

**COMMONWEALTH OF PUERTO RICO / OFFICE OF THE GOVERNOR**

**FINAL TITLE V OPERATING PERMIT  
AIR QUALITY AREA  
ENVIRONMENTAL QUALITY BOARD**



**Permit Number:** PFE-TV-2833-09-0397-0030  
**Date of Receipt of the Application:** March 26, 1997  
**Final Issue and/or Effective Date:** October 31, 2006  
**Expiration Date:** October 31, 2011

Pursuant to the provisions of Part VI of the Environmental Quality Board Regulations for the Control of Atmospheric Pollution (RCAP) and the provisions of the Code of Federal Regulations (CFR), Title 40, Part 70

**Pfizer Pharmaceuticals LLC (CRUCE DAVILA)  
Barceloneta, Puerto Rico**

hereinafter the permittee or **Pfizer CRUCE DAVILA**, is authorized to operate a stationary source of air pollutant emissions limited to the units and conditions described in this permit. The permit holder may release air pollutants resulting from processes and activities that are directly related to and/or associated with the emission sources, as required, limited or conditioned by this permit, until its expiration date or until the permit is modified or revoked.

The conditions in this permit shall be enforceable by the federal and state governments. Those requirements that may be enforced only by the state government shall be identified as such in this permit. Copy of this permit must be kept in the aforementioned facility at all times.

*ENVIRONMENTAL AGENCIES BUILDING, ROAD 8838 SECTOR EL CINCO, RIO PIEDRAS, PR 00926  
BOX 11488 SANTURCE, PUERTO RICO 00910*

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## **Section I- General Information**

### **I. Facility Information**

Name: **PFIZER PHARMACEUTICALS LLC (CRUCE DAVILA)**

Postal Address: **P. O. BOX 11247**

City: **BARCELONETA** State: **PUERTO RICO** Zip Code: **00617**

Name of Facility: **PFIZER PHARMACEUTICALS LLC (CRUCE DAVILA)**

Postal Address of the Facility: **P. O. BOX 11247, BARCELONETA, 00617**

Physical Address: **STATE ROAD 140, KM 64.4, BARCELONETA, P.R. 00617**

Responsible Official: **Juan Vázquez Crespo** Telephone: **(787) 846-5000**  
**General Manager**

Contact Person in the Facility: **Mr. Eduardo Cordero, Eng.** Telephone: **(787) 621-5145**  
**EHS Director** Fax: **(787) 621-5188**

SIC Primary Code: **2833, 2834**

### **II. Process Description**

PFIZER PHARMACEUTICALS LLC (CRUCE DAVILA) is a industry dedicated to the chemical synthesis manufacturing of active ingredients pharmaceuticals and finished pharmaceutical formulations. The company is located on state road PR-140, Km 64.4 to the south of highway PR-2, Barceloneta, Puerto Rico.

The original facilities were established in 1973 on 56 *cuerdas*. The physical plant covers approximately 392,000 square feet including four large buildings and several small structures, a tank farm, chemical storage area, solvent recovery area and a wastewater pretreatment plant.

Emissions units of the Chemical Synthesis area include the following activities: reactor loading, steam/gas displacement, loss of pressure, gas venting in empty tanks, gas heating and evolution, gas venting to maintain inert atmosphere, vacuum and atmospheric distillation, and vacuum drying. A series of condensers, a process gas scrubber, and several dust collectors are used as air pollution control equipment. The gas scrubber is used for compliance with the Pharmaceutical Industry MACT and the condensers or dust collectors for compliance with the Rule 419 of RCAP. Pfizer Cruce Dávila maintains the Leak Detection and Repair Program (LDAR) to control the fugitive emissions of the components.

Emission units in the pharmaceutical formulation area include the following activities: production of aerosol medications and parenteral products. Human health care products are manufactured in batches during campaigns that last from a few days to several months. The raw materials for the production of aerosols and parenterals originate in the warehouse and are sent to be weighted. The aerosol solution is cooled together with the propellant agent for bottling. Prior to packaging, the bottles are stored to verify there are no leaks. Parenteral solutions are sent to the preparation and filtration rooms. Afterwards, they are transferred to the filling lines and then to the packaging and labeling lines. A series of dust collectors is used as air pollution control equipment.

Bulk storage tanks in the tank farm are used to store chemical materials used in the Chemical Synthesis area. Condensers are used as air pollution control equipment.

Three (3) boilers are used to provide steam to the whole facility. The boilers are prepared to consume #4 or #5 fuel or distilled oil (kerosene, diesel, naphtha, etc.). One of the boilers is reserved as back up. Each boiler is vented by means of separate stacks.

Storage tanks located in the tank farm are used to accumulate process wastes from the chemical synthesis area, which are regulated under the Resource Conservation and Recovery Act (RCRA). Condensers are used as air pollution control equipment in several of the storage tanks.

Wastewaters are discharged into the plant's pretreatment system. The plant has two separate wastewater systems: the Pharmacy area water system and the Chemical Plant water system. Both systems collect the waters to be sent to the pretreatment system. The effluent is discharged into the Barceloneta Regional Wastewater Treatment Plant.

Several ozone-depleting substances are used as refrigerants in the process cooling equipment, HVAC systems and miscellaneous cooling equipment not associated with the manufacturing processes.

**SECTION II - DESCRIPTION OF THE EMISSION UNITS**

The emission units regulated by this permit are as follows:

<b>Emission Unit</b>	<b>Description of Emission Unit</b>	<b>Control Equipment</b>
<p>EU-Chemical Plant (EU-2)</p>	<p>Prior to beginning any batch, the operator makes sure that the equipment to be used is empty. Immediately the raw materials are charged in the designated vessels. The contents are heated or cooled to the acceptable temperature. When the contents of the vessel reach the desired conditions, the materials are crystallized and then the materials are separated by the centrifuges into wet solids and the mother liquors that will go to the vessels that collect the dangerous waste for final disposition.</p> <p>The operator makes sure that the drying equipment to be used is empty prior to begin processing any batch. The wet solids are loaded into the designated drying equipment to minimize the humidity content to the desired level. The condensate in the drying equipment is transferred to the vessels. The dried material is emptied or unloaded to tote bins or fiber drums and transferred to the Pin Mill PMPA.</p> <p>The operator makes sure that the grinding equipment to be used is empty, prior to begin any batch. Then the material is loaded onto the equipment since the tote bin or fiber drums. On the grinding process finished, the materials are transferred to the fiber drums and sent to the designated storage area.</p> <p>This emission unit uses the gas scrubber as control equipment for compliance with MACT and the condenser for the compliance with the control requirement of the Rule 419 of the RCAP for those equipments that are not MACT affected. At the moment this emission unit does not have waste water (determination point) nor tanks affected by the MACT requirements.</p>	<p>The gas scrubber (for the effect of the compliance with the Pharmaceutical Industry MACT) and the condensers or gas scrubber (for the effect of the Rule 419 of the RCAP)</p>
<p>EU-Combustion Equipment (EU-4)</p>	<p>There are three boilers that supply steam and other company utilities. Normally, there are two identical boilers in operation (boilers 1 and 2), while the remaining boiler (boiler 3) is used as back up. Boilers 1 and 2 are 500 hp each and boiler 3 is 600 hp.</p> <p>The boilers can use fuel #5 with 0.91% sulfur content by weight or fuel #2 with 0.5% by weight. The fuel is stored in 4 storage tanks throughout the facilities.</p>	

Emission Unit	Description of Emission Unit	Control Equipment
EU-Solvent Recovery (EU-6)	Distillation units for solvent recovery for reuse. These solvents are recovered using a series of filling, heating, and separating steps.  This unit is not currently in operation.	Condensers
EU-Tank Farm (EU-7)	This unit consists of bulk storage tanks for chemical substances used in production. Some of these tanks have conservation vents or condensers.	Condensers
EU-Wastewater Pretreatment Plant (EU-8)	Collection of wastewaters, transfer and treatment of process and sanitary waters prior to final disposition to the Barceloneta Regional Treatment Plant.	
EU-Ozone-Depleting Substances (EU-9)	Chlorofluorocarbons (CFC) are ozone-depleting substances used in a pharmaceutical production area. These substances are part of the production process and are used as propellants in pharmaceutical production.  Pfizer Pharmaceuticals LLC (CRUCE DAVILA) has CFC-12, CFC-114, Mixture of CFC-12 and CFC-114 refrigerant storage tanks. Pfizer Pharmaceuticals LLC (Cruce Dávila) use refrigerant system that to contain regular refrigerant for the production areas and to create a comfortable work environment.	Carbon Adsorber

### SECTION III- GENERAL CONDITIONS OF THE PERMIT

1. **Sanctions and Penalties:** The permittee shall be obliged to comply with all the terms, conditions, requirements, limitations, and restrictions established in this permit. Any violation of the terms of this permit shall be subject to administrative, civil or criminal measures, as established under Article 16 of the Environmental Public Policy Act, (Public Law Number 416 of September 22 of 2004).
  
2. **Right of Entry:** Pursuant to the provisions of Rules 103 and 603I(2) of the RCAP, the permittee shall grant access to EQB representatives to its facilities, upon presentation of credentials, to perform the following:
  - a) Enter upon any premises where an emission source is located, or where air emission-related activities are conducted, or where records must be kept under the conditions of the permit, the agreement with the RCPA, or the US Clean Air Act;
  
  - b) Have access to and copy, at reasonable times, any records that must be kept under the conditions of the permit, the agreement with the RCPA or the US Clean Air Act;
  
  - c) Inspect and examine any facilities, equipment (including air monitoring and pollution control equipment), practices or operations (including methods

used for quality control) regulated or required under the permit, and perform emission and fuel sampling;

- d) As authorized by the Act and the Regulations sample substances or parameters, at reasonable times, for the purpose of assuring compliance with the permit or applicable requirements.

3. **Sworn Statement:** All reports required pursuant to Rule 103(D) of the RCAP (to wit, semiannual sampling reports and annual certification of compliance), shall be submitted together with a sworn statement or affidavit of the Responsible Official or authorized representative. Such sworn statement shall attest to the truthfulness, correctness, and completeness of such records and reports.
4. **Data Availability:** As provided by rule 104 of the RCAP, all emissions data obtained by or submitted to the EQB, including data reported pursuant to Rule 103 of the RCAP, and any data otherwise obtained, shall be available for public inspection and may also be made available to the public in any additional ways that the EQB may deem appropriate.
5. **Emergency Plan:** Pursuant to Rule 107 of the RCAP, the permittee shall have an Emergency Response Plan available, which must be consistent with adequate safety practices, and which provides for the reduction or retention of facility emissions during periods classified by the EQB as air pollution alerts, warnings, or emergencies. These plans will include the reduction to be achieved for each source and the means by which such reduction will be accomplished. These plans will be available for inspection by any authorized EQB representative, at any time.
6. **Control Equipment:** The permittee shall comply with Rule 108 of the RCAP, as follows:
  - A. All air pollution control equipment or control measures shall provide for continuous compliance with applicable rules and regulations. Such equipment or measures shall be installed, maintained, and operated according to those conditions imposed by this Title V Permit, within the operational limits specified by the manufacturer.
  - B. The material collected from the air pollution control equipment shall be disposed of in accordance with applicable rules and regulations. The removal, handling, transport, storage, treatment or disposal shall be done in such a way that it will not produce environmental degradation, and in accordance with applicable rules and regulations.
  - C. The EQB may require 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, when deemed appropriate to safeguard the health and welfare of human beings. Furthermore, the Board may require that such additional air pollution control equipment be operated continuously and together with the primary air pollution control equipment.

- D. All air pollution control equipment shall be operated at all times when the source being controlled is in operation.
- E. In case of a shutdown of air pollution control equipment for the necessary scheduled maintenance, the Board shall be informed of the intention to shut down such equipment, at least three days prior to the planned shutdown. Such prior notice shall include, but is not limited to:
  - (1) Identification of the specific source to be removed from service, including its location and permit number.
  - (2) The expected length of time that the air pollution control equipment will be out of service.
  - (3) The nature and quantity of the air pollutants that are likely to be emitted during the control equipment shutdown period.
  - (4) Special measures to be taken to minimize the duration of the control equipment shutdown period, such as the use of irregular personnel and additional equipment.
  - (5) The reasons why it will be impossible or impractical to shut down the operations of the facility during the repair period.
- F. To the extent possible, maintain and operate any affected source and associated air pollution control equipment at all times, including startup, shutdown and malfunction periods, and shall do so in a manner that is consistent with the original manufacturer's design specifications, and in compliance with applicable rules and regulations and permit conditions.

- 7. Certification of Compliance:** As specified under Rule 602 (c)(2)(ix)(C) of the RCAP, the permittee shall submit each year a compliance certification to both the Board and the EPA<sup>1</sup>, no later than ninety (90) days after the date of anniversary of this permit. The certification shall include the information required under Rule 603 (c) of the RCAP.

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<sup>1</sup> The certification to the EQB shall be mailed to: Manager, Air Quality Area, P.O. Box 11488, Santurce, PR, 00910. The certification to the EPA shall be mailed to: Chief, Permitting Section, Air Program Branch, EPA Region II, 290 Broadway, New York, NY, 10007.

- 8. Location Approval:** Pursuant to Rule 201 of the RCAP, nothing in this permit shall be construed as authorizing the location or construction of a major stationary source, or the significant modification of a major stationary source, without first obtaining a location approval from the EQB, and without showing compliance with the National Ambient Air Quality Standards (NAAQS). This permit does not authorize the construction of a new minor source without first obtaining a construction permit as provided under Rule 203 of the RCAP.
- 9. Open Burning:** Pursuant to Rule 402 of the RCAP, no permittee shall cause or permit the open burning of refuse in the premises except as provided in paragraph (E) of said rule which authorizes fire fighting training or investigation of fire fighting techniques. The permit holder shall:

  - a) Keep records of training or investigation-related fire fighting activities. These records shall be available upon request.
  - a) Submit to the Board, on an annual basis, a schedule of the training or investigation-related fire fighting activities and notify the Board seven days in advance of the date of each activity.
- 10. Fugitive Emissions of Particulate Matter:** Pursuant to Rule 404 of the RCAP, no permittee shall cause or permit:

  - a) any materials to be handled, transported or stored in a building or its appurtenances, or a road to be used, constructed, altered, repaired or demolished without taking reasonable precautions to prevent particulate matter from becoming airborne.
  - b) visible emissions of fugitive dust beyond the boundary line of the property on which the emissions originate.
- 11. Objectionable odors:** Pursuant to Rule 420 of the RCAP, no permittee shall cause or permit the emission to the atmosphere of matter that produces *objectionable or disagreeable* odors that can be perceived in an area other than that designated for industrial purposes. The permittee shall show compliance with Rule 420 (A)(1) as follows: if objectionable odors are detected beyond the area designated for industrial purposes and complaints are received, the permittee shall investigate and take measures to minimize or eliminate the objectionable odors, as needed [State enforceable condition only.]
- 12. Permit Renewal Applications:** Pursuant to Rule 602(a)(1)(iv) of the RCAP, the permittee shall submit a permit renewal application to the EQB at least 12 months

prior to its expiration date. The responsible official shall certify each of the forms required pursuant to paragraph (c)(3) of Rule 602 of the RCAP.

- 13. Permit Duration:** Pursuant to Rule 603 of the RCAP, the following terms shall govern for the duration of this permit:

  - a) **Effective Date:** The permit shall become valid and in effective after it is signed by the Governing Board of the Environmental Quality Board, unless objected by EPA within their 45 day review period.
  - b) **Expiration:** This authorization shall have a fixed term of five (5) years. The expiration date will be automatically extended until the Board approves or denies a renewal application (Rule 605(c)(4)(ii) of the RCAP) but only in those cases where the permittee submits a complete renewal application at least twelve (12) months before the expiration date. (Rule 603 (a)(2), Rule 605 (c)(2) and Rule 605 (c)(4) of the RCAP)
  - c) **Permit Shield:** As specified under Rule 605 I(4)(i) of the RCAP, the permit shield may be extended until the time it is renewed if a timely and complete renewal application is submitted.
  - d) In the case that this permit is is subject to any challenge by third parties, the permit shall remain in effect until the time it is revoked by a court of law with jurisdiction in the matter.
- 14. Recordkeeping Requirements:** Pursuant to Rule 603(a)(4)(ii) of the RCAP, the permittee must keep records of all required sampling data and support information for 5 years from the date of the sampling, measurement, report or sampling application.
- 15. Sampling Reporting Requirements:** Pursuant to Rule 603(a)(5)(i) of the RCAP, the permittee must submit reports of any required sampling every six months, or more frequently if required by the EQB or any other applicable requirement. All instances of deviations from permit requirements must be clearly identified in such reports. All required reports must be certified by a responsible official consistent with Rule 602(c)(3) of the RCAP.
- 16. Reporting of Deviations Due to Emergency:** Pursuant to Rule 603(a)(5)(ii)(a) of the RCAP, any deviation attributable to upset conditions (such as sudden failure or rupture) or emergency as defined in Rule 603(e) of the RCAP must be reported within two working days. Said notification may be used as an affirmative defense should any action be brought against the permittee. If the permittee asserts the emergency defense in an action for compliance, the permittee shall have the burden of proof to show that the deviation was a result of an emergency and that the Board

was adequately notified. If such deviation for emergency were to extend beyond 24 hours, the affected units may be operated until the end of the cycle or 48 hours, whichever comes first. The Board may only extend the operation of an existing source of emission beyond 48 hours if the source were to show, to the Board's Satisfaction, that the National Ambient Air Quality Standards (NAAQS) would not be exceeded and it would not constitute a risk to public health.

- 17. Notification of Deviations (Hazardous Air Pollutants):** The source shall immediately cease to operate or act as stipulated in its Emergency Response Plan (established in Rule 107 I), when said plan has demonstrated that there is no significant impact in premises other than those designated for industrial use. (State enforceable condition only.) Pursuant to Rule 603 (a)(5)(ii)(b) of the RCAP, the Board shall be notified within 24 hours of any deviation that results in a release of emissions of hazardous air pollutants that continues for more than one hour in excess of the applicable limit. In case of a release of any regulated air pollutant that continues for more than 2 hours in excess of the applicable limit, the Board shall be notified within 24 hours of the deviation. The permittee shall, also, within 7 days of the deviation, submit to the EQB a written detailed report including the probable causes, time and duration of the deviation, remedial action taken, and steps that are being undertaken to prevent a reoccurrence.
- 18. Deviations:** Pursuant to Rule 603(a)(5)(ii)(c) of the RCAP, all other deviations must be reported in the permittee's semiannual report unless the permit or applicable requirement requires more frequent reporting.
- 19. Severability Clause:** Pursuant to Rule 603(a)(6) of the RCAP, the permit clauses are severable. In the event of a successful challenge to any part of the permit in an administrative or judicial forum, or should any of the clauses of the permit be declared invalid, said determination shall not affect the remaining clauses contained herein, including those that deal with emission limits, terms and conditions, whether specific or general, and sampling requirements, and maintenance of records and reports.
- 20. Noncompliance with the Permit:** Pursuant to Rule 603(a)(7)(i) of the RCAP, the permittee must comply with all the conditions of the permit. Any permit noncompliance constitutes a violation of the Regulations and shall be grounds for enforcement action, sanctions, revocation, termination, modification, reissuance of the permit, or for denial of a permit renewal application.
- 21. Non-permissible Defense:** Pursuant to Rule 603(a)(7)(ii) of the RCAP, the permittee may not allege as 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 the permit.

- 22. Modification and Revocation of the Permit:** Pursuant to Rule 603(a)(7)(iii) of the RCAP, the permit may be modified, revoked, reopened, reissued or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance or termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit conditions.
- 23. Property Rights:** Pursuant to Rule 603(a)(7)(iv) of the RCAP, this permit does not create or convey any property rights of any sort, or any exclusive privilege.
- 24. Obligation to Furnish Information:** Pursuant to Rule 603(a)(7)(v) of the RCAP, the permittee shall furnish the EQB, within a reasonable time, any information that the EQB may request to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit or to determine compliance with the permit. Upon request, the permittee shall also furnish to the EQB copies of records required to be kept by the permit.
- 25. Change of Operating Scenario:** Pursuant to Rule 603(a)(10) of the RCAP, the permittee shall, contemporaneously with making a change from one operating scenario to another, record in a log the scenario under which it is operating. This record shall be kept in the facilities at all times.
- 26. Final Action:** Pursuant to Rule 605(d) of the RCAP, no permit shall be deemed 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 take final action on a permit application within 18 months should be treated as a final action solely for the purpose of obtaining judicial review in state court.
- 27. Administrative Amendments and Permit Modifications:** Pursuant to Rule 606 of the RCAP, no amendments or changes may be made to the permit without first complying with the administrative amendment and permit modification requirements established by the RCAP.
- 28. Permit Reopening:** Pursuant to Rule 608(a)(1) of the RCAP, the permit may be reopened and reviewed for any of the following circumstances:

  - a. When additional requirements under any law or regulation become applicable to the permittee with a remaining permit term of three (3) or more years. Such a reopening shall be completed eighteen (18) months after promulgation of the 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 has been extended pursuant to Rule 605I(4)(i) or 605I(4) (ii) of the RCAP.

