

COMMONWEALTH OF PUERTO RICO / OFFICE OF THE GOVERNOR

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



Permit Number:	PFE-TV-2834-44-0197-0002
Operating Permit application received:	January 30, 1997
Issue and/or Effective Date:	August 24, 2004 ¹
Expiration Date:	August 24, 2009

In accordance with the provisions of Part VI of the Regulation for the Control of Atmospheric Pollution (RCAP) for Puerto Rico and the provisions of the 40 CFR part 70,

**SCHERING PLOUGH PRODUCTS, LLC
LAS PIEDRAS, PUERTO RICO**

hereinafter referred to as The Permittee, or **Schering-Plough Las Piedras** is authorized to operate a stationary source of air contaminants consisting of emissions units described in this permit. Until such time as this permit expires or is modified or revoked, the permittee is allowed to discharge air pollutants from those processes and activities directly related to or associated with air contaminant source(s) in accordance with the requirements, limitations, and conditions of this permit. All conditions in this permit are federally enforceable and state enforceable unless otherwise specified. Requirements which are only state enforceable are identified in the permit. A copy of this permit shall be kept on-site at the above named facility at all times.

¹ The conditions marked with an asterisk were revised or added by a reconsideration process according to Resolution PA-SPP-7 and are effective by February 15, 2006.

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Section I - General Information

A. Facility Information

Company Name: **Schering Plough Products, LLC**

Mailing Address: **P.O. Box 1779**

City: **Las Piedras** State: **P.R.** Zip Code: **00771**

Plant Name: **Schering Plough Products, L.L.C.**

Plant Location: **Road PR-183, PRIDCO Industrial Park
Las Piedras, P.R.**

Plant Mailing Address: **P.O. Box 1779, Las Piedras, P.R. 00771**

Responsible Official: **Gilberto López** Phone: **787-733-2323**
Environmental Manager

Technical Contact: **Luis Lozada** Phone: **787-733-2323**
Environmental Engineer Fax: **787-733-3229**

Primary SIC Code: **2834**

B. Process Description

Schering Plough Products, LLC is located at PRIDCO Industrial Park, Road PR-183 in the Municipality of Las Piedras. Schering-Plough Las Piedras facility's primary function is the manufacture of pharmaceutical products and intermediates and the performance of trial lots for the manufacturing process validation. The facility infrastructure consists of various operations including, but not limited to, the following: production area, Quality Control Laboratories, temporary storage areas and warehouse, utilities, tank farm, wastewater treatment plant and administrative buildings.

Raw material (active drug, excipients, solvents) is dispensed from a central weighing area in exact proportions for each batch of each product. The operating environment (chemical usage, formulation procedures, operating procedures, and temperatures varies from process to process, but is constant for each batch within a given process. The raw materials are mixed, blended, granulated, coated and dried in the various manufacturing equipment.

The emission units include the manufacturing processes and solvent recovery operations consisting in an activated carbon unit and distillation of volatile organic compounds (VOCs), hazardous air pollutants (HAPs) and other pollutant emissions from various

process equipment. Fugitive emissions are also discharged and consist, of those emissions from pumps, valves, flanges, compressors, and connectors. In addition to VOCs and HAPs, certain manufacturing processes also emit particulates and are controlled by dust collectors. Other processes only emit particulates and are controlled by dust collectors.

* Combustion sources include a catalytic oxidizer, five boilers, and four emergency electricity generators that burn distillate fuels (fuel oil No. 2 or diesel). They also include various tanks used to store solvents (methanol, isopropyl alcohol, acetone and methylene chloride) that are used in manufacturing processes. These tanks contain conservation vents in order to minimize emissions, which are vented to the solvent recovery system or the catalytic oxidizer. Two tanks used for storage of No. 2 fuel oil are also present at the facility to supply the fuel needed at the facility.

Schering Plough Products, LLC is considered a major source of emissions since it has the potential to emit more than 100 tons per year of each one of the following criteria pollutants: sulfur dioxide (SO₂) and oxides of nitrogen (NO_x) and more than 10 tons per year of methanol and methylene chloride.

Section II - Emission Units and Control Device Descriptions

The emissions units regulated by this permit issuance are the following:

Emission Unit	Description²	Emission Point or Fugitive	Control Equipment³
EU- BOILERS- NON-NSPS	This emission unit includes two identical boilers identified as EPBO1 and EPBO2 with a power of 300 hp each that are subject to the same applicable requirements. Both boilers burn distillate fuel oil No. 2 with a maximum sulfur content of 0.5% by weight.	EPBO1, EPBO2	LSFO ⁴

² See Appendix II for the combustion equipment description.

³ See Appendix III for the control equipment description.

⁴ *Low Sulfur Fuel Oil* – SO₂ emissions are controlled using distillate fuel oil with a maximum sulfur content of 0.5% by weight.

*

Emission Unit	Description²	Emission Point or Fugitive	Control Equipment³
EU-BOILERS-NSPS	This emission unit includes three identical boilers identified as EPBO3, EPBO4 and EPBO5 with a power of 300 hp each that are subject to the same applicable requirements, including 40 CFR part 60, subpart Dc. The boilers burn distillate fuel oil No. 2 with a maximum sulfur content of 0.5% by weight.	EPBO3, EPBO4, EPBO5	LSFO ³
EU-VOC-PM-NON-MACT	This emission unit includes the manufacturing processes utilizing Glatts 1, 3, and 9, Granulation 1 and 2 and coating operations which emit volatile organic compounds and particulate matter and are subject to the same applicable requirements. These emissions are controlled by a catalytic oxidizer and dust collectors. This unit is not affected by the Pharmaceutical MACT.	EPGL1, EPGL3, EPGL9, EPGRAN1, EPGRAN2, EPCOAT1	CD-C01 CDDC-1, CDDC-3, CDDC-4, CDDC-9, CDDC-20
EU-VOC-PM-MACT	This emission unit includes the manufacturing processes and solvent recovery operations utilizing Glatts 2, 4, 5, 6, 7, and 8 which emit volatile organic compounds, hazardous air pollutants, and particulate matter and are subject to the same applicable requirements, including the Pharmaceutical MACT. These emissions are controlled by a solvent recovery system and dust collectors.	EPGL2, EPGL4, EPGL5, EPGL6, EPGL7, EPGL8	CDSRS, CDDC-2, CDDC-7, CDDC-10, CDDC-13, CDDC-14, CDDC-15, CDDC-16

Emission Unit	Description²	Emission Point or Fugitive	Control Equipment³
* EUCO1	This unit includes combustion emissions from the catalytic oxidizer used to control emissions of non-chlorinated VOC and non-regulated pollutants emitted from various manufacturing process areas. The catalytic oxidizer has a heat input capacity of 21 MMBtu/hr and burns No. 2 fuel with a maximum of 0.5% sulfur content by weight, and propane gas for startup.	EPCO1	LSFO ³
* EUGEN1	This emission unit includes four emergency electric generators identified as EPGEN1, EPGEN2, EPGEN3 and EPGEN4 rated three at 1500 hp and one at 2682 hp. They burn No. 2 fuel oil with a maximum of 0.5% of sulfur content by weight.	EPGEN1, EPGEN2, EPGEN3, EPGEN4	LSFO ³
EU-FUG-MACT	This emission unit includes those pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems which are subject to the same applicable requirements under the Leak Detection And Repair Program (LDAR) of the Pharmaceutical MACT.	EPGL2, EPGL4, EPGL5, EPGL6, EPGL7, EPGL8 Fugitives	Pharmaceutical MACT LDAR Program

Emission Unit	Description ²	Emission Point or Fugitive	Control Equipment ³
EUPM1	This emission unit consists of pharmaceutical operations identified as EPMFG1, EPMFG2, EPMFG3, EPMFG4, EPMFG5, EPMFG6, EPMFG7 and EPMFG8 which emit particulates and are subject to the same applicable requirements.	EPMFG1, EPMFG2, EPMFG3, EPMFG4, EPMFG5, EPMFG6, EPMFG7, EPMFG8	CDDC-5, CDDC-6, CDDC-8, CDDC-11, CDDC-12, CDDC-17
Methanol Tank	Storage capacity of 10,000 gallons of methanol.	Unidentified	Conservation Vent
MeCl ₂ Tank	Storage capacity of 10,000 gallons of methylene chloride.	Unidentified	Conservation Vent
IPA Tank	Storage capacity of 10,000 gallons of isopropyl alcohol (isopropanol).	Unidentified	Conservation Vent
Acetone Tank	Storage capacity of 10,000 gallons of acetone.	Unidentified	Conservation Vent

Section III General Permit Conditions

1. **Sanctions and Penalties:** Schering-Plough Las Piedras is obligated to comply with all terms, conditions, requirements, limitations and restrictions set forth in this permit. Any violation of the terms of this permit will be subject to administrative, civil or criminal penalties as established in the Puerto Rico Environmental Public Policy Act, Article 16 (Act Number 416, September 22, 2004).
2. **Right of Entry:** As specified under Rules 103 and 603(c)(2) of the RCAP, Schering-Plough Las Piedras shall allow the Board or an authorized representative, upon presentation of credentials and other documents as may be required by law, to perform the following activities:

- a) Enter upon Schering-Plough Las Piedras premises where an emission source is located or where emissions related activities are conducted, or where records must be kept under the conditions of this permit, under the RCAP, or under the Clean Air Act;
 - b) Have access to and copy, at reasonable times, any records that must be kept under the conditions of the permit, under the RCAP, or under the Clean Air Act;
 - c) Inspect and examine any facility, equipment (including monitoring and air pollution control equipment), practices or operations (including QA/QC methods) regulated or required under this permit; as well as sampling emissions of air quality and fuels; and
 - d) As authorized by the Clean Air Act and the RCAP, to sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with the permit or other applicable requirements.
3. **Sworn Statement:** All reports required pursuant Rule 103(D) of the RCAP (i.e., semiannual monitoring reports and annual compliance certification) shall be submitted together with a sworn statement or affidavit by the Responsible Official or a duly authorized representative. Such sworn statement shall attest to the truth, correctness and completeness of such records and reports.
 4. **Data Availability:** As specified under Rule 104 of the RCAP, all emission data obtained by or submitted to the Board, including data reported pursuant to Rule 103 of the RCAP, as well as that obtained in any other way, shall be available for public inspection and may also be made available to the public in any additional manner that the Board may deem appropriate.
 5. **Emergency Plan:** As specified under Rule 107 of the RCAP, Schering-Plough Las Piedras shall have available an Emergency Plan which must be consistent with adequate safety practices, and provides for the reduction or retention of the emissions from the plant during periods classified by the Board as air pollution alerts, warnings or emergencies. These plans shall identify the emission sources, include the reduction to be accomplished for each source, and the means by which such reduction will be accomplished. These plans will be available for any representative of the Board at any time.
 6. **Control Equipment:** Schering-Plough Las Piedras 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 the Board, within the specified operating limitations of the manufacturer.
 - (B) The collected material from air pollution control equipment shall be disposed in accordance with applicable rules and regulations. The removal, manipulation, transportation, storage, treatment or disposal will be done in such or manner that shall not

to produce environmental degradation, and in accordance with applicable rules and regulations.

