and results of each compliance test required for compressors subject to the provisions in section 63.164(i) of the 40 CFR and the dates and results of the monitoring following a pressure release for each pressure relief device subject to the provisions in sections 63.165(a) and (b) of the 40 CFR. The results shall include:

- i. The background level measured during each compliance test. [40 CFR §63.1255(g)(6)(i)]
- ii. The maximum instrument reading measured at each piece of equipment during each compliance test. [40 CFR §63.1255(g)(6)(ii)]

g. Records for closed-vent systems. According to 40 CFR §63.1255(g)(7), Abbott shall maintain records of the information specified in paragraphs (g)(7)(i) through (iii) of section 63.1255 of the 40 CFR for closed-vent systems and control devices subject to

the provisions of paragraph (b)(4)(ii) of section 63.1255 of the 40 CFR. The records specified in paragraph (g)(7)(i) of section 63.1255 of the 40 CFR shall be retained for the life of the equipment. The records specified in paragraphs (g)(7)(ii) and (g)(7)(iii) of section 63.1255 of the 40 CFR shall be retained for 2 years.

i. The design specifications and performance demonstrations specified in paragraphs (g)(7)(i)(A) through (g)(7)(i)(D) of section 63.1255 of the 40 CFR, mentioned below:

(A) Detailed schematics, design specifications of the control device, and piping and instrumentation diagrams. [40 CFR §63.1255(g)(7)(A)]

(B) The dates and descriptions of any changes in the design specifications. [40 CFR §63.1255(g)(7)(B)]

(C) The flare design (i.e., steam assisted, air assisted, or non-assisted) and the results of the compliance demonstration required by §63.11(b) of the 40 CFR. [40 CFR §63.1255(g)(7)(C)]

(D) A description of the parameter or parameters monitored, as required in paragraph (b)(4)(ii) of section 63.1255, to ensure that control devices are operated and maintained in conformance with their design and an explanation of why that parameter (or parameters) was selected for the monitoring. [40 CFR §63.1255(g)(7)(D)]

ii. Records of operation of closed-vent systems and control devices. [40 CFR §63.1255(g)(7)(ii)]

(A) Dates and durations when the closed-vent systems and control devices required in paragraph (c) of §63.1255 and §63.164 through §63.166 are not operated as designed as indicated by the monitored parameters, including periods when a flare pilot light system does not have a flame. [40 CFR §63.1255(g)(7)(ii)(A)]

(B) Dates and durations during which the monitoring system or monitoring device is inoperative. [40 CFR §63.1255(g)(7)(ii)(B)]

(C) Dates and durations of startups and shutdowns of control devices required in paragraph (c)(7) of section 63.1255 and sections 63.164 through 63.166 of the 40 CFR. [40 CFR §63.1255(g)(7)(ii)(C)]

iii. Records of inspections of closed-vent systems subject to the provisions of §63.172 of the 40 CFR. [40 CFR §63.1255(g)(7)(iii)]

(A) For each inspection conducted in accordance with the provisions of section 63.172(f)(1) or (f)(2) of the 40 CFR during which no leaks were detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected. [40 CFR §63.1255(g)(7)(iii)(A)]

(B) For each inspection conducted in accordance with the provisions of section 63.172(f)(1) or (f)(2) of the 40 CFR during which leaks were detected, the information specified in paragraph (g)(4) of section 63.1255 of the 40 CFR shall be recorded. [40 CFR §63.1255(g)(7)(iii)(B)]

h. Records for components in heavy liquid service. -Information, data, and analysis used to determine that a piece of equipment or process is in heavy liquid service shall be recorded. Such a determination shall include an analysis or demonstration that the process fluids do not meet the criteria of "in light liquid or gas service." Examples of information that could document this include, but are not limited to, records of chemicals purchased for the process, analyses of process stream composition, engineering calculations, or process knowledge. [40 CFR §63.1255(g)(8)]

i. Records of exempt components. Identification, either by list, location (area or group) of equipment in organic HAP service less than 300 hours per year subject to the provisions of section 63.1255 of the 40 CFR. [40 CFR §63.1255(a)(9)]

j. Records of alternative means of compliance determination. In accordance with 40 CFR §63.1255(g)(10), owners and operators choosing to comply with the requirements of §63.179 shall maintain the following records:

i. Identification of the process(es) and the organic HAP they handle. [40 CFR §63.1255(g)(10)(i)]

ii. A schematic of the process, enclosure, and closed-vent system. [40 CFR §63.1255(g)(10)(ii)]

iii. A description of the system used to create a negative pressure in the enclosure to ensure that all emissions are routed to the control device. [40 CFR §63.1255(g)(10)(iii)]

22. Reporting Requirements. [40 CFR §63.1255(h)]

- a. According to 40 CFR §63.1255(h)(1), each owner or operator of a source subject to section 63.1255 shall submit the reports listed in paragraphs (h)(1)(i) through (ii) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(h)(1)]
- i. A Notification of Compliance Status Report described in paragraph (h)(2) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(h)(1)(i)]
- ii. Periodic reports described in paragraph (h)(3) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(h)(1)(ii)]
- b. Notification of Compliance Status Report. According to 40 CFR §63.1255(h)(2), each owner or operator of a source subject section 63.1255 shall submit the information specified in paragraphs (h)(2)(i) through (iii) of this section in the Notification of Compliance Status Report described in section 63.1260(f) 40 CFR.
- i. The notification shall provide the information listed in paragraphs (h)(2)(i)(A) through (C) of this section 63.1255 for each process subject to the requirements of paragraphs (b) through (g) of 40 CFR section 63.1255 of the 40 CFR.
- (A) Process group identification. [40 CFR §63.1255(h)(2)(i)(A)]
- (B) Number of each equipment type (e.g., valves, pumps) in organic HAP service, excluding equipment in vacuum service. [40 CFR §63.1255(h)(2)(i)(B)]
- (C) Method of compliance with the standard (for example, “monthly leak detection and repair” or “equipped with dual mechanical seals”). [40 CFR §63.1255(h)(2)(i)(C)]
- ii. The notification shall provide the information listed in paragraphs (h)(2)(ii)(A) and (B) of section 63.1255 for each process subject to the requirements of paragraph (b)(4)(iv) of section 63.1255 and 63.178(b) of the 40 CFR. [40 CFR §63.1255(h)(2)(ii)]
- (A) Products or product codes subject to the provisions of section 63.1255 of the 40 CFR, and [40 CFR §63.1255(h)(2)(ii)(A)]

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(B) Planned schedule for pressure testing when equipment is configured for production of products subject to the provisions of section 63.1255 of the 40 CFR. [40 CFR §63.1255(h)(2)(ii)(B)]

iii. The notification shall provide the information listed in paragraphs (h)(2)(iii)(A) and (B) of section 63.1255 of the 40 CFR for each process subject to the requirements in 63.179 of the 40 CFR. [40 CFR §63.1255(h)(2)(iii)]

(A) Process identification. [40 CFR §63.1255(h)(2)(iii)(A)]

(B) A description of the system used to create a negative pressure in the enclosure and the control device used to comply with the requirements of paragraph (b)(4)(ii) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(h)(2)(iii)(B)]

iv. Any change in the information submitted under paragraph (h) of 40 CFR §63.1255 shall be provided to the Board and EPA as part of the periodic reports thereafter.

v. Section 63.9(j) shall not apply to the Notification of Compliance Status report described in this paragraph (h)(2) of 40 CFR Section 63.1255.