- b. When 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. When the EQB or the EPA determines that the permit must be revised or revoked to assure compliance with the applicable requirements.
- 29. Change of Name or Ownership:** This permit is issued to **Pfizer Pharmaceuticals LLC (Cruce Dávila)**. Should the name of the company or facility change, or should it be transferred to a different owner, the new responsible official shall submit an administrative amendment that complies with the requirements of Rule 606 of the RCAP.
- 30. Renovation / Demolition Activities:** The permittee must comply with the provisions under 40 CFR §61.145 and §61.150 and Rule 422 of the RCAP when carrying out any renovation or demolition in its facilities.
- 31. Risk Management Plan:** If during the effective date of this permit, the permittee were subject to 40 CFR Part 68, said permittee must submit a Risk Management Plan in accordance with the schedule of compliance in 40 CFR Part 68.10. If during the effectiveness of this permit, the permittee were subject to 40 CFR Part 68, as part of the annual certification of compliance required under 40 CFR Part 70, said permittee must include a certification of compliance with the requirements of Part 68, including recordkeeping and Risk Management Plan. The permittee must comply with the general obligation requirements of section 112I(1) of the act as follows:
- a) Identify the risks that may result in accidental leaks using appropriate risk evaluation techniques.
  - b) Design, maintain, and operate a safe facility.
  - c) Minimize the consequences of accidental leaks, should they occur.
- 32. Emergency Generators:**
- a) The operation of each generator identified as insignificant activity is limited to 500 hours per year.
  - b) The permittee shall keep a record of the hours of operation and fuel use of each generator. This record shall be available for inspection by Board and EPA personnel.
- 33. Fire pumps:**

- a) The operation of each fire pump is limited to 500 hours per year.
  - b) The permittee shall keep a record of the hours of operation and fuel use of each fire pump. This record shall be available for inspection by Board and EPA personnel.
- 34. Weatherproofing of Roof Surfaces:** Pursuant to Rule 424 of the RCAP, the permittee shall not cause or permit hot tar or any other weatherproofing material containing organic compounds to be applied without the prior authorization of the Board. The use of used oils or hazardous wastes for weatherproofing is prohibited. State enforceable only.
- 35. Compliance Clause:** Compliance with the permit shall in no way exempt the permittee from complying with all other state and federal laws, regulations, permits, administrative orders or applicable judicial decrees.
- 36. Calculation of Emissions:** On April 1<sup>st</sup> of each year, the permittee shall send the estimate of real or permissible emissions for the previous calendar year. The estimate of emissions shall be provided in the forms prepared by the EQB for such purposes. The responsible official will certify that all the information submitted is correct, true and representative of the permitted activity. On June 30 of each year, or earlier, the permittee shall pay for the emissions of the previous calendar year.
- 37. Annual Fee:** The permittee shall submit an annual payment based on real emissions of regulated pollutants at a rate of \$37.00 per ton unless the Board determines a different fee based on the provisions of Rule 610(b)(2)(iv) of the RCAP. Payment shall be made on June 30 of each year or earlier.
- 38. Reservation of Rights or Reserved Rights:** Except as expressly provided in this Title V permit:
- a) Nothing herein shall bar the Board or the EPA from taking administrative or legal action to enforce the terms of the Title V permit, including, but not limited to, the right to request an injunction, impose statutory penalties and fines.
  - b) Nothing herein shall be construed as a limitation of the rights of the Board or the EPA to take any criminal action against the permit holder or any other person.
  - c) Nothing herein shall be construed as a limitation of the authority of the Board or the EPA to take any action in response to conditions that constitute a

substantial and imminent danger to the health or well being of the public or the environment.

- d) Nothing herein shall be construed as a limitation of the right of the permittee to an administrative hearing and judicial review of a termination/ revocation/ denial action pursuant to the Environmental Public Policy Act and Regulations.

- 39. Amendments or New Regulations:** Should a new regulation be established or an existing regulation be amended (state or federal) and if it is determined that it applies to your facility, you must comply with the stipulations of said regulation or amendment once it becomes effective.
- 40. General Obligation:** Under Section 112 I of the US Clean Air Act, Pfizer Pharmaceuticals LLC (Cruce Dávila) has a general duty to identify hazards that may result in accidental releases of a controlled substance or any other extremely hazardous substance of a process by using generally accepted assessment techniques and designing, maintaining and operating a safe facility and minimizing the consequences of accidental releases, if they should occur, as required under 112 I(1) of the US Clean Air act and Rule 107 (D) of the RCAP.
- 41. Industrial, Commercial or Institutional Boilers and Process Heaters:** All existing sources having or operating industrial, commercial or institutional boilers and process heaters are subject to the National Emission Standards for Hazardous Air Pollutants for industrial, commercial or institutional boilers and process heaters in Subpart DDDDD of 40 CFR. The affected sources must comply with the emission limits of this subpart no later than 3 years after the date of publication of the final rule in the Federal Register, unless it is determined that said regulation is not applicable or Pfizer Pharmaceuticals LLC (Cruce Dávila) has an extension of compliance with the emission standards that is consistent with 40 CFR §63.6(i) in which case it must comply with said requirements by the date specified in the extension of compliance granted. Unless it is determined that said regulations are not applicable to it, Pfizer Pharmaceuticals LLC (Cruce Dávila) must comply with the notification provisions of 40 CFR §63.7545 according to the schedule in 40 CFR §63.7545 and 40 CFR part 63, Subpart A. According to §63.7495(d) of 40 CFR, some of the notifications must be submitted before Pfizer Pharmaceuticals LLC (Cruce Dávila) is required to comply with the emission limits and work practice standards of 40 CFR part 63 subpart DDDDD.
- 42. Reports:** All reports required by the Board must be addressed to: Manager Quality Area, Box 11488, Santurce, P. R. 00910.
- 43. Off-Permit Changes:** Pursuant to Rule 607(b)(1), Pfizer Pharmaceuticals LLC (CRUCE DAVILA) can make changes without obtaining a permit review if such

changes are not mentioned or prohibited under this permit, unless said changes constitute modifications under Title I of the US Clean Air Act.

- i. Each such change shall meet all applicable requirements and shall not violate any existing permit term or condition.
- ii. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must provide contemporaneous written notice to the Board and the EPA of each such change except for changes that qualify as insignificant under paragraph I(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 as a result of the change.
- iii. The change shall not qualify for the shield under paragraph (d) of Rule 603.
- iv. The permittee shall keep a record describing changes made at the source that could 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.

**44. Storage Tanks:** Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall keep records of the distilled fuel (diesel) storage tanks listed as insignificant activities showing the dimensions of the storage tanks and an analysis showing the capacity of the storage tanks pursuant to §60.116(b) of 40 CFR. Said documents shall be available for review by Board technical personnel and will be kept in the facility for the life of each tank.

#### **SECTION IV - ALLOWABLE EMISSIONS**

The emissions that are described in the following table represent the potential emissions of the facility at the time of the permit application and shall be used for fee payment purposes only. In agreement with the Resolution R-97-47-1, the emissions calculations will be based on the actual emissions of the Pfizer Pharmaceuticals LLC (Cruce Dávila), although calculations based on permissible emissions of the source will be accepted. If Pfizer Pharmaceuticals LLC (Cruce Dávila) wants to make the calculations being based on permissible emissions they will pay the same fee (charge) by tons that the sources that the calculations make being based on actual emissions. In addition, when Pfizer Pharmaceuticals LLC (Cruce Dávila), applies for a modification, administrative amendments or minor permit modification to the Title V permit, will only have to pay the payment by ton based on the increase in emissions by caused ton, if some, by the change and not it totality of the positions in agreement with the Rule 610(a) of the RCAP.

<b>Pollutants</b>	<b>Permissible Emissions (tons/year)</b>
PM <sub>10</sub>	22
SO <sub>x</sub>	100
NO <sub>x</sub>	100
VOC	722
CO	46
HAP's	180
CFC	57

## **SECTION V - SUBMISSION OF REPORTS**

Pursuant to Rule 112(B) of the RCAP, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must submit a certification of compliance for the previous calendar year before April 1 of each year, with all the requirements specified in this permit. Said certification must be signed by the responsible official who will certify its validity pursuant to Rule 602 (c)(3) of the RCAP.

## **SECTION VI - PERMIT CONDITIONS**

### **A. Requirements for the Entire Facility**

#### **1. Tank ST-14 B [PFE-09-0801-1905-I-C]:**

- i. Authorized emissions represent the storage of 2,878,193 gallons per year of 70% isopropyl alcohol (IPA) in tank ST-14 B.
- ii. Will keep a monthly record with the following information:
  - a. Monthly amount of stored solvent, in gallons.
  - b. The materials safety data sheet (MSDS)
  - c. Evidence of solvent purchase.

It shall be available at all times in the facility for review by Board technical personnel.

#### **2. Particulate collectors and gas scrubber [PFE-01-09-0898-0077-I-C]:**

- i. The facility must operate and maintain all air pollution control mechanisms, such as dust collectors and gas scrubbers in order to comply with regulations in effect and these shall be operated at all times when the source being

controlled is in operation.

- ii. Dust collectors designed to control particulate matter emissions must be provided with a pressure drop gauge to determine the operational efficiency of the control unit, which must be calibrated annual. The calibration results must be accessible at Pfizer Pharmaceuticals LLC (Cruce Dávila) for evaluation by our technical personnel, as required. A daily record of the readings of these gauges shall be kept. The pressure load must comply with the limits stipulated by the manufacturer.
- iii. The flow meter in the gas scrubber must be calibrated annually in compliance with condition 2(i) of this section. The calibration results and the methodology used shall be kept accessible at the plant for evaluation by our technical personnel, as they deem pertinent.

**B. Requirements for Each Emission Unit**

The table below summarizes the applicable requirements and the test methods for all emission units identified in Section II of this permit.

**1. EU-Chemical Plant (EU-2)**

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reporting Frequency
VOC emission limit	VOC	3	Pounds per hour	N/A	N/A	N/A	N/A
		15	Pounds per day				
Process Source Limit	Particulate Mater (PM)	Value will be determined using the table in Rule 407 (a)	output lbs/ input lbs-hr	Records	Daily	Record Book	Biannually

**A. VOC EMISSION LIMIT:**

- (i) Pursuant to Rule 419 of the RCAP, the permittee shall not permit the emission of 3 lbs/hr or 15 lbs/day of VOC from any item, machine, equipment or any other device unless it is provided with a control system, pollution prevention and reduction mechanism or programs

or both, as approved or required by the Board. [State enforceable condition only.]

- (ii) The permittee shall comply with the above condition using the gas scrubber and the condensers in the emission units described as EU-Chemical Plant (EU-2).
- (iii) The permittee shall operate all air pollution control equipment at all times when emissions in excess of the limits established in Rule 419 of the RCAP are or may be generated during the manufacturing process.

## **B. PROCESS SOURCE LIMITS:**

- (i) The permittee shall determine the maximum amount of particulate matter emissions from a process source using the Table in Rule 407 (A). Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall not cause or permit the emission of particulate matter in excess of that amount from uncontrolled emissions of a process source for any one-hour period. [Rule 407 of the RCAP].
- The permittee shall read and record the water flow in the gas scrubber as specified in the Pharmaceutical Industry MACT. Pfizer (CRUCE DAVILA) shall calibrate annually the water flow meter and shall keep the record with the data and calibration methodology and made accessible to Environmental Quality Board personnel. The records shall be kept at the facility for five (5) years. [Rule 603 (A)(4)(ii) of the RCAP]
- (iii) The permittee shall demonstrate compliance with the above requirements by maintaining the water flow for the gas scrubber.

## **2. General Conditions for EU-Chemical Plant (EU-2)**

- (i) Heat exchangers using *THERMINOL* (E-82-01, E-82-02, E-84-01 y E-84-02) may be used instead of gas scrubbers (S-303). The permittee must show by means of good engineering practices that the heat exchangers have a removal efficiency of 93%. The Board reserves the right to request an efficiency test, at its discretion. [Condition 6 of PFE-09-1100-2112-II-C]
- (ii) The water flow meter in the gas scrubber shall be calibrated annually. The calibration results and methodology must be kept accessible at

the plant for evaluation by our technical personnel, as required.  
 [Condition 4 of PFE-01-09-0898-0077-I-C]

- (iii) The dust collector designed to control particulate matter emissions must be provided with a pressure drop gauge to determine the operational efficiency of the control unit, which must be calibrated at least twice a year. The calibration results shall be kept in an accessible location in the facility for evaluation by our technical personnel, as required. A daily record of the readings of this gauge shall be kept. The pressure load must comply with the limits stipulated by the manufacturer. [PFE-09-0899-1287-I-C]

**3. Combustion Equipment (EU-4): Two 500 hp Boilers and One 600 hp Boiler**

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reporting Frequency
Particulate matter limit	Particulate matter	0.3	Pounds per million BTU	Stack Test using Method # 5 of Appendix A, 40 CRF Part 60, during the first year of the permit.	During the first year of the permit.	Keep a copy of the final report for five (5) years from the date of the report [Regulation 603 (A)(4)(ii)].	Sixty (60) days after sampling.
SO <sub>2</sub> emission limit	Fuel	0.50	Per cent by weight	Certification by supplier	Every time fuel is received	Record of sulfur percent	Monthly
	Distillate (No. 2)						
	No. 5	0.91					
Fuel consumption	Fuel	2,764,840	Gallons/ Year	Flow meter	Calculate daily consumption	Daily record of the fuel consumption of that reflect annual compliance of 365 rotative days.	Annually
	Distillate (núm.2)						
	No. 5	1,374,005					
Visible emissions	Visible emissions	20	Average percent 6 minutes	Method 9  Visible emissions	Once during the first permit year.  Weekly	With each reading	Sixty days from the date of the reading.
Limit for simultaneous operation of	N/A	N/A	N/A	Keep record	Daily	Record Book	Monthly

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reporting Frequency
no more than 2 boilers							

**A. PARTICULATE MATTER LIMIT:**

- (i) The permittee shall not cause or permit the emission, from any fuel burning equipment burning solid or liquid fuel, of particulate matter in excess of 0.3 pounds per million Btu of heat input. [Rule 406 of the RCAP]
- (ii) The permittee shall perform a sampling during the first year of the permit to determine compliance with the standard using Method 5 of 40 CFR 60, Appendix A. [Rule 602 I(2)(ix)I of the RCAP]
- (iii) The permittee shall submit a sampling protocol to the EQB (30) days prior to the start of the test. [Rule 106 I of the RCAP]
- (iv) The permittee shall provide fifteen (15) days prior written notification of any sampling, to afford the EQB the opportunity to have an observer present. [Rule 106 (D) of the RCAP]
- (v) The permittee shall submit a final report within sixty (60) days after the performance of the sampling [Rule 106 (E) of the RCAP]
- (vi) Pursuant to Rule 603(a)(4)(ii) of the RCAP, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must retain records of all required sampling data and support information for 5 years from the date of the sampling, measurement, report or sampling application.

**B. SO<sub>2</sub> EMISSION LIMIT:**

- (i) Pursuant to Rule 410 of the RCAP, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall burn distilled fuel (no. 2) with a maximum sulfur content of 0.5% by weight and fuel oil # 5 with a maximum sulfur content of 0.91% by weight in the three boilers.
- (ii) Pursuant to Rule 603(A)(4)(ii) of the RCAP, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must retain records of all required sampling data and support information for 5 years from the date of the sampling, measurement, report or sampling application. This

includes a record of the fuel consumption and sulfur content monthly reports for the burned fuels.

- (iii) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must submit, during the first fifteen (15) days of the month following the reported month, monthly reports indicating fuel consumption and the sulfur content by weight for the fuels consumed in the three boilers. These reports must include a copy of the certification of sulfur content provided by the supplier.
- (iv) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall keep a supplier-certified copy indicating the sulfur content in the fuels (distillate no. 2 and no. 5) to comply with the requirement to keep a daily record of the sulfur content of burned fuels.
- (v) Each year, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must file a copy of the monthly and annual fuel consumption reports for the three boilers, together with the annual certification of compliance.

#### **C. FUEL CONSUMPTION LIMIT:**

- (i) The permittee shall not exceed a fuel oil #2 consumption of 2,764,840 gallons annually and a fuel oil # 5 consumption of 1,374,005 annually in all three boilers for any period of 365 rotative days. Compliance with this specified limit shall be determined based on a daily rolling average plus the total fuel used during the preceding 364 days, for the day in question. The consumption limit of fuel #2 of 2,764,840 gals/year operate the independent form of the consumption limit of fuel #5 of 1,374,005 gallons/year.
- (ii) The permittee shall install and operate fuel flow meters in the three boilers. The fuel meters must be calibrated every six months as recommended by the manufacturer. The calibration results and the methodology must be available in the facility for inspection by the Board's technical personnel.
- (iii) Daily records for the consumption of fuel oil # 5 and diesel (#2), the sulfur content, hours of operations, vapor production and rate of auxiliary fuel consumption shall be maintained for each boiler. [PFE-09-1100-2112-II-C]
- (iv) Every month, a daily record of the fuel consumption of each boiler and its percent sulfur content by weight shall be submitted to the Board no later than the 15<sup>th</sup> day of the month following the report, as

required by Rule 410 of the RCAP. Said report must be sent to the Head of the Validation and Data Management Division of the Air Quality Section and must be available at all times at the facility for review by Board technical personnel.

- (v) Pursuant to Rule 603(A)(4)(ii) of the RCAP, the permittee must retain records of all required sampling data and support information for 5 years from the date of the sampling, measurement, report or sampling application. This includes a record of the monthly and annual consumption reports for fuel and the sulfur content of the fuels burned. The compliance with this specified limit will be determined in a daily rotative average, by adding the total fuel used to the 364 days after the day in question.
- (vi) Every year, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must file a copy of the fuel consumption reports for each boiler, based on monthly and annual consumption, together with the annual certification of compliance.

#### **D. VISIBLE EMISSION LIMITS:**

- (i) The permittee shall not exceed the 20% opacity limit in a six-minute average. However, pursuant to Rule 403 (A) of the RCAP, it may discharge visible emissions of opacity of up to 60% for a period of no more than 4 minutes in any consecutive 30-minute interval.
- (ii) The permittee shall hire an independent opacity reader, certified by an institution approved by the EPA to perform an opacity reading in each stack for the three boilers during the first year of the permit using Method 9 of 40 CFR part 60, Appendix A. The boilers must be in operation at the time of the opacity reading.
- (iii) The permittee shall submit a sampling protocol to the EQB at least thirty (30) days prior to the start of the test. [Rule 106 I of the RCAP].
- (iv) The permittee shall provide at least fifteen (15) days of prior written notification of any sampling, to afford the EQB the opportunity to have an observer present. [Rule 106 (D) of the RCAP]
- (v) The permittee shall submit a final report within sixty (60) days after the performance of the sampling. [Rule 106 (E) of the RCAP]
- (vi) The permittee shall perform weekly visual opacity inspections during the daytime using a Visible Emissions Reader certified by a program

approved by the EPA or the EQB. When a certified reader establishes that the opacity limit is being exceeded pursuant to Rule 403 of the RCAP, Pfizer Pharmaceuticals LLC (Cruce Dávila) must verify that the equipment and control equipment causing the visible emissions is operating as per manufacturing specifications and permit conditions. Should it not be operating adequately, corrective actions will immediately be taken to eliminate the excess opacity.

- (vii) The Board reserves the right to require additional visible emission readings in order to demonstrate compliance with the opacity limit.
- (viii) The permittee must retain the records of all required sampling data and support information for a period of five years from the date of the sampling, measurement, report or sampling application. This includes a record of the visible emission readings including the dates and times of the readings, and information regarding the corrective measures taken.

#### **E. SIMULTANEOUS OPERATION LIMIT:**

- (i) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may operate the two 500 hp boilers simultaneously. The 600 hp boiler has permit to operate in place of one of the 500 hp boilers. [PFE-09-1100-2112-II-C]
- (ii) The conditions related to boiler limitations may only be changed if favorable results are obtained in a new run of the dispersion model with additional restrictions in fuel consumption and its sulfur content. [PFE-09-0992-1170-I-II-O]
- (iii) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall make a note of the daily hours of operation of each boiler. The files shall be in the form of records and will include the date and time of operation of each boiler to ensure that no more than two boilers operate simultaneously.
- (iv) The 600 hp boiler may be used in place of one of the 500 hp boilers when one of these is out of service, always maintaining the fuel consumption limit of 1,374,005 gallons per year and sulfur content of 0.91% by weight. [PFE-09-1100-2112-II-C]

#### **4. EU-Solvent Recovery (EU-6)**

**A. VOC EMISSION LIMIT:**

- (i) Pursuant to Rule 419 of the RCAP, the permit holder shall not permit the emission of 3 pounds per hour or 15 pounds daily of VOC from any item, machine, equipment or any other device unless it is provided with a control system, pollution prevention and reduction mechanism or programs or both, as approved or required by the Board. [State enforceable only condition]
- (ii) The permittee shall operate all air pollution control equipment at all times when emissions in excess of the limits established in Rule 419 of the RCAP are or may be generated during the manufacturing process.

**5. EU-TANK FARM (EU-7)**

**A. VOC EMISSION LIMITS FOR TANKS THAT ARE NOT COVERED UNDER RULE 417 OF THE RCAP:**

- (i) Pursuant to Rule 419 of the RCAP, the permittee shall permit the emission of 3 lbs/hr or 15 lbs/day of VOC from any item, machine, device or any other equipment unless it is provided with a control system, pollution prevention and reduction mechanism or programs or both, as approved or required by the Board. [State enforceable only].
- (ii) Pursuant to Rule 419(F)(6), tanks used to store VOC with a capacity of less than 40,000 gallons, provided such storage tanks are equipped with a conservation vent, a flame arrestor, or any other equipment whose emissions control effect is equivalent to these, shall be exempt from this Rule.

**6. Ozone Depleting Substances (EU-9)**

Condition	Test Method	Method Frequency	Recordkeeping Requirements	Reporting Frequency
Protection of Stratospheric Ozone 40 CRF Part 82, Subpart F	Management Practices for equipment with CFC (82.156)  Recycling Practices (82.158)	Handling practices for equipment with CFC (82.156)	Recordkeeping Maintenance Requirements (82.166)	Reporting Requirements (82.166)

**A. PROTECTION OF STRATOSPHERIC OZONE:**

- (i) Should the permittee have cooling equipment or small cooling appliances in its installations, including air conditioners that use refrigerants with Class I or II rating under 40 CFR Part 82, Subpart A, Appendices A and B, it must provide maintenance, service or repair according to the practices, personnel certification requirements, disposal requirements, and certification of recycling and recovery equipment pursuant to 40 CFR Part 82, Subpart F.
- (ii) Owners/operators of devices or equipment normally containing 50 or more pounds of refrigerant must keep records of refrigerant purchases and the refrigerant added to such equipment pursuant to §82.166.

**B. Labeling of Products Using Ozone-Depleting Substances:** The permittee must comply with the labeling standards for products using ozone-depleting substances in accordance with 40 CFR, Part 82, Subpart E.