- (C) The Board may require, when deemed appropriate to safeguard the health and welfare of human beings, the installation and maintenance of additional, complete and separate air pollution control equipment of a capacity equal to the capacity of the primary control equipment. Furthermore, the Board may require that such additional air pollution control equipment be operated continuously and conjunctionally with the primary air pollution control equipment.
- (D) All air pollution control equipment shall be operated at all times while the source being controlled is in operation.
- (E) In the case of a shutdown of air pollution control equipment for the necessary scheduled maintenance, the intent to shutdown such equipment shall be reported to the Board at least three days prior to the planned shutdown. Such prior notice shall include, but is not limited to the following:
 - (1) Identification of the specific source to be taken out of service with 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 emissions of air pollutants likely to be permitted during the shutdown period.
 - (4) Measures such as the use of off-shift labor and equipment that will be taken to minimize the length of the shutdown period.
 - (5) The reasons why it will be impossible or impractical to shutdown the operating source during the maintenance period.
- (F) Schering-Plough Las Piedras shall to the extent possible, maintain and operate at all times, including periods of start-up, shutdown and malfunction, any affected source and the associated air pollution control equipment, in a manner consistent with the original manufacturers design specifications and in compliance with applicable rules and regulations and permit conditions.
- (G) Schering-Plough Las Piedras shall maintain copies of all the monthly calibrations and inspections of the control equipments such as baghouses and scrubbers. Schering-Plough Las Piedras shall record in a logbook all the periods when the control equipment is in shutdown and the process continues its operation. All the records shall be available to the EQB personnel.

- * 7. **Compliance Certification:** According to Rule 602(c)(2)(ix)(C) of the RCAP, Schering-Plough Las Piedras shall submit every year a Compliance Certification. This certification shall be submitted to both the Board and the EPA⁵ no later than 90 days after the anniversary of the granted permit. In I case there are conditions subject to a reconsideration process to the final permit adopted by the Board, the compliance certification for the conditions included in the reconsideration will only be applicable for the time passed since the effective date determined by the Administrative Judge once the applicable procedure has been resolved and after the 45-day review period by the EPA. It shall include, but will not be limited to, the information required by Rule 603(c) of the RCAP.
- 8. **Regulation Compliance:** As specified under Rule 115 of the RCAP, any violation to the RCAP, or to any other applicable rule or regulation, shall be grounds for the Board to suspend, modify, or revoke any relevant permit, approval, variance or other authorization issued by the Board.
- 9. **Location Approval:** As specified under Rule 201 of the RCAP, nothing in this permit shall be interpreted as authorizing the location or construction of a major stationary source, or the modification of a major stationary source, or a major modification of a significant source, without obtaining first a location approval from the Board and without first demonstrating compliance with the National Ambient Air Quality Standards (NAAQS). This permit does not allow the construction of new minor sources without the required permit under Rule 203 of the RCAP, unless it is exempted by Rule 206 of the RCAP.
- * 10. **Open Burning:** As specified under Rule 402 of the RCAP, Permittee shall not cause or permit the open burning of refuse in their premises except as established under Rule 402 (E) of the RCAP to conduct training or research of fire fighting techniques. Schering-Plough Las Piedras shall,
 - a) Keep records of fire fighting activities related to research or training. These records shall be kept and shall be made available upon request.
- 11. **Particulate Fugitive Emissions:** As established in Rule 404 of the RCAP, Schering-Plough Las Piedras shall not cause or permit:
 - a) any materials to be handled, transported, or stored in a building, 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) the discharge of visible emissions of fugitive dust beyond the boundary line of the property on which the emissions originate.

⁵ 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: CEPD Director, US EPA-Region II, Centro Europa Building 1492, Ponce de Leon Ave. Stop 22, Santurce, PR 00909

12. **Objectionable Odors:** As specified under Rule 420 of the RCAP, Schering-Plough Las Piedras shall not cause or permit emissions to the atmosphere of any matter which produces an *objectionable* odor that can be perceived in an area other than that designated for industrial purposes. Schering-Plough Las Piedras shall demonstrate compliance with Rule 420 (A)(1) as follows: if malodors are detectable beyond Schering-Plough Las Piedras property perimeter, and complaints are received, Schering-Plough Las Piedras shall investigate and take measures to minimize and/or eliminate the malodors, if necessary. [This condition is enforceable only by the State].
13. **Permit Renewal Applications:** As established under Rule 602 (a)(1)(iv) of the RCAP, Schering-Plough Las Piedras's applications for permit renewal shall be submitted at least 12 months prior to the date of permit expiration. A responsible official must certify all required applications consistent with paragraph (c)(3) of Rule 602.
14. **Permit Duration:** As specified under Rule 603 of the RCAP, the following terms will apply during the duration of this permit:
- a) Expiration: This authorization shall have a fixed term of 5 years. 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 Schering-Plough Las Piedras submits a complete renewal application at least 12 months before the expiration date. [Rules 603 (a)(2), 605 (c)(2), and 605(c)(4) of the RCAP]
 - b) Permit Shield: As specified under Rule 605 (c)(4)(i) of the RCAP, the permit shield may be extended until the time the permit is renewed if a timely and complete renewal application is submitted.
 - c) In case that this permit is subject to any challenge by third parties, the permit shall remain in effect until the time it is revoked by a court of law with jurisdiction in the matter.
15. **Recordkeeping Requirement:** As established under Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain records of all required monitoring data and support information for a period of 5 years from the date of the monitoring sample, measurement, report, or application.
16. **Reporting Requirement:** As established under Rule 603(a)(5)(i) of the RCAP, Schering-Plough Las Piedras shall submit reports of all required monitoring every 6 months, or more frequently if required by the Board or any other underlying applicable requirement. All instances of deviations from permit requirements must be clearly identified in such reports. All required reports must be certified by a responsible official as established under Rule 602(c)(3) of the RCAP.
17. **Deviations Reporting due to Emergencies:** As specified under Rule 603(a)(5)(ii)(a) of the RCAP, any deviation resulting from an upset (such as sudden malfunction or break-down) or

emergency conditions, as defined in Rule 603(e) of the RCAP, must be reported within the next 2 working days. Such notification may be used to assert an affirmative defense upon an enforcement action against Schering-Plough Las Piedras. If Schering-Plough Las Piedras raises the emergency defense upon an enforcement action, Schering-Plough Las Piedras shall demonstrate that such deviation happens due to an emergency and that the Board was adequately notified. If such emergency deviation last for more than 24 hours, the affected units, except the sources affected by 40 CFR part 63, subpart GGG (Pharmaceutical MACT) and included in the Startup, Shutdown and Malfunction Plan (SSMP) that shall comply with 40 CFR §63.6(e)(3) specifically, may be operated until the end of the cycle or 48 hours, what occurs first. The Board may only extend the operation of an emission source in excess of 48 hours, if the source demonstrates to the Board's satisfaction that the National Air Quality Standards have not been exceeded and that there is no risk to the public health.

18. **Deviation Reporting (Hazardous Air Pollutants):** The source (except the sources affected by 40 CFR part 63, subpart GGG (Pharmaceutical MACT) and included in the SSMP that shall comply with 40 CFR §63.6(e)(3) specifically) shall shut down its operations immediately or shall act as specified in its Emergency Response Plan (established in Rule 107 (C) of the RCAP), when such Plan has demonstrated that there is no significant impact at the fence line. [This condition is enforceable only by the State]. Pursuant to Rule 603 (a)(5)(ii)(b), a notification will be required if a deviation occurs that results in the release of emissions of hazardous air pollutants for more than an hour in excess of the applicable limit. Schering-Plough Las Piedras shall notify the Board within 24 hours of the deviation. For the discharge of any regulated air pollutant that continues for more than 2 hours in excess of the applicable limit, Schering-Plough Las Piedras shall notify the Board within 24 hours of the deviation. Schering-Plough Las Piedras shall also submit to the Board, within 7 days of the deviation, a detailed written report, which includes probable causes, time and duration of the deviation, remedial action taken, and steps, which are being taken to prevent a reoccurrence.
19. **Severability Clause:** As established under Rule 603(a)(6) of the RCAP, the clauses in this permit are severable. In the event of a successful challenge to any portion of the permit in an administrative or judicial forum, or in the event any of its clauses is held to be invalid, all other portions of the permit shall remain valid and effective, including those related to emission limits, terms and conditions, be they specific or general, as well as monitoring, record keeping and reporting requirements.
20. **Permit Noncompliance:** As established under Rule 603(a)(7)(i) of the RCAP, Schering-Plough Las Piedras must comply with all conditions of this permit. Permit noncompliance constitutes a violation of the RCAP and will be grounds for taking the appropriate enforcement action, impose sanctions, revoke, terminate, modify, and/or reissue the permit, or to deny a permit renewal application.
21. **Defense not Allowed:** As specified under Rule 603(a)(7)(ii) of the RCAP, it shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

22. **Permit Modification and Revocation:** As specified under Rule 603(a)(7)(iii) of the RCAP, the permit may be modified, revoked, reopened, reissued, or terminated for cause. The filing of a request by Schering-Plough Las Piedras for a permit modification, revocation, reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit condition.
23. **Property Rights:** As specified under Rule 603(a)(7)(iv) of the RCAP, this permit does not convey any property rights of any sort, nor does it grant any exclusive privilege.
24. **Obligation to Furnish Information:** As specified under Rule 603(a)(7)(v) of the RCAP, Schering-Plough Las Piedras shall furnish to the Board, within a reasonable time, any information that the Board may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit or to determine compliance with the permit. Upon request, Schering-Plough Las Piedras shall also furnish to the Board copies of records required to be kept by the permit.
25. **Changes in Operating Scenarios:** As specified under Rule 603(a)(10) of the RCAP, Schering-Plough Las Piedras shall record in a logbook, contemporaneously with making a change from one operating scenario to another, the scenario under which it is operating. This logbook must be kept at Schering-Plough Las Piedras's facility at all times.
26. **Prohibition on Default Issuance:** As specified under Rule 605(d) of the RCAP, it shall never be considered that a permit has been issued by default as a result of the Board's failure to take final action on a permit application within 18 months as of the application completeness date. The Board's failure to issue a final permit within 18 months should be treated as a final action solely for the purpose of obtaining judicial review in a state court.
27. **Administrative Permit Amendments and Permit Modifications:** As specified under Rule 606 of the RCAP, the permit shall not be amended nor modified unless Schering-Plough Las Piedras complies with the requirements for administrative permit amendments and permit modifications as described in the RCAP.
28. **Permit Reopenings:** As specified under Rule 608(a)(1), this permit shall be reopened and revised under the following circumstances:
- a) Whenever additional applicable requirements under any law or regulation become applicable to Schering-Plough Las Piedras, when the remaining permit term is of 3 or more years. Such reopening shall be completed 18 months after promulgation of said applicable requirement. No such reopening is required if the effective date of the requirement is later than the date on which the permit is due to expire, unless the original permit or any of its terms and conditions have been extended pursuant to Rule 605(c)(4)(i) or Rule 605(c)(4)(ii) of the RCAP.