c. Periodic reports. According to the 40 CFR §63.1255(h)(3), the owner or operator of a source subject to section 63.1255 of the 40 CFR shall submit Periodic Reports.

i. A report containing the information in paragraphs (h)(3)(ii), (iii), and (iv) of 40 CFR Section 63.1255 shall be submitted semiannually. The first report shall be submitted no later than 240 days after the Notification of Compliance Status Report is due and shall cover the 6-month period beginning on the date the Notification of Compliance Status Report is due. Each subsequent report shall cover the 6-month period following the preceding period. Abbott shall submit the reports on May 15 and November 15 of each year. [40 CFR §63.1255(h)(3)(i)]

ii. For equipment complying with the provisions of paragraphs (b) through (g) of section 63.1255, except paragraph (b)(4)(iv) of §63.1255 and §63.179, the summary information listed in paragraphs (h)(3)(ii)(A) through (L) of section 63.1255 of the 40 CFR for each monitoring period during the 6-month period. [40 CFR §63.1255(h)(3)(ii)]

- (A) The number of valves for which leaks were detected as described in paragraph (e)(3) of section 63.1255 of the 40 CFR, the percent leakers, and the total number of valves monitored; [40 CFR §63.1255(h)(3)(ii)(A)]
- (B) The number of valves for which leaks were not repaired as required in paragraph (e)(7) of section 63.1255 of the 40 CFR, identifying the number of those that are determined non-repairable; [40 CFR §63.1255(h)(3)(ii)(B)]
- (C) Separately, the number of pumps and agitators for which leaks were detected as described in paragraph (c)(2) of section 63.1255 of the 40 CFR, the total number of pumps and agitators monitored, and, for pumps, the percent leakers; [40 CFR §63.1255(h)(3)(ii)(C)]
- (D) Separately, the number of pumps and agitators for which leaks were not repaired as required in paragraph (c)(3) of §63.1255; [40 CFR §63.1255(h)(3)(ii)(D)]
- (E) The number of compressors for which leaks were detected as described in §63.164(f); [40 CFR §63.1255(h)(3)(ii)(E)]
- (F) The number of compressors for which leaks were not repaired as required in §63.164(g) of the 40 CFR; [40 CFR §63.1255(h)(3)(ii)(F)]
- (G) The number of connectors for which leaks were detected as described in §63.174(a) of the 40 CFR, the percent of connectors leaking, and the total number of connectors monitored. [40 CFR §63.1255(h)(3)(ii)(G)]
- (H) The number of connectors for which leaks were not repaired as required in §63.174(d) of the 40 CFR, identifying the number of those that are determined nonrepairable; [40 CFR §63.1255(h)(3)(ii)(H)]
- (I) The facts that explain any delay of repairs and, where appropriate, why a process shutdown was technically infeasible. [40 CFR §63.1255(h)(3)(ii)(I)]

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- (J) The results of all monitoring to show compliance with sections 63.164(i), 63.165(a), and 63.172(f) of the 40 CFR conducted within the semiannual reporting period. [40 CFR §63.1255(h)(3)(ii)(J)]
  - (K) If applicable, the initiation of a monthly monitoring program under either paragraph (c)(4)(ii) or paragraph (e)(4)(i) of section 63.1255 of the 40 CFR. [40 CFR §63.1255(h)(3)(ii)(K)]
  - (L) If applicable, notification of a change in connector monitoring alternatives as described in §63.174(c)(1) of the 40 CFR. [40 CFR §63.1255(h)(3)(ii)(L)]
- iii. For owners or operators electing to meet the requirements of §63.178(b), the report shall include the information listed in paragraphs (h)(3)(iii)(A) through (E) of section 63.1255 of the 40 CFR for each process. [40 CFR §63.1255(h)(3)(iii)]
- (A) Product process equipment train identification; [40 CFR §63.1255(h)(3)(iii)(A)]
  - (B) The number of pressure tests conducted; [40 CFR §63.1255(h)(3)(iii)(B)]
  - (C) The number of pressure tests where the equipment train failed either the retest or two consecutive pressure tests; [40 CFR §63.1255(h)(3)(iii)(C)]
  - (D) The facts that explain any delay of repairs; and [40 CFR §63.1255(h)(3)(iii)(D)]
  - (E) The results of all monitoring to determine compliance with §63.172(f) of Subpart H of the 40 CFR. [40 CFR §63.1255(h)(3)(iii)(E)]
- iv. Any revisions to items reported in earlier Notification of Compliance Status report, if the method of compliance has changed since the last report. [40 CFR §63.1255(h)(3)(iv)]

Standards: Wastewater – 40 CFR §63.1256

23. Currently Abbott has not affected wastewater by 40 CFR Part 63 Subpart GGG at the facility. Should Abbott have affected wastewater, it shall comply with 40 CFR §63.1256.

Test Methods and Compliance Procedures. [40 CFR §63.1257]

24. General: Except as specified in paragraph (a)(5) of section 63.1257 of the 40 CFR, the procedures specified in paragraphs (c), (d), (e), and (f) of section 63.1257 are required to demonstrate initial compliance with standards for storage tanks, process vents, equipment leaks and wastewater. The provisions in paragraphs (a)(2) and (3) of section 63.1257 apply to performance tests that are specified in paragraphs (c), (d), and (e) of section 63.1257 of the 40 CFR. The provisions in paragraph (a)(5) of section 63.1257 of the 40 CFR are used to demonstrate initial compliance with the alternative standards specified in sections 63.1253(d) and 63.1254(c) of the 40 CFR. The provisions in paragraph (a)(6) of §63.1257 are used to comply with the outlet concentration requirements specified in sections 63.1253(c), 63.1254(a)(2)(i), and (a)(3)(ii)(B), 63.1254(b)(i), and 63.1256(h)(2) of the 40 CFR. Performance tests shall be conducted under such conditions representative of performance of the affected source for the period being tested. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

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- a. Design evaluation. – To demonstrate that a control device meets the required control efficiency, a design evaluation must address the composition and organic HAP concentration of the vent stream entering the control device. A design evaluation also must address other vent stream characteristics and control device operating parameters as specified in any one of paragraphs (a)(1)(i) through (vi) of section 63.1257 of the 40 CFR, depending on the type of control device that is used. If the vent stream is not the only inlet to the control device, the efficiency demonstration also must consider all other vapors, gases, and liquids, other than fuels, received by the control device. [40 CFR §63.1257(a)(1)]

25. Test methods. – When testing is conducted to measure emissions from an affected source, the test methods specified in paragraphs (b)(1) through (10) of section 63.1257 of the 40 CFR shall be used, in compliance with section §63.1257 of the 40 CFR.
26. Initial compliance with storage tank provisions. – The owner or operator of an affected storage tank shall demonstrate initial compliance with section 63.1253(b) or (c), as applicable, by fulfilling the requirements of paragraph (c)(1), or (c)(2), or (c)(3) of 63.1257 of the 40 CFR.

27. Initial compliance with process vent provisions. – According to section 63.1257(d) of the 40 CFR, Abbott shall comply with the process vent standards in §63.1254 demonstrating compliance using the procedures described in paragraphs (d)(1) through (4) of 63.1257.