- (i) All containers used to store or transport a class I or class II substance, all containers containing a class I substance, and all products manufactured directly with a class I substance must bear the required warning statement if they are to be introduced into interstate commerce in accordance, except as established on sections §82.106(b)(1)-(b)(7) of the 40 CFR.
- (ii) The placement of the required warning statement shall meet the requirements of §82.108.
- (iii) The form of the label bearing the warning statement must meet the requirements of §82.110.
- (iv) No person will modify, remove, or interfere with the required warning statement except as described in §82.112.

## **SECTION VII ALTERNATIVE OPERATING SCENARIOS**

### **A. Scenario 1: Operation and Maintenance Requirements (40 CFR subpart A, §63.6)-EU-2, EU-3, EU-6 y EU-7**

Should Pfizer Pharmaceuticals LLC (CRUCE DAVILA) experience malfunctions in control equipment during product manufacturing, especially during startup and shutdown, this scenario would allow it to continue operating during said malfunctions.

1. At all times, including periods of startup, shutdown and malfunction,<sup>2</sup> Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must operate and maintain any affected source, including associated air pollution control equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. During a period of malfunction, startup, or shutdown, this general duty to minimize emissions requires that Pfizer Pharmaceuticals LLC (CRUCE DAVILA) reduce emissions from the affected source to the greatest extent which is consistent with safety and good air pollution control practices. The general duty to minimize emissions during a period of malfunction, startup, or shutdown does not require Pfizer Pharmaceuticals LLC (CRUCE DAVILA) to achieve emission levels that would be required by the applicable standard at other times if this is not consistent with safety and good air pollution control practices, nor does it require Pfizer Pharmaceuticals LLC (CRUCE DAVILA) to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether such operation and maintenance procedures are being used will be based on information available to the Board and the EPA which may include, but is not limited to, sampling results, review of operation and maintenance procedures (including the malfunction, startup, and shutdown plan required in paragraph (e)(3) of §63.2.), review of operation and maintenance records, and inspection of the source. [40 CFR, §63.6(e)(1)(i)]
2. Malfunctions must be corrected as soon as practicable after their occurrence in accordance with the malfunction, startup, and shutdown plan required in paragraph (e)(3) of §63.6 of 40 CFR. To the extent that an unexpected event arises during a malfunction, startup, or shutdown, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must comply by minimizing emissions during such a malfunction, startup, or shutdown event consistent with safety and good air pollution control practices. [40 CFR, §63.6(e)(1)(ii)]
  - i. Operation and maintenance requirements established pursuant to section 112 of the Act are enforceable independent of emissions limitations or other requirements in relevant standards.<sup>3</sup> [40 CFR, §63.6(e)(1)(iii)]

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<sup>2</sup> According to §63.2 of 40 CFR, a malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control and monitoring equipment, process equipment, or a process to operate in a normal or usual manner which causes, or has the potential to cause, the emission limitations in an applicable standard to be exceeded. Failures that are caused in part by poor maintenance or careless operation are not malfunctions.

<sup>3</sup> According to §63.2 of 40 CFR, relevant standards mean an emission standard, an alternative emission standard, an alternative emission limitation, or an equivalent emission limitation established pursuant to section 112 of the Act that applies to the stationary source, the group of stationary sources or the portion of the stationary source regulated by said standard or limitation. A relevant standard may include or consist of a design, equipment, work practice, or operational requirement, or other measure, process, method, system, or technique (including prohibition of emissions) that the EPA (or a State) establishes for new or existing sources to which such standard or limitation applies. Every relevant standard established pursuant to section 112 of the Act includes subpart A of part 63 and all applicable appendices of part 63 or of other parts of chapter 1 that are referenced in that standard.

- ii. Malfunction, startup, and shutdown plan. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must develop and implement a written malfunction, startup, and shutdown plan that describe, in detail, procedures for operating and maintaining the source during periods of malfunction, startup, and shutdown, and a program of corrective action for malfunctioning process and air pollution control and monitoring equipment used to comply with the relevant standard. This plan must be developed by the source's compliance date for that relevant standard. [40 CFR, §63.6(e)(3)(i)]
  - iii. During periods of startup, shutdown, and malfunction, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) operates and maintains each affected source, (including associated air pollution control and monitoring equipment) in accordance with the procedures specified in the malfunction, startup, and shutdown plan developed under paragraph (e)(3)(i) of §63.6. [40 CFR, §63.6(e)(3)(ii)]
  - iv. When actions taken by Pfizer Pharmaceuticals LLC (CRUCE DAVILA) during a malfunction, startup, or shutdown (including actions taken to correct a malfunction) are consistent with the procedures specified in the affected source's malfunction, startup, and shutdown plan, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must keep records for that event which demonstrate that the procedures specified in the plan were followed. These records may take the form of a "checklist," or other effective form of recordkeeping that confirms conformance with the malfunction, startup, and shutdown plan for that event. In addition, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must keep records of these events as specified in §63.10(b), including records of the occurrence and duration of each malfunction, startup, or shutdown of operation and each malfunction of the air pollution control and monitoring equipment. Furthermore, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall confirm that actions taken during the relevant reporting period during periods of malfunction, startup, and shutdown were consistent with the affected source's startup, shutdown and malfunction plan in the semiannual (or more frequent) malfunction, startup, and shutdown report required in §63.10(d)(5). [40 CFR, §63.6(e)(3)(iii)]
  - v. If an action taken by Pfizer Pharmaceuticals LLC (CRUCE DAVILA) during a malfunction, startup, or shutdown (including an action taken to correct a malfunction) is not consistent with the procedures specified in the affected source's malfunction, startup, and shutdown plan, and the source exceeds any applicable emission limitation in the relevant emission standard, then Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must record the actions taken for that event and must report such actions by means of a telephone call or fax to
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EQB and EPA within 2 working days after commencing actions inconsistent with the plan, followed by a letter within 7 working days after the end of the event, in accordance with §63.10(d)(5) (unless Pfizer Pharmaceuticals LLC (CRUCE DAVILA) makes alternative reporting arrangements, in advance, with the Board and the EPA). [40 CFR, §63.6(e)(3)(iv)]

- vi. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must maintain a written copy of the malfunction, startup, and shutdown plan on file and must make the plan available to the Board or the EPA, upon request, for inspection, for the life of the affected source or until the affected source is no longer subject to the provisions of part 63. In addition, if the malfunction, startup, and shutdown plan is subsequently revised, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must maintain on file each previous (i.e., superseded) version of the malfunction, startup, and shutdown plan, and must make each such previous version available for inspection at the request of the Board or the EPA for a period of 5 years after revision of the plan. If at any time after adoption of a malfunction, startup, and shutdown plan the affected source ceases operation or is otherwise no longer subject to the provisions of part 63, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must retain a copy of the most recent plan for 5 years from the date the source ceases operation or is no longer subject to part 63 and must make the plan available upon request for inspection and copying by the Board or the EPA. The Board or the EPA may at any time request in writing that Pfizer Pharmaceuticals LLC (CRUCE DAVILA) submit a copy of any malfunction, startup, and shutdown plan (or a portion thereof) which is maintained at the affected source or in the possession of Pfizer Pharmaceuticals LLC (CRUCE DAVILA). Upon receipt of such a request, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must promptly submit a copy of the requested plan (or a portion thereof) to the Board and the EPA. The Board or the EPA may request that Pfizer Pharmaceuticals LLC (CRUCE DAVILA) submit a particular malfunction, startup, or shutdown plan (or a portion thereof) whenever a member of the public submits a specific and reasonable request to examine or to receive a copy of that plan or portion of a plan. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to submit the required copy of any malfunction, startup, and shutdown plan to the Board and the EPA in an electronic format. If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) claims that any portion of such a malfunction, startup, and shutdown plan is confidential business information entitled to protection from disclosure under section 114I of the Act or 40 CFR 2.301, the material which is claimed as confidential must be clearly designated in the submission. [40 CFR, §63.6(e)(3)(v)]
- vii. To satisfy the requirements of §63.6 to develop a malfunction, startup, and shutdown plan, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may use the affected source's standard operating procedures (SOP) manual, or an

Occupational Safety and Health Administration (OSHA) or other plan, provided the alternative plans meet all the requirements of §63.6 and are made available for inspection or submitted when requested by the Board or the EPA. [40 CFR, §63.6(e)(3)(vi)]

- viii. According to 40 CFR, §63.6(e)(3)(vii) and based on the results of a determination made under paragraph (e)(1)(i) of §63.6, the Board or the EPA may require that Pfizer Pharmaceuticals LLC (CRUCE DAVILA) make changes to the malfunction, startup, and shutdown plan for that source. The Board or the EPA must require appropriate revisions to a malfunction, startup, and shutdown plan, if the Board or the EPA finds that the plan:
  - a. Does not address a malfunction, startup, or shutdown event that has occurred;
  - b. Fails to provide for the operation of the source (including associated air pollution control and monitoring equipment) during a malfunction, startup, or shutdown event in a manner consistent with the general duty to minimize emissions established by paragraph (e)(1)(i) of §63.6;
  - c. Does not provide adequate procedures for correcting malfunctioning process and/or air pollution control and monitoring equipment as quickly as practicable; or
  - d. Includes an event that does not meet the definition of malfunction, startup, or shutdown listed in §63.2.
3. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) will periodically revise the malfunction, startup, and shutdown plan for the affected source as necessary to satisfy the requirements of part 63 to reflect changes in equipment or procedures at the affected source. Unless the Board or the EPA provides otherwise, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must make such revisions to the malfunction, startup, and shutdown plan without prior approval by the Board or the EPA. However, each such revision to a malfunction, startup, and shutdown plan must be reported in the semiannual report required by §63.10(d)(5). If the malfunction, startup, and shutdown plan fails to address or inadequately addresses an event that meets the characteristics of a malfunction but was not included in the malfunction, startup, and shutdown plan at the time Pfizer Pharmaceuticals LLC (CRUCE DAVILA) developed the plan, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must revise the malfunction, startup, and shutdown plan within 45 days after the event to include detailed procedures for operating and maintaining the source during similar malfunction events and a program of corrective action for similar malfunctions of process or air pollution control and monitoring equipment. In

the event that Pfizer Pharmaceuticals LLC (CRUCE DAVILA) makes any revision to the malfunction, startup, and shutdown plan which alters the scope of the activities at the source which are deemed to be a malfunction, startup, or shutdown, or otherwise modifies the applicability of any emission limit, work practice requirement, or other requirement in a standard established under part 63, the revised plan shall not take effect until after Pfizer Pharmaceuticals LLC (CRUCE DAVILA) provides a written notice describing the revision to the Board and the EPA. [40 CFR, §63.6(e)(3)(viii)]

4. This title V permit requires that Pfizer Pharmaceuticals LLC (CRUCE DAVILA) adopt a malfunction, startup, and shutdown plan which conforms to the provisions of part 63 of 40 CFR and that it operate and maintain the source in accordance with the procedures specified in the current malfunction, startup, and shutdown plan. However, any revisions made to the malfunction, startup, and shutdown plan in accordance with the procedures established by part 63 shall not be deemed to constitute permit revisions under part 70 or part 71 of Chapter I of 40 CFR. Moreover, none of the procedures specified by the malfunction, startup, and shutdown plan for an affected source shall be deemed to fall within the permit shield provision in section 504(f) of the Act. [40 CFR, §63.6(e)(3)(ix)]

**B. Scenario 2:**

The use of fuel oil #4 and kerosene in the three boilers (EU-4), emergency generators and fire pumps.

**EU-Combustion Equipment (EU-4): Two 500 hp Boilers and One 600 hp Boiler**

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reporting Frequency
Particulate matter limit	Particulate matter	0.3	Pounds per million BTU	Stack Test using Method # 5 of Appendix A, 40 CFR Part 60, during the first year of the permit.	During the first year of the permit.	Keep a copy of the final report for five (5) years from the date of the report [Rule 603 (A)(4)(ii)].	Sixty (60) days after sampling.
SO <sub>2</sub> emission limit	Fuel	0.50	Percent by weight	Certification of supplier	Every time fuel is received	Record of % sulfur	Monthly
	No. 4 or kerosene						
	Fuel						

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reporting Frequency
Fuel consumption	No. 4 or kerosene	2,628,000	Gallons/Year	Flow meter	Calculate daily consumption	Daily record of fuel consumption.	Annually

**1. PARTICULATE MATTER LIMIT:**

- (i) The permittee shall not cause or permit the emission, from any fuel burning equipment burning solid or liquid fuel, of particulate matter in excess of 0.3 pounds per million Btu of heat input. [Rule 406 of the RCAP]
- (ii) The permittee shall perform a sample during the first year of the permit to determine compliance with the standard using Method 5 of 40 CFR 60, Appendix A. [Rule 602 I(2)(ix)I of the RCAP]
- (iii) The permittee shall submit a sampling protocol to the EQB (30) days prior to the start of the test. [Rule 106 I of the RCAP]
- (iv) The permittee shall provide fifteen (15) days prior written notification of any sampling, to afford the EQB the opportunity to have an observer present. [Rule 106 (D) of the RCAP]
- (v) The permittee must submit a final report within 60 days after the date the sampling ends. [Rule 106 (E) of the RCAP]
- (vi) Pursuant to Rule 603 (A)(4)(ii) of the RCAP, Pfizer Pharmaceuticals LLC must retain the records of all required sampling data and support information for a period of five years from the date of the monitoring, measurement, report, or application.

**2. SO<sub>2</sub> EMISSION LIMITS:**

- (i) Pursuant to Rule 410 of the RCAP, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall burn fuel oil #4 or kerosene with 0.5% percent sulfur content by weight in the three boilers.
- (ii) Pursuant to Rule 603(A)(4)(ii) of the RCAP, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must retain records of all required sampling data and support information for 5 years from the date of the sampling, measurement, report or sampling application. This includes

a record of the fuel consumption and sulfur content monthly reports for the burned fuels.

- (iii) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must submit, during the first fifteen (15) days of the month following the reported month, monthly reports indicating fuel consumption and the sulfur content by weight for the fuels consumed in the three boilers. These reports must include a copy of the certification of sulfur content provided by the supplier.
- (iv) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall keep a supplier-certified copy indicating the sulfur content in fuel oil # 4 or kerosene to comply with the requirement to keep a daily record of the sulfur content of burned fuels.
- (v) Each year Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must file a copy of the monthly and annual fuel consumption reports for the three boilers, together with the annual certification of compliance.

**3. FUEL CONSUMPTION EMISSION LIMIT:**

- (i) The permittee shall not exceed fuel oil #4 or kerosene consumption of 2,628,000 gallons annually or fuel oil # 5 consumption of 1,374,005 gallons annually in all three boilers for any consecutive 12-month period. Compliance with this specified limit shall be determined based on a daily rolling average plus the total fuel used during the preceding 364 days, for the day in question
- (ii) The permittee shall install and operate fuel flow meters in the three boilers. The fuel meters must be calibrated every six months or as recommended by the manufacturer, whichever comes first. The calibration results and the methodology must be available in the facility for inspection by the Board's technical personnel.
- (iii) Pursuant to Rule 603(A)(4)(ii) of the RCAP, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must retain records of all required sampling data and support information for 5 years from the date of the sampling, measurement, report or sampling application. This includes a record of the fuel consumption monthly and annual fuel consumption reports for each combustion unit. Monthly compliance is determined by adding the total amount of each fuel consumed during the previous eleven (11) months.

- (iv) Each year Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must file a copy of the monthly and annual fuel consumption reports for each boiler, together with the annual certification of compliance.

## **SECTION VIII – NATIONAL EMISSION STANDARDS FOR THE PHARMACEUTICAL INDUSTRY – CHEMICAL PLANT (EU-2)**

### **A. Applicability**

1. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must comply with the provisions of 40 CFR part 63 subpart A contained in Table 1 of subpart GGG. [§63.1250I]
2. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must follow the procedures specified in §63.1250(e)(1)-(5) to determine to which PMPU a storage tank shall belong.
3. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must be in compliance with the National Emission Standards for Pharmaceuticals Production contained in 40 CFR part 63 subpart GGG for October 21, 2002, according to §63.1250(f).
4. All the provisions set forth in subpart GGG shall apply at all times except that emission limitations shall not apply during periods of: startup; shutdown; and malfunction, if this precludes the ability of a particular emission point of an affected source to comply with one or more specific emission limitations to which it is subject and Pfizer Pharmaceuticals LLC (CRUCE DAVILA) follows the provisions for periods of malfunction, startup, and shutdown, as specified in §§63.1259(a)(3) and 63.1260(i). [40 CFR §63.1250(g)(1)]
5. All the provisions of §63.1255 of subpart GGG shall apply at all times except during periods of non-operation 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 applies. [40 CFR §63.1250(g)(2)]
6. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall not shut down items of equipment that are required or utilized for compliance with the emissions 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 of this subpart applicable to such items of equipment. This premise does not apply if the item of equipment is malfunctioning, or if Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must

shut down the equipment to avoid damage due to a malfunction of the PMPU or portion thereof. [40 CFR §63.1250(g)(3)]

7. During startups, shutdowns, and malfunctions when the emissions limitations of this subpart do not apply pursuant to paragraphs (g)(1) through (3), Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall implement, to the extent reasonably possible, measures to prevent or minimize excess emissions to the extent practical. The measures to be taken shall be identified in the applicable malfunction, startup, and shutdown plan, and may include, but are not limited to, air pollution control technologies, work practices, pollution prevention, sampling, and/or changes in the manner of operation of the source. Back-up control equipment are not required, but may be used if available. [40 CFR §63.1250(g)(4)]
8. After the compliance dates specified in §63.1250(f), a facility subject to the provisions of subpart GGG that is also subject to the provisions of any other subpart of part 63 may elect with which of the subparts to comply as to the maintenance of records and reporting to EPA. [40 CFR §63.1250(h)(1)(i)]
9. After the compliance dates specified in paragraph (f) of §63.1250(f), an offsite reloading or cleaning facility subject to §63.1253(f) shall be deemed to be in compliance with the provisions of §63.1253(f)(7)(ii) or (iii) if it complies with the emission standards and initial compliance, sampling, recordkeeping, and reporting provisions associated to any other subpart of part 63. [40 CFR §63.1250(h)(1)(ii)]
10. After the compliance dates specified in §63.1250(f), if any control equipment subject to this subpart is also subject to monitoring, recordkeeping, and reporting requirements in 40 CFR part 264, subpart AA, BB, or CC, or is subject to sampling and recordkeeping requirements in 40 CFR part 265, subpart AA, BB, or CC, and Pfizer Pharmaceuticals LLC (CRUCE DAVILA) complies with the periodic reporting requirements under 40 CFR part 264, subpart AA, BB, or CC that would apply to the equipment if the facility had final-permitted status, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to comply either with the monitoring, recordkeeping, and reporting requirements of subpart GGG, or with parts 264 and/or 265, as described in §63.1250(h)(2)(i), which shall constitute compliance with the monitoring, recordkeeping, and reporting requirements of subpart GGG. If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to comply with the provisions of parts 264 and/or 265, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall report all information required by §63.1260(g) and (i). Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall identify in the Notification of Compliance Status, required by §63.1260(f), the monitoring, recordkeeping, and reporting authority under which Pfizer Pharmaceuticals LLC (CRUCE DAVILA) will comply. [40 CFR §63.1250(h)(2)(i)]

11. After the compliance dates specified in §63.1250(f), if any equipment at an affected source that is subject to §63.1255, is also subject to 40 CFR part 264, subpart BB, or to 40 CFR part 265, subpart BB, then compliance with the recordkeeping and reporting requirements of 40 CFR parts 264 and/or 265 may be used to comply with the recordkeeping and reporting requirements of §63.1255, to the extent that the requirements of 40 CFR parts 264 and/or 265 duplicate the requirements of §63.1255. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall identify in the Notification of Compliance Status, required by §63.1260(f), if it will comply with the recordkeeping and reporting authority under 40 CFR parts 264 and/or 2655. [40 CFR §63.1250(h)(2)(ii)]
12. After the compliance dates specified in §63.1250(f), a storage tank controlled with a floating roof and in compliance with the provisions of 40 CFR 60.112b, subpart Kb, constitutes compliance with the provisions of subpart GGG. A storage tank with a fixed roof, closed vent system, and control equipment in compliance with the provisions of 40 CFR 60.112b, subpart Kb must comply with the sampling, recordkeeping, and reporting provisions of subpart GGG. [40 CFR §63.1250(h)(3)]
13. After the compliance dates specified in §63.1250(f), an affected source with equipment subject to subpart I of part 63 may elect to comply with either the provisions of §63.1255 or the provisions of subpart H of part 63 for all such equipment. [40 CFR §63.1250(h)(4)]
14. After the compliance dates specified in §63.1250(f), the owner or operator of affected wastewater that is also subject to provisions in 40 CFR parts 260 through 272 may elect to determine whether part 63 subpart GGG or parts 260 through 272 contain the more stringent control, testing, sampling, recordkeeping, and reporting requirements. Compliance with provisions of 40 CFR parts 260 through 272 that are determined to be more stringent than the requirements of subpart GGG constitutes compliance with this subpart. [40 CFR §63.1250(h)(5)]
15. After the compliance dates specified in §63.1250(f), an affected source with equipment in a PMPU that is also part of an affected source under subpart PPP of part 63 may elect to demonstrate compliance with §63.1254 by controlling all process vents in accordance with §63.1425 (b), (c)(1), (c)(3), (d), and/or (f). Alternatively, the owner or operator may elect to determine which process vents must be controlled to comply with the percent reduction requirements of §63.1254 and control only those vents in accordance with §63.1425 (b), (c)(1), (c)(3), (d), and/or (f). For any PMPU controlled in accordance with the requirements of §63.1425, the owner or operator must also comply with all other requirements in subpart PPP. [40 CFR §63.1250(h)(6)]