- b) Whenever the Board or EPA determines that the permit contains a material mistake or that inaccurate statements were made in establishing the emission standards or other terms or conditions of the permit.
 - c) Whenever the Board or EPA determines that the permit must be revised or revoked to assure compliance with the applicable requirements.
29. **Changes in Name and/or Ownership:** This permit is issued to **Schering Plough Products, LLC**. In the event that the company and/or installation changes its name or is transferred to a different owner, the new responsible official must submit a sworn statement in which he/she accepts and promises to comply with all the conditions of this permit.
30. **Renovation/Demolition Work:** Schering-Plough Las Piedras shall comply with the provisions set forth in 40 CFR §61.145 and §61.150, and Rule 422 of the RCAP when conducting any renovation or demolition activities of asbestos containing materials at the facility.
31. **Risk Management Plan:** If during the effectiveness of this permit, Schering-Plough Las Piedras is subject to the 40 CFR part 68, Schering-Plough Las Piedras shall submit a Risk Management Plan according with the compliance schedule in the 40 CFR part 68.10. If during the effectiveness of this permit, Schering-Plough Las Piedras is subject to the 40 CFR part 68, Schering-Plough Las Piedras shall submit a compliance certification with the requirements of part 68 as part of the annual compliance certification required under 40 CFR part 70, including the recordkeeping and the Risk Management Plan.
32. **General Duty Requirements:** Schering-Plough Las Piedras has the general obligation of identifying hazards which may result from accidental releases of any controlled substance under section 112(r) of the Clean Air Act or any other extremely hazardous substance in a process, using appropriate hazard assessment techniques, designing, maintaining, and operating a safe facility and minimizing the consequences of accidental releases if they occur as required in section 112(r)(1) of the Act and Rule 107(D) of the RCAP.
33. **Requirements for Refrigerants (Climatologic and Stratospheric Ozone Protection):**
- a) In the event that Schering-Plough Las Piedras has equipment or appliances, including air conditioning units, which use Class I or II refrigerants as defined in 40 CFR part 82, subpart A, Appendices A and B, he/she shall take the necessary measures to ensure that all maintenance, service or repair services performed are done so according to the practices, certification and personnel requirements, disposition requirements, and recycling and/or recovery equipment certification requirements specified under 40 CFR part 82, subpart F.
 - b) Owners/ operators of appliances normally containing 50 or more pounds of refrigerant must keep records of refrigerant purchased and added to such appliances pursuant to §82.166 of the 40 CFR.

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

34. Labeling of Products Using Ozone-Depleting Substances: Schering-Plough Las Piedras shall comply with the standards for labeling of products using ozone-depleting substances pursuant to 40 CFR part 82, subpart E.

- a) All containers in which a class I or class II substance is stored or transported, all products containing a class I substance, and all products directly manufactured with a class I substance must bear the required warning statement if it is being introduced into interstate commerce pursuant to §82.106 of the 40 CFR.
- b) The placement of the required warning statement must comply with the requirements pursuant to §82.108 of the 40 CFR.
- c) The form of the label bearing the required warning statement must comply with the requirements pursuant to §82.110 of the 40 CFR.
- d) No person may modify, remove, or interfere with the required warning statement except as described in §82.112 of the 40 CFR.

35. Fire Pumps: The operation for each fire pump identified as insignificant activities in Section IX of this permit activity is limited to 500 hours per year. Schering-Plough Las Piedras shall keep a record of the hours of operation and fuel consumption for each fire pump. It shall be kept available at any time for inspection by EQB and EPA personnel.

36. Roof Surface Coating: This is a state-only requirement. Schering-Plough Las Piedras shall not cause or permit the roof surface coating by applying hot tar or any other coating material containing organic compounds without previous notification to the Board. This requirement will not apply to activities where tar or sealing material is applied without heat and such material is asbestos-free. The use of used oil or hazardous waste for roof surface coating is prohibited.

37. Storage Tanks: Schering-Plough Las Piedras shall keep records of all distillate fuel oil (diesel) storage tanks listed as insignificant activities showing the dimensions of each tank and an analysis showing the capacity of each tank pursuant to the 40 CFR §60.116b. This

documentation shall be readily available at any time for inspection of EQB personnel and shall be kept onsite for the life of the tank.

38. **Compliance Clause:** Under no circumstances does compliance with this permit exempt Schering-Plough Las Piedras from complying with all other applicable state or federal laws, regulations, permits, administrative orders or applicable court orders.
39. **Emissions Calculations:** Schering-Plough Las Piedras shall submit, on the first day of April each year, the actual or permissible emissions calculations for the previous natural year. The emissions calculations shall be submitted on the forms prepared by the Board for this purpose and the responsible official must certify all the information submitted as true, correct and representative of the permitted activity. Schering-Plough Las Piedras must make the applicable payment for the emissions calculations for the previous year on or before June 30 of each year.
40. **Annual fee:** As specified under Rule 610 of the RCAP, Schering-Plough Las Piedras must submit an annual payment based on the emissions calculations for each regulated pollutant. The payment will be based on their actual emissions at a rate of \$37.00 per ton, unless the Board decides otherwise as permitted under Rule 610(b)(2)(iv) of the RCAP. This payment for the previous year must be made on or before June 30 of each year.
41. **New or Amended Regulation:** Whether a federal or state regulation is promulgated or amended and the facility is affected by it, the owner or operator shall comply with the requirements of the new or amended regulation.
42. **Miscellaneous Organic Chemical Manufacturing Units:** Any existent source that have or operate miscellaneous organic chemical manufacturing units will be subject to the National Emission Standards for Hazardous Air Pollutants for the Miscellaneous Manufacturing of Organic Chemical Substances contained in the 40 CFR part 63, subpart FFFF. The source must comply with the requirements on this subpart no later than November 10, 2006 unless it is determined that this regulation does not apply to Schering-Plough Las Piedras or Schering-Plough Las Piedras had obtained an extension of compliance with the emission standards according to 40 CFR §63.6(i) in which case Schering-Plough Las Piedras shall comply by the date specified in the extension of compliance granted. Unless it is determined that this regulations does not apply, Schering-Plough Las Piedras shall comply with the notification requirements of 40 CFR §63.2515 according to the schedule in 40 CFR §63.2515 and in 40 CFR part 63, subpart A. According to §63.2445(c) of 40 CFR, some of the notifications shall be submitted before it is required to Schering-Plough Las Piedras to comply with the emission limits and work practices standards in 40 CFR part 63 subpart FFFF.
43. **Boilers and Process Heaters:** Any existent source that have or operate industrial, commercial and institutional boilers and process heaters will be subject to the National Emission Standards for Hazardous Air Pollutants for industrial, commercial and institutional boilers and process heaters contained in the 40 CFR part 63, subpart DDDDD. The affected source shall comply with all applicable requirements 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 this regulation is not applicable to Schering-Plough Las Piedras or Schering-Plough Las Piedras had obtained an extension of compliance with the emission standards according to 40 CFR §63.6(i) in which case Schering-Plough Las Piedras shall comply by the date specified in the extension of compliance granted. Unless it is determined that this regulations does not apply, Schering-Plough Las Piedras shall comply with the notification requirements of 40 CFR §63.7545 according to the schedule in 40 CFR §63.7545 and in 40 CFR part 63, subpart A. According to §63.7495(d) of 40 CFR, some of the notifications shall be submitted before it is required to Schering-Plough Las Piedras to comply with the emission limits and work practices standards in 40 CFR part 63 subpart DDDDD.

44. **Reports:** Any requirement of information submittal to the Board shall be addressed to: Manager, Air Quality Area, PO Box 11488, Santurce, P.R. 00910.

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

- a) Nothing herein shall prevent EPA or the Board from taking administrative enforcement measures or seeking legal or equitable relief to enforce the terms of the Title V permit, including but not limited to the right to seek injunctive relief, and imposition of statutory penalties and fines.
- b) Nothing herein shall be construed to limit the rights of EPA or the Board to undertake any criminal enforcement activity against Schering-Plough Las Piedras or any person.
- c) Nothing herein shall be construed to limit the authority of EPA or the Board to undertake any actions in response to conditions that present an imminent and substantial endangerment to public health or welfare, or the environment.
- d) Nothing herein shall be construed to limit Schering-Plough Las Piedras's rights to administrative hearing and judicial appeal of termination/ revocation/ disputes over modification/ denial actions in accordance with regulations and the Environmental Public Policy Act.

46. **Discrepancies and Inconsistencies:** In case that exists discrepancies or inconsistencies between the federal regulation and permit conditions, Schering-Plough Las Piedras shall apply for an administrative amendment to the permit to clarify the discrepancy.

* 47. **Source Modifications without a permit revision:** According to Rule 607 of the RCAP, Schering-Plough Las Piedras may perform:

(a) Source changes

- (1) Permitted sources may make Section 502(b)(10) changes without requiring a permit revision, if the changes are not modifications under any provision of Title I of the

Act and the changes do not exceed the emissions allowable under the permit (whether expressed therein as a rate of emissions or in terms of total emissions).