Monitoring Requirements. [40 CFR §63.1258]

28. Abbott shall provide evidence of continued compliance with the standard as specified under section 63.1258 of 40 CFR. Monitoring requirements are summarized below:

a. Abbott shall comply with the monitoring requirements included in the following table:

Equipment	Parameter	Value	Monitoring Frequency	Averaging Period	Requirements for the indicators or monitors
Bypass lines	Valve position	Closed/Open	Monthly	N/A	N/A
Thermal Oxidizer	Temperature of the combustion chamber, §63.1258 (b)(1)(vii) of 40 CFR	Greater than or equal to 1,800°F	Continuous (every 15 minutes)	Daily	The temperature monitoring device must be accurate to within ±0.75% percent of the temperature measured in degrees Celsius or ±2.5 °C, whichever is greater.  Must be calibrated annually
Enclosed Flare (EFVCD)	Temperature of the combustion chamber	1,600 °F	Continuous (every 15 minutes)	Daily	The temperature monitoring device must be accurate to within ±0.75% percent of the temperature measured in degrees Celsius or ±2.5 °C, whichever is greater.  Must be calibrated annually

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Equipment	Parameter	Value	Monitoring Frequency	Averaging Period	Requirements for the indicators or monitors
Gas Scrubber	Flow rate of the solution, 40 CFR §63.1258 (b)(1)(ii)	15 gpm	Continuous (every 15 minutes)	Daily	The monitoring device must be accurate within ±10 percent of the design scrubber liquid flowrate. [40CFR §63.1258 (b)(1)(ii)(B)]  Shall be calibrated annually. [40 CFR §63.1258(b)(1)(ii)(C)]
	pH, 40 CFR §63.1258 (b) (1) (ii)	≥9.0	Continuous <sup>15</sup> (Every -1-hour)	Daily	Shall be calibrated annually [40CFR §63.1258(b)(1)(ii)(C)]
Closed Vent Systems	Visual inspection, §63.1258 (b)(1)(xi) of 40 CFR	N/A	Monthly	N/A	N/A

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- b. The monitoring of the control equipment's operating parameters shall take place during the periods in which the device is working to achieve the removal of HAPs required by Subpart GGG.
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- c. Temperature gauges and flow meters used to comply with the monitoring requirements of this permit shall be calibrated annually, as required by sections 63.1258(b)(1)(ii)(C) and 63.1258(b)(1)(viii)(B) of the 40 CFR, or more frequently, as required by the EQB. Abbott shall prepare and maintain a log of the date, time and results of the calibrations available for inspection by technical personnel of the Board.
- d. Abbott shall perform monthly visual inspections of each closed vent system as specified in Section 63.1252(b) of 40 CFR. [40 CFR §63.1258(b)(1)(xi)].
- e. A daily average (24-hour) average shall be calculated as the average of all values for a monitored parameter level set according to the procedures in (b)(3)(iii) of the 40 CFR recorded during the operating day or block. [40 CFR 63.1258(b)(2)(i)]

<sup>15</sup>Section 63.1258 (b)(1)(ii) of 40 CFR states that the pH should be monitored at least once daily. However, permit PFE-09-0193-0057-I-II-C requires that the pH is monitored every hour.

- f. Monitoring values taken during periods in which the control devices are not functioning in controlling emissions, as indicated by periods of no flow, shall not be considered in the averages. Where flow to the device could be intermittent, the owner or operator shall install, calibrate and operate a flow indicator at the inlet or outlet of the control device to identify periods of no flow. [40 CFR §63.1258(b)(2)(iii)]
- g. Abbott shall maintain a record where no-flow periods are identified, which will be available for review by the technical personnel of the Board.
- h. Instead of monitoring the HCl concentration using a CEM to monitor halogenated vent stream that are controlled by a combustion equipment followed by a scrubber, Abbott shall monitor scrubber operating parameters as specified in the previous table included under this condition that demonstrate the HCl emissions are reduced by at least 95% by weight, in compliance with §63.1258(b)(5)(i)(C) of the 40 CFR.
- i. Exceedances of operating parameters - According to section 63.1258(b)(6) of 40 CFR, an exceedance of an operating parameter is defined as one of the following:
  - i. If the parameter, averaged over an operating day or block, is below a minimum value established during the initial compliance demonstration. [40 CFR §63.1258(b)(6)(i)]
  - ii. If the parameter, averaged over an operating day or block, is above the maximum value established during the initial compliance demonstration. [40 CFR §63.1258(b)(6)(i)]
  - iii. Each loss of all pilot flames for flares. [40 CFR 63.1258(b)(6)(iii)]
- j. Excursions - According to section 63.1258(b)(7) of 40 CFR, excursions are defined by either of the two cases mentioned below:
  - i. When the period of control device operation is 4 hours or greater in an operating day and monitoring data are insufficient to constitute a valid hour of data, as defined in paragraph (b)(7)(iii) of §63.1258, for at least 75 percent of the operating hours.[40 CFR §63.1258(b)(7)(i)]
  - i. When the period of control device operation is less than 4 hours in an operating day and more than one of the hours during the period of operation does not constitute a valid hour of data due to insufficient monitoring data.[40 CFR §63.1258(b)(7)(ii)]

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- iii. Monitoring data are insufficient to constitute a valid hour of data, as used in paragraphs (b)(7)(i) and (ii) of section 63.1258, if measured values are unavailable for any of the required 15-minute periods within the hour. [40 CFR §63.1258(b)(7)(iii)]
- k. Violations - Exceedances of parameters monitored according to the provisions of paragraphs (b)(1)(ii), (iv) through (ix), and (b)(5)(ii)(A) and (B) of 40 CFR section 63.1258, or excursions as defined by paragraphs (b)(7)(i) through (iii) of 40 CFR section 63.1258 constitute violations of the operating limit according to paragraphs (b)(8)(i), (ii), and (iv) of 40 CFR section 63.1258. Exceedances of the temperature limit monitored according to the provisions of paragraph (b)(1)(iii) of 40 CFR section 63.1258 constitute violations of the emission limit according to paragraphs (b)(8)(i), (ii), and (iv) of 40 CFR section 63.1258. [40 CFR §63.1258(b)(8)]
- i. Except as provided in paragraph (b)(8)(iv) of section 63.1258, for episodes that occur more than once per day, exceedances of established parameter limits or excursions will result in no more than one violation per day of operation for each monitored item of equipment used in the process. [40 CFR §63.1258 (b) (8) (i)]
- ii. Except as provided in paragraph (b)(8)(iv) of section 63.1258 of the 40 CFR, for control devices used for more than one process in the course of an operating day, exceedances or excursions will result in no more than one violation per operating day, per control device, for each process for which the control device is in service. [40 CFR §63.1258(b)(8)(i)]
29. Monitoring for equipment leaks - According to 63.1258(d) of 40 CFR, for equipment leaks, Abbott shall meet the monitoring requirements described in section 63.1255 of the 40 CFR.
30. Leak inspection provisions for vapor suppression equipment, 40 CFR §63.1258(h) - Except as provided in paragraph (h)(9) and (10) of §63.1258, for each vapor collection system, closed-vent system, fixed roof, cover, or enclosure required to comply with §63.1258 of the 40 CFR, the owner or operator shall comply with the requirements of paragraphs (h)(2) through (8) of section 63.1258(h) of the 40 CFR, described below: [40 CFR §63.1258(h)(1)]
- a. Except as provided in paragraphs (h)(6) and (7) of section 63.1258, each vapor collection system and closed-vent system shall be inspected according to the procedures and schedule specified in paragraphs (h)(2)(i) and (ii) of this section and each fixed roof, cover, and enclosure shall be inspected according to the procedures and schedule specified in §63.1258(h)(2)(iii) of the 40 CFR. [40 CFR §63.1258(h)(2)]