## **B. General**

1. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall control Hazardous Air Pollutants (HAP) emissions to the level specified in §63.1252 on and after the compliance dates specified in §63.1250(f). Continuous compliance shall be demonstrated in accordance with the provisions of §63.1258. [40 CFR §63.1252]
  - a. Opening of a safety device, as defined in §63.1251, is allowed at any time conditions require it to do so to avoid unsafe conditions. [40 CFR §63.1252(a)].
  - b. The owner or operator of a closed-vent system that contains bypass lines that could divert a vent stream away from a control equipment used to comply with the requirements in §§63.1253, and 63.1254 shall comply with the requirements of Table 4 to subpart GGG and one of the following alternatives:
    - i. 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 equipment to the atmosphere. [40 CFR §63.1252(b)(1)].
    - ii. 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 §63.1259(i)(6)(ii). [40 CFR §63.1252(b)(2)]
  - c. Except as provided in paragraph I(2) of §63.1252, owners and operators of affected sources shall comply with the requirements in paragraph I(1) of this section for heat exchange systems that cool process equipment or materials used in pharmaceutical manufacturing operations. [40 CFR §63.1252I]
    - i. The heat exchange system shall be treated according to the provisions of §63.104, except that the sampling frequency shall be no less than quarterly. [40 CFR §63.1252I(1)]
    - ii. 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. [40 CFR §63.1252I(2)]

- d. Except as specified in paragraphs (d)(1) through (5) of §63.1252, owners or operators of storage tanks or processes subject to the provisions of §§63.1253 and 63.1254 may choose to comply by using emissions averaging requirements specified in §63.1257(g) or (h) for any storage tank or process. [40 CFR §63.1252(d)]
  - i. Not more than 20 processes subject to §63.1254(a)(1)(i), and 20 storage tanks subject to §63.1253(b)(1) or (c)(1)(i) at an affected source may be included in an emissions averaging group. [40 CFR §63.1252(d)(6)]
  - ii. Compliance with the emission standards in §63.1253 shall be satisfied when the annual percent reduction efficiency is greater than or equal to 90 percent for those tanks meeting the criteria of §63.1253(a)(1) and 95 percent for those tanks meeting the criteria of §63.1253(a)(2), as demonstrated using the test methods and compliance procedures specified in §63.1257(g). [40 CFR §63.1252(d)(7)]
  - iii. Compliance with the emission standards in §63.1254(a)(1)(i) shall be satisfied when the annual percent reduction efficiency is greater than or equal to 93 percent, as demonstrated using the test methods and compliance procedures specified in §63.1257(h). [40 CFR §63.1252(d)(8)]
- e. Except as provided in paragraph (e)(1) of §63.1252, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may choose to meet the pollution prevention alternative requirement specified in either paragraph (e)(2) or (3) of this section for any PMPU or for any situation described in paragraph (e)(4) of this section, in lieu of the requirements specified in §§63.1253, 63.1254, 63.1255, and 63.1256. [40 CFR §63.1252(e)]
- f. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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 §63.1252. [40 CFR §63.1252(f)]
- g. If a combustion equipment is used to comply with the provisions of §§63.1253, 63.1254, 63.1256(h) for a halogenated vent stream, then the vent stream shall be sent to a halogen reduction equipment such as, but not limited to, a scrubber, before it is discharged to the atmosphere. The halogen

reduction equipment must reduce emissions by the amounts specified in one of the following: [40 CFR §63.1252(g)]

- i. A halogen reduction equipment after the combustion control equipment must reduce overall emissions of hydrogen halides and halogens, as defined in §63.1251, by 95 percent or to a concentration less than or equal to 20 ppmv. [40 CFR §63.1252(g)(1)]
- ii. A halogen reduction equipment located before the combustion control equipment must reduce the halogen atom content of the vent stream to a concentration less than or equal to 20 ppmv. [40 CFR §63.1252(g)(2)]

### **C. Storage Tanks**

1. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must comply with the requirements of §63.1253(b) for the methanol tank and for every tank whose design capacity is equal or greater than 10,000 gallons but less than 20,000 gallons storing a liquid for which the maximum true steam pressure of total HAP is greater than or equal to 1.9 psia. [40 CFR §63.1253(a)(1)]
2. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall equip the methanol storage tank and any other affected storage tank with one of the following alternatives a fixed roof with internal floating roof, an external floating roof, an external floating roof converted to an internal floating roof, or a closed-vent system meeting the conditions of §63.1252(b) with a control equipment that meets any of the following conditions. [40 CFR §63.1253(b)]:
  - a. Reduces inlet emissions of total HAP by 90 percent by weight or greater;
  - b. Reduces emissions to outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens;
  - c. Is an enclosed combustion equipment that provides a minimum residence time of 0.5 seconds at a minimum temperature of 760 °C;
  - d. Is a flare that meets the requirements of §63.11(b); or
  - e. Is a control equipment specified in §63.1257(a)(4).
3. The owner or operator of a tank with design capacity equal or greater than 20,000 gallons storing a liquid for which the maximum true steam pressure of total HAP is greater than or equal to 1.9 psia must comply with the requirements of §63.1253I. [40 CFR §63.1253(a)(2)]

4. Alternate standard – (To comply with the standard of §63.1253 one of the following alternatives may be used.)
  - a. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall route storage tank vents to a:
    - i. Combustion control equipment achieving an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 20 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 20 ppmv or less.
    - ii. Non-combustion control equipment, achieving an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 50 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 50 ppmv or less. [40 CFR §63.1253(d)]
5. The specifications and requirements in paragraphs (b) through (d) of §63.1253 for control equipment do not apply during periods of planned routine maintenance. Periods of scheduled routine maintenance of the control equipment (including centralized combustion control equipment subject to §63.1252(h)), during which the control equipment does not meet the specifications of paragraphs (b) through (d) of §63.1253, as applicable, shall not exceed 240 hours in any 365-day period. [40 CFR §63.1253(e)]
6. As an alternative to complying with the requirements in paragraphs (b) and (c) of §63.1253, Pfizer Pharmaceuticals LLC (CRUCE DAVILA), may implement vapor balancing in accordance with paragraphs (f)(1) through (7) of this same section. [40 CFR §63.1253(f)]

**D. Process Vents**

1. Existing Sources – For each process, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must comply with the requirements in paragraphs (a)(1) and (3) of §63.1254. [40 CFR §63.1254]
2. New Sources
  - a. Except as provided in paragraph (b)(2) of §63.1254, uncontrolled HAP emissions from the sum of all process vents within a process at a new affected source shall be reduced by 98 percent or greater by weight or controlled in accordance with any of requirements of paragraphs (a)(1)(ii)(A) through (D) of §63.1254. [40 CFR §63.1254(b)(1)]

- b. The actual HAP emissions from the sum of all process vents for which Pfizer Pharmaceuticals LLC (CRUCE DAVILA) is not complying with the above requirement are limited to 900 kg in any 365-day period. [40 CFR §63.1254(b)(2)]
3. Process-based emission reduction requirement
- a. Uncontrolled HAP emissions from the sum of all process vents within a process that are not subject to the requirements of paragraph (a)(3) of §63.1254 shall be reduced by 93 percent or greater by weight, as specified in paragraph (a)(1)(ii) of §63.1254. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall notify of changes in the compliance method according to the procedures in §63.1260(h). [40 CFR §63.1254(a)(1)(i)]
  - b. Any one or more vents within a process must be controlled in accordance with any of the procedures in paragraphs (a)(1)(ii)(A) through (D):
    - i. Outlet concentrations shall be less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens;
    - ii. By a flare that meets the requirements of §63.11(b);
    - iii. By a control equipment specified in §63.1257(a)(4); or
    - iv. In accordance with the alternative standard specified in paragraph (c) of §63.1254. [40 CFR §63.1254(a)(1)(ii)]
4. For New and Existing Sources – *Alternative Standard* – (To comply with the standard for this section one of the following alternatives may be used.)
- a. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall route the vents from a process to a non-combustion control equipment achieving an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 50 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 50 ppmv or less. [40 CFR §63.1254I]

**E. Standards for equipment leaks**

- 1. General Equipment Leak Requirements
  - a. The provisions of 40 CFR §63.1255 apply to pumps, compressors, agitators, pressure relief equipment, sampling connection systems, open-ended valves or lines, valves,

- connectors, instrumentation systems, control equipment, 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 source subject to the provisions of 40 CFR part 63, subpart GGG. [40 CFR §63.1255(a)(1)]
- b. Consistency with other regulations. After the compliance date for a process, equipment subject to §63.1255 and any of the sections of 40 CFR parts 60 or 61 shall be required to comply only with the provisions of 40 CFR part 63, subpart GGG. [40 CFR §63.1255(a)(2)]
- c. The provisions in §63.1(a)(3) of subpart A of part 63 do not alter the provisions in paragraph (a)(2) of §63.1255. [40 CFR §63.1255(a)(4)]
- d. Lines and equipment not containing process fluids are not subject to the provisions of §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)]
- e. The provisions of §63.1255 do not apply to bench-scale<sup>4</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)]
- f. Equipment to which §63.1255 applies shall be identified such that it can be distinguished readily from equipment that is not subject to §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)]
- g. Equipment that is in vacuum service is excluded from the requirements of §63.1255. [40 CFR §63.1255(a)(8)]
- h. Equipment that is in organic HAP service, but is in such service less than 300 hours per calendar year, is excluded from the requirements of §63.1255 if it is identified as required in paragraph (g)(9) of §63.1255. [40 CFR §63.1255(a)(9)]

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<sup>4</sup> *Bench-scale batch process* means a batch process (other than a research and development facility) that is capable of being located on a laboratory bench top. This bench-scale equipment will typically include reagent feed vessels, a small reactor and associated product separator, recovery and holding equipment. These processes are only capable of producing small quantities of product. [40 CFR §63.1251]

- i. According to 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:
  - i. A weatherproof and readily visible identification, marked with the equipment identification number, shall be attached to the leaking equipment.
  - 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 §63.1255, and no leak has been detected during the follow-up monitoring.
  - iii. The identification on equipment, except on a valve in light liquid or gas/vapor service, may be removed after it has been repaired.
  
- j. Except as provided in paragraph (a)(11)(i) of §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, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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 §63.1255.
  - ii. Time periods specified in subpart GGG for completion of required tasks may be changed by mutual agreement between Pfizer Pharmaceuticals LLC (CRUCE DAVILA) and the Board and the EPA, 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.
  - iii. Except as provided in paragraph (a)(11)(i) or (ii) of §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 §63.1255, as appropriate.
    - 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

- 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.
  - iv. In all instances where a provision of subpart GGG requires completion of a task during each of multiple successive periods, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall 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.
  - k. In all cases where the provisions of subpart GGG require an owner or operator to repair leaks by a specified time after the leak is detected, it is a violation of §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 §63.1255. However, if the repairs are unsuccessful, and a leak is detected the owner or operator shall take further action as required by applicable provisions of §63.1255. [40 CFR §63.1255(a)(12)]
2. References.
- a. The owner or operator of a source subject to §63.1255 shall comply with the provisions of subpart H of part 63, as specified in paragraphs (b)(2) through (4) of §63.1255. The term “process unit” as used in subpart H of part 63 shall be considered to mean 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 the purposes of subpart GGG. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with the provisions specified in paragraphs (b)(2)(i) through (viii) of §63.1255. [40 CFR §63.1255(b)(2)]
    - i. Sections 63.160 and 63.162 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraph (a) of §63.1255;
    - ii. Section 63.161 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with §63.1251;
    - iii. Sections 63.163 and 63.173 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraph I of §63.1255;
    - iv. Section 63.167 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraph (d) of §63.1255;

- v. Section 63.168 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraph (e) of §63.1255;
  - vi. Section 63.170 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with §63.1254;
  - vii. Section 63.181 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraph (g) of §63.1255; and
  - viii. Section 63.182 shall not apply; instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraph (h) of §63.1255.
- c. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with §§63.165, 63.166, 63.169, 63.177, and 63.179 in their entirety, except that when these sections reference other sections of subpart H of part 63, references shall mean the sections specified in paragraphs (b)(2) and (4) of §63.1255. Section 63.165 applies to pressure relief equipment in gas/vapor service. Section 63.166 applies to sampling connection systems. In respect to Pfizer Pharmaceuticals LLC (CRUCE DAVILA), section 63.169 applies to instrumentation systems; and pressure relief equipment in liquid service. Section 63.177 applies to general alternative means of emission limitation. Section 63.179 applies to alternative means of emission limitation for enclosed-vented process units. [40 CFR §63.1255(b)(3)]
- d. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with §§63.171, 63.172, 63.174, 63.178, and 63.180, except as specified in paragraphs (b)(4)(i) through (vi) of §63.1255. [40 CFR §63.1255(b)(4)]
- i. Section 63.171 shall apply, except §63.171(a) shall not apply. Instead, delay of repair of equipment for which leaks have been detected is allowed if one of the conditions in paragraphs (b)(4)(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 the next scheduled process shutdown. [40 CFR §63.1255(b)(4)(i)(A)]
    - b. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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 the next scheduled process shutdown. [40 CFR §63.1255(b)(4)(i)(B)]
  - ii. Section 63.172 shall apply for closed-vent systems used to comply with §63.1255, and for control equipment used to comply with §63.1255 only, except:

- a) Section 63.172(k) and (l) shall not apply. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall instead comply with paragraph (f) of §63.1255. [40 CFR §63.1255(b)(4)(ii)(A)]
  - b) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may, instead of complying with the provisions of §63.172(f), design a closed-vent system to operate at a pressure below atmospheric pressure. The system shall be equipped with at least one pressure gauge or other pressure measurement 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). Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may not comply with the planned routine maintenance provisions in §63.1252(h). [40 CFR §63.1255(b)(4)(ii)(C)]
- iii. Section 63.174 shall apply except:
- a) Sections 63.174(f), (g), and (h) shall not apply. Instead of §63.174(f), (g), and (h), Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraph (f) of §63.1255. Section 63.174(b)(3) shall not apply. Instead of §63.174(b)(3), Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with paragraphs (b)(4)(iii)(B) through (F) of §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 percent during the initial monitoring period, monitoring shall be performed once per year until the percent leaking connectors is less than 0.5 percent. [40 CFR §63.1255(b)(4)(iii)(B)]
  - c) If the percent leaking connectors was less than 0.5 percent, but equal to or greater than 0.25 percent, during the initial or last required monitoring period, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to monitor once every 4 years. An owner or operator may comply with the requirements of paragraph (b)(4)(iii)(C) of §63.1255 by monitoring at least 40 percent 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 §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, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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 percent, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor once per year until the percent leaking connectors is less than 0.5 percent. If, at the end of a monitoring period, the percent leaking connectors is less than 0.5 percent, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor in accordance with paragraph (b)(4)(iii)(C) or (F) of §63.1255, as appropriate. [40 CFR §63.1255(b)(4)(iii)(D)]

- e) If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) determines that 1 percent or greater of the connectors in a group of processes are leaking, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor the connectors once per year. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to use the provisions of paragraph (b)(4)(iii)(C), (D), or (F) of §63.1255, 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) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to perform monitoring once every 8 years if the percent leaking connectors in the group of processes was less than 0.25 percent during the initial or last required monitoring period. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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 §63.1255. [40 CFR §63.1255(b)(4)(iii)(F)]

iv. Section 63.178 shall apply except:

- a) For pumps, the phrase “at the frequencies specified in Table 1 of subpart” GGG in §63.178I(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 no 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 §§63.171, 63.172, 63.174, 63.178, and 63.180 reference other sections in subpart H of part 63, the references shall mean those sections specified in paragraphs (b)(2) and (b)(4)(i) through (v) of §63.1255, as applicable. [40 CFR §63.1255(b)(4)(vi)]
3. Standards for Pumps in Light Liquid Service and Agitators in Gas/Vapor Service and in Light Liquid Service.
- a. The provisions of §63.1255 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 §63.1255I(1)]
  - b. *Monitoring.* Each pump and agitator subject to §63.1255 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 §63.1255, and paragraphs (c)(5) through (9) of §63.1255. [40 CFR §63.1255(c)(2)(i)]
  - c. *Leak definition.* According to 40 CFR §63.1255I(2)(ii), The instrument reading, as determined by the method as specified in §63.180(b), that defines a leak is:
    - i. For agitators, an instrument reading of 10,000 parts per million or greater. [40 CFR §63.1255I(2)(ii)(A)]
    - ii. For pumps, an instrument reading of 2,000 parts per million or greater. [40 CFR §63.1255I(2)(ii)(B)]
  - d. *Visual Inspections.* According to 40 CFR §63.1255I(2)(iii), 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, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall follow the procedure specified in either paragraph I(2)(iii)(A) or (B) of §63.1255 prior to the next weekly inspection.
    - i. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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)]
    - ii. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall eliminate the visual indications of liquids dripping. [40 CFR §63.1255I(2)(iii)(B)]

e. *Repair provisions.*

- i. When a leak is detected pursuant to paragraph I(2)(i), I(2)(iii)(A), (c)(5)(iv)(A), or (c)(5)(vi)(B) of §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 §63.1255. [40 CFR §63.1255(c)(3)(i)]
- ii. According to 40 CFR §63.1255I(3)(ii), the 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.
  - b) Ensuring that the flush seal is operating at design pressure and temperature.

f. *Calculation of percent leakers.*

- i. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall decide no later than the end of the first monitoring period what groups of processes will be developed. Once Pfizer Pharmaceuticals LLC (CRUCE DAVILA) has decided, all subsequent percent calculations shall be made on the same basis. [40 CFR §63.1255I(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 leaks, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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 §63.1255I(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 §63.1255I(4)(iii)]
- iv. According to 40 CFR §63.1255I(4)(iv), the percent leaking pumps shall be determined by the following Equation:

$$\%P_L = [(P_L - P_S) / (P_T - P_S)] * 100$$

Where:

$\%P_L$  = percent leaking pumps.

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

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

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

- g. *Exemptions.* According to 40 CFR §63.1255I(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 I(1) through I(4)(iii) of §63.1255, provided the following requirements are met:
- 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
    - b) Equipped with a barrier fluid degassing reservoir that is connected by a closed-vent system to a control equipment that complies with the requirements of paragraph (b)(4)(ii) of §63.1255; or
    - c) Equipped with a closed-loop system that purges the barrier fluid into a process stream.
  - ii. The barrier fluid is not in light liquid service.
  - iii. Each barrier fluid system is equipped with a sensor that will detect failure of the seal system, the barrier fluid system, or both.
  - 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, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall follow the procedures specified in either paragraph I(5)(iv)(A) or (B) of §63.1255 prior to the next required inspection. [40 CFR §63.1255(c)(5)(iv)]
    - a) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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 §63.1255, a leak is detected. [40 CFR §63.1255(c)(5)(iv)(A)]

- b) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall eliminate the visual indications of liquids dripping. [40 CFR §63.1255I(5)(iv)(B)]
- v. Each sensor as described in paragraph I(5)(iii) of §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 §63.1255I(5)(v)]
- vi. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) determines based on design considerations and operating experience, the criterium applicable to the presence and frequency of drips and to the sensor that indicates failure of the seal system, the barrier fluid system, or both. [40 CFR §63.1255I(5)(vi)(A)]
- vii. If indications of liquids dripping from the pump/agitator seal exceed the criterium established in paragraph I(5)(vi)(A) of §63.1255, or if, based on the criterium established in paragraph (c)(5)(vi)(A) of §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)]
- viii. When a leak is detected pursuant to paragraph I(5)(iv)(A) or (B) of §63.1255, the leak must be repaired as specified in paragraph (c)(3) of §63.1255. [40 CFR §63.1255(c)(5)(vii)]
- h. Any pump/agitator that is designed with no externally actuated shaft penetrating the pump/agitator housing is exempt from the requirements of paragraphs I(1) through (3) of §63.1255. [40 CFR §63.1255I(6)]
- i. 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 equipment that complies with the requirements of paragraph (b)(4)(ii) of §63.1255 is exempt from the requirements of paragraphs (c)(2) through (5) of §63.1255. [40 CFR §63.1255(c)(7)]
- j. Any pump/agitator that is located within the boundary of an unmanned plant site is exempt from the weekly visual inspection requirement of paragraphs I(2)(iii) and I(5)(iv) of §63.1255 and the daily requirements of paragraph I(5)(v) of §63.1255, provided that each pump/agitator is visually inspected as often as practicable and at least monthly. [40 CFR §63.1255I(8)]
- k. more than 90 percent of the pumps in a group of processes meet the criteria in either paragraph I(5) or (6) of §63.1255, the group of processes is exempt from the requirements of paragraph I(4) of §63.1255. [40 CFR §63.1255I(9)]

4. *Standards: Open-Ended Valves or Lines.*

- a. 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 §63.1255. [40 CFR §63.1255(d)(1)(i)]
- b. 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)]
- c. 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)]
- d. 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 §63.1255 at all other times. [40 CFR §63.1255(d)(3)]
- e. 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 §63.1255. [40 CFR §63.1255(d)(4)]
- f. Open-ended valves or lines containing materials which would auto catalytically polymerize are exempt from the requirements of paragraphs (d)(1) through (d)(3) of §63.1255. [40 CFR §63.1255(d)(5)]
- g. 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) through (d)(3) of §63.1255 are exempt from the requirements of paragraphs (d)(1) through (d)(3) of §63.1255. [40 CFR §63.1255(d)(6)]

5. *Standards: Valves in Gas/Vapor Service and in Light Liquid Service.*

- a. The provisions of §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 §63.1255 shall be monitored, except as provided in paragraph (f) of §63.1255 and in §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 §63.1255 and shall comply with all other provisions of §63.1255, except as provided in paragraph (b)(4)(ii) of §63.1255 §§63.178 and 63.179.
- i) The valves shall be monitored to detect leaks by the method specified in §63.180(b).
  - ii) An instrument reading of 500 parts per million or greater defines a leak.
- d. *Subsequent monitoring frequencies.* According to 40 CFR §63.1255(e)(4), after conducting the initial survey required in paragraph (e)(2) of §63.1255, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor valves for leaks at the intervals specified below:
- i. For a group of processes with 2 percent or greater leaking valves, calculated according to paragraph (e)(6) of §63.1255, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor each valve once per month, except as specified in paragraph (e)(9) of §63.1255.
  - ii. For a group of processes with less than 2 percent leaking valves, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor each valve once each quarter, except as provided in paragraphs (e)(4)(iii) through (e)(4)(v) of §63.1255.
  - iii. For a group of processes with less than 1 percent leaking valves, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to monitor each valve once every 2 quarters (every six months).
  - iv. For a group of processes with less than 0.5 percent leaking valves, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to monitor each valve once every 4 quarters (every 12 months).
  - v. For a group of processes with less than 0.25 percent leaking valves, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may elect to monitor each valve once every 2 years.
- e. *Calculation of percent leakers.* According to 40 CFR §63.1255(e)(5), For a group of processes to which subpart GGG applies, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may choose to subdivide the valves in the applicable group of processes and apply the provisions of paragraph (e)(4) of §63.1255 to each subgroup. If Pfizer

Pharmaceuticals LLC (CRUCE DAVILA) elects to subdivide the valves in the applicable group of processes, then the provisions of paragraphs (e)(5)(i) through (e)(5)(viii) of §63.1255 apply.