- (i) For each such change, the facility must provide the Administrator and the Board with written notification in advance of the proposed changes, which shall be seven (7) days. The written notification shall include a brief description of the change within the permitted facility, the date on which the change will occur, any change in emissions, and any permit term or condition that is no longer applicable as a result of the change. The source, the Board, and EPA shall attach each such notice to their copy of the relevant permit.
 - (ii) The permit shield described in paragraph (d) of Rule 603 shall not apply to any change made pursuant to section (a)(1) of Rule 607.
- (2) Permitted sources may trade increases and decreases in emissions in the permitted facility for the same pollutant, where the permit provides for such emissions trades without requiring a permit revision and based on the 7-day notice prescribed in section (a)(2) of Rule 607. This provision is available in those cases where the permit does not already provide for such emissions trading.
 - (i) Under paragraph (a)(2) of Rule 607, the written notification required shall include such information as may be required by the provision in the Puerto Rico State Implementation Plan (PR-SIP) authorizing the emissions trade, including when the proposed change will occur, a description of each such change, any change in emissions, the permit requirements with which the source will comply using the emissions trading provisions of the PR-SIP, and the pollutants emitted subject to the emissions trade. The notice shall also refer to the provisions with which the source will comply in the PR-SIP and that provide for the emissions trade.
 - (ii) The permit shield described in paragraph (d) of Rule 603 shall not extend to any change made under section (a)(2) of Rule 607. Compliance with the permit requirements that the source will meet using the emissions trade shall be determined according to requirements of the applicable implementation plan authorizing the emissions trade.
- (3) If a permit applicant requests it, the Board shall issue permits that contain terms and conditions (including all terms required under sections (a) and (c) of Rule 603 to determine compliance) allowing for the trading of emissions increases and decreases in the permitted facility solely for the purpose of complying with a federally-enforceable emissions cap. Such a cap must be established in the permit independent of otherwise applicable requirements. The permit applicant shall include in its application proposed replicable procedures and permit terms that ensure the emissions trades are quantifiable and enforceable. The Board shall not be

required to include in the emissions trading provisions any emissions units for which emissions are not quantifiable or for which there are no replicable procedures to enforce the emissions trades. The permit shall also require compliance with all applicable requirements.

- (i) Under section (a)(3) of Rule 607, the written notification required shall state when the change will occur and shall describe the changes in emissions that will result and how these increases and decreases in emissions will comply with the terms and conditions of the permit.
 - (ii) The permit shield described in paragraph (d) of Rule 603 may extend to terms and conditions that allow such increases and decreases in emissions.
- (b) Off-Permit Changes. The Board may allow changes that are not addressed or prohibited by the permit and/or State Law.
- (1) A permitted facility may make changes without obtaining a permit revision if such changes are not addressed or prohibited by the permit, other than those described in paragraph (c) of Rule 607.
 - (i) Each such change shall meet all applicable requirements and shall not violate any existing permit term or condition.
 - (ii) Sources must provide contemporaneous written notice to the Board and EPA of each such change, except for changes that qualify as insignificant under paragraph (c)(1) of Rule 602. Such written notice shall describe each such change, including the date, any change in emissions, pollutants emitted and any applicable requirement that would apply because of the change.
 - (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 result in emissions of a regulated air pollutant subject to an applicable requirement, but not otherwise regulated under the permit, and the emissions resulting from those changes.
- (c) A permitted facility cannot make changes without a permit revision if such changes are modifications under any provision of Title I of the Act.

- * 48. (a) Schering-Plough Las Piedras may make changes under section 502(b)(10) of the Act without requiring a permit revision if such changes:

- (1) are not modifications under any provision of Title I of the Act,
 - (2) do not exceed the allowable emissions under the permit,
 - 3) do not result in the emission of any pollutant not previously emitted,
 - (4) do not violate any applicable requirement or contravene federally enforceable terms and permit conditions such as monitoring (including test methods), recordkeeping, reporting and compliance certification requirements,
 - (5) are not changes under Title I of the Act to an emission limit, a work practice or a voluntary emission cap.
- (b) Rule 203 of the RCAP is required for any construction or modification of an emission source, except if it is exempted under Rule 206 of the RCAP. For purposes of part II of the RCAP, a modification is defined as any physical change in, change in the method of operation or a change in type of fuel used of an existing stationary source, that would result in a net increase in that stationary source's potential to emit any air pollutant (subject to any standard), or which results in the emission of any pollutant (subject to an standard) not previously emitted. A physical change shall not include routine maintenance, repair and the replacement of any equipment having the same capacity, equal efficiency or greater environmental benefit to be used for the same purpose.
- (c) The written notification addressed in condition 37(a)(1)(i) refer to changes covered under condition 37(a)(1). Changes not covered will be processed under the requirements of Rule 203 of the RCAP.
- (d) Any emission trading as provided in condition 37(a)(2) above will not be authorized if the facility does not provide the reference to the PR-SIP provisions authorizing such emissions trading.
- (e) If Schering-Plough Las Piedras requests so, the Board may allow the emission trading in the facility solely for the purpose of complying with a federally enforceable emissions cap. The application shall be based in replicable procedures and shall include permit terms that ensure the emission trades are quantifiable, replicable and enforceable.
- (f) Off- permit changes will not be exempt from complying with the requirements and procedures of Rule 203 of the RCAP, if applicable.

* **Section IV Potential Emissions**

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A. The emissions described on the following table represent the facility potential emissions at the moment of the permit application and will be used only for payment purposes. According to Resolution R-97-47-1, the emission calculations shall be based on Schering-Plough Las Piedras actual emissions, although calculations based on the facility permissible emissions will be accepted. If Schering-Plough Las Piedras decides to perform the calculations based on permissible emissions, Schering-Plough Las Piedras shall pay the same charge per ton as the facilities that decides to do the calculations based on actual emissions. Also, when Schering-Plough Las Piedras applies for a modification, administrative change or minor modification to its Title V permit, the source will pay only those charges related with any emission increase (if any) per ton, based on the change and not based on the total fees paid previously according to Rule 610(a) of the RCAP.

*

Pollutants	Potential Emissions (tons/year)
PM ₁₀	41.75
SO ₂	133.53
NO _x	261.67
CO	68.87
VOC	68.86
Lead	0.0017
Methylene Chloride	240.68
Methanol	164.74
Total HAP's	405.29

Section V Reporting Requirements

* A. According to Rule 602(c)(2)(ix)(C) of the RCAP, Schering-Plough Las Piedras shall submit every year a Compliance Certification. This certification shall be submitted to both the Board and the EPA⁶ no later than 90 days after the anniversary of the granted permit. In I case there are conditions subject to a reconsideration process to the final permit adopted by the Board, the compliance certification for the conditions included in the reconsideration will only be applicable for the time passed since the effective date determined by the Administrative Judge once the applicable procedure has been resolved and after the 45-day review period by the EPA. It shall include, but will not be limited to, the information required by Rule 603(c) of the RCAP.

6 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: CEPD Director, US EPA-Region II, Centro Europa Building 1492, Ponce de Leon Ave. Stop 22, Santurce, PR 00909

Section VI Specific Permit Conditions

A. Facility wide Emission Limits

1. Fuel Consumption Limit for Units EU-BOILERS-NON-NSPS and EU-BOILERS-NSPS⁷

Condition	Parameter	Value	Units	Test Method	Frequency of the Method	Recordkeeping Requirements	Reporting Requirements
* Fuel Consumption Limit	Distillate Fuel Oil No .2 (diesel)	3,153,600	Gallons per year	Consumption	Daily	Records	Quarterly

- * a. The maximum total fuel consumption for the boilers EPBO1, EPBO2, EPBO3, EPBO4 and EPBO5 shall not exceed 3,153,600 gallons annually.
- * b. The five boilers shall be equipped with a fuel flow meter, each one, in order to verify the fuel consumption. Shall calibrate the flow meters every six months and keep records or documents of the calibrations in the facility available to EQB’s personnel for review. [PFE-44-0703-1181-I-II-C]
- * c. Schering-Plough Las Piedras shall keep a daily record indicating the date, the reading of the fuel flow meter and the total fuel used daily on each boiler for evaluation and review of EQB’s technical personnel. The consumption recorded daily in the flow meter shall be used to calculate the accumulated fuel consumption which will be maintained in a daily basis in a 365-day rolling period. The fuel consumption calculation during any 365 day period shall be calculated by adding the fuel consumptions of any day to the total fuel consumption of the 364 previous days.
- * d. Shall record the fuel consumption for each boiler even when the boilers are operating as backup or in stand-by mode and include it in the total fuel consumption. [PFE-44-0703-1181-I-II-C]
- * e. The consumption reports based on the fuel flow meter readings shall be submitted every three months to this Board no later than the next 15 days of the following period for which the report is representative. [PFE-44-0703-1181-I-II-C]
- * f. Schering-Plough Las Piedras shall permit the simultaneous operation of boilers EPBO1, EPBO2, EPBO3, EPBO4 and EPBO5, as long as the fuel consumption limit is not exceeded.

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⁷ In case that exists discrepancies or inconsistencies between the table information and the narrative permit conditions, Schering-Plough Las Piedras shall apply for an administrative amendment to the permit to clarify the discrepancy.

- g. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application. These include records of quarterly and annual fuel consumption reports and the results and methodology used for the flow meters calibrations for each combustion unit.
- h. Schering-Plough Las Piedras shall submit each year, with the annual compliance certification, a report about the total fuel consumption burned during the previous calendar year and the maximum sulfur content in weight percent in the burned fuels.