- i. According to §63.1258 (h)(2)(i) of 40 CFR, if the vapor collection system or closed-vent system is constructed of hard piping, Abbott shall:
  - (A) Conduct an initial inspection according to the procedures in 40 CFR §63.1258(h)(3) [ §63.1258(h)(2)(i)(A)].
  - (B) Conduct annual visual inspections for visible, audible, or olfactory indications of leaks. [40 CFR §63.1258(h)(2)(i)(B)]
- ii. Each vapor collection system and closed-vent systems shall be inspected according to the requirements of §63.1258(h)(3) del 40 CFR.
- iii. Leaks, as indicated by an instrument reading greater than 500 parts per million above background or by visual inspections, shall be repaired as soon as practicable, except as provided in of §63.1258(h)(5) del 40 CFR. [40 CFR §63.1258(h)(4)]
  - (A) A first attempt at repair shall be made no later than 5 calendar days after the leak is detected. [40 CFR §63.1258(h)(4)(i)]
  - (B) Repair shall be completed no later than 15 calendar days after the leak is detected, except as provided in §63.1258(h)(4)(ii). [40 CFR §63.1258(h)(4)(i)]
  - (C) For leaks found in vapor collection systems used for transfer operations, repairs shall be completed no later than 15 calendar days after the leak is detected or at the beginning of the next transfer loading operation, whichever is later. [40 CFR §63.1258(h)(4)(iii)]
- iv. Delay in repair a vapor collection system, closed-vent system, fixed roof, cover, or enclosure for which leaks have been detected is allowed if the repair is technically infeasible without a shutdown as defined in §63.1251 or if Abbott determines that emissions resulting from immediate repair would be greater than the fugitive emissions that would result from a delay in repair. The repair of such equipment shall be completed by the end of next shutdown. [40 CFR §63.1258(h)(5)]
- v. Any part of a vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated as described in (h)(8) of section 63.1258 of the

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40 CFR, as unsafe to inspect are exempt from the inspection requirements of paragraphs (h)(2)(i), (ii) or (iii) of section 63.1258 if they meet the requirements of paragraphs (h)(6)(i) and (ii) of section 63.1258 of the 40 CFR. [40 CFR §63.1258(h)(6)]

- vi. Any parts of a vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated, as described in (h)(8) of section 63.1258 of the 40 CFR, as difficult to inspect are exempt from the inspection requirements of paragraphs (h)(2)(i), (ii) or (iii) of section 63.1258 if they meet the requirements of paragraphs (h)(7)(i) and (ii) of section 63.1258 of the 40 CFR. [40 CFR §63.1258(h)(7)]
- g. Records shall be maintained as specified in §63.1259(i)(4) through (9). [40 CFR §63.1258(h)(8)]
- h. If a closed-vent system subject to §63.1258 is also subject to the equipment leak provisions of section 63.1255 as described in (h)(8) of section 63.1258 of the 40 CFR, the owner or operator shall comply with the provisions of §63.1255 and is exempt from the requirements of §63.1258 of the 40 CFR. [40 CFR §63.1258(h)(9)]

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Recordkeeping requirements. [40 CFR §63.1259]

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44. According to section 63.1259(a) of the 40 CFR, Abbott shall comply with the recordkeeping requirements in Subpart A of 40 CFR Part 63 as specified in Table 1 of Subpart GGG and in paragraphs (a)(1) through (5) of section 63.1259 of the 40 CFR.

- a. Data retention - Abbott shall keep copies of all records and reports required by subpart GGG for at least 5 years, as specified in §63.10(b)(1). [40 CFR §63.1259(a)(1)]
- b. Malfunction records - Abbott shall maintain records of the occurrence and duration of each malfunction of operation (i.e., process equipment), air pollution control equipment, or monitoring equipment. Abbott shall maintain records of actions taken during periods of malfunction to minimize emissions in accordance with §63.1250(g)(3), including corrective actions to restore malfunctioning process and air pollution control and monitoring equipment to its normal or usual manner of operation. [40 CFR 63.1259(a)(3)]

- c. Recordkeeping requirements for sources with continuous monitoring systems - Abbott shall maintain records specified in § 63.10(c)(1) through (14) for the continuous monitoring systems. [40 CFR §63.1259(a)(4)]
- d. Application for approval of construction or reconstruction - For new affected sources, Abbott shall comply with Rule 203 of the RCAP and the provisions in §63.5 regarding construction and reconstruction, excluding the provisions specified in §63.5(d)(1)(ii)(H), (d)(2), and (d)(3)(ii) of the 40 CFR.
45. Records of equipment operation - According to section 63.1259(b) of the 40 CFR, Abbott must keep the following records up-to-date and readily accessible:
- a. Each measurement of a control device operating parameter monitored in accordance with §63.1258 of the 40 CFR and each measurement of a treatment process parameter monitored in accordance with §63.1258(g)(2) and (3). [40 CFR §63.1259(b)(1)]
- b. For each continuous monitoring system used to comply with this subpart, records documenting the completion of calibration checks and maintenance of continuous monitoring systems. [40 CFR §63.1259(b)(3)]
- c. A schedule or log of each operating scenario updated daily or, at a minimum, each time a different operating scenario is put into operation. [40 CFR §63.1259(b)(8)]
- d. Description of worst-case operating conditions as required in §63.1257(b)(8). [40 CFR §63.1259(b)(9)]
- e. Periods of planned routine maintenance as described in §63.1252(h) and §63.1257(c)(5). [40 CFR §63.1259(b)(10)]
- f. All maintenance performed on the air pollution control equipment. [40 CFR §63.1259(b)(13)]
46. Records of operating scenarios - Abbott shall keep records of each operating scenario which demonstrates compliance with subpart GGG of part 63 of the 40 CFR. [40 CFR §63.1259(c)]

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47. Records of equipment leak detection and repair programs - Abbott shall implement the recordkeeping requirements in section 63.1255 of subpart GGG of part 63 of the 40 CFR. [40 CFR §63.1259(d)]
48. Records of delay of repair - Documentation of a decision to use a delay of repair due to unavailability of parts, as specified in §63.1256(i), shall include a description of the failure, the reason additional time was necessary (including a statement of why replacement parts were not kept onsite and when delivery from the manufacturer is scheduled), and the date when the repair was completed. [40 CFR §63.1259(f)]
49. Record of wastewater stream or residual transfer - Abbott shall keep a record of the notice sent to the treatment operator when transferring an affected wastewater stream or residual removed from an affected wastewater stream in accordance with §63.1256(a)(5). The notice shall state that the wastewater stream or residual contains organic HAP which are required to be managed and treated in accordance with the provisions of Subpart GGG. [40 CFR §63.1259(g)]
50. Records of extensions - Abbott shall keep documentation of a decision to use an extension, as specified in §63.1256(b)(6)(ii) or (b)(9) of the 40 CFR, in a readily accessible location. The documentation shall include a description of the failure, documentation that alternate storage capacity is unavailable, and specification of a schedule of actions that will ensure that the control equipment will be repaired and the tank will be emptied as soon as practical. [40 CFR §63.1259(h)]
51. Records of inspections - Abbott shall keep applicable records specified in paragraphs (i)(1) through (9) of section 63.1259 of the 40 CFR:
- a. A record that each waste management unit inspection required by §63.1256(b) through (f) of the 40 CFR was performed. [40 CFR §63.1259(i)(1)]
  - b. A record that each inspection for control devices required by §63.1256(h) was performed. [40 CFR §63.1259(i)(2)]
  - c. Records identifying all parts of the vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated as unsafe to inspect in accordance with §63.1258(h)(6) of the 40 CFR, an explanation of why the equipment is unsafe to inspect, and the plan for inspecting the equipment. [40 CFR §63.1259(i)(4)]