- i. The overall performance of total valves in the applicable group of processes must be less than 2 percent leaking valves, as detected according to paragraphs (e)(3) (i) and (ii) of §63.1255 and as calculated according to paragraphs (e)(6) (ii) and (iii) of §63.1255.
- 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 §63.1255.
  - a) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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.
  - b) Any valve or subgroup 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 events and associated next percent leaking valves calculation for that group.
  - 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). Non-repairable valves may not be reassigned to a less frequently monitored subgroup.
- iii. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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 percent leaking valves or greater, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall revert to the program required in paragraphs (e)(2) through (e)(4) of §63.1255. 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 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 §63.1255

$V_i$  = number of valves in subgroup I

n = number of subgroups

- iv. *Records.* In addition to records required by paragraph (g) of §63.1255, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall maintain records specified in paragraphs (e)(5)(iv)(A) through (D) of §63.1255.
  - a) Which valves are assigned to each subgroup,
  - b) Monitoring results and calculations made for each subgroup for each monitoring period,
  - c) Which valves are reassigned and when they were reassigned, and
  - d) The results of the semiannual overall performance calculation required in paragraph (e)(5)(iii) of §63.1255.
- v. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall notify the Board and the 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.
- vi. *Semiannual reports.* In addition to the information required by paragraph (h)(3) of §63.1255, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall submit in the periodic reports the information specified in paragraphs (e)(5)(vi)(A) and (B) of §63.1255.

- a) Valve reassignments occurring during the reporting period, and
- b) Results of the semiannual overall performance calculation required by paragraph (e)(5)(iii) of §63.1255.
- vii. To determine the monitoring frequency for each subgroup, the calculation procedures of paragraph (e)(6)(iii) of §63.1255 shall be used.
- viii. Except for the overall performance calculations required by paragraphs (e)(5)(i) and (e)(5)(iii) of §63.1255, each subgroup shall be treated as if it were a process for the purposes of applying the provisions of §63.1255.
- f. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall decide no later than the implementation date of subpart GGG or upon revision of an operating permit how to group the processes. Once Pfizer Pharmaceuticals LLC (CRUCE DAVILA) has decided, all subsequent percentage calculations shall be made on the same basis. [40 CFR §63.1255(e)(6)(i)]
- g. According to 40 CFR §63.1255(e)(6)(ii), the 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 §63.1255.

$V_L =$  number of leaking valves found excluding those that cannot be repaired as provided in paragraph (e)(6)(iv)(A) of §63.1255.

$V_T =$  total valves monitored, in a monitoring period excluding valves monitored as required by (e)(7)(iii) of §63.1255.

- h. 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)]

- i. 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 §63.1255. 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 calculation of percent leaking valves for subsequent monitoring periods. [40 CFR §63.1255(e)(6)(iv)(A)]
- j. If the number of non-repairable valves exceeds 1 percent of the total number of valves in organic HAP service at a process, the number of non-repairable valves exceeding 1 percent 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)]
- k. *Repair provisions.*
  - 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 §63.1255. [40 CFR §63.1255(e)(7)(i)]
  - ii. 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>5</sup>” and “first attempt at repair<sup>6</sup>”. [40 CFR §63.1255(e)(7)(iii)]
    - a) The monitoring shall be conducted as specified in §63.180(b) and (c) as appropriate to determine whether the valve has resumed leaking.
    - b) The monitoring required by paragraphs (e)(2) through (4) of §63.1255 may be used to satisfy the requirements of paragraph (e)(7)(iii) of §63.1255, if the timing of the monitoring period coincides with the time specified in paragraph (e)(7)(iii) of §63.1255. Alternatively, other monitoring may be performed to satisfy the

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<sup>5</sup> Repaired means that the equipment has been adjusted or otherwise altered to eliminate the leak as defined in the applicable paragraphs of §63.1255 and is, unless otherwise specified in applicable provisions of §63.1255, monitored as specified in §63.180(b) and (c) as appropriate, to verify that equipment emissions are below the applicable definition for leak. [40 CFR §63.1251]

<sup>6</sup> First attempt at repair means to take action for the purpose of stopping or reducing leakage of organic material to the atmosphere. [40 CFR §63.1251]

requirements of paragraph (e)(7)(iii) of §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 §63.1255.

- c) If a leak is detected by monitoring that is conducted pursuant to paragraph (e)(7)(iii) of §63.1255, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall follow the provisions of paragraphs (e)(7)(iii)I(1) and (2) of §63.1255 to determine whether that valve must be counted as a leaking valve for purposes of paragraph (e)(6) of §63.1255.
  - 1) If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to use periodic monitoring required by paragraphs (e)(2) through (4) of §63.1255 to satisfy the requirements of paragraph (e)(7)(iii) of §63.1255, then the valve shall be counted as a leaking valve.
  - 2) If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to use other monitoring prior to the periodic monitoring required by paragraphs (e)(2) through (4) of §63.1255 to satisfy the requirements of paragraph (e)(7)(iii) of §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.
- l. According to 40 CFR §63.1255(e)(8), first attempts at repair include, but are not limited to, the following practices where practicable:
  - a) Tightening of bonnet bolts,
  - b) Replacement of bonnet bolts,
  - c) Tightening of packing gland nuts, and
  - d) Injection of lubricant into lubricated packing.
- m. 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 §63.1255. Instead, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall monitor each valve in organic HAP service for leaks once each quarter, or comply with paragraph (e)(4)(iii), (iv), or (v) of §63.1255, except as provided in paragraph (f) of §63.1255. [40 CFR §63.1255(e)(9)]

6. *Unsafe to monitor, difficult to monitor, and inaccessible equipment.*
  - a. According to 40 CFR §63.1255(f)(1), equipment that is designated as unsafe to monitor, difficult to monitor, or inaccessible is exempt from the monitoring requirements as specified in paragraphs (f)(1)(i) through (iv) of §63.1255 provided Pfizer Pharmaceuticals LLC (CRUCE DAVILA) meets the requirements specified in paragraph (f)(2), (3), or (4) of §63.1255, 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.
    - i. For pumps and agitators, paragraphs (c)(2), (3), and (4) of §63.1255 do not apply.
    - ii. For valves, paragraphs (e)(2) through (7) of §63.1255 do not apply.
    - iii. For connectors, §63.174(b) through (e) and paragraphs (b)(4)(iii)(B) through (F) of §63.1255 do not apply.
    - iv. For closed-vent systems, §63.172(f)(1) and (2) and §63.172(g) do not apply.
  - b. *Equipment that is unsafe to monitor or unsafe to inspect.*
    - i. Valves, connectors, agitators, and pumps may be designated as unsafe to monitor if Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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 §63.1255. [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 §63.1255. [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, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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.*

- i. A valve, agitator, or pump may be designated as difficult to monitor if Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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 Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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 §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 §63.1255 may be designated as difficult to inspect. At a new affected source, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may designate no more than 3 percent of valves as difficult to monitor. [40 CFR §63.1255(f)(3)(iii)]
- 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, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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 equipment and ceramic or ceramic-lined connectors.*

- i. According to 40 CFR §63.1255(f)(4)(i), a connector may be designated as inaccessible if it is:
  - 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 staircase 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 a staircase. [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 §63.1255 may be designated as inaccessible. At a new affected source, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may designate no more than 3 percent of connectors as inaccessible. [40 CFR §63.1255(f)(4)(iii)]
  - iv. If any 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 §63.1255. [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 §63.1255. [40 CFR §63.1255(f)(4)(v)]

**7. *Recordkeeping Requirements. (E)(7)***

- a. An owner or operator of more than one group of processes subject to the provisions of §63.1255 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 §63.1255 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 §63.1255 and in paragraph (a)(9) of §63.1255, the following information pertaining to all equipment subject to the requirements in §63.1255 shall be recorded:
- i. A list of identification numbers for equipment (except connectors that are subject to paragraph (f)(4) of §63.1255) subject to the requirements of §63.1255. Except for equipment subject to the recordkeeping requirements in paragraphs (g)(2)(ii) through (viii) of §63.1255, equipment need not be physically 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 §63.1255 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)]
  - ii. A schedule for monitoring connectors subject to the provisions of §63.174(a) and valves subject to the provisions of paragraph (e)(4) of §63.1255. [40 CFR §63.1255(g)(2)(i)(B)]
  - iii. Physical tagging of the equipment to indicate that it is in organic HAP service is not required. Equipment subject to the provisions of §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)I]
  - iv. A list of identification numbers for equipment that Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to equip with a closed-vent system and control equipment, under the provisions of paragraph I(7) of §63.1255, §63.164(h), or §63.165I. [40 CFR §63.1255(g)(2)(ii)(A)]
  - v. A list of identification numbers for pressure relief equipment subject to the provisions in §63.165(a). [40 CFR §63.1255(g)(2)(iii)(A)]
  - vi. A list of identification numbers for pressure relief equipment equipped with rupture disks, under the provisions of §63.165(d). [40 CFR §63.1255(g)(2)(iii)(B)]

- vii. Identification of instrumentation systems subject to the provisions of §63.1255. Individual components in an instrumentation system need not be identified. [40 CFR §63.1255(g)(2)(iv)]
  - viii. 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 paragraph I(5)(vi)(A) of section §63.1255 and §63.164(e)(2), and an explanation of the design criteria; and
    - b) Any changes to these criteria and the reasons for the changes.
  - ix. A list of equipment designated as unsafe to monitor/inspect or difficult to monitor/inspect under paragraph (f) of §63.1255 and a copy of the plan for monitoring or inspecting this equipment. [40 CFR §63.1255(g)(2)(vi)]
  - x. A list of connectors removed from and added to the processes, as described in §63.174(i)(1), and documentation of the integrity of the weld for any removed connectors, as required in §63.174(j). This is not required unless the net credits for removed connectors is expected to be used. [40 CFR §63.1255(g)(2)(vii)]
  - xi. For the equipment Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to monitor as provided under §63.178I, a list of equipment added to batch product processes since the last monitoring period required in §63.178I(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 Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to adjust monitoring frequency by the time in use, as provided in §63.178I(3)(iii), records demonstrating the proportion of the time during the calendar year the equipment is in use in a manner subject to the provisions of §63.1255 are required. Examples of suitable documentation are records of time in use for individual items of equipment or average time in use for the process unit. [40 CFR §63.1255(g)(2)(viii)]
- c. *Records of visual inspections.* For visual inspections of equipment subject to the provisions of paragraphs I(2)(iii) and I(5)(iv) of §63.1255, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall document that the inspection was conducted and the date of the inspection. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall maintain records as specified in paragraph (g)(4) of §63.1255 for leaking equipment identified in this inspection, except as provided in paragraph (g)(5) of §63.1255. These records shall be retained for 2 years. [40 CFR §63.1255(g)(3)]

- d. *Monitoring Records.* According to 40 CFR §63.1255(g)(4), when each leak is detected as specified in paragraph I of §63.1255, and paragraph (e) of §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.
  - ii. The date the leak was detected and the date of the first attempt to repair the leak.
  - iii. The date of successful repair of the leak.
  - 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.
  - v. “Repair delayed” and the reason for the delay if a leak is not repaired within 15 calendar days after discovery of the leak.
    - a) Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall develop a written procedure that identifies the conditions that justify a delay of repair. The written procedures shall be included either as part of the startup/shutdown/malfunction plan, required by §63.1259(a)(3), or in a separate 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.
    - 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.
  - vi. If repairs were delayed, dates of process shutdowns that occur while the equipment is not repaired.
  - vii. If the alternative in §63.174I(1)(ii) 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).
  - viii. The date and results of follow-up monitoring as required in §63.174I(1)(i) and I(2)(ii). If identification of disturbed connectors is made by location, then

all connectors within the designated location shall be monitored.

- ix. The date and results of the monitoring required in §63.178I(3)(i) for equipment added to a batch process since the last monitoring period required in §63.178I(3)(ii) and (iii). If no leaking equipment is found in this monitoring, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall record that the inspection was performed. Records of the actual monitoring results are not required.
  - x. Copies of the periodic reports as specified in paragraph (h)(3) of §63.1255, if records are not maintained on a computerized data base capable of generating summary reports from the records.
- e. *Records of relief equipment compliance tests.* According to 40 CFR §63.1255(g)(6), and the dates and results of the monitoring following a pressure release for each pressure relief equipment subject to the provisions in §§63.165(a) and (b). The results shall include:
- i. The background level measured during each compliance test.
  - ii. The maximum instrument reading measured at each piece of equipment during each compliance test.
- f. *Records for closed-vent systems.* According to 40 CFR §63.1255(g)(7), Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall maintain records of the information specified in paragraphs (g)(7)(i) through (iii) of §63.1255 for closed-vent systems and control equipment subject to the provisions of paragraph (b)(4)(ii) of §63.1255. The records specified in paragraph (g)(7)(i) of §63.1255 shall be retained for the life of the equipment. The records specified in paragraphs (g)(7)(ii) and (g)(7)(iii) of §63.1255 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 §63.1255.
    - a) Detailed schematics, design specifications of the control equipment, and piping and instrumentation diagrams.
    - b) The dates and specifications of any changes in the design specifications.
    - c) A description of the parameter or parameters monitored, as required in paragraph (b)(4)(ii) of §63.1255, to ensure that all control equipment is operated and maintained in conformance with their design and an explanation of why that parameter (or parameters) was

selected for the monitoring.

- ii. *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 §63.1255. [40 CFR §63.1255(g)(9)]
  - iii. *Records of alternative means of compliance determination.* According to 40 CFR §63.1255(g)(10), owners and operators choosing to comply with the requirements of §63.179 shall maintain the following records:
    - a) Identification of the process(es) and the organic HAP they handle.
    - b) A schematic of the process, enclosure, and closed-vent system.
    - c) A description of the system used to create a negative pressure in the enclosure to ensure that all emissions are routed to the control equipment.
- g. *Reporting Requirements.*
- a. According to 40 CFR §63.1255(h)(1), each owner or operator subject to §63.1255 shall submit the reports listed in paragraphs (h)(1)(i) through (ii) of §63.1255.
    - i. A Notification of Compliance Status Report described in paragraph (h)(2) of §63.1255,
    - ii. Periodic reports described in paragraph (h)(3) of §63.1255.
  - b. *Notification of compliance status report.* According to 40 CFR §63.1255(h)(2), each owner or operator of a source subject to §63.1255 shall submit the information specified in paragraphs (h)(2)(i) through (iii) of §63.1255 in the Notification of Compliance Status Report described in §63.1260(f).
    - i. The notification shall provide the information listed in paragraphs (h)(2)(i)(A) through (C) of §63.1255 for each process subject to the requirements of paragraphs (b) through (g) of §63.1255.
      - a) Process group identification.
      - b) Number of each equipment type (*e.g.*, valves, pumps) in organic HAP service, excluding equipment in vacuum service.

- c) Method of compliance with the standard (for example, “monthly leak detection and repair” or “equipped with dual mechanical seals”)
  - ii. The notification shall provide the information listed in paragraphs (h)(2)(ii)(A) and (B) of §63.1255 for each process subject to the requirements of paragraph (b)(4)(iv) of §63.1255 and §63.178(b).
    - a) Products or product codes subject to the provisions of §63.1255, and
    - b) Planned schedule for pressure testing when equipment is configured for production of products subject to the provisions of §63.1255.
  - iii. The notification shall provide the information listed in paragraphs (h)(2)(iii)(A) and (B) of §63.1255 for each process subject to the requirements in §63.179.
    - a) Process identification.
    - b) A description of the system used to create a negative pressure in the enclosure and the control equipment used to comply with the requirements of paragraph (b)(4)(ii) of §63.1255.
  - iv. Any change in the information submitted under paragraph (h) of §63.1255 shall be provided to the Board and the EPA as part of subsequent Periodic Reports. Section 63.9(j) shall not apply to the Notification of Compliance Status Report described in paragraph (h)(2) of §63.1255.
- c. *Periodic reports.* According to 40 CFR §63.1255(h)(3), the owner or operator of a source subject to §63.1255 shall submit Periodic Reports.
  - i. A report containing the information in paragraphs (h)(3)(ii), (iii), and (iv) of §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.
  - ii. For equipment complying with the provisions of paragraphs (b)

through (g) of §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 §63.1255 for each monitoring period during the 6-month period.

- a) The number of valves for which leaks were detected as described in paragraph (e)(3) of §63.1255, the percent leakers, and the total number of valves monitored;
  - b) Separately, the number of pumps and agitators for which leaks were detected as described in paragraph (c)(2) of §63.1255, the total number of pumps and agitators monitored, and the percent leakers.
  - c) Separately, the number of pumps and agitators for which leaks were not repaired as required in paragraph (c)(3) of §63.1255;
  - d) The number of connectors for which leaks were detected as described in §63.174(a), the percent of connectors leaking, and the total number of connectors monitored.
  - e) The number of connectors for which leaks were not repaired as required in §63.174(d), identifying the number of those that are determined non-repairable;
  - f) The facts that explain any delay of repairs and, where appropriate, why a process shutdown was technically infeasible.
  - g) The results of all monitoring to show compliance with §§63.164(i), 63.165(a), and 63.172(f) conducted within the semiannual reporting period.
  - h) If applicable, the initiation of a monthly monitoring program under either paragraph I(4)(ii) or paragraph (e)(4)(i) of §63.1255.
  - i) If applicable, notification of a change in connector monitoring alternatives as described in §63.174I(1).
- iii. Any revisions to items reported in earlier Notification of Compliance Status report, if the method of compliance has changed since the last

report.

*d. Monitoring Requirements.*

- a. *Emissions averaging.* According to §63.1258(f), the owner or operator of any affected source that chooses to comply with the requirements of §63.1252(d) shall meet all monitoring requirements specified in paragraphs (b)(1) and (3) of §63.1258, as applicable, for all processes and storage tanks included in the emissions averaging. [40 CFR §63.1258]

*e. Reporting Requirements*

- a. *Reports of Leak Detection and Repair (LDAR) programs:* According to §63.1260(j), the owner or operator of any affected source implementing the LDAR program specified in §63.1255 of subpart GGG shall implement the reporting requirements in §63.1255 of subpart GGG. 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), as follows:

- i. According to 40 CFR §63.10(b)(1) part 63, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall maintain files of all information (including all reports and notifications) required by part 63 recorded in a form suitable and readily available for expeditious inspection and review. The files shall be retained for at least 5 years following the date of each occurrence, measurement, maintenance, corrective action, report, or record. At a minimum, the most recent 2 years of data shall be retained on site. The remaining 3 years of data may be retained off site. Such files may be maintained on microfilm, on a computer, on computer floppy disks, on magnetic tape disks, or on microfiche. [40 CFR §63.10(b)(1)]

**F. Test Methods**

1. Except as specified in paragraph (a)(5) of §63.1257, the procedures specified in paragraphs (c), (d), (e), and (f) of §63.1257 are required to demonstrate initial compliance with §§63.1253, 63.1254, 63.1256, and 63.1252(e), respectively. The provisions in paragraphs (a) (2) through (3) apply to performance tests that are specified in paragraphs (c), (d), and (e) of §63.1257. The provisions in paragraph (a)(5) of this section are used to demonstrate initial compliance with the alternative standards specified in §§63.1253(d) and 63.1254(c). The provisions in paragraph (a)(6) of §63.1257 are used to comply with the outlet concentration requirements specified in §§63.1253(c), 63.1254 (a)(2)(i) and (a)(3)(ii)(B), 63.1254(b)(i) and 63.1256(h)(2). [40 CFR §63.1257(a)]

2. To demonstrate that the control equipment meets the required control efficiency, a design evaluation must address the composition and organic HAP concentration of the vent stream entering the control equipment. A design evaluation also must address other vent stream characteristics and control equipment operating parameters *as specified in any one of paragraphs (a)(1) (i) through (vi) of §63.1257, depending on the type of control equipment that is used.* If the vent stream is not the only inlet to the control equipment, the efficiency demonstration also must consider all other vapors, gases, and liquids, other than fuels, received by the control equipment. [40 CFR §63.1257(a)(1)]
3. An owner or operator using *any control equipment specified in paragraphs (a)(4)(i) through (iv) of §63.1257* is exempt from the initial compliance provisions in paragraphs (c), (d), and (e) of §63.1257. [40 CFR §63.1257(a)(4)]
4. When testing is conducted to measure emissions from an affected source, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall use the test methods specified in paragraphs (b)(1) through (10) of §63.1257. [40 CFR §63.1257(b)]
5. An owner or operator with two or more affected storage tanks may demonstrate compliance with §63.1253, as applicable, by fulfilling the requirements of paragraphs (g)(1) through (4) of §63.1257. [40 CFR §63.1257(g)]
6. An owner or operator with two or more affected processes complying with §63.1254 by using emissions averaging shall demonstrate compliance with paragraphs (h)(1), (2) and (3) of §63.1257. [40 CFR §63.1257(h)]
7. The overall percent reduction efficiency shall be calculated using Equation 62 of subpart GGG. [40 CFR §63.1257(h)(4)]

#### **G. Monitoring Requirements**

1. The owner or operator of any existing, new, or reconstructed affected source shall provide evidence of continued compliance with the standard as specified in §63.1258. During the initial compliance demonstration, maximum or minimum operating parameter levels, as appropriate, shall be established for emission sources that will indicate the source is in compliance. Test data, calculations, or information from the evaluation of the control equipment design shall be used to establish the operating parameter level. [40 CFR §63.1258(a)]
2. Except as specified in paragraph (b)(1)(i) of §63.1258, for each control equipment, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall install and operate sampling equipment and operate within the established parameter levels to ensure continued

compliance with the standard. Sampling parameters are specified for control scenarios in Table 4 of subpart GGG and in paragraphs (b)(1)(ii) through (xi) of section 63.1258 of the 40 CFR.