B. Emission Limit per Emission Unit

1. EU-BOILERS-NON-NSPS (EPBO1 and EPBO2)⁸

Condition	Parameter	Value	Units	Test Method	Frequency of the Method	Recordkeeping Requirements	Reporting Requirements
Particulate Matter Emission Limit	Particulate Matter	0.3	Pounds per million Btu	Method 5	During the first year of the permit	Logbook	No later than 60 days after the performance of the test
Visible Emissions	Visible Emissions	20	Percent 6-minute average	Method 9 Visible Emissions	During the first year of the permit Monthly	With each reading	No later than 60 days after the reading
SO ₂ Emission Limit	Sulfur Content	0.5	Percent by weight	Fuel Supplier Analysis	With each receipt	Daily Record of the sulfur content on fuel	Monthly

*

- a. **Particulate Matter Emission Limit**
 - i. Schering-Plough Las Piedras shall not cause nor permit the emission of particulate matter, from any equipment burning solid or liquid fuel, in excess of 0.3 pounds per million Btu. [Rule 406 of the RCAP]
 - ii. Schering-Plough Las Piedras shall perform a performance test during the first year of the permit using Method 5 of the 40 CFR

⁸ In case there is any discrepancy or inconsistencies between the information in the tables and the narrative conditions in the permit, Schering-Plough Las Piedras shall apply for an administrative amendment for the permit to clarify the discrepancy.

part 60, Appendix A in order to verify compliance with the standard. [Rule 602 (c)(2)(ix)(C) of the RCAP]

- iii. Schering-Plough Las Piedras must submit to EQB 30 days prior to the start of the test, a test protocol. [Rule 106(C) of the RCAP]
- iv. Schering-Plough Las Piedras must submit a written notification 15 days prior of the performance test in order to allow EQB to assign an observer. [Rule 106 (D) of the RCAP]
- v. Schering-Plough Las Piedras must submit a final report within 60 days after the performance test. [Rule 106(E) of the RCAP]
- vi. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application.

b. Visual Emission Limit

- i. Schering-Plough Las Piedras shall not exceed the opacity limit of 20% for unit EU-BOILERS-NON-NSPS in a 6 minutes average. Nevertheless, and as specified under Rule 403(A) of the RCAP, Schering-Plough Las Piedras may discharge into the atmosphere visible emissions of opacity of up to 60% for a period of no more than 4 minutes in any consecutive 30 minutes period.
- ii. Schering-Plough Las Piedras shall contract an independent opacity reader, certified in a school approved by EPA, to perform one opacity reading to the common stack of units EPBO1 and EPBO2 during the first year of the permit using Method 9 established in the 40 CFR part 60, Appendix A. Both boilers shall be operating at the time of performance of the opacity reading.
- iii. Schering-Plough Las Piedras must submit to EQB 30 days prior to the start of the test, a test protocol. [Rule 106(C) of the RCAP]
- iv. Schering-Plough Las Piedras must submit a written notification 15 days prior of the performance test in order to allow EQB to assign an observer. [Rule 106 (D) of the RCAP]
- v. Schering-Plough Las Piedras must submit a final report within 60 days after the performance test. [Rule 106(E) of the RCAP]

*

vi. During the operation of the unit EU-BOILERS-NON-NSPS, Schering-Plough Las Piedras shall conduct monthly a visible emissions test of the affected unit with a three minutes minimum duration, during the hours of the day. The person performing the visible emissions shall be certified by a program endorsed by EPA or EQB such that he/she receives an acceptable training for EQB to recognize if the opacity limit is being exceeded, according to Rule 403 of the RCAP. When the certified reader establishes that the opacity limit is being exceeded, according to Rule 403 of the RCAP, Schering-Plough Las Piedras shall verify that the equipment causing the visible emissions is operating according to the manufacturer's specifications and the permit conditions. If it is not operating appropriately, Schering-Plough Las Piedras shall take corrective steps immediately to eliminate the excess opacity. Shall prepare and maintain a record indicating the date and the results of the monthly inspections performed, available at the facility at all times for review by EQB's technical personnel.

- *
 - vii. EQB reserves the right to perform or require to perform an opacity evaluation under Method 9 at any time during the hours of the day in which the equipments are operating in order to demonstrate compliance with the opacity limit.
 - viii. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application. These include a record of the visible emissions readings, which contains the dates and hours of the readings realized.

c. SO₂ Emission Limits

- i. Schering-Plough Las Piedras shall not burn or permit the use of any fuel with a sulfur content, by weight, which exceeds 0.5% in the boilers EPBO1 and EPBO2.
- *
 - ii. According to Rule 410 of the RCAP, Schering-Plough Las Piedras shall keep a daily record of the fuel consumption used by each combustion equipment and its sulfur content (weight percent) for evaluation and review by the Board. [PFE-44-0703-1181-I-II-C]
 - iii. Schering-Plough Las Piedras shall keep a copy of the fuel supplier certification indicating the fuel sulfur content to demonstrate compliance with the requirement of keeping a daily record of the sulfur content in the diesel. Schering-Plough Las Piedras shall obtain an analysis of the sulfur content with each receipt of fuel using Method ASTM 4294 or ASTM 2880-71.
 - iv. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and

supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application. These include a record of the results of fuel sampling, monthly fuel consumption reports and the sulfur content in the fuels burned.

- v. Schering-Plough Las Piedras shall submit to EQB a monthly report indicating the daily fuel consumption and the sulfur content, by weight, for the fuel consumed in the units EPBO1 and EPBO2. This report shall be submitted to the Board within the first 15 days of the following month for which the report is representative. The report shall be addressed to the Chief of the Validations and Data Management Division and shall be kept available at any time at the facility for EQB and EPA revision. [Rule 410 of the RCAP]
- vi. Schering-Plough Las Piedras shall submit each year, with the annual compliance certification, a report with the total consumption of fuel burned during the previous calendar year and the maximum sulfur content in percent by weight in the fuel burned.

* **2. EU-BOILERS-NSPS (EPBO3, EPBO4 and EPBO5)⁹**

Condition	Parameter	Value	Units	Test Method	Frequency of the Method	Recordkeeping Requirements	Reporting Requirements
Particulate Matter Emission Limit	Particulate Matter	0.3	Pounds per million Btu	Method 5	During the first year of the permit	Logbook	No later than 60 days after the performance of the test
Visible Emissions	Visible Emissions	20	Percent 6-minute average	Method 9	During the first year of the permit	With each reading	No later than 60 days after the reading
				Visible Emissions	Monthly		
SO ₂ Emission Limit	Sulfur Content	0.5	Percent by weight	Fuel Supplier Analysis	With each receipt	Daily Record of the sulfur content on fuel	Monthly

a. **Particulate Matter Emission Limit**

⁹ In case there is any discrepancy or inconsistencies between the information in the tables and the narrative conditions in the permit, Schering-Plough Las Piedras shall apply for an administrative amendment for the permit to clarify the discrepancy.

- i. Schering-Plough Las Piedras shall not cause nor permit the emission of particulate matter, from unit EU-BOILERS-NSPS, in excess of 0.3 pounds per million Btu. [Rule 406 of the RCAP]
 - ii. Schering-Plough Las Piedras shall perform a performance test during the first year of the permit using Method 5 of the 40 CFR part 60, Appendix A in order to verify compliance with the standard. [Rule 602 (c)(2)(ix)(C) of the RCAP]
 - iii. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application.
 - iv. Schering-Plough Las Piedras must submit to EQB 30 days prior to the start of the test, a test protocol. [Rule 106(C) of the RCAP]
 - v. Schering-Plough Las Piedras must submit a written notification 15 days prior of the performance test in order to allow EQB to assign an observer. [Rule 106 (D) of the RCAP]
 - vi. Schering-Plough Las Piedras must submit a final report within 60 days after the performance test. [Rule 106(E) of the RCAP]
- b. Visible Emissions Limit
- i. Schering-Plough Las Piedras shall not exceed the opacity limit of 20% for unit EU-BOILERS-NSPS in a 6 minutes average. Nevertheless, and as specified under Rule 403(A) of the RCAP, Schering-Plough Las Piedras may discharge into the atmosphere visible emissions of opacity of up to 60% for a period of no more than 4 minutes in any consecutive 30 minutes period.
 - * ii. Schering-Plough Las Piedras shall contract an independent opacity reader, certified in a school approved by EPA, to perform one opacity reading to the common stack of units EPBO3 and EPBO4, and in the stack of unit EPBO5 during the first year of the permit using Method 9 established in the 40 CFR part 60, Appendix A. The boilers shall be operating at the time of performance of the opacity reading.
 - iii. Schering-Plough Las Piedras must submit to EQB 30 days prior to the start of the test, a test protocol. [Rule 106(C) of the RCAP]

- iv. Schering-Plough Las Piedras must submit a written notification 15 days prior of the performance test in order to allow EQB to assign an observer. [Rule 106 (D) of the RCAP]
- v. Schering-Plough Las Piedras must submit a final report within 60 days after the performance test. [Rule 106(E) of the RCAP]
- * vi. During the operation of the unit EU-BOILERS-NSPS, Schering-Plough Las Piedras shall conduct monthly a visible emissions test of the affected unit with a three minutes minimum duration, during the hours of the day. The person performing the visible emissions shall be certified by a program endorsed by EPA or EQB such that he/she receives an acceptable training for EQB to recognize if the opacity limit is being exceeded, according to Rule 403 of the RCAP. When the certified reader establishes that the opacity limit is being exceeded, according to Rule 403 of the RCAP, Schering-Plough Las Piedras shall verify that the equipment causing the visible emissions is operating according to the manufacturer's specifications and the permit conditions. If it is not operating appropriately, Schering-Plough Las Piedras shall take corrective steps immediately to eliminate the excess opacity. Shall prepare and maintain a record indicating the date and the results of the monthly inspections performed, available at the facility at all times for review by EQB's technical personnel.
- * vii. EQB reserves the right to perform or require to perform an opacity evaluation under Method 9 at any time during the hours of the day in which the equipments are operating in order to demonstrate compliance with the opacity limit.
- viii. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application. These include a record of the visible emissions readings, which contains the dates and hours of the readings realized.
- c. SO₂ Emission Limit
 - * i. Schering-Plough Las Piedras shall not burn or permit the use of any fuel with a sulfur content, by weight, which exceeds 0.5% in the boilers EPBO3, EPBO4 and EPBO5. [40 CFR §60.40c(g)]
 - * ii. According to Rule 410 of the RCAP, Schering-Plough Las Piedras shall keep a daily record of the fuel consumption used by each

combustion equipment and its sulfur content (weight percent) for evaluation and review by the Board. [PFE-44-0703-1181-I-II-C]

- iii. Schering-Plough Las Piedras shall keep a copy of the fuel supplier certification indicating the fuel sulfur content to demonstrate compliance with the requirement of keeping a daily record of the sulfur content in the diesel. Schering-Plough Las Piedras shall obtain an analysis of the sulfur content with each receipt of fuel using Method ASTM 4294 or ASTM 2880-71. [40 CFR §60.43c(h)]
 - iv. Fuel supplier certification shall include the name of the oil supplier, and a statement from the oil supplier that the oil complies with the specifications under the definition of distillate oil¹⁰ in 40 CFR §60.41c. [40 CFR, §60.42c(f)(1)]
 - v. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application. These include a record of the results of fuel sampling, monthly fuel consumption reports and the sulfur content in the fuels burned.
 - * vi. Schering-Plough Las Piedras shall submit to EQB a monthly report indicating the daily fuel consumption and the sulfur content, by weight, for the fuel consumed in units EPBO3, EPBO4 and EPBO5. This report shall be submitted to the Board within the first 15 days of the month following for which the report is representative. The report shall be addressed to the Chief of the Validations and Data Management Division and shall be kept available at any time at the facility for EQB and EPA revision. [Rule 410 of the RCAP]
 - vii. Schering-Plough Las Piedras shall submit each year, with the annual compliance certification, a report with the total consumption of fuel burned during the previous natural year and the maximum sulfur content in percent by weight in the fuel burned and the quantity of SO₂ emissions in tons per year.
- d. Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units

¹⁰ Pursuant to 40 CFR §60.41c, distillate oil means fuel oil that complies with the specifications for fuel oil numbers 1 or 2, as defined by the American Society for Testing and Materials in ASTM D396-78 "Standard Specification for Fuel Oils".