- d. Records identifying all parts of the vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated as difficult to inspect in accordance with §63.1258(h)(7) of the 40 CFR, an explanation of why the equipment is difficult to inspect, and the plan for inspecting the equipment. [40 CFR §63.1258(h)(7)]
- e. For each vapor collection system or closed-vent system that contains bypass lines that could divert a vent stream away from the control device and to the atmosphere, Abbott shall keep a hourly records of whether the flow indicator specified under §63.1252(b)(1) was operating and whether a diversion was detected at any time during the hour, as well as records of the times and durations of all periods when the vent stream is diverted from the control device or the flow indicator is not operating. [40 CFR §63.1259(i)(6)(i)]
- f. For each inspection conducted in accordance with § 63.1258(h)(2) and (3) during which a leak is detected, a record of the information specified in paragraphs (i)(7)(i) through (ix) of §63.1259 of the 40 CFR:
  - i. Identification of the leaking equipment. [40 CFR §63.1259(i)(7)(i)]
  - ii. The instrument identification numbers and operator name or initials, if the leak was detected using the procedures described in §63.1258(h)(3); or a record that the leak was detected by sensory observations. [40 CFR §63.1259(i)(7)(ii)]
  - iii. The date the leak was detected and the date of the first attempt to repair the leak. [40 CFR §63.1259(i)(7)(iii)]
  - iv. Maximum instrument reading measured by the method specified in §63.1258(h)(4) after the leak is successfully repaired or determined to be non-repairable. [40 CFR §63.1259(i)(7)(iv)]
  - v. "Repair delayed" and the reason for the delay if a leak is not repaired within 15 calendar days after discovery of the leak. [40 CFR §63.1259(i)(7)(v)]
  - vi. The name, initials, or other form of identification of the owner or operator (or designee) whose decision it was that repair could not be effected without a shutdown. [40 CFR §63.1259(i)(7)(vi)]

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- vii. The expected date of successful repair of the leak if a leak is not repaired within 15 calendar days. [40 CFR §63.1259(i)(7)(vii)]
- viii. Dates of shutdowns that occur while the equipment is unrepaired. [40 CFR §63.1259(i)(7)(viii)]
- ix. The date of successful repair of the leak. [40 CFR §63.1259(i)(7)(ix)]
- g. For each inspection conducted in accordance with §63.1258(h)(3) during which no leaks are detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected. [40 CFR §63.1259(i)(8)]
- h. For each visual inspection conducted in accordance with 40 CFR §63.1258(h)(2)(i)(B) or (h)(2)(iii)(B) of the 40 CFR during which no leaks are detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected. [40 CFR §63.1259(i)(9)]

Reporting requirements [40 CFR §63.1260]

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- 52. Abbott shall comply with the reporting requirements of paragraphs (b) through (n) of 40 CFR §63.1260. Applicable reporting requirements of sections 63.9 and 63.10 of the 40 CFR are also summarized in Table 1 of Subpart GGG. [40 CFR §63.1260(a)]
  - 53. Periodic reports – Abbott shall prepare Periodic reports in accordance with paragraphs (g)(1) and (2) of §63.1260 and submit them to the Board. [40 CFR §63.1260(g)]
    - a. Submittal schedule – Except as provided in paragraphs (g)(1)(i), (ii), and (iii) of section 63.1260 of the 40 CFR, Abbott shall submit periodic reports semiannually. The first report shall be submitted no later than 240 days after the Notification of Compliance Status is due and shall cover the 6-month period beginning on the date the Notification of Compliance Status is due. Each subsequent Periodic report shall cover the 6-month period following the preceding period. [40 CFR §63.1260 (g) (1)]
    - i. The Administrator may determine on a case-by-case basis that more frequent reporting is necessary to accurately assess the compliance status of the affected source. [40 CFR §63.1260(g)(1)(i)]

- ii. Quarterly reports shall be submitted when the source experiences an exceedance of a temperature limit monitored according to the provisions of §63.1258(b)(1)(iii) or an exceedance of the outlet concentration monitored according to the provisions of §63.1258(b)(1)(x) or (b)(5). Once an affected source reports quarterly, the affected source shall follow a quarterly reporting format until a request to reduce reporting frequency is approved. If Abbott submits a request to reduce the frequency of reporting, the provisions in §63.10(e)(3)(ii) and (iii) shall apply, except that the phrase "excess emissions and continuous monitoring system performance report and/or summary report" shall mean "Periodic report" for the purposes of section 63.1260 of the 40 CFR. [40 CFR §63.1260 (g)(1)(ii)]
- iii. If a new operating scenario has been operated since the last report, quarterly reports shall be submitted. [40 CFR §63.1260(g)(1)(iii)]

- b. Content of periodic report [40 CFR §63.1260(g)(2)] – Abbott shall include the information in paragraphs (g)(2)(i) through (vii) of 40 CFR §63.1260, as applicable.

54. Notification of process change [40 CFR §63.1260(h)]

- a. Except as specified in paragraph (h)(2) of section 63.1260, whenever a process change is made, or a change in any of the information submitted in the Notification of Compliance Status Report, Abbott shall submit the information specified in paragraphs (h)(1)(i) through (iv) of §63.1260 with the next Periodic report required under paragraph (g) of section 63.1260. [40 CFR §63.1260(h)(1)]
  - i. A brief description of the process change. [40 CFR §63.1260(h)(1)(i)]
  - ii. A description of any modifications to standard procedures or quality assurance procedures. [40 CFR §63.1260(h)(1)(ii)]
  - iii. Revisions to any of the information reported in the original Notification of Compliance Status Report under paragraph (f) of section 63.1260. [40 CFR §63.1260(h)(1)(iii)]

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- iv. Information required by the Notification of Compliance Status Report under paragraph (f) of section 63.1260 for changes involving the addition of processes or equipment. [40 CFR §63.1260(h)(1)(iv)]
  - b. Abbott must submit a report 60 days before the scheduled implementation date of either of the following; [40 CFR §63.1260(h)(2)]
    - i. Any change in the activity covered by the Pre-compliance report. [40 CFR §63.1260(h)(2)(i)]
    - ii. A change in the status of a control device from small to large. [40 CFR §63.1260(h)(2)(ii)]
- 55. Abbott shall submit a report of the number, duration, and a brief description for each type of malfunction which occurred during the reporting period and which caused or may have caused any applicable emission limitation to be exceeded. The report must also include a description of actions taken by Abbott during a malfunction of an affected source to minimize emissions in accordance with §63.1250(g)(3) of the 40 CFR, including actions taken to correct a malfunction. The report shall be submitted on the same schedule as the periodic reports required under §63.1259(g).
- 56. Reports of Leak Detection and Repair programs [40 CFR §63.1260(j)] – Abbott shall implement the reporting requirements in §63.1255 of the 40 CFR. Copies of all reports shall be retained as records for a period of 5 years, in accordance with the requirements of §63.10(b)(1) of the 40 CFR.
- 57. Notification of Performance Test and Test Plan [40 CFR §63.1260(l)] – According to §63.1260(l), Abbott shall notify the EQB of the planned date of a performance test at least 60 days before the test in accordance with §63.7(b). Abbott also must submit the test plan required by §63.7(c) and the emission profile required by 63.1257(b)(8)(ii) with the notification of the performance test. The tests shall be conducted in accordance with the requirements of Subpart GGG and in compliance with Rule 106 of the RCAP.