- a. For control equipment that control vent streams totaling less than 1 ton/yr HAP emissions, before control, sampling shall consist of a daily verification that the equipment is operating properly. If the control equipment is used to control batch process vents alone or in combination with other streams, the verification may be on a per batch basis. This verification shall include, but not be limited to, a daily or per batch demonstration that the unit is working as designed and may include the daily measurements of the parameters described in (b)(1)(ii) through (x) of §63.1258. [40 CFR §63.1258(b)(1)(i)]
3. *Procedures for setting parameter levels for control equipment used to control emissions.*
- a. *Small control equipment.* Except as provided in paragraph (b)(1)(i) of this section, for equipment controlling less than 10 tons per year of HAP for which a performance test is not required, the parametric levels shall be set based on the design evaluation required in §63.1257(d)(3)(i). If a performance test is conducted, the sampling parameter level shall be established according to the procedures in (b)(3)(ii) of this section. [40 CFR §63.1258(b)(3)(i)]
  - b. *Large control equipment.* According to the requirements of 40 CFR section 63.1258(b)(3)(ii), for equipment controlling greater than 10 tons per year of HAP for which a performance test is required, the parameter level must be established as follows:
    - i. If the operating parameter level to be established is a maximum, it must be based on the average of the values from each of the three test runs. [40 CFR §63.1258(b)(3)(ii)(A)]
    - ii. If the operating parameter level to be established is a minimum, it must be based on the average of the values from each of the three test runs. [40 CFR §63.1258(b)(3)(ii)(B)]
    - iii. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may establish the parametric sampling level(s) based on the performance test supplemented by engineering assessments and manufacturer's recommendations. Performance testing is not required to be conducted over the entire range of expected parameter values. The rationale for the specific level for each parameter, including any data and calculations used to develop the level(s) and a description of why



§63.1254(a)(2) shall demonstrate continuous compliance with the 900 and 1,800 kg/yr emission limits by calculating daily 365-day rolling summations of emissions. During periods of planned routine maintenance when emissions are controlled as specified in §63.1252(h), Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must calculate controlled emissions assuming the HAP emissions are reduced by 93 percent. For any owner or operator opting to switch compliance strategy from the 93 percent control requirement to the annual mass emission limit method, as described in §63.1254(a)(1)(i), the rolling summations, beginning with the first day after the switch, must include emissions from the past 365 days. [40 CFR §63.1258(c)]

7. The owner or operator of any affected source complying with the requirements of §63.1255 of subpart GGG shall meet the sampling requirements described §63.1255 of subpart GGG. [40 CFR §63.1258(d)]
8. The owner or operator of any affected source that chooses to comply with the requirements of §§63.1252(e)(2) and (3) shall calculate a yearly rolling average of kg HAP consumption per kg production and kg VOC consumption per kg production every month or every 10 batches. Each rolling average kg/kg factor that exceeds the value established in §63.1257(f)(1)(ii) will be considered a violation of the emission limit. [40 CFR §63.1258(e)]
9. The owner or operator of any affected source that chooses to comply with the requirements of §63.1252(d) shall meet all sampling requirements specified in paragraphs (b)(1) and (3) of this section, as applicable, for all processes and storage tanks included in the emissions average. [40 CFR §63.1258(f)]
10. Leak inspection provisions for vapor suppression equipment.
  - a. Except as provided in paragraph (h)(9) §63.1258, for each vapor collection system, closed-vent system, fixed roof, cover, or enclosure required to comply with §63.1258, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with the requirements of paragraphs (h)(2) through (8) of § 63.1258. [40 CFR §63.1258(h)(1)]
  - b. If a closed-vent system subject to §63.1258 is also subject to the equipment leak provisions of §63.1255, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with the provisions of §63.1255 and is exempt from the requirements of §63.1258. [40 CFR §63.1258(h)(9)]
  - c. Instead of complying with the provisions of paragraphs (h)(2) through (8) of §63.1258, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may design a closed-vent system to operate at a pressure below atmospheric pressure. The system shall be equipped with at least one pressure gauge or other pressure measurement 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 §63.1258(h)(10)]

## **H. Recordkeeping requirements**

1. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with the recordkeeping requirements in subpart A of part 63 as specified in Table 1 of subpart GGG and in paragraphs (a)(1) through (5) of §63.1259. [40 CFR §63.1259(a)]
2. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must keep the records mentioned in paragraphs (b)(1) to (13) of §63.1259 up-to-date and readily. [40 CFR §63.1259(b)]
3. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall keep records of each operating scenario, which demonstrates compliance with subpart GGG. [40 CFR §63.1259I]
4. The owner or operator of any affected source implementing the leak detection and repair (LDAR) program specified in §63.1255 of subpart GGG, shall implement the recordkeeping requirements in §63.1255 of §63.1255. [40 CFR §63.1259(d)]
5. The owner or operator of any facility that chooses to comply with the requirements of §63.1252(d) shall maintain up-to-date records of the information detailed in §63.1259(e)(1) through (4). [40 CFR §63.1259(e)]
6. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall keep records specified in paragraphs (i)(1) through (9) of §63.1259, as applicable [40 CFR §63.1259(i)].

## **I. Reporting requirements**

1. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall comply with the reporting requirements detailed in the conditions below. Applicable reporting requirements of §§63.9 and 63.10 are summarized in Table 1 of subpart GGG. [40 CFR §63.1260(a)]
2. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall submit the applicable initial notification in accordance with §63.9(b) or (d). [40 CFR §63.1260(b)]
3. An owner or operator who is subject to §63.5(b)(3) shall submit to the Board and the EPA an application for approval of the construction of a new major affected source, the reconstruction of a major affected source, or the reconstruction of a major source such that the source becomes a major affected source subject to the standards. The application shall be prepared in accordance with §63.5(d). [40 CFR §63.1260(c)]

4. An owner or operator who is required by the Board or the EPA to conduct a compliance evaluation for a continuous monitoring system shall notify the Board and the EPA of the date of the compliance evaluation as specified in §63.8(e)(2). [40 CFR §63.1260(d)]
  
5. For new sources, the Pre-compliance report shall be submitted at least six months before the compliance date of the standard. For new sources, the Pre-compliance report shall be submitted to the Board and the EPA with the application for approval of construction or reconstruction. EQB and EPA have 90 days to approve or deny the plan. The plan shall be considered approved if the Board or EPA approves the plan in writing or if fails to approve the plan in writing. The 90-days period shall begin when EQB or EPA receive the application. If the request is denied, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) must still be in compliance with the standard by the compliance date. To change any of the information submitted in the report, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall notify the Board and the EPA 90 days before the planned change is to be implemented. The Pre-compliance report shall include: [40 CFR §63.1260(e)]
  - a. Requests for approval to use alternative sampling parameters or requests to set sampling parameters according to §63.1258(b)(4). [40 CFR §63.1260(e)(1)]
  - b. Descriptions of the daily or per batch demonstrations to verify that the control equipment subject to §63.1258(b)(1)(i) is operating as designed. [40 CFR §63.1260(e)(2)]
  - c. A description of test conditions, and the corresponding sampling parameter values for parameters that are set according to §63.1258(b)(3)(ii)(C). [40 CFR §63.1260(e)(3)]
  - d. For owners and operators complying with the requirements of §63.1252(e), the P2 demonstration summary required in §63.1257(f). [40 CFR §63.1260(e)(4)]
  - e. Data and rationale used to support an engineering assessment to calculate uncontrolled emissions from process vents as required in §63.1257(d)(2)(ii). [40 CFR §63.1260(e)(5)]
  - f. Data and other information supporting the determination of annual average concentrations by process simulation as required in §63.1257(e)(1)(ii). [40 CFR §63.1260(e)(6)]
  - g. Bench scale or pilot-scale test data and rationale used to determine annual

average concentrations as required in §63.1257(e)(1)(ii)I. [40 CFR §63.1260(e)(7)]

6. The Notification of Compliance Status report required under §63.9 shall be submitted no later than 150 days after the compliance date and shall include:
  - a. The results of any applicability determinations, emission calculations, or analyses used to identify and quantify HAP emissions from the affected source. [40 CFR §63.1260(f)(1)]
  - b. The results of emissions profiles, performance tests, engineering analyses, design evaluations, or calculations used to demonstrate compliance. For performance tests, results should include descriptions of sampling and analysis procedures and quality assurance procedures. [40 CFR §63.1260(f)(2)]
  - c. Descriptions of sampling equipment, sampling frequencies, and the values of sampled parameters established during the initial compliance determinations, including data and calculations to support the levels established. [40 CFR §63.1260(f)(3)]
  - d. Listing of all operating scenarios. [40 CFR §63.1260(f)(4)]
  - e. Descriptions of worst-case operating and/or testing conditions for control equipment. [40 CFR §63.1260(f)(5)]
  - f. Identification of emission points subject to overlapping requirements described in §63.1250(h) and the authority under which the owner or operator will comply. [40 CFR §63.1260(f)(6)]
  
7. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall prepare Periodic reports in accordance with the following and submit them to the Board and the EPA:
  - a. Except as provided in paragraphs (g)(1)(i), (ii), and (iii) of §63.1260, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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. When the Board or the EPA determines on a case-by-case basis that more frequent reporting is necessary to accurately assess the compliance status of the affected source; or [40 CFR §63.1260(g)(1)(i)]

- ii. Quarterly reports shall be submitted when the source experiences an exceedance of a temperature limit sampled according to the provisions of §63.1258(b)(1)(iii) or an exceedance of the outlet concentration sampled 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 Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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 sampling system performance report and/or summary report” shall mean “Periodic report” for the purposes of §63.1260. [40 CFR §63.1260(g)(1)(ii)]
  - iii. When a new operating scenario has been operated since the last report, in which case quarterly reports shall be submitted. [40 CFR §63.1260(g)(1)(iii)]
- b. *Content of Periodic report.* Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall include the information that follows, as applicable.
- i. Each Periodic report must include the information in §63.10(e)(3)(vi)(A) through (I) and (K) through (M). For each continuous sampling system, the Periodic report must also include the information in §63.10(e)(3)(vi)(J). [40 CFR §63.1260(g)(2)(i)]
  - ii. If the total duration of excess emissions, parameter exceedances, or excursions for the reporting period is 1 percent or greater of the total operating time for the reporting period, or the total continuous sampling system downtime for the reporting period is 5 percent or greater of the total operating time for the reporting period, the Periodic report must include the following information:
    - 1. Sampling data, including 15-minute sampling values as well as daily average values of sampled parameters, for all operating days when the average values were outside the ranges established in the Notification of Compliance Status report or operating permit. [40 CFR §63.1260(g)(2)(ii)(A)]
    - 2. Duration of excursions, as defined in §63.1258(b)(7). [40 CFR §63.1260(g)(2)(ii)(B)]
    - 3. Operating logs and operating scenarios for all operating scenarios for all operating days when the values are outside the

levels established in the Notification of Compliance Status report or operating permit. [40 CFR §63.1260(g)(2)(ii)I]

4. When a continuous sampling system is used, the information required in §63.10I(5) through (13). [40 CFR §63.1260(g)(2)(ii)(D)]
- iii. For each inspection conducted in accordance with §63.1258(h)(2) or (3) during which a leak is detected, the records specified in §63.1259(i)(7) must be included in the next Periodic report. [40 CFR §63.1260(g)(2)(iii)]
- iv. For each vapor collection system or closed vent system with a bypass line subject to §63.1252(b)(1), records required under §63.1259(i)(6)(i) of all periods when the vent stream is diverted from the control equipment through a bypass line. For each vapor collection system or closed vent system with a bypass line subject to §63.1252(b)(2), records required under §63.1259(i)(6)(ii) of all periods in which the seal mechanism is broken, the bypass valve position has changed, or the key to unlock the bypass line valve was checked out. [40 CFR §63.1260(g)(2)(iv)]
- v. The information in paragraphs (g)(2)(v)(A) through (D) of §63.1260 shall be stated in the Periodic report, when applicable.
  - a) No excess emissions. [40 CFR §63.1260(g)(2)(v)(A)]
  - b) No exceedances of a parameter. [40 CFR §63.1260(g)(2)(v)(B)]
- vi. No excursions. [40 CFR §63.1260(g)(2)(v)(C)]
- vii. No continuous sampling system has been inoperative, out of control, repaired, or adjusted. [40 CFR §63.1260(g)(2)(v)(D)]
- viii. The information specified in paragraphs (g)(2)(vi)(A) through (C) of §63.1260 for periods of planned routine maintenance. [40 CFR §63.1260(g)(2)(vi)] For each storage tank subject to the control requirements, periods of routine maintenance planned during which the control equipment does not comply with the specifications in section 63.1253(b) of the 40 CFR.
- ix. Each new operating scenario which has been operated since the time period covered by the last Periodic report. For each operating

scenario, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall provide verification that the operating conditions for any associated control or treatment equipment have not been exceeded, and that any required calculations and engineering analyses have been performed. For the initial Periodic report, each operating scenario for each process operated since the due date of the Notification of Compliance Status Report shall be submitted. [40 CFR §63.1260(g)(2)(vii)]

- x. If Pfizer Pharmaceuticals LLC (CRUCE DAVILA) elects to comply with the provisions of §63.1253(b) or (c) by installing a floating roof, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall submit the information specified in §63.122(d) through (f) as applicable. References to §63.152 from §63.122 shall not apply for the purposes of subpart GGG. [40 CFR §63.1260(g)(2)(viii)]

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

- a. Whenever a process change is made, or a change in any of the information submitted in the Notification of Compliance Status Report, Pfizer Pharmaceuticals LLC (CRUCE DAVILA), 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 §63.1260. The report shall include:
  - 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 §63.1260. [40 CFR §63.1260(h)(1)(iii)]
  - iv. Information required by the Notification of Compliance Status Report under paragraph (f) of §63.1260 for changes involving the addition of processes or equipment. [40 CFR §63.1260(h)(1)(iv)]
- b. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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.
  - ii. A change in the status of a control equipment from small to large.

9. Reports of malfunction, startup and shutdown. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall prepare malfunction, startup and shutdown reports as specified in paragraphs (i)(1) and (2) of §63.1260, as follows:
  - a. If actions taken by Pfizer Pharmaceuticals LLC (CRUCE DAVILA) during a malfunction, startup and shutdown of an affected source (including actions to correct a malfunction) are consistent with the procedures specified in the source's malfunction, startup and shutdown plan, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall state this fact in a malfunction, startup and shutdown report. The report shall also include the information specified in §63.1259(a)(3)(i) and (ii) and shall contain the name, title, and signature of the owner or operator or other responsible official who is certifying its accuracy. For the purposes of subpart GGG, the malfunction, startup and shutdown reports shall be submitted on the same schedule as the periodic reports required under paragraph (g) of §63.1260 instead of the schedule specified in §63.10(d)(5)(i). Reports are only required if a malfunction, startup and shutdown occurred during the reporting period. [40 CFR §63.1260(i)(1)]
  - b. Any time Pfizer Pharmaceuticals LLC (CRUCE DAVILA) takes an action that is not consistent with the procedures specified in the affected source's malfunction, startup and shutdown plan, Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall submit immediate malfunction, startup and shutdown reports as specified in §63.10(d)(5)(ii). [40 CFR §63.1260(i)(2)]
10. The owner or operator of any affected source implementing the LDAR program specified in §63.1255 shall implement the reporting requirements in that same section §63.1255. 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). [40 CFR §63.1260(j)]
11. The owner or operator of any affected source that chooses to comply with the requirements of §63.1252(d) shall submit the implementation plan described in §63.1259(e) 6 months prior to the compliance date of the standard and the following information in the periodic reports:
  - a. The records specified in §63.1259(e) for each process or storage tank included in the emissions average;
  - b. All information as specified in paragraph (g) of section §63.1260 for each process or storage tank included in the emissions average;
  - c. Any changes of the processes or storage tanks included in the average.

- d. The calculation of the overall percent reduction efficiency for the reporting period.
  - e. Changes to the Implementation Plan which affect the calculation methodology of uncontrolled or controlled emissions or the hazard or risk equivalency determination.
  - f. Every second semiannual or fourth quarterly report, as appropriate, shall include the results according to §63.1259(e)(4) to demonstrate the emissions averaging provisions of §§63.1252(d), 63.1257(g) and (h), 63.1258(f), and 63.1259(f) are satisfied. [40 CFR §63.1260(k)(1-6)]
12. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) shall notify the Administrator of the planned date of a performance test at least 60 days before the test in accordance with §63.7(b). Pfizer Pharmaceuticals LLC (CRUCE DAVILA) 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. [40 CFR §63.1260(l)]
13. Pfizer Pharmaceuticals LLC (CRUCE DAVILA) may submit to the Administrator a request for an extension of compliance in accordance with §63.1250(f)(4). [40 CFR §63.1260(m)]

## SECTION IX - INSIGNIFICANT EMISSION UNITS

Note: The list of insignificant activities below was provided by the emission source in order to permit a better understanding of its operations. Given that it is not required to keep this list up-to-date, the activities may have suffered changes from the time when it was submitted.

Identification Emission Unit	Quantity	Description (Exemption Criteria)
EU- Pharmaceutical Production (EU-3)	---	Emission units with an actual emission rates of less than the following tons per year should be considered insignificant activities: <u><b>Contaminant</b></u> <u><b>Tons/Year</b></u> Particulate Matter (PM) 2 Sulfur Oxides (SO <sub>x</sub> ) 2 Nitrogen Oxides (NO <sub>x</sub> ) 1 Volatile Organic Compounds (VOC) 1 Carbon Monoxide (CO) 1 PM <sub>10</sub> 1 (Appendix B(3)(ii)(P) of the RCAP).
Permanent Emergency electric generators	10	Emergency generators with operation rates of less than 500 hrs/yr. (Appendix B(3)(ii)(O) of the RCAP)
Portable Electric Generators for periods of huracanes, routine maintenance jobs, special projects, expansion projects and maintenance jobs during planned operations shut downs and/or emergencies.	20	Emergency generators with operation rates of less than 500 hrs/yr. (Appendix B(3)(ii)(O) of the RCAP)
Maintenance activities throughout the whole facility	4 times per year (approximately)	Activities at maintenance factory like brazing soldering equipment, welding, and soldering equipment used as an auxiliary media to the principal equipment of the source. (Appendix B(3)(ii)(E) of the RCAP)
Pilot plants and Laboratories throughout the whole facility	1	Pilot plants and Laboratories engaging in research development and quality control activities. (Appendix B(3)(ii)(M) of the RCAP)
Storage tanks with capacity of less than 10,000 gallons	7	Storage tanks with capacity of less than 10,000 gallons. (Appendix B(3)(ii)(N) of the

Identification Emission Unit	Quantity	Description (Exemption Criteria)
throughout the whole facility		RCAP)
Quality Control and Environmental Compliance Laboratories throughout the whole facility	5	Laboratories used solely for the purpose of quality control or environmental compliance testing that are associated with manufacturing, production or other industrial or commercial facilities.( Appendix (B)(3)(xxi) of the RCAP)
Aboveground fuel storage tanks with a capacity of less than 10,000 gallons throughout the whole facility	12	Aboveground storage tanks for gasoline, diesel fuel and kerosene with a capacity of less than 10,000 gallons. (Appendix B(3)(xi) of the RCAP)
Air compressors and pumps throughout the whole facility	5 (air pumps approximately)	Air compressors and pumps. (Appendix B(3)(xxiii) of the RCAP).
Non routine tanks and equipments cleaning for employees entrance, preparation for maintenance or decomission throughout the whole facility	10 times per year (approximately)	Non routine tanks and equipments cleaning for employees entrance, preparation for maintenance or decomission (AppendixB(3)(xxvi) of the RCAP).
Spill collection tanks throughout the whole facility	1	Spill collection tanks. (Appendix B(3)(xxxiv) of the RCAP)
Vents or stacks for drainage of deareators, transformers or MCC rooms.	10 (approximately)	Stacks or vent systems for buildings, transformation closed areas, control panels and electric engines and deareators. (Appendix B(3)(xxxix) of the RCAP)
Food preparation for cafeteria and dining hall services	2	Food preparation in cafeteria and dining hall services.( Appendix (B)(3)(ii)(J) of the RCAP)
Training facilities to respond to fire, explosions and other that require and involve the use and combustion of fuels and chemicals.	1	Training facilities to respond to fire, explosions and other, required under the contingency and safety plan and that involve the use and combustion of fuels and chemicals as part of the training. (Appendix B(3)(xvi) of the RCAP)
Diesel fuel storage tank used only as distribution facility.	1	Dispensing facilities for refueling diesel-powered vehicles or equipment, including any diesel fuel storage tank serving only such dispensing facility. (Appendix B(3)(xxv) of the RCAP)

Identification Emission Unit	Quantity	Description (Exemption Criteria)
Water cooling tower	6	Water-cooling tower, except for systems including contact process water or water treatment with chromium-based chemicals. (Appendix B(3)(xxxiii) of the RCAP)
Boiler water treatment operations	3	Boiler water treatment operations except those involving the use of hydrazine. (Appendix B (3)(xxxvi) of the RCAP)
Manufacture of validation and test batches	---	Emissions of criteria pollutants is equal or less than 2 tons/year or 5 tons/year of a combination of the criteria pollutants and less than the de-minimis levels for hazardous pollutants in Appendix E. (Appendix B(2) of the RCAP)
Storage of substances in closed drums, barrels, bottles, or closed cylinders throughout the whole facility.	10	Storage of substances in closed drums, barrels, bottles or closed cylinders. (Appendix B(3)(xxxiv) of the RCAP)
Refrigeration Systems	95	Refrigeration Systems. (Appendix B(3)(xxxv) of the RCAP)
Stationary storage tanks which are used for the storage of water or distillates of air.	4	One of the following types of source operations: i. Source operations which have not potential for emitting any air contaminants, including but not limited to: (A) Stationary storage tanks which are used for the storage of water or distillates of air (Appendix B(3)(i)(A) of the RCAP)
First aid or emergency medical care	1	First aid or emergency medical care including sterilization and preparation of medicine. (Appendix B(3)(ii)(F) of the RCAP)
Maintenance activities of the physical plant throughout the whole facility.	10 times per year (approximately)	Maintenance activities of the physical plant to take care of buildings and structures at the facility, including painting and roofing. (Appendix B(3)(ii)(H) of the RCAP.)
Activities of external maintenance of the land through all the installation including the maintenance of grass, painting buildings, etc.	Throughout the year	Activities of external maintenance of the land through all the installation including the maintenance of grass, painting buildings, etc. (Appendix B(3)(ii)(I) of the RCAP)