- * i. Units EPBO3, EPBO4 and EPBO5 are subject to the Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units of the Code of Federal Regulations, 40 CFR part 60, subpart Dc.

3. EUCO1¹¹

Condition	Parameter	Value	Units	Test Method	Frequency of the Method	Recordkeeping Requirements	Reporting Requirements
Visible Emissions	Visible Emissions	20	Percent 6-minute average	Method 9 Visible Emissions	During the first year of the permit Monthly	With each reading	No later than 60 days after the reading
SO ₂ Emission Limit	Sulfur Content	0.5	Percent by weight	Fuel Supplier Analysis	With each receipt	Daily Record of the sulfur content on fuel	Monthly
Fuel Consumption Limit	Distillate Fuel Oil No. 2 (diesel) ¹²	250,000	Gallons per year	Consumption	Monthly	Logbook	Annually

a. Visible Emission Limit

- i. Schering-Plough Las Piedras shall not exceed the opacity limit of 20% for unit EUCO1 in a 6 minutes average. Nevertheless, and as specified under Rule 403(A) of the RCAP, Schering-Plough Las Piedras may discharge into the atmosphere visible emissions of opacity of up to 60% for a period of no more than 4 minutes in any consecutive 30 minutes period.
- ii. Schering-Plough Las Piedras shall contract an independent opacity reader, certified in a school approved by EPA, to perform one opacity reading to the stack of unit EUCO1 during the first year of the permit using Method 9 established in the 40 CFR part 60, Appendix A.
- iii. Schering-Plough Las Piedras must submit to EQB 30 days prior to the start of the test, a test protocol. [Rule 106(C) of the RCAP]

11 In case there is any discrepancy or inconsistencies between the information in the tables and the narrative conditions in the permit, Schering-Plough Las Piedras shall apply for an administrative amendment for the permit to clarify the discrepancy.

12 Propane is used to light the pilot that starts the operation of the catalytic oxidizer.

- iv. Schering-Plough Las Piedras must submit a written notification 15 days prior of the performance test in order to allow EQB to assign an observer. [Rule 106 (D) of the RCAP]
 - v. Schering-Plough Las Piedras must submit a final report within 60 days after the performance test. [Rule 106(E) of the RCAP]
 - * vi. During the operation of the unit EUCO1, Schering-Plough Las Piedras shall conduct monthly a visible emissions test of the affected unit with a three minutes minimum duration, during the hours of the day. The person performing the visible emissions reading shall be certified by a program endorsed by EPA or EQB such that he/she receives an acceptable training for EQB to recognize if the opacity limit is being exceeded, according to Rule 403 of the RCAP. When the certified reader establishes that the opacity limit is being exceeded, according to Rule 403 of the RCAP, Schering-Plough Las Piedras shall verify that the equipment causing the visible emissions is operating according to the manufacturer's specifications and the permit conditions. If it is not operating appropriately, Schering-Plough Las Piedras shall take corrective steps immediately to eliminate the excess opacity. Shall prepare and maintain a record indicating the date and the results of the monthly inspections performed, available at the facility at all times for review by EQB's technical personnel.
 - * vii. EQB reserves the right to perform or require to perform an opacity evaluation under Method 9 at any time during the hours of the day in which the equipments are operating in order to demonstrate compliance with the opacity limit.
 - viii. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application. These include a record of the visible emissions readings, which contains the dates and hours of the readings realized.
- b. SO₂ Emission Limit
- i. Schering-Plough Las Piedras shall not burn or permit the use of any fuel with a sulfur content, by weight, which exceeds 0.5% in the unit EUCO1. [PFE-44-1294-1439-I-C]
 - ii. Schering-Plough Las Piedras shall keep a copy of the fuel supplier certification indicating the fuel sulfur content to demonstrate

compliance with the requirement of keeping a daily record of the sulfur content in the diesel. Schering-Plough Las Piedras shall obtain an analysis of the sulfur content with each receipt of fuel using Method ASTM 4294 or ASTM 2880-71.

iii. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application. These include a record of the results of fuel sampling, monthly fuel consumption reports and the sulfur content in the fuels burned.

* iv. Schering-Plough Las Piedras shall submit to EQB a monthly report indicating the daily fuel consumption and the sulfur content, by weight, for the diesel and propane fuels consumed in unit EUCO1. This report shall be submitted to the Board within the first 15 days of the month following for which the report is representative. The report shall be addressed to the Chief of the Validations and Data Management Division and shall be kept available at any time at the facility for EQB and EPA revision. [Rule 410 of the RCAP]

v. Schering-Plough Las Piedras shall submit each year, with the annual compliance certification, a report of the total fuels burned during the previous calendar year, the maximum sulfur content in weight percent in the burned fuels and the amount of SO₂ emissions in tons per year.

c. Fuel consumption limit

i. Schering-Plough Las Piedras shall not exceed the consumption limit of distillate oil No. 2 (diesel) of 250,000 gallons for any period of 12 consecutive months for unit EUCO1. The fuel consumption for any consecutive 12-month period shall be calculated by adding the monthly consumption for the unit to the total fuel consumption for the unit for the previous 11 months. [PFE-44-1294-1439-I-C]

ii. Schering-Plough Las Piedras shall install, maintain, and operate a fuel flow meter in unit EUCO1 to verify the fuel consumption. Schering-Plough Las Piedras shall calibrate the flow meter every six months in accordance with the manufacturer's specifications and maintain the records of the periodic calibrations available for EQB or EPA review.

*

- iii. Schering-Plough Las Piedras shall keep a record with the consumption of propane used for the startup of the catalytic oxidizer, available for inspection by the Board's technical personnel.
 - iv. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application. These include records of monthly and annual fuel consumption reports and the results and methodology used for the flow meters calibrations for each combustion unit. The monthly compliance is determined adding the total quantity of fuel consumption in the 11 previous months.
 - v. Schering-Plough Las Piedras shall submit each year, with the annual compliance certification, a report of the total fuel consumption burned in the natural previous year on the catalytic oxidizer.
- d. Operational limits
- i. The catalytic oxidizer EUCO1 may oxidize acetone, isopropanol (IPA) and ethyl acetate. [PFE-44-0393-0386-I-II-III-O]
 - ii. The oxidation of liquid and solid waste is not authorized in unit EUCO1. [PFE-44-0393-0386-I-II-III-O]
 - iii. Schering-Plough Las Piedras shall not permit the oxidation of chloroform or chlorinated compounds in unit EUCO1. [PFE-44-0393-0386-I-II-III-O]
 - iv. Schering-Plough Las Piedras shall calibrate, maintain and efficiently operate continuous monitors to determine the quantity and concentration of total solvents at the inlet and outlet of the catalytic oxidizer EUCO1. [PFE-44-0393-0386-I-II-III-O]
 - v. Schering-Plough Las Piedras shall keep a daily record of the quantity and concentration of total solvents at the inlet and outlet of the catalytic oxidizer EUCO1.
 - vi. The continuous monitors of unit EUCO1 shall be calibrated every six months. Schering-Plough Las Piedras shall maintain a record of the calibrations realized to these meters.

- vii. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application.

* **4. EUGEN1 (EPGEN1, EPGEN2 , EPGEN3 and EPGEN4)¹³**

Condition	Parameter	Value	Units	Test Method	Frequency of the Method	Recordkeeping Requirements	Reporting Requirements
PM Emission Limit	Particulate Matter	0.3	Pounds per million Btu	Method 5	During the first year of the permit	Logbook	No later than 60 days after the performance of the test
Visible Emissions	Visible Emissions	20	Percent 6-minute average	Method 9	During the first year of the permit	With each reading	No later than 60 days after the reading
				Visible Emissions	Monthly		
SO ₂ Emission Limit	Sulfur Content	0.5	Percent by weight	Fuel Supplier Analysis	With each receipt	Daily Record of the sulfur content on fuel	Monthly
Limit of Operating Hours	Operating Hours	4,562	Hours per year per generator	Record	Monthly	Logbook	Annually
Fuel Consumption Limit	Fuel Consumption	958,074	gal/year	Record	Daily	Daily	Monthly
							Annually

a. Particulate Matter Emission Limit

- i. Schering-Plough Las Piedras shall not cause nor permit the emission of particulate matter, from any equipment burning solid or liquid fuel, in excess of 0.3 pounds per million Btu. [Rule 406 of the RCAP]
- ii. Schering-Plough Las Piedras shall perform a performance test during the first year of the permit using Method 5 of the 40 CFR part 60, Appendix A in order to verify compliance with the standard. [Rule 602 (c)(2)(ix)(C) of the RCAP]
- iii. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and

¹³ In case there is any discrepancy or inconsistencies between the information in the tables and the narrative conditions in the permit, Schering-Plough Las Piedras shall apply for an administrative amendment for the permit to clarify the discrepancy.

supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application.

- iv. Schering-Plough Las Piedras must submit to EQB 30 days prior to the start of the test, a test protocol. [Rule 106(C) of the RCAP]
- v. Schering-Plough Las Piedras must submit a written notification 15 days prior of the performance test in order to allow EQB to assign an observer. [Rule 106 (D) of the RCAP]
- vi. Schering-Plough Las Piedras must submit a final report within 60 days after the performance test. [Rule 106(E) of the RCAP]

b. Visual Emission Limit

- i. Schering-Plough Las Piedras shall not exceed the opacity limit of 20% for unit EUGEN1 in a 6 minutes average. Nevertheless, and as specified under Rule 403(A) of the RCAP, Schering-Plough Las Piedras may discharge into the atmosphere visible emissions of opacity of up to 60% for a period of no more than 4 minutes in any consecutive 30 minutes period.
- ii. Schering-Plough Las Piedras shall contract an independent opacity reader, certified in a school approved by EPA, to perform one opacity reading to the stack of unit EUGEN1 during the first year of the permit using Method 9 established in the 40 CFR part 60, Appendix A.
- iii. Schering-Plough Las Piedras must submit to EQB 30 days prior to the start of the test, a test protocol. [Rule 106(C) of the RCAP]
- iv. Schering-Plough Las Piedras must submit a written notification 15 days prior of the performance test in order to allow EQB to assign an observer. [Rule 106 (D) of the RCAP]
- v. Schering-Plough Las Piedras must submit a final report within 60 days after the performance test. [Rule 106(E) of the RCAP]
- * vi. During the operation of the unit EUGEN1, Schering-Plough Las Piedras shall conduct monthly a visible emissions test of the affected unit with a three minutes minimum duration, during the hours of the day. The person performing the visible emissions reading shall be certified by a program endorsed by EPA or EQB such that he/she receives an acceptable training for EQB to recognize if the opacity limit is being exceeded, according to Rule

403 of the RCAP. When the certified reader establishes that the opacity limit is being exceeded, according to Rule 403 of the RCAP, Schering-Plough Las Piedras shall verify that the equipment causing the visible emissions is operating according to the manufacturer's specifications and the permit conditions. If it is not operating appropriately, Schering-Plough Las Piedras shall take corrective steps immediately to eliminate the excess opacity. Shall prepare and maintain a record indicating the date and the results of the monthly inspections performed, available at the facility at all times for review by EQB's technical personnel.