Section VI - Alternate Operating Scenarios

Under this permit, the following alternate operating scenarios are authorized:

A. AOS-1

This scenario contemplates the operation of the EFVCS as an alternate backup equipment for the thermal oxidizer/gas scrubber system. The conditions applicable to this scenario are the following:

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
Hours of Operation	Operation time	2080	hours/year	Records	In each event	logbook	Semiannual
EFVCS Operating Parameters	Temperature	1600	°F	Temperature sensor	Continuous (Every -1-hour)	Records	Semiannual
Fuel Consumption Limit	Diesel consumption	74,880	gallons/year	Flowmeter	Continuous	Record with the monthly fuel consumption	Semiannual
Sulfur content limit in the fuel	Sulfur Content	0.5	percentage per weight	Fuel supplier certification	With each fuel receipt	Record with each receipt of fuel sulfur content	Semiannual
Visible Emissions Limit	Visible Emissions	20	percentage 6-minutes average	Method 9	Once during the first year of the permit	With each reading	60 days after each reading date
				Visible Emissions	Weekly		Semiannual
40 CFR Part 63 Subpart GGG	See Section V.B. of this permit	---	---	---	---	---	---

I. Operation Hours

- a. Abbott will operate an *Enclosed Flame Vapor Combustor System* (EFVCS) as alternate control equipment, to control emissions of emission units EU-1, EU-14 and EU-18.

- b. The EFVCS shall operate for a period not greater than 2,080 hrs/year when the thermal oxidizer/scrubber system is out of operation whether by scheduled maintenance of the equipment or malfunction of the control device.
- c. Abbott shall maintain a record with the time of operation of equipment, and the reasons why the thermal oxidizer/scrubber system was not in service. The logs must be available at all times for inspection by the technical personnel of the EQB.

2. Operating Parameter

- a. Shall maintain a temperature of 1600°F or higher in the EFVCS, based on an average of 24 hours (midnight to midnight). [PFE-09-0193-0057-I-II-C]
- b. The EFVCS must be equipped with a temperature sensor to record the operating temperature of the burner. [PFE-09-0193-0057-I-II-C]
- c. Abbott shall maintain a record with the temperature of operation of the burner, which must be available at all times for inspection by the technical personnel of the EQB.

3. Fuel consumption

- a. Diesel fuel consumption of EFVCS shall be limited to 74,880 gal/year. [Cumulative increase]
- b. The EFVCS must be provided with a diesel flow meter, so that fuel consumption can be verified. The fuel flowmeters shall be calibrated every six months. Abbott shall maintain the calibration records or documents available at all times for inspection by the technical personnel of the EQB.

4. Sulfur Content Limit in the Fuel

- a. The EFVCS shall use diesel fuel with a maximum sulfur content of 0.5% by weight.
- b. Abbott will keep a copy of the fuel supplier certification whenever fuel is received in the facility. Such certification shall indicate the fuel sulfur content to demonstrate compliance with the above condition.
- c. Abbott shall submit a report every six months indicating the monthly fuel consumption, the hours of operation and daily fuel sulfur content in weight

percent. This report shall be sent to the Data Validation and Mathematical Modeling Division of the Air Quality Area of the EQB no later than the next 15 days from the end of each period of six calendar months. A copy of this report must be available at the facility for inspection by the technical personnel of the EQB.

- d. Abbott must submit a summary with the information contained in these reports in the annual compliance certification.

5. Visible Emissions Limit

- a. Abbott shall not exceed the opacity limit of 20% for the EFVCS in a 6-minutes average. However, according to RCAP Rule 403(A), the permittee may discharge visible emissions with an opacity of 60% for a period no longer than 4 minutes in any consecutive 30 minutes. [RCAP Rule 403(A)]
- b. Abbott shall hire an independent opacity reader, certified in a school endorsed by the EPA to make one opacity reading on the EFVCS chimney stack during the first year of the permit using Method 9 described in Appendix A of 40 CFR Part 60. The equipment should be operating at the time of the opacity reading.
- c. Abbott 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 readings of visible emissions.
- d. Abbott shall notify in writing to the Board at least fifteen (15) days before the initial reading using Method 9, to afford the Board the opportunity to have an observer present. [RCAP Rule 106(D)]
- e. Two (2) copies of the initial sampling results report using Method 9 shall be submitted within 60 days after the tests. This report shall contain the information required under Rule 106(E) of the RCAP.
- f. Abbott will conduct weekly visual opacity inspections of the EFVCS during daylight hours in the chimney stack of the equipment using a Visible Emissions Reader certified by a program endorsed by the EPA or the Board. When the certified reader establishes that the opacity limit under RCAP Rule 403 is being exceeded, Abbott shall verify that the equipment causing the visible emissions is operating in accordance with the manufacturer's

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specifications and permit conditions. If the unit is not working properly, shall take immediate corrective actions in order to eliminate the excess opacity and document the steps taken to correct any deficiencies.

- i. Weekly visible emission tests shall be conducted in accordance with Method 9 of 40 CFR Part 60, Appendix A, for a minimum of 6 minutes, and in accordance with the following requirements:
- (1) Shall conduct weekly opacity readings for at least 8 consecutive weeks. If no emissions above the established provisions are observed, then -
  - (2) May take the opacity readings once every two weeks for a period of 8 consecutive weeks. If emissions above the provisions of RCAP Rule 403 are observed, Abbott must revert the frequency to weekly readings (according to subparagraph (i) above). If emissions above the provisions of RCAP Rule 203 are not observed, then-
  - (3) The opacity readings may be performed once per month. If emissions above the provisions of RCAP Rule 403 are observed, Abbott shall revert the frequency to weekly readings (according to subparagraph (i) above).
  - (4) If the facility reverts to a weekly frequency at any time, the frequency of tests shall progress in the same way from the initial frequency. This means that, upon completion of step (1), may proceed to step (2) and subsequently to step (3), if emissions above the provisions of RCAP Rule 403 are not observed, and so forth successively.
- ii. All visible emissions readings shall be recorded in accordance with Method 9. Shall prepare and keep a record indicating the dates and results of the readings, such record of the readings must be available in the facility at all times for Board staff to review.
- iii. If the unit is not in operation on the day that corresponds to taking a reading, or the conditions of Method 9 are not met, the permittee shall document such in the readings record, and inform it in the visible emissions summary to be submitted to the Board with the semiannual report required in this permit.

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- g. The permittee shall submit a summary of the visible emissions readings along with the semiannual reports required in this permit. This report shall include a summary of the results of the readings with their beginning and ending time, and the date when the reading of visible emissions was performed. The report shall also include the total number of visible emission readings made in that period for units subject to this requirement. The permittee shall retain a copy of the visible emission readings including date and time of the reading for at least five years, pursuant to RCAP Rule 603(A)(4)(ii).
  - h. The Board reserves the right to require additional visible emissions readings in order to demonstrate compliance with the opacity limit.
6. Abbott must maintain and implement a Preventive Maintenance Plan for EFVCS. Shall maintain a record of maintenance performed on the thermal oxidizer and the scrubber. This record must be kept in the facility at all times for Board technical staff review or submission to the Board when required.
7. The EFVCS shall comply with the requirements established under 40 CFR Part 63, Subpart GGG, included in section V.B. of this permit, when controlling emission sources subject to the requirements of this subpart.