<b>Identification Emission Unit</b>	<b>Quantity</b>	<b>Description (Exemption Criteria)</b>
Engines of any vehicle, including but without limiting to, any motor vehicles, any forklift, tranctor, mobile construction equipment, including any auxiliary engine that provides cooling or refrigeration to the vehicle.	50	Engines of any vehicle, including but without limiting to, any motor vehicles, any forklift, tranctor, mobile construction equipment, including any auxiliary engine that provides cooling or refrigeration to the vehicle. (Appendix B(3)(iii) of the RCAP)
Treatment equipment for drinking water, excluding air stripper units. The clorination is included.	2	Treatment equipment for drinking water, excluding air stripper units. (Appendix B(3)(v) of the RCAP)
Application operations of sand blasting throughout the whole facility.	Once per year (approximately)	Operations of application of sand blasting in closed areas or outside, that satisfies the conditions with respect to particulate emission and fugitive emissions, location, reason of application, recordkeeping and reporting approval. (Appendix B(3)(viii) of the RCAP)
Vapor vents and leaks from boilers and vapor distribution systems.	From 1 to 2 per year	Vapor vents and leaks from boilers and vapor distribution systems. (Appendix B(3)(xxxv) of the RCAP)
Treatment systems of waste water (drinking water, cooling water and water from the boilers).	1	Raw material process water treatment systems (Appendix B(3)(xxxii) of the RCAP)
Herbicides mixing and application activities that does not involves herbicides manufacturing.	<u>1</u>	Herbicides mixing and application activities that does not involves herbicides manufacturing. (Appendix B(3)(xxxvii) of the RCAP)
Mobile and portable containers.	Approximately 100	Mobile and portable containers. (Appendix B(3)(xxxviii) of the RCAP)
Pump seals	Approximately 100	Pump seals (Appendix B(3)(xxxix) of the RCAP)
Rupture disks for systems managing gases.	Approximately 60	Rupture disks for systems managing gases. (Appendix B (3)(xxxix) of the RCAP)
Storage cabinets for solvents including packages.	Approximately 50	Storage cabinets for solvents including packages. (Appendix B (3)(xxviii) of the RCAP)
Sampling conecctions and systems used exclusively to remove materials for analysis	(approximately) 30	Sampling conecctions and systems used exclusively to remove materials for analysis and tests, including air contaminants

Identification Emission Unit	Quantity	Description (Exemption Criteria)
and tests, including air contaminants detectors and lines of escape.		detectors and lines of escape. (Appendix B(3)(xxvii) of the RCAP)
Pharmaceutical formulation operations are considered insignificant activities because the dust collectors emits at a rate lower than 2 tons/year.	Three pharmaceutical production areas (F-1, F-2, and F-3)	Emissions of criteria pollutants is equal or less than 2 tons/year or 5 tons/year of a combination of the criteria pollutants and less than the de-minimis levels for hazardous pollutants in Appendix E. (Appendix B (2) of the RCAP)

**SECTION X - PERMIT SHIELD**

Pursuant to Rule 603(d) of the RCAP, compliance with the conditions of the permit shall be deemed compliance with any applicable requirements as of the date of permit issuance, provided that such applicable requirements are specifically identified in the permit. Likewise, it shall be deemed in compliance with any requirement specifically identified as Not Applicable in the permit. However, according to 40 CFR §63.6(e)(3)(ix), none of the procedures specified by the malfunction, startup, and shutdown plan for an affected source shall be deemed to fall within the permit shield provision in section 504(f) of the Act.

A. Non applicable requirements

Federal	Reason
National Emission Standards for Organic Liquids Distribution (40 CFR Part 63, Subpart EEEE)	Pfizer Cruce Dávila does not have any organic liquid with more than 5% by weight of listed in Table 1 of Subpart EEEE of Part 63 of the 40 CFR.
National Emission Standards for the Miscellaneous Manufacturing of Chemical Organics Substances (40 CFR Part 63, Subpart FFFF)	Pfizer Cruce Dávila does not produce any of the SOCFI listed in Table 1 of the Subpart F, part 63 of the CFR.
40 CFR Part 82, Subpart B	It is not applicable because Pfizer Cruce Davila does not repair air conditioners from motor vehicles.

## **SECTION XI - PERMIT APPROVAL**

Pursuant to the powers granted to the Environmental Quality Board by the Environmental Public Policy Act, Public Law Number 416 of September 22, 2004, and after verifying the administrative record and in compliance with the Uniform Administrative Procedures Act, Public Law Number 170 of August 12, 1998, as amended, the US Clean Air Act, the Puerto Rico Environmental Public Policy Act and the Environmental Quality Board Regulations for the Control of Atmospheric Pollution, the Environmental Quality Board approves the permit and the terms and conditions stipulated therein.

In San Juan, Puerto Rico, on October 25, 2006.

### **ENVIRONMENTAL QUALITY BOARD**

*/s/*  
Eugene Scott Amy  
Vice President

*/s/*  
Angel O. Berríos Silvestre  
Associate Member

*/s/*  
Carlos W. Lopez Freytes  
President

## **Attachments and Appendices**

**ATTACHMENT 1- INFORMATION ABOUT THE EMISSION SOURCES**

**LIST OF EMISSION UNITS OF CHEMICAL PLANT (EU-2)**

<b>Emission Unit Identification number</b>	<b>Emission unit Description</b>	<b>Emission Point Number or Fugitive Emissions</b>	<b>Control Device Identification Number</b>
EU-Chemical Plant (EU-2) TRAIN # 1			
	K-82, REACTOR	QII-1	E-82-01, E-82-02 & S-303 or S-303 B
	K-82, REACTOR	QII-2	DC-X-311 (Non affected by Pharma MACT)
	K-84, REACTOR	QII-1	E-84-01, E-84-02 & S-303 or S-303 B
	K-84, REACTOR	QII-2	DC-X-311 (Non affected by Pharma MACT)
	C-411, CENTRIFUGE	QII-6	E-415-01
	S-2001, RECEIVER	QII-1	E-2001, E301 & S-303 or S-303 B
	C-412, CENTRIFUGE	QII-7	E-415-02
	S-2002, RECEIVER	QII-1	E-2002, E-301 & S-303 or S-303 B
	K-62, REACTOR	QII-1	E-62, E-301 & S-303 or S-303 B
	K-305, REACTOR	QII-1	E-305, E-301 & S-303 or S-303 B
	K-306, REACTOR	QII-1	E-306, E-301 & S-303 or S-303 B
	C-414, CENTRIFUGE	QII-8	E-415-03
	S-416, RECEIVER	QII-1	E-416, E-301 & S-303 or S-303 B
	TD-417, DRYING TOMBOLA	QII-2	DC-X-311 (Non affected by Pharma MACT)
	R-417-01, RECEIVER	QII-1	E-417-01 (Non affected by Pharma MACT)
	R-417-02, RECEIVER	QII-1	E-417-02 (Non affected by Pharma MACT)
	PIN MILL	QII-4	DC-X-310 (Non affected by Pharma

Emission Unit Identification number	Emission unit Description	Emission Point Number or Fugitive Emissions	Control Device Identification Number
			MACT)
	R-1310, RECEIVER	QII-1	E-1310-01 (Non affected by Pharma MACT)
	R-1311, RECEIVER	QII-1	E-1311 (Non affected by Pharma MACT)
	WEIGHTING ROOM	QII-2	DC-X-311 (Non affected by Pharma MACT)
	R-499, TANK	Insignificant Activity	N/A
	ST-443, TANK	Insignificant Activity	N/A
	ST-444, TANK	Insignificant Activity	N/A
	M-337, VENTURI	QII-1	N/A
	M-2101, VENTURI	QII-1	N/A
	S-303, COLUMN	QII-1	N/A
	S-303, STACK	QII-1	N/A
EU-Chemical Plant (EU-2) TRAIN # 2			
	K-5146-01, TANK	QII-1	E-499 & S-303 or S-303 B
	K-5146-02, TANK	QII-1	E-499 & S-303 or S-303 B
	K-5146-03, TANK	QII-1	E-499 & S-303 or S-303 B
	K-112, REACTOR	QII-1	E-412-01, E-412-02 & S-303 or S-303 B
	K-112, REACTOR	QII-5 AND/OR QII-15	DC-X-312 and/or DC-X-401 (Non affected by Pharma MACT)
	K-104, REACTOR	QII-1	E-404-01, E-404-02 & S-303 o S-303 B
	K-104, REACTOR	QII-5 AND/OR QII-15	DC-X-312 and/or DC-X-401 (Non affected by Pharma MACT)

<b>Emission Unit Identification number</b>	<b>Emission unit Description</b>	<b>Emission Point Number or Fugitive Emissions</b>	<b>Control Device Identification Number</b>
	R-111, RECEIVER	QII-1	E-491, E-499 & S-303 or S-303 B
	R-332, RECEIVER	Insignificant Activity	N/A
	K-113, REACTOR	QII-1	E-413-01, E-499 & S-303 or S-303 B
	TD-116, DRYNG TOMBOLA	QII-16	DC-X-402 (Non affected by Pharma MACT)
	K-301, REACTOR	QII-1	E-5149-01, E-499 & S-303 or S-303 B
	K-403, REACTOR	QII-1	E-5151-01, E-499 & S-303 or S-303 B
	C-5153-01, CENTRIFUGE	QII-12	E-5153-02
	C-5154-01, CENTRIFUGE	QII-13	E-5154-01
	K-5155-01, REACTOR	QII-1	E-5155-01, E-499 & S-303 or S-303 B
	K-5157-01, REACTOR	QII-1	E-5157-01, E-499 & S-303 or S-303 B
	K-5160-01, REACTOR	QII-1	E-5160-01, E-499 & S-303 or S-303 B
	K-5162-01, REACTOR	QII-1	E-5162-01, E-499 & S-303 or S-303 B
	C-402, CENTRIFUGE	QII-10	E-5164-01 (Non affected by Pharma MACT)
	C-5175-01, CENTRIFUGE	QII-11	E-5165-01
	TD-5177-01, DRYNG TOMBOLA	QII-2	DC-X-311 (Non affected by Pharma MACT)
	TD-126, DRYNG TOMBOLA	QII-2	DC-X-311 (Non affected by Pharma MACT)
	S-5178-01, RECEIVER	QII-1	E-5178-01, E-499 & S-303 or S-303 B
	S-5178-02, RECEIVER	QII-1	E-5178-02, E-499 & S-303 or S-303 B
	R-316, RECEIVER	QII-1	E-402, E-499 & S-303

Emission Unit Identification number	Emission unit Description	Emission Point Number or Fugitive Emissions	Control Device Identification Number
			or S-303 B
	S-1632, RECEIVER	QII-1	E-1632, E-499 & S-303 or S-303 B
	R-67 (S-6003), RECEIVER	QII-1	E-6007, E-6008 & S-303 or S-303 B
	S-2004, RECEIVER	QII-1	KC-127 A and/or KC-127 B & S-303 or S-303 B
	ST-0217-01, TANK	Insignificant Activity	N/A
	ST-0217-02, TANK	Insignificant Activity	N/A
	FS-400-01, COLUMN	QII-1	N/A
	FS-400-02, COLUMN	QII-1	N/A
	FS-400, STACK	QII-19	N/A
Train #1 & 2 (Common Use Equipments)			
	VP-0227-01, VACCUM PUMP	QII-20	E-0227-01 (Non affected by Pharma MACT)
	VP-0227-02, VACCUM PUMP	QII-20	E-0227-02 (Non affected by Pharma MACT)
	T-0227, TANK	QII-20	E-0227-01 or E-0227-02 (Non affected by Pharma MACT)
	T-0227-01, TANK	QII-20	E-0227-01 or E-0227-02 (Non affected by Pharma MACT)
	VP-0228-01, VACCUM PUMP	QII-21	E-0228-01 (Non affected by Pharma MACT)
	VP-0228-02, VACCUM PUMP	QII-21	E-0228-02 (Non affected by Pharma MACT)
	T-0228, TANK	QII-21	E-0228-01 or E-0228-02 (Non affected by Pharma MACT)
	T-0228-01, TANK	QII-21	E-0228-01 or E-0228-02 (Non affected by Pharma MACT)

Emission Unit Identification number	Emission unit Description	Emission Point Number or Fugitive Emissions	Control Device Identification Number
	VP-0229-01, VACCUM PUMP	QII-22	E-0229-01 (Non affected by Pharma MACT)
	VP-0229-02, VACCUM PUMP	QII-22	E-0229-02 (Non affected by Pharma MACT)
	T-0229, TANK	QII-22	E-0229-01 or E-0229-02 (Non affected by Pharma MACT)
	T-0229-01, TANK	QII-22	E-0229-01 or E-0229-02 (Non affected by Pharma MACT)
	VP-301, VACCUM PUMP	QII-1	E-417-01, E-417-02 & S-303 (Non affected by Pharma MACT)
	VP-1630, VACCUM PUMP	QII-1	E-499 & S-303 (Non affected by Pharma MACT)
	VP-1631, VACCUM PUMP	QII-1	E-499 & S-303 (Non affected by Pharma MACT)
	VP-6007, VACCUM PUMP	QII-1	KC-127 A/B & S-303 (Non affected by Pharma MACT)
	VP-6008, VACCUM PUMP	QII-1	KC-127 A/B & S-303 (Non affected by Pharma MACT)
	VP-1310, VACCUM PUMP	QII-1	E-1310 & S-303 (Non affected by Pharma MACT)
	VP-1311, VACCUM PUMP	QII-1	E-1311 & S-303 (Non affected by Pharma MACT)
	VP-5178-01, VACCUM PUMP	QII-1	E-5178-01, E-5178-02 & S-303 (Non affected by Pharma MACT)
	Leaks Components (Pumps, Filters, Flanges, Valves, Conectores, PRD,	QII-9 (Fugitives)	LDAR Programs of RCRA Subpart BB and LDAR of Pharma

Emission Unit Identification number	Emission unit Description	Emission Point Number or Fugitive Emissions	Control Device Identification Number
	Instrumentations, open end valves, open end lines, etc.)		MACT
EU-Chemical Plant (EU-2) Existent Equipments but without use	C-106, CENTRIFUGE	QII-1	E-491 (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	S-1441, RECEIVER	QII-1	E-491 (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	C-109, CENTRIFUGE	QII-1	E-491 (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	S-1442, RECEIVER	QII-1	E-498 (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	S-1631, RECEIVER	QII-1	E-1631 (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	R-5006, RECEIVER	QII-1	E-1910 A (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	DT-118, RECEIVER	QII-1	E-1311 (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	K-120, REACTOR	QII-1	E-120 A/B Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	K-91, REACTOR	QII-1	E-91 A/B (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	R-107, RECEIVER	QII-1	E-107 A/B (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	R-115, RECEIVER	QII-1	E-115 A/B (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	R-125, RECEIVER	QII-1	E-125 A/B (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments	R-61, RECEIVER	QII-1	E-1432 A/B (Non affected by Pharma

Emission Unit Identification number	Emission unit Description	Emission Point Number or Fugitive Emissions	Control Device Identification Number
but without use			MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	R-86, RECEIVER	QII-1	E-1621 A/B (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	R-87, RECEIVER	QII-1	E-87 A/B (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	RF-121, RECEIVER	QII-1	E-121 A/B (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	RF-122, RECEIVER	QII-1	E-122 A/B (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	R-108, RECEIVER	QII-1	E-498, E-499 (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	TD-114, DRYING TOMBOLA	QII-3	DC-X-434 (Non affected by Pharma MACT)
EU-Chemical Plant (EU-2) Existent Equipments but without use	S-5002, RECEIVER	QII-1	E-5002 (Non affected by Pharma MACT)

**INFORMATION ABOUT THE EMISSION SOURCES**

**LIST OF EMISSION UNITS OF PHARMAECEUTICAL PRODUCTION (EU-3)**

<b>Emission Unit Identification number</b>	<b>Emission unit Description</b>	<b>Emission Point Number or Fugitive Emissions</b>	<b>Control Device Identification Number</b>
<b>EU-PHARMACEUTICAL PRODUCTION (EU-3)</b>			
	PRODUCTION ROOM # 1	PHI-1	Dust Collector (Insignificant Activity)
	PRODUCTION ROOM # 2	PHI-1	Dust Collector (Insignificant Activity)
	PRODUCTION ROOM # 3	PHI-1	Dust Collector (Insignificant Activity)
	PRODUCTION ROOM # 4	PHI-1	Dust Collector (Insignificant Activity)
	PRODUCTION ROOM # 5	PHI-1	Dust Collector (Insignificant Activity)
	PRODUCTION ROOM # 6	PHI-1	Dust Collector (Insignificant Activity)
	PRODUCTION ROOM # 8	PHI-2	Dust Collector (Insignificant Activity)
	PRODUCTION ROOM # 11	PHI-2	Dust Collector (Insignificant Activity)
	PRODUCTION ROOM # 12	PHI-2	Dust Collector (Insignificant Activity)
	PRODUCTION ROOM # 13	PHI-2	Dust Collector (Insignificant Activity)
	PRODUCTION ROOM # 14	PHI-2	Dust Collector (Insignificant Activity)

Emission Unit Identification number	Emission unit Description	Emission Point Number or Fugitive Emissions	Control Device Identification Number
	PRODUCTION ROOM # 15	PHI-2	Dust Collector (Insignificant Activity)
	PRODUCTION ROOM # 16	PHI-2	Dust Collector (Insignificant Activity)
	PRODUCTION ROOMS	PHI-3 (FUGITIVES)	N/A
	PRODUCTION ROOM # 1012	PHI-6	Dust Collector (DC-920 & DC-920 A) (Insignificant Activity)

**NOTE:**

Formulations of pharmaceutical operations are considered insignificant activities because the dust collectors emits at a rate lower than 2 ton/year. Appendix B (3)(ii)(P) of the RCAP.

**INFORMATION ABOUT THE EMISSION SOURCES**

**L LIST OF EMISSION UNITS OF COMBUSTION EQUIPMENTS (EU-4)**

<b>Emission Unit Identification number</b>	<b>Emission unit Description</b>	<b>Emission Point Number or Fugitive Emissions</b>	<b>Control Device Identification Number</b>
<b>EU-COMBUSTION EQUIPMENT (EU-4)</b>			
	BOILER #1	B-1	NON APPLICABLE
	BOILER #2	B-2	NON APPLICABLE
	BOILER #3	B-3	NON APPLICABLE
	EMERGENCY GENERATOR #1 (WWTP)	INSIGNIFICANT (EG-1)	NON APPLICABLE
	EMERGENCY GENERATOR #2 (Utilities-II)	INSIGNIFICANT (EG-2)	NON APPLICABLE
	EMERGENCY GENERATOR #3 (Amenities)	INSIGNIFICANT (EG-3)	NON APPLICABLE
	EMERGENCY GENERATOR #5 (I.T.)	INSIGNIFICANT (EG-5)	NON APPLICABLE
	EMERGENCY GENERATOR #4 (DCS chemical plant)	QII-14 (INSIGNIFICANT)	NON APPLICABLE
	EMERGENCY GENERATOR #8 (west side of chemical plant)	QII-17 (INSIGNIFICANT)	NON APPLICABLE
	EMERGENCY GENERATOR #9 (west side of chemical plant)	QII-18 (INSIGNIFICANT)	NON APPLICABLE
	FIRE PUMP #1	INSIGNIFICANT (FP-1)	NON APPLICABLE
	FIRE PUMP #2	INSIGNIFICANTE (FP-2)	NON APPLICABLE
	FIRE PUMP #3	INSIGNIFICANT (FP-3)	NON APPLICABLE
	FUEL TANK, S-1902	INSIGNIFICANT (FO-N)	NON APPLICABLE
	FUEL TANK, S-1903	INSIGNIFICANT (FO-S)	NON APPLICABLE
	FUEL TANK, ST-453-01	INSIGNIFICANT (FO-E)	NON APPLICABLE
	FUEL TANK, ST-453-02	INSIGNIFICANT (FO-W)	NON APPLICABLE

<b>Emission Unit Identification number</b>	<b>Emission unit Description</b>	<b>Emission Point Number or Fugitive Emissions</b>	<b>Control Device Identification Number</b>
	TANK, ST-301	INSIGNIFICANT	NON APPLICABLE
	TANK, ST-302	INSIGNIFICANT	NON APPLICABLE
	TANK, BT-470	INSIGNIFICANT	NON APPLICABLE
	TANK, ST-30A	INSIGNIFICANT	NON APPLICABLE
	TANK, ST-30B	INSIGNIFICANT	NON APPLICABLE
	TANK, S-1904	INSIGNIFICANT	NON APPLICABLE
	TANK, S-1905	INSIGNIFICANT	NON APPLICABLE
	FUEL TANK FOR THE FIRE PUMPS	INSIGNIFICANT	NON APPLICABLE
	FUEL TANK FOR THE FIRE PUMPS	INSIGNIFICANT	NON APPLICABLE
	FUEL TANK FOR THE EMERGENCY GENERATOR OF WWTP	INSIGNIFICANT	NON APPLICABLE
	FUEL TANK FOR THE EMERGENCY GENERATOR OF UTILITIES-II	INSIGNIFICANT	NON APPLICABLE
	FUEL TANK FOR THE EMERGENCY GENERATOR OF AMENITIES	INSIGNIFICANT	NON APPLICABLE
	FUEL TANK FOR THE EMERGENCY GENERATOR OF DCS OF CHEMICAL PLANT.	INSIGNIFICANT	NON APPLICABLE
	FUEL TANK FOR THE EMERGENCY GENERATOR OF PHARMACEUTICAL PRODUCTION	INSIGNIFICANT	NON APPLICABLE
	FUEL TANK FOR THE EMERGENCY GENERATOR OF PHARMACEUTICAL PRODUCTION	INSIGNIFICANT	NON APPLICABLE
	FUEL TANK FOR THE EMERGENCY GENERATOR OF I.T.	INSIGNIFICANT	NON APPLICABLE
	TANK, BT-481	INSIGNIFICANT	NON APPLICABLE
	CLORINATION SYSTEM	DE MINIMIS FUGITIVE (CHL-1)	NON APPLICABLE