- * vii. EQB reserves the right to perform or require to perform an opacity evaluation under Method 9 at any time during the hours of the day in which the equipments are operating in order to demonstrate compliance with the opacity limit.
- viii. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application. These include a record of the visible emissions readings, which contains the dates and hours of the readings realized.

c. SO₂ Emission Limits

- i. Schering-Plough Las Piedras shall not burn or permit the use of any fuel with a sulfur content, by weight, which exceeds 0.5% in unit EUGEN1.
- * ii. According to Rule 410 of the RCAP, Schering shall keep a daily record of the fuel consumption used by each combustion equipment and its sulfur content (weight percent) for evaluation and review by the Board. [PFE-44-0703-1181-I-II-C]
- iii. Schering-Plough Las Piedras shall keep a copy of the fuel supplier certification indicating the fuel sulfur content to demonstrate compliance with the requirement of keeping a daily record of the sulfur content in the diesel. Schering-Plough Las Piedras shall obtain an analysis of the sulfur content with each receipt of fuel using Method ASTM 4294 or ASTM 2880-71.
- iv. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application. These

include a record of the results of fuel sampling, monthly fuel consumption reports and the sulfur content in the fuels burned.

- * v. Schering-Plough Las Piedras shall submit to EQB a monthly report indicating the daily fuel consumption in unit EUGEN1 and the sulfur content, by weight, for the fuel consumed. This report shall be submitted to the Board within the first 15 days of the month following for which the report is representative. The report shall be addressed to the Chief of the Validations and Data Management Division and shall be kept available at any time at the facility for EQB and EPA revision. [PFE-44-0703-1181-I-II-C]
- vi. Schering-Plough Las Piedras shall submit each year, with the annual compliance certification, a report with the total consumption of fuel burned during the previous calendar year and the maximum sulfur content in percent by weight in the fuel burned and the quantity of SO₂ emissions in tons per year.
- * d. Fuel consumption limit
 - * i. The maximum total consumption for the four electricity generators shall not exceed 958,074 gallons annually. [PFE-44-0703-1181-I-II-C]
 - * ii. The four electricity generators shall be provided with a hours of operation meter such that the hours of operation can be verified and calculate the fuel consumption [PFE-44-0703-1181-I-II-C]
 - * iii. Schering-Plough Las Piedras shall keep a daily record with the date, the reading of the hours of operation meter and the total daily hours of operation of each electricity generator for evaluation and review by the Board's technical personnel. The hours recorded daily in the meter shall be used to calculate the accumulated fuel consumption which will be maintained on a daily basis in a 365-day rolling period. The fuel consumption calculation during any 365-day period shall be calculated by adding the fuel consumptions of every day to the total fuel consumption of the 364 previous days. [PFE-44-0703-1181-I-II-C]
 - * iv. The fuel consumption reports based on the reading of the hours of operation meter of the electricity generator shall be submitted every three months to this Board no later than the 15 days following the next period for which the report is representative. [PFE-44-0703-1181-I-II-C]

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v. As specified in Rule 603(a)(4)(ii) of the RCAP, Schering-Plough Las Piedras shall retain all records for required monitoring and supporting information for a period of 5 years from the date of the monitoring sample, measurement, report or application. These include records of quarterly and annual fuel consumption reports and the results and methodology used for the calibrations hours of operation meters of each combustion unit.

vi. Schering-Plough Las Piedras shall submit each year, with the annual compliance certification, a report of the total fuel consumption burned in the previous calendar year on each electricity generator.

* 5. Requirements for the Methanol Tank and the Methylene Chloride Tank

* i. The Permittee shall not place, store or hold any VOC in any stationary tank, reservoir, or other container of more than 40,000 gallons, unless such tank, reservoir, or other container is a pressure tank capable of maintaining working pressures sufficient, under normal operating conditions, to control vapor or gas loss to the atmosphere, or unless it is equipped with: a floating roof as indicated in Rule 417(A), a vapor recovery system as indicated in Rule 417(B), and any other federal applicable requirements.

* ii. Compliance of the above condition i. is exempted for the following:

* a. Storage of any liquid having no photochemical reactivity (including those compounds listed under the definition of VOC) and/or having a true vapor pressure less than 0.75 psia.

* b. Tanks that treat wastewater permitted under the Clean Water Act and exempted by rule from Resource Conservation and Recovery Act.

* c. Exemptions based on vapor pressure shall be demonstrated with calculations using Antoine's equation and average liquid surface temperature.

* iii. Schering-Plough Las Piedras shall keep records showing the dimension of the storage vessels and an analysis showing the capacity of each storage vessel. The records shall be available for inspection by EQB technical personnel.

* iv. The records required by the previous condition will be kept at the facility for the life of the tank.

C. Other operational limits

The following requirements are not federally enforceable:

EU-VOC-PM-MACT, EU-VOC-PM-NON-MACT

* 1. Rule 419 of the RCAP:

- i. As determined by Rule 419 of the RCAP, Schering-Plough Las Piedras shall not permit the emission of 3 pounds of volatile organic compounds (VOC) in any one hour, no more than 15 pounds in any day from an article, machine, equipment or any other contrivance unless it is provided with a control system, pollution prevention and reductions mechanism or programs or both, as approved or required by the Board.
- ii. Schering-Plough Las Piedras shall provide an acceptable control system for these units or establish a program of prevention and reduction of ethanol emissions no later than 180 days from the date of approval of this permit

Section VII - Compliance with Standards and Maintenance Requirements

A. Operation and Maintenance Requirements (40 CFR subpart A, section 63.6)

1. At all times, including periods of startup, shutdown, and malfunction¹⁴, Schering-Plough Las Piedras must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. During a period of startup, shutdown, or malfunction, this general duty to minimize emissions requires that Schering-Plough Las Piedras 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 startup, shutdown, or malfunction does not require Schering-Plough Las Piedras 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 Schering-Plough Las Piedras 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

¹⁴ According to 40 CFR §63.2, 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.

EQB and EPA which may include, but is not limited to, monitoring results, review of operation and maintenance procedures (including the startup, shutdown, and malfunction plan required in paragraph (e)(3) of section 63.6), 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 startup, shutdown, and malfunction plan required in paragraph (e)(3) of section 63.6 of 40 CFR. To the extent that an unexpected event arises during a startup, shutdown, or malfunction, Schering-Plough Las Piedras must comply by minimizing emissions during such a startup, shutdown, and malfunction event consistent with safety and good air pollution control practices. [40 CFR §63.6(e)(1)(ii)]
3. Operation and maintenance requirements established pursuant to section 112 of the Act are enforceable independent of emissions limitations or other requirements in relevant standards.¹⁵ [40 CFR §63.6(e)(1)(iii)]
4. Startup, shutdown, and malfunction plan. Schering-Plough Las Piedras must develop and implement a written startup, shutdown, and malfunction plan that describes, in detail, procedures for operating and maintaining the source during periods of startup, shutdown, and malfunction, and a program of corrective action for malfunctioning process and air pollution control and monitoring equipment used to comply with the relevant standard. Schering-Plough Las Piedras must develop this plan by the source's compliance date for that relevant standard. [40 CFR §63.6(e)(3)(i)]
5. During periods of startup, shutdown, and malfunction, Schering-Plough Las Piedras must operate and maintain such source (including associated air pollution control and monitoring equipment) in accordance with the procedures specified in the startup, shutdown, and malfunction plan developed under paragraph (e)(3)(i) of section 63.6. [40 CFR §63.6(e)(3)(ii)]
6. When actions taken by Schering-Plough Las Piedras during a startup, shutdown, or malfunction (including actions taken to correct a malfunction) are consistent with the procedures specified in the affected source's startup, shutdown, and malfunction plan, Schering-Plough Las Piedras must keep records for that event

¹⁵ According to 40 CFR §63.2, a relevant standard means 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 a stationary source regulated by such 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 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 I that are referenced in that standard.

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 startup, shutdown, and malfunction plan for that event. In addition, Schering-Plough Las Piedras must keep records of these events as specified in section 63.10(b), including records of the occurrence and duration of each startup, shutdown, or malfunction of operation and each malfunction of the air pollution control and monitoring equipment. Furthermore, Schering-Plough Las Piedras shall confirm that actions taken during the relevant reporting period during periods of startup, shutdown, and malfunction were consistent with the affected source's startup, shutdown and malfunction plan in the semiannual (or more frequent) startup, shutdown, and malfunction report required in Sec. 63.10(d)(5). [40 CFR §63.6(e)(3)(iii)]

7. If an action taken by Schering-Plough Las Piedras during a startup, shutdown, or malfunction (including an action taken to correct a malfunction) is not consistent with the procedures specified in the affected source's startup, shutdown, and malfunction plan, and Schering-Plough Las Piedras exceeds any applicable emission limitation in the relevant emission standard, then Schering-Plough Las Piedras must record the actions taken for that event and must report such actions 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 section 63.10(d)(5) (unless Schering-Plough Las Piedras makes alternative reporting arrangements, in advance, with EPA and EQB. [40 CFR §63.6(e)(3)(iv)]
8. Schering-Plough Las Piedras must maintain at the affected source a current startup, shutdown, and malfunction plan and must make the plan available upon request for inspection and copying by EQB or EPA. In addition, if the startup, shutdown, and malfunction plan is subsequently revised as provided in paragraph (e)(3)(viii) of section 63.6, Schering-Plough Las Piedras must maintain at the affected source each previous (i.e., superseded) version of the startup, shutdown, and malfunction plan, and must make each such previous version available for inspection and copying by EQB or EPA for a period of 5 years after revision of the plan. If at any time after adoption of a startup, shutdown, and malfunction plan the affected source ceases operation or is otherwise no longer subject to the provisions of part 63, Schering-Plough Las Piedras 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 this part and must make the plan available upon request for inspection and copying by EQB or EPA. EQB or EPA may at any time request in writing that Schering-Plough Las Piedras submit a copy of any startup, shutdown, and malfunction plan (or a portion thereof) which is maintained at the affected source or in the possession of Schering-Plough Las Piedras. Upon receipt of such a request, Schering-Plough Las Piedras must promptly submit a copy of the requested plan (or a portion thereof) to EQB and EPA. EQB or EPA must request Schering-Plough Las Piedras submit a particular startup, shutdown, or

malfunction 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. Schering-Plough Las Piedras may elect to submit the required copy of any startup, shutdown, and malfunction plan to EQB and EPA in an electronic format. If Schering-Plough Las Piedras claims that any portion of such a startup, shutdown, and malfunction plan is confidential business information entitled to protection from disclosure under section 114(c) 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)]