B. AOS-2

  
  
This scenario allow the execution of pollutant emitting activities of temporary and experimental nature typical of the pharmaceutical business development and operations such as trial runs at existing process equipment to: validate new products, conduct pilot manufacturing research trial runs and conduct engineering/technical assessments. This scenario is subject to the following conditions:

1. The operation of this scenario does not authorize construction or modification, as defined under Rule 102 of the RCAP, without first obtaining a construction permit under Rule 203 of the RCAP.
2. Activities under this operating scenario will be subject to the same requirements applicable to emission unit EU-1. The operation under this alternate scenario is unauthorized if it is subject to new applicable requirements not included in the emission unit EU-1. For such changes, shall comply with the requirements established under Rule 607 of the RCAP.

3. Activities under this alternate scenario will be temporary in nature (period not exceeding two years) and shall use the existing equipment corresponding to the emission unit EU-1.
4. Shall maintain records indicating the nature of the activities carried out under this alternate operation scenario, amount and type of pollutants emitted, and the equipment used. The logs must be available at all times for inspection by the technical personnel of the EQB.

C. According to Rule 603(a)(10) of the RCAP, the permittee shall, contemporaneously with making a change from one scenario to another, keep a record of the scenario under which it is operating. The record shall be kept at the facility at all times.

**Section VII - Insignificant Emission Units**

1. **Abbott** provided the following list of insignificant activities for a better understanding of its operations and equipment layout. Since there is no requirement to update this list, activities may have changed since the time it was submitted, however **Abbott** shall include the list of insignificant activities that are exempted because of size or production rate. The following activities are considered insignificant if **Abbott** meets the descriptions below.

Emission Unit Identification	Capacity	Description (Exemption basis)
Technical Support Lab	N/A	Appendix B.1 of the RCAP
Diesel Tank	2,250 gal.	Appendix B.3.xi of the RCAP
Propane Tank	500 gal	Appendix B.2 of the RCAP
EU-25 Guide Wires Manufacturing	N/A	Appendix B.2 of the RCAP (VOC Emissions: 0.36 ton/year, according to PFE-09-0607-0644-I-C, June 10, 2009)

**Section VIII - Permit Shield**

A. In accordance with RCAP Rule 603(D), compliance with permit conditions shall be deemed as compliance with any requirement applicable at the date of issuance, provided that this requirement is included and specifically identified in the permit. Similarly, it is considered in compliance with any requirement specifically identified as "Not Applicable" in the permit.

B. Non-Applicable Requirements

Non-Applicable Requirement	Regulation	Fundament/Basis
Chemical Accident Prevention Provisions	40 CFR Part 68	Not applicable since it does not store any substances regulated by this regulation.
Fuel Burning Equipment	Rule 406 of the RCAP	Not applicable to thermal oxidizer or the EFVCS as they are not fuel burning equipment as defined in Rule 102 of the RCAP.

Section IX - Permit Approval

By virtue of the authority conferred upon the Environmental Quality Board by the Environmental Public Policy Act, Law No. 416 of September 22, 2004, as amended, and after verifying the administrative record and compliance with the Uniform Administrative Procedure Law, Law No. 170 of August 12, 1988, as amended, the Clean Air Act, Environmental Public Policy Act and the Regulation for the Control of Atmospheric Pollution of Puerto Rico, the Environmental Quality Board approves the permit subject to the terms and conditions herein established.

In San Juan, Puerto Rico, today March \_\_, 2016.

ENVIRONMENTAL QUALITY BOARD

\_\_\_\_\_  
Suzette M. Meléndez Colón  
Vice President

\_\_\_\_\_  
Rebeca Acosta Pérez  
Associate Member

\_\_\_\_\_  
Weldin F. Ortiz Franco  
President

ABBOTT HEALTHCARE (PUERTO RICO) LTD.  
BARCELONETA, PR  
PFE-TV-2833-09-1096-0011-B  
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APPENDICES

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Appendix I - Definitions y Abbreviations

I. Definitions:

1. Act - Clean Air Act, as amended, *42 U.S. 7401, et seq.*
2. Administrator - Administrator of the Federal Environmental Protection Agency and its authorized representative or the Administrator of a State Agency for Air Pollution Control.
3. Responsible Officer - See the definition of Responsible Officer as established under the Regulation for the Control of Atmospheric Pollution of the Environmental Quality Board (1995).
4. Regulation - Regulation for the Control of Atmospheric Pollution of the Environmental Quality Board.
5. Permittee - Person and/or entity to which the Environmental Quality Board of Puerto Rico has issued an Operating Permit for an Emission Source covered under Title V.
6. Title V - Title V of the Federal Clean Air Act (*42 U.S.C. 7661*).

II. Abbreviations

1. ADI - Abbott Diagnostics
2. AHL - Abbott Healthcare
3. CAM - Compliance Assurance Monitoring
4. cfm - cubic feet per minute (cfm)
5. CFR - Code of Federal Regulations
6. cGMP - current Good Manufacturing Practices
7. CO - Carbon monoxide
8. CO<sub>2</sub>e - Carbon dioxide equivalent
9. EFVCS - Enclosed Flame Vapor Combustion System
10. EPA - Environmental Protection Agency
11. EU - Emission Unit

12. °F - degrees Fahrenheit
13. ft - feet
14. gal - gallons
15. gpm - gallons per minute
16. HAP - Hazardous Air Pollutants
17. hr - hour
18. IR - Interpretative Resolution
19. EQB - Environmental Quality Board of Puerto Rico
20. kg - kilogram
21. lb - pounds
22. LPG - Liquefied Petroleum Gas
23. MACT - Maximum Achievable Control Technology
24. NAAQS - National Ambient Air Quality Standards
25. NO<sub>x</sub> - Nitrogen oxides
26. SIP - State Implementation Plan
27. PM - particulate matter
28. PM<sub>10</sub> - Particulate matter with a particle which diameter has an aerodynamic mass size equal to or less than (10) microns
29. ppmw - parts per million by weight
30. RCAP - Regulation for the Control of Atmospheric Pollution of the Environmental Quality Board.
31. SIC - Standard Industrial Classification
32. SO<sub>2</sub> - Sulfur dioxide
33. ton - ton
34. VOC - Volatile Organic Compound

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Appendix II - Emission Units with their Respective Emission Points

Description		
EU-01		
Equipment Number	Capacity	Control Equipment
Reactor 100	2,500 gallons	DF-100/SC-103 or DF-200 DC-792
Reactor 200	2,500 gallons	DF-100/SC-103 or DF-200
Reactor 225	2,500 gallons	DF-100/SC-103 or DF-200
Reactor 300	2,500 gallons	DF-100/SC-103 or DF-200
Mix Tank 321	2000 gallons	DF-100/SC-103 or DF-200
Reactor 400	3,000 gallons	DF-100/SC-103 or DF-200
Reactor 405	2,500 gallons	DF-100/SC-103 or DF-200 and DC-794
Reactor 500	3,000 gallons	DF-100/SC-103 or DF-200
Dissolving Tank 600	3,000 gallons	
Reactor 900	1,500 gallons	DF-100/SC-103 or DF-200
Reactor 910	2,000 gallons	DF-100/SC-103 or DF-200
Reactor 915	2,000 gallons	DF-100/SC-103 or DF-200
Reactor 920	2,000 gallons	DF-100/SC-103 or DF-200
Reactor RX930	3,000 gallons	DF-100/SC-103 or DF-200
Reactor RX935	3,000 gallons	DF-100/SC-103 or DF-200
Mix Tank 215	1,500 gallons	DF-100/SC-103 or DF-200
Crystallizer 515	3,000 gallons	DF-100/SC-103 or DF-200
Re-Crystallizer 614	3,000 gallons	DF-100/SC-103 or DF-200
Re-Crystallizer 616	3,000 gallons	DF-100/SC-103 or DF-200
Mix Tank - 105	2,500 gallons	DF-100/SC-103 or DF-200
Intermediate Tank TA-118	100 gallons	DF-100/SC-103 or DF-200
Intermediate tank TA-218	100 gallons	DF-100/SC-103 or DF-200
Intermediate Tank TA-220	300 gallons	DF-100/SC-103 or DF-200
Intermediate Tank TA-221	1,000 gallons	DF-100/SC-103 or DF-200
Intermediate Tank TA-418	100 gallons	DF-100/SC-103 or DF-200
Tank TA-626	500 gallons	DF-100/SC-103 or DF-200
Intermediate Tank TA-643	100 gallons	DF-100/SC-103 or DF-200
Intermediate Tank TA-655	100 gallons	DF-100/SC-103 or DF-200
Tank TA-555	200 gallons	DF-100/SC-103 or DF-200
Tank TA-690	200 gallons	DF-100/SC-103 or DF-200
Receiver Tank TA-203	300 gallons	DF-100/SC-103 or DF-200
Tank TA-212	2,000 gallons	DF-100/SC-103 or DF-200
Receiver Tank TA-303	300 gallons	DF-100/SC-103 or DF-200