<b>Emission Unit Identification number</b>	<b>Emission unit Description</b>	<b>Emission Point Number or Fugitive Emissions</b>	<b>Control Device Identification Number</b>
	EMERGENCY GENERATOR # 6 (Pharmaceutical Production)	PHI-4 (INSIGNIFICANT)	NON APPLICABLE
	EMERGENCY GENERATOR # 7 (Pharmaceutical Production)	PHI-5 (INSIGNIFICANT)	NON APPLICABLE
	EMERGENCY GENERATOR # 10 (Q/C)	EG-10 (INSIGNIFICANT)	NON APPLICABLE
	FUEL TANK FOR THE EMERGENCY GENERATOR OF Q/C	INSIGNIFICANTE	NON APPLICABLE
	TANK, IS-480	INSIGNIFICANT	NON APPLICABLE
	TANK, BT-426	INSIGNIFICANT	NON APPLICABLE
	TANK, AS-480	INSIGNIFICANT	NON APPLICABLE

**INFORMATION ABOUT THE MISIÓN SOURCES**

**LIST OF EMISSION UNITS OF SOLVENT RECOVERY (EU-6)**

<b>Emission Unit Identification number</b>	<b>Emission unit Description</b>	<b>Emission Point Number or Fugitive Emissions</b>	<b>Control Device Identification Number</b>
<b>EU-SOLVENT RECOVERY (EU-6)</b>			
	V-1- DESTILLATOR	SR-1, SR-2	NON APPLICABLE
	RC-1-RECEIVER	SR-1, SR-2	NON APPLICABLE
	C1- TANK	SR-1, SR-2	NON APPLICABLE
	T-1- DESTILLATOR	SR-1, SR-2	NON APPLICABLE
	T-6- RECEIVER	SR-1, SR-2	NON APPLICABLE
	T-4- RECEIVER	SR-1, SR-2	NON APPLICABLE
	T-3- RECEIVER	SR-1, SR-2	NON APPLICABLE
	T-5- RECEIVER	SR-1, SR-2	NON APPLICABLE
	R-401- TANK	SR-1, SR-2	NON APPLICABLE
	DC-401 – DESTILLATOR	SR-1, SR-2	NON APPLICABLE
	T-2-IPA- TANK	SR-1, SR-2	NON APPLICABLE
	R-402- RECEIVER	SR-1, SR-2	E-407
	R-403- RECEIVER	SR-1, SR-2	E-403
	R-404- RECEIVER	SR-1, SR-2	E-404
	R-405- RECEIVER	SR-1, SR-2	E-405
	R-406- RECEIVER	SR-1, SR-2	E-406
	PERVAPORATOR	SR-1, SR-2	NON APPLICABLE
	DC-503- DESTILLATOR	SR-1, SR-2	NON APPLICABLE
	R-508- RECEIVER	SR-1, SR-2	NON APPLICABLE
	R-509- RECEIVER	SR-1, SR-2	NON

<b>Emission Unit Identification number</b>	<b>Emission unit Description</b>	<b>Emission Point Number or Fugitive Emissions</b>	<b>Control Device Identification Number</b>
			APPLICABLE
	DC-503-TANK	SR-1, SR-2	NON APPLICABLE
	SP-3 SEPARATOR	SR-12	E-SP-3
	SP-4 SEPARATOR	SR-13	E-SP-4
	SP-5 SEPARATOR	SR-14	E-SP-5
	Leaks Components (Pumps, Filters, Flanges, Valves Cconectors, PRD, Instrumentations, open end valves, open end lines, etc.)	Fugitive	NON APPLICABLE

**INFORMATION ABOUT THE EMISSION SOURCES**

**LIST OF EMISSION UNITS OF TANK FARM (EU-7)**

Emission Unit Identification number	Emission unit Description	Emission Point Number or Fugitive Emissions	Control Device Identification Number
<b>EU-TANK FARM (EU-7) Existen tanks in use</b>			
	TANK ST-9	ST-9 (Insignificant)	E-420
	TANQK ST-10	ST-9 (Insignificant)	E-420 and/or E-421
	TANK ST-13	ST-13	E-424
	TANK ST-14A	ST-14	E-425
	TANK ST-14B	ST-14	E-425
	TANK R-407	R-407 (Insignificant)	NON APPLICABLE
	TANK ST-440	ST-440	E-440
	TANK ST-441	ST-441	E-441
	Leaks Components (Pumps, Filters, Flanges, Valves Coconnectors, PRD, Instrumentations, open end valves, open end lines, etc.)	FUGITIVES	LDAR Programs of RCRA Subpart BB and LDAR of Pharma MACT
<b>EU-Tank Farm (EU-7) Existent tanks not in use</b>			
	TANK ST-442	ST-442	E-442
	TANK ST-445	ST-445	E-445
	TANK ST-446	ST-446	E-446
	TANK ST-1021	ST-1021	NON APPLICABLE
	TANK ST-1031	ST-1031 (Insignificant)	NON APPLICABLE
	ST-12 TANK		E-ST-12

Emission Unit Identification number	Emission unit Description	Emission Point Number or Fugitive Emissions	Control Device Identification Number
		ST-12	
	ST-401 TANK	ST-401 (Insignificant)	E-ST-401
	ST-402 TANK	ST-402 (Insignificant)	E-ST-402

**NOTE:**

Tanks ST-9, ST-10, R-407, ST-1031, ST-11, ST-401, and ST-402 are considered insignificant activities because the capacity is less than 10,000 gallons. Appendix B (3)(ii)(N) of the RCAP.

**INFORMATION ABOUT THE EMISSION SOURCES**

**LIST OF EMISSION UNITS OF WASTEWATER PRETREATMENT PLANT (EU-8)**

<b>Emission Unit Identification number</b>	<b>Emission unit Description</b>	<b>Emission Point Number or Fugitive Emissions</b>	<b>Control Device Identification Number</b>
<b>EU-Wastewater Pretreatment Plant (EU-8)</b>			
	NEUTRALIZATION TANK	WWTP-NT-1	NON APPLICABLE
	NEUTRALIZATION TANK	WWTP-NT-2	NON APPLICABLE
	QUARANTINE TANK	WWTP-QT-1	NON APPLICABLE
	QUARANTINE TANK	WWTP-QT-2	NON APPLICABLE
	EQUALIZATION TANK	WWTP-ET	NON APPLICABLE
	SULFURIC ACID TANK	INSIGNIFICANT WWTP-SAST-1	NON APPLICABLE
	SULFURIC ACID TANK	INSIGNIFICANT WWTP-SAST-2	NON APPLICABLE
	CAUSTIC TANK	INSIGNIFICANT WWTP-CST-1	NON APPLICABLE
	CAUSTIC TANK	INSIGNIFICANT WWTP-CST-2	NON APPLICABLE
	REACTOR #1	WWTP-SBR-1	NO APLICA
	REACTOR #2	WWTP-SBR-2	NON APPLICABLE
	AEROBIC DIGESTOR TANK	WWTP-AD	NON APPLICABLE
	PRESS FILTER	INSIGNIFICANT WWTP-FP	NON APPLICABLE
	EFLUENT SAMPLING TANK	WWTP-EST	NON APPLICABLE
	SANITARY WATER TANK	INSIGNIFICANT WWTP-SWST	NON APPLICABLE
	EMERGENCY TANK	WWTP-SET	NON APPLICABLE
	NUTRIENTS ADDITION TANK	INSIGNIFICANT WWTP-NAT	NON APPLICABLE

**INFORMATION ABOUT THE EMISSION SOURCES**

**LIST OF EMISSION UNITS OF OZONE DEPLETING SUBSTANCES (EU-9)**

<b>Emission Unit Identification number</b>	<b>Emission unit Description</b>	<b>Emission Point Number or Fugitive Emissions</b>	<b>Control Device Identification Number</b>
<b>EU- Ozone Depleting Substances (EU-9)</b>			
	Activation and verification point (“testing point”) of CFC as propulsor agent of the medicine in the pharmaceutical production area.	PHI-7	Activated carbon filter
	TANK CFC-12 A	EXENT	NON APPLICABLE
	TANK CFC-12 B	EXENT	NON APPLICABLE
	TANK CFC-114 A	EXENT	NON APPLICABLE
	TANK CFC-114 B	EXENT	NON APPLICABLE
	TANK CFC-114 C	EXENT	NON APPLICABLE
	TANK CFC-114 D	EXENT	NON APPLICABLE
	TANK CFC-114 E	EXENT	NON APPLICABLE
	MIXING TANK CFC- 12 / 114	EXENT	NON APPLICABLE

## Attachment 2: Status of Tank Farm Tanks (EU-7)

TANK	STATUS
ST-9	Existing and In Service
ST-10	Existing and In Service
ST-13	Existing and In Service
ST-14A	Existing and In Service
ST-14B	Existing and In Service
R-407	Existing and In Service
ST-440	Existing and In Service
ST-441	Existing and In Service
S-2001	Existing and In Service Process Tank
S-2002	Existing and In Service Process Tank
S-416	Existing and In Service Process Tank
R-417-01	Existing and In Service Process Tank
R-417-02	Existing and In Service Process Tank
R-111	Existing and In Service Process Tank
S-1632	Existing and In Service Process Tank
R-316	Existing and In Service Process Tank
S-5178	Existing and In Service Process Tank
R-67 (S-6003)	Existing and In Service Process Tank
S-2004	Existing and In Service Process Tank
ST-442	Unused Existing Tank
ST-445	Unused Existing Tank
ST-446	Unused Existing Tank
ST-1021	Unused Existing Tank
ST-1031	Unused Existing Tank
ST-11	Unused Existing Tank
ST-12	Unused Existing Tank
ST-401	Unused Existing Tank
ST-402	Unused Existing Tank

### **Attachment 3-Calculation Methodology**

Pfizer Pharmaceuticals LLC (Cruce Dávila) shall calculate monthly the annual emissions of the facility to demonstrate compliance with the emission limits included in Section IV of this permit, based in a rolling period of twelve (12) month period. Pfizer Pharmaceuticals LLC (Cruce Dávila) shall utilize the calculation methodology included in this attachment to calculate the annual emissions that must be included in the annual compliance certification required in condition 7 of Section III of this permit.

#### 1. General Requirements

As of the approval date of this permit, Pfizer Pharmaceuticals LLC (Cruce Dávila) shall calculate the monthly emissions of the facility and shall add them to the previous monthly emissions since the first month until reaching twelve (12) months. The calculations must be completed before the ending of the month. Once completed the calculations for the twelve (12) months, Pfizer shall calculate the month 13 and shall add them to the emissions of the previous eleven (11) months, and so on. The annual emissions of the facility based in the rolling period of twelve (12) months shall not exceed the emission limits included in the Section IV of this permit.

#### 2. Process Vents

Pfizer Pharmaceuticals LLC (Cruce Dávila) shall calculate the emissions using the computer program Emission Master, which is structured using the following documents of the Federal Environment Protection Agency (EPA) called *Control of Volatile Organic Compound Emissions from Batch Proceses, Compilation of Air Pollution Emissions Factors and Control of Volatile Organic Emissions from Manufacturing Synthesized Pharmaceutical Products*.

Also, Pfizer shall use the removal efficiency of the control system determined through stack tests, if required, approved for the Environmental Quality Board (EQB) or guarantees provided by the manufacturer. Pfizer shall obtain all the necessary variables to make these calculations, the process descriptions, documents and procedures of batch manufacturing. The variables shall include but not be limited to, the quantity of loaded raw material, process temperature and the purge time. Pfizer Pharmaceuticals LLC (Cruce Dávila) shall develop the emissions factor of VOC or HAP for batch and use it to calculate the monthly emissions using as variable the batch production during that month in particular.

Pfizer Pharmaceuticals LLC (Cruce Dávila) shall use the following control efficiency to determine the control emissions:

- i. Minimum of 93% of removal efficiency for hazardous atmospheric pollutants (HAP) in the gas scrubber.
- ii. Average of 85% of removal efficiency for volatile organic compound in the gas

scrubber.

### 3. Storage Tanks

Pfizer Pharmaceuticals LLC (Cruce Dávila) shall calculate the emissions using the computer program Emission Master, which is structured using the following documents of the Federal Environment Protection Agency called *Control of Volatile Organic Compound Emissions from Batch Proceses*, *Compilation of Air Pollution Emission Factors* and *Control of Volatile Organic Emissions from Manufacturing Synthesized Pharmaceutical Products*.

Pfizer Cruce Dávila shall use the monthly data and the stored liquid characteristics for each tank to realize the calculations. All outstanding information of the tank as the diameter, tank type, operation volume, shell colors, if the tank operates at vaccum or in pressure, etc., those that apply, shall be used as data for emission calculations. Pfizer shall maintain in a logbook all the information about the liquid used, chemical composition, tank geometry and the emissions with or without control. If no control equipment is used, the emissions without control shall be considered the actual emissions.

To obtain the emissions by tank by month, Pfizer shall add emissions with or without control, of all the storage tanks, adding the emissions of VOC and HAP by month of each tank.

The computer program Emission Master, shall use the metereological data of Puerto Rico, if it is available and is is possible to use on the program for the emission calculations of the tanks. If not, Pfizer shall use the metereological data more representative of Puerto Rico that it is the Corpus Christi, Texas.

### 4. Equipment leak

Pfizer Pharmaceuticals LLC (Cruce Dávila) shall calculate the emissions from equipment leaks of the emission unit of Chemical Plant (EU-2) and hazardous waste tanks associated to the emission unit of Chemical Plant (EU-2) using emission factors generated specifically for those activities. The emission factors were generated using the rank method of monitoring (also known as leak/no-leak) of EPA.

The following tables present the emission factors for batchs applicable to Pfizer Pharmaceuticals LLC (Cruce Dávila):

Table 1: Represents the emission factors for the train #1 with the hazardous waste tanks associated to train #1.

<b>POLLUTANTS</b>	<b>CLASIFICACION</b>	<b>EMISSION FACTORS (KG/BATCH)</b>
IPA	VOC	7.6553
ETFA	VOC	0.2539
Sodium Methoxide	VOC	0.3562
4-MAP	VOC	0.1823
MeOh	HAP	0.3206

Table 2: Represents the emission factors for the train #2 with the hazardous waste tanks associated to train #2.

<b>POLLUTANTS</b>	<b>CLASIFICACION</b>	<b>EMISSION FACTORS (KG/BATCH)</b>
IPA	VOC	6.481
ETFA	VOC	0.2859
Sodium Methoxide	VOC	0.4012
4-MAP	VOC	0.2053
MeOh	HAP	0.3343

The emissions of equipment leaks for the associated components of Train #1, Train #2 and hazardous waste associated to these two trains shall be obtained multiplying the emission factors for the batch manufactured during the month.

Pfizer Pharmaceuticals LLC (Cruce Dávila) shall calculate the resulting emissions of the equipment leaks of the emission unit of tanks Farm (EU-7) using Average SOCFI emission factors.

Table 3: Represents the Average SOCFI emission factors for the storage tanks of the raw material in the emission unit of the tank farm (EU-7).

<b>EQUIPMENT TYPE</b>	<b>SERVICE</b>	<b>EMISSION FACTORS (KG/HR)</b>
Valves	Gas	0.00597
Valves	Light Liquid	0.00403
Seal of Pumps	Light Liquid	0.0199
<b>EQUIPMENT TYPE</b>	<b>SERVICE</b>	<b>EMISSION</b>

		<b>FACTORS (KG/HR)</b>
Seal of Compressor	Gas	0.228
Valves of Security	Gas	0.104
Connectors (flanges, instrumentation, monitoring points)	All	0.00183
Open Lines	All	0.0017
Connections	All	0.0150

The emissions of equipment leaks for the associated components of raw material tanks shall be obtained multiplying the emission factor and for the exposure time of the equipment.

### 5. Combustion Sources

Pfizer Pharmaceutical LLC (Cruce Dávila) shall use the emission factors of AP-42 to calculate the resulting emissions of fuel use, unless a stack test is realized and the approved emission factors obtained are used.

The following tables present the applicable emission factors of AP-42 of Pfizer Pharmaceuticals LLC (Cruce Dávila):

Table 4: Represents the AP-42 factors, Table 1.3-1, for the boilers less than 100 MMBtu/hr for the fuel #5. Table 1.3-3 for the TOC Factor.

<b>POLLUTANTS</b>	<b>FACTORS (LB/1,000 GALLONS)</b>
SO <sub>x</sub>	157*S
NO <sub>x</sub>	55
CO	5
PM	9.19(S) + 3.22
TOC	1.28

S indicates that the 1% for sulfur weight in the fuel have to be multiplied for the given value. For example, if the fuel has 1% of sulfur, then S=1.

Table 5: Represents the AP-42 factors, Table 1.3-1, for the boilers less than 100 MMBtu/hr for the distillate fuel (diesel or WP-4). Table 1.3-3 for the TOC Factor.

<b>POLLUTANTS</b>	<b>FACTORS (LB/1,000 GALLONS)</b>
SO <sub>x</sub>	142*S
NO <sub>x</sub>	20
CO	5
PM	2
TOC	0.252

S indicates that the 1% for sulfur weight in the fuel have to be multiplied for the given value. For the example, if the fuel has 1% of sulfur, then S=1.

Table 5: Represents the AP-42 factors, Table 1.3-1, for the boilers less than 100 MMBtu/hr for the distillate fuel (diesel or WP-4). Table 1.3-3 for the TOC Factor.

<b>POLLUTANTS</b>	<b>FACTORS (LB/1,000 GALLONS)</b>
SO <sub>x</sub>	142*S
NO <sub>x</sub>	20
CO	5
PM	2
TOC	0.252

Table 6: Represents the AP-42 factors, Table 3.3-1, for the emergency generators and fire pumps with combustion motors less than 600 hp for distillate fuel (diesel).

<b>POLLUTANTS</b>	<b>FACTORS (Lb/MMBtu)</b>
SO <sub>x</sub>	0.29
NO <sub>x</sub>	4.41
CO	0.95
PM	0.31
TOC	0.36

Table 7: Represents the AP-42 factors, Table 3.4-1, for the emergency generators with combustion motors greater than 600 hp for distillate fuel (diesel).

<b>POLLUTANTS</b>	<b>FACTORS (Lb/MMBtu)</b>
SO <sub>x</sub>	0.505
NO <sub>x</sub>	3.2
CO	0.85
PM	0.0573
TOC	0.0819

Pfizer Pharmaceuticals LLC (Cruce Dávila) shall calculate the resulting emissions of the combustion equipment in a period of 365 rotative days.

#### 6. Ozone Depleting Substances

Pfizer Pharmaceuticals LLC (Cruce Dávila) shall calculate the resulting emissions of the pharmaceutical production that uses CFC as propellants agents in the Ozone Depleting Substances (EU-9) using generated emissions factors specifically for those activities.

The following table presents the applicable emission factors for produced units applicable to Pfizer Pharmaceuticals LLC (Cruce Dávila):

Table 8: Represents the emission factors for the pharmaceutical production that use CFC as propellants agents.

<b>POLLUTANT</b>	<b>EMISSION FACTOR (kg/ producible unit)</b>
Mixture of CFC-12 and CFC-114	0.0001

#### 7. Wastewater Pretreatment Plant

Pfizer Pharmaceutical LLC (Cruce Dávila) shall calculate the resulting emissions of the Wastewater Pretreatment Plant using a laboratory analysis combination and calculations using engineering criteria. The permittee shall determine and register the atmospheric pollutants emissions in a monthly base.

Once the actual emissions value is obtained for the period of each month, Pfizer shall include it in the comparison with the permissible emission limit.

## Appendix A - Definitions and Abbreviations

### I. Definitions:

1. **Act** – US Clean Air Act, as amended, 42 *U.S.* 7401, *et seq.*
2. **Responsible Official** – See definition for Responsible Official as established in the Environmental Quality Board Regulations for the Control of Atmospheric Pollution (1995).
3. **Regulations**- Environmental Quality Board Regulations for the Control of Atmospheric Pollution.
4. **Permit Holder** – Person and entity to which the Puerto Rico Environmental Quality Board has issued an Emission Source Operation Permit covered under Title V.
5. **Title V** - Title V of the US Clean Air Act (42 *U.S.C.* 7661).

### II. Abbreviations

1. **BTu** British Thermal Unit
2. **CFR** Code of Federal Regulations
3. **CO** Carbon Monoxide
4. **HAP** Hazardous Air Pollutant
5. **EPA** US Environmental Protection Agency
6. **EQB** Puerto Rico Environmental Quality Board
7. **MACT<sub>1</sub>** Maximum Available Control Technology
8. **MACT<sub>2</sub>** Maximum Achievable Control Technology
9. **NAQS** National Air Quality Standards
10. **NESHAP** National Emission Standards for Hazardous Air Pollutants
11. **NO<sub>x</sub>** Nitrogen Oxide
12. **NSPS** New Source Performance Standards
13. **PM** Particulate Matter
14. **PM<sub>10</sub>** Particulate matter with a mass median aerodynamic diameter equal or less than 10 micrometers
15. **PSNSS** Performance Standards for New Stationary Sources

16. **RCAP** Environmental Quality Board Regulations for the Control of Atmospheric Pollution
17. **SIC** Standard Industrial Classification
18. **SO<sub>2</sub>** Sulfur Dioxide
19. **TOC** Total Organic Compounds
20. **VOC** Volatile Organic Compounds