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Description		
EU-01		
Equipment Number	Capacity	Control Equipment
Receiver Tank TA-403	300 gallons	DF-100/SC-103 or DF-200
Tank TA-424	1,000 gallons	DF-100/SC-103 or DF-200
Receiver Tank TA-503	300 gallons	DF-100/SC-103 or DF-200
Receiver Tank TA-518	300 gallons	DF-100/SC-103 or DF-200
Receiver Tank TA-606	300 gallons	DF-100/SC-103 or DF-200
Tank TA-608	300 gallons	DF-100/SC-103 or DF-200
Reactor RX-910	2,000 gallons	DF-100/SC-103 or DF-200
Tank TA-612	2,500 gallons	DF-100/SC-103 or DF-200
Tank TA-613	2,000 gallons	DF-100/SC-103 or DF-200
Tank TA-940	200 gallons	DF-100/SC-103 or DF-200
Tank TA-950	200 gallons	DF-100/SC-103 or DF-200
Washing Tank TA-527	200 gallons	DF-100/SC-103 or DF-200
Tank WT-940	120 liters	DF-100/SC-103 or DF-200
Tank WT-950	200 gallons	DF-100/SC-103 or DF-200
Centrifuge Holding Tank TA-525	1,500 gallons	DF-100/SC-103 or DF-200
Centrifuge CE-530	N/A	DF-100/SC-103 or DF-200
Centrifuge CE-630	N/A	DF-100/SC-103 or DF-200
Centrifuge CE-950	N/A	DF-100/SC-103 or DF-200
Dryer/Mixer DR-640	100 ft <sup>3</sup>	DF-100/SC-103 or DF-200
Dryer/Mixer DR-652	100ft <sup>3</sup>	DF-100/SC-103 or DF-200
Dryer/Mixer DR-960	100ft <sup>3</sup>	DF-100/SC-103 or DF-200
Fitz Mill FM 900	N/A	DC-795 (95%)
Fitz Mill FM 901	N/A	DC-793
Ethanol Recovery Equipment	1.65X10 <sup>6</sup> gal/year of ethanol	DF-100/SC-103 or DF-200
Steam Stripper Separation Column	N/A	DF-100/SC-103 or DF-200
Feno Acid Cleaning Operations	N/A	DF-100/SC-103 or DF-200
Dust Collector (791)	N/A	N/A
Dust Collector (792)	N/A	N/A
Dust Collector (793)	N/A	N/A
Dust Collector (794)	N/A	N/A
Dust Collector (795)	N/A	N/A
Acid Gases Scrubber	N/A	DF-100/SC-103 or DF-200

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Description		
EU-14		
Tank Number	Capacity	Control Equipment
TA-130	15,000 gallons	DF-100/SC-103 or DF-200
TA-140	15,000 gallons	DF-100/SC-103 or DF-200
TA-300	15,000 gallons	DF-100/SC-103 or DF-200
TA-310	15,000 gallons	DF-100/SC-103 or DF-200
TA-320	15,000 gallons	DF-100/SC-103 or DF-200
TA-330	15,000 gallons	DF-100/SC-103 or DF-200
TA-340	15,000 gallons	DF-100/SC-103 or DF-200
TA-350	15,000 gallons	DF-100/SC-103 or DF-200
TA-360	15,000 gallons	DF-100/SC-103 or DF-200
TA-380	15,000 gallons	DF-100/SC-103 or DF-200
TA-390	15,000 gallons	DF-100/SC-103 or DF-200
TA-400	15,000 gallons	DF-100/SC-103 or DF-200
TA-410	15,000 gallons	DF-100/SC-103 or DF-200
TA-420	15,000 gallons	DF-100/SC-103 or DF-200
TA-440	15,000 gallons	DF-100/SC-103 or DF-200
TA-450	15,000 gallons	DF-100/SC-103 or DF-200
TA-460	15,000 gallons	DF-100/SC-103 or DF-200
TA-600	15,000 gallons	DF-100/SC-103 or DF-200
TA-610	15,000 gallons	DF-100/SC-103 or DF-200
TA-620	15,000 gallons	DF-100/SC-103 or DF-200
TA-630	20,000 gallons	DF-100/SC-103 or DF-200
TA-640	20,000 gallons	DF-100/SC-103 or DF-200
TA-650	15,000 gallons	DF-100/SC-103 or DF-200
TA-660	15,000 gallons	DF-100/SC-103 or DF-200
TA-690	15,000 gallons	DF-100/SC-103 or DF-200
TA-700	15,000 gallons	DF-100/SC-103 or DF-200
TA-720	20,000 gallons	DF-100/SC-103 or DF-200
TA-740	15,000 gallons	DF-100/SC-103 or DF-200
TA-750	15,000 gallons	DF-100/SC-103 or DF-200

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Description	
EU-18	
Equipment	Control Equipment
Evaporator Feed Tank	DF-100/SC-103 or DF-200
Molecular Sieve Feed Tank	DF-100/SC-103 or DF-200
Distillation Column Feed Tank	DF-100/SC-103 or DF-200
Column Forecut Tank	DF-100/SC-103 or DF-200
Waste Mixture Tank	DF-100/SC-103 or DF-200
2 Ethanol Process Tanks	DF-100/SC-103 or DF-200
Stripper Column	DF-100/SC-103 or DF-200

Appendix III - Control Equipment

ID	Emission Point	Description	Manufacturer	Pollutant	Design Efficiency
DF-100	EU1-P1	Thermal Oxidizer - 5.0 MMBtu/hr	Callidus # 302000	VOC/HAP	99%
SC-103	EU1-P1	Gas Scrubber	Ceilcote SPT-42-120	Acid Gases/SO <sub>2</sub>	90%/95%
DF-200	EU1-P5	Enclosed Flame Vapor Combustion System (EFVCS) - 6.0 MMBtu/hr	Callidus	VOC/HAP	99%
DC-791	EU1-P3	Dust Collector	N/A	PM	95%
DC-792	EU1-P4	Dust Collector	N/A	PM	95%
DC-793	EU1-P20	Dust Collector	N/A	PM	95%
DC-794	EU1-P21	Dust Collector	N/A	PM	95%
DC-795	EU1-P2	Dust Collector Sieve	N/A	PM	95%

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