9. To satisfy the requirements of section 63.6 to develop a startup, shutdown, and malfunction plan, Schering-Plough Las Piedras 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 section 63.6 and are made available for inspection when requested by EQB or EPA. [40 CFR §63.6(e)(3)(vi)]
10. According to 40 CFR §63.6(e)(3)(vii), and based on the results of a determination made under paragraph (e)(1)(i) of section 63.6, EQB or EPA may require that Schering-Plough Las Piedras make changes to the startup, shutdown, and malfunction plan for that source. EQB or EPA may require reasonable revisions to a startup, shutdown, and malfunction plan, if EQB or EPA finds that the plan:
 - a. Does not address a startup, shutdown, or malfunction event that has occurred;
 - b. Fails to provide for the operation of the source (including associated air pollution control and monitoring equipment) during a startup, shutdown, or malfunction event in a manner consistent with the general duty to minimize emissions established by paragraph (e)(1)(i) of section 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 startup, shutdown, or malfunction listed in Sec. 63.2.
11. Schering-Plough Las Piedras may periodically revise the startup, shutdown, and malfunction plan for the affected source as necessary to satisfy the requirements of part 63 or to reflect changes in equipment or procedures at the affected source. Unless EQB or EPA provides otherwise, Schering-Plough Las Piedras may make such revisions to the startup, shutdown, and malfunction plan without prior approval by EQB or EPA. However, each such revision to a startup, shutdown, and malfunction plan must be reported in the semiannual report required by

§63.10(d)(5). If the startup, shutdown, and malfunction plan fails to address or inadequately addresses an event that meets the characteristics of a malfunction but was not included in the startup, shutdown, and malfunction plan at the Schering-Plough Las Piedras developed the plan, Schering-Plough Las Piedras must revise the startup, shutdown, and malfunction 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 Schering-Plough Las Piedras makes any revision to the startup, shutdown, and malfunction plan which alters the scope of the activities at the source which are deemed to be a startup, shutdown, or malfunction, 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 Schering-Plough Las Piedras has provided a written notice describing the revision to EQB and EPA. [40 CFR §63.6(e)(3)(viii)]

12. This title V permit require that Schering-Plough Las Piedras adopt a startup, shutdown, and malfunction plan which conforms to the provisions of part 63, and that Schering-Plough Las Piedras operate and maintain the source in accordance with the procedures specified in the current startup, shutdown, and malfunction plan. However, any revisions made to the startup, shutdown, and malfunction 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 startup, shutdown, and malfunction 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)]

* 13. Compliance with nonopacity emission standards:

* a) Applicability. The non-opacity emission standards set forth in 40 CFR part 63 shall apply at all times except during periods of startup, shutdown, and malfunction, and as otherwise specified in an applicable subpart. If a startup, shutdown, or malfunction of one portion of an affected source does not affect the ability of particular emission points within other portions of the affected source to comply with the non-opacity emission standards set forth in 40 CFR part 63, then that emission point must still be required to comply with the non-opacity emission standards and other applicable requirements. [40 CFR §63.6(f)(1)]

* b) Methods for determining compliance:

* 1) The Administrator¹⁶ will determine compliance with nonopacity emission standards in 40 CFR part 63 based on the results of

¹⁶The Administrator is EQB and/or EPA.

performance tests conducted according to the procedures in §63.7, unless otherwise specified in an applicable subpart of 40 CFR part 63. [40 CFR §63.6(f)(1)(i)]

- * 2) The Administrator will determine compliance with nonopacity emission standards in 40 CFR part 63 by evaluation of Schering-Plough Las Piedras's conformance with operation and maintenance requirements, including the evaluation of monitoring data, as specified in §63.6(e), and applicable subparts of 40 CFR part 63. [40 CFR §63.6(f)(2)(ii)]
- * 3) According to 40 CFR §63.6(f)(2)(iii), if an affected source conducts performance testing at startup to obtain an operating permit in the State in which the source is located, the results of such testing may be used to demonstrate compliance with a relevant standard if the requirements from (A) to (D) of 40 CFR §63.6(f)(2)(iii) are met.
- * 4) The Administrator will determine compliance with design, equipment, work practice, or operational emission standards in 40 CFR part 63 by review of records, inspection of the source, and other procedures specified in applicable subparts of 40 CFR part 63. [40 CFR §63.6(f)(2)(iv)]
- * 5) The Administrator will determine compliance with design, equipment, work practice, or operational emission standards in 40 CFR part 63 by evaluation of Schering-Plough Las Piedras' conformance with operation and maintenance requirements, as specified in paragraph (e) of section 63.6 and applicable subparts of 40 CFR part 63. [40 CFR §63.6(f)(2)(v)]
- * 6) Finding of compliance. The Administrator will make a finding concerning an affected source's compliance with a non-opacity emission standard, as specified in paragraphs (f)(1) and (2) of §63.6, upon obtaining all the compliance information required by the relevant standard (including the written reports of performance test results, monitoring results, and other information, if applicable), and information available to the Administrator pursuant to paragraph (e)(1)(i) of section 63.6. [40 CFR §63.6(f)(3)]

Section VIII - National Emission Standards for the Pharmaceutical Industry

A. Applicability

1. Schering-Plough Las Piedras shall comply with the provisions of the Title 40 of the Code of Federal Regulations part 63 subpart A contained in Table 1 subpart GGG. [40 CFR §63.1250(c)]
2. Schering-Plough Las Piedras shall follow the procedures specified in paragraphs §63.1250(e)(1) through (5) to determine to which pharmaceutical manufacturing process unit (PMPU) a storage tank shall belong. If Schering-Plough Las Piedras produces only pharmaceutical products, the procedures specified in §63.1250(e)(1)-(5) are required only to determine applicability and demonstrate compliance with the pollution-prevention alternative specified in §63.1252(e), or to determine new source applicability for a PMPU dedicated to manufacturing a single product as specified in §63.1250(b). [40 CFR§63.1250(e)]
3. According to §63.1250(f), Schering-Plough Las Piedras must comply with the provisions of the National Emission Standards for Pharmaceutical Industry in 40 CFR part 63 subpart GGG no later than October 21, 2002.
4. Each provision 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 the startup, shutdown, and malfunction 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 Schering-Plough Las Piedras follows the provisions for periods of startup, shutdown, and malfunction, as specified in §§63.1259(a)(3) and 63.1260(i). [40 CFR §63.1250(g)(1)]
5. The provisions set forth in §63.1255 of subpart GGG shall apply at all times except during periods of nonoperation of the PMPU (or specific portion thereof) in which the lines are drained and depressurized resulting in the cessation of the emissions to which §63.1255 applies. [40 CFR §63.1250(g)(2)]
6. Schering-Plough Las Piedras 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 subpart GGG applicable to such items of equipment. This does not apply if the item of equipment is malfunctioning, or if Schering-Plough Las Piedras 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 subpart GGG do not apply pursuant to paragraphs (g)(1) through (3) of section 63.1250, shall implement, to the extent reasonably available, measures to prevent or minimize excess emissions to the extent practical. The measures to be taken shall be identified in the applicable startup, shutdown, and malfunction plan, and may include, but are not limited to, air pollution control technologies, work practices, pollution prevention, monitoring, and changes in the manner of operation of the source. Back-up control devices 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), an affected source subject to the provisions of subpart GGG that is also subject to the provisions of any other subpart of part 63 may elect to comply with either the provisions of subpart GGG or the provisions of another applicable subpart governing the maintenance of records and reporting to EPA. [40 CFR §63.1250(h)(1)(i)]
9. After the compliance dates specified in §63.1250(f), at an offsite reloading or cleaning facility subject to §63.1253(f), compliance with the emission standards and associated initial compliance, monitoring, recordkeeping, and reporting provisions of any other subpart of part 63 constitutes compliance with the provisions of §63.1253(f)(7) (ii) or (iii). [40 CFR §63.1250(h)(1)(ii)]
10. After the compliance dates specified in §63.1250(f), if any control device subject to subpart GGG is also subject to monitoring, recordkeeping, and reporting requirements in 40 CFR part 264, subpart AA, BB, or CC, or is subject to monitoring and recordkeeping requirements in 40 CFR part 265, subpart AA, BB, or CC, and Schering-Plough Las Piedras complies with the periodic reporting requirements under 40 CFR part 264, subpart AA, BB, or CC that would apply to the device if the facility had final-permitted status, Schering-Plough Las Piedras may elect to comply either with the monitoring, recordkeeping, and reporting requirements of subpart GGG, or with the monitoring, recordkeeping, and reporting requirements in 40 CFR 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 Schering-Plough Las Piedras elects to comply with the monitoring, recordkeeping, and reporting requirements in 40 CFR parts 264 and/or 265, Schering-Plough Las Piedras shall report all information required by §63.1260(g) and (i). Schering-Plough Las Piedras shall identify in the Notification of Compliance Status, required by §63.1260(f), the monitoring, recordkeeping, and reporting authority under which Schering-Plough Las Piedras 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. Schering-Plough Las Piedras shall identify in the Notification of Compliance Status, required by §63.1260(f), if Schering-Plough Las Piedras will comply with the recordkeeping and reporting authority under 40 CFR parts 264 and/or 265. [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 device in compliance with the provisions of 40 CFR 60.112b, subpart Kb must comply with the monitoring, 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 an affected wastewater stream that is also subject to provisions in 40 CFR parts 260 through 272 may elect to determine whether subpart GGG or 40 CFR parts 260 through 272 contain the more stringent control requirements, testing, monitoring, recordkeeping, and reporting. 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 pharmaceutical manufacturing process unit 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. Schering-Plough Las Piedras shall control HAP emissions to the level specified in section on and after the compliance dates specified in §63.1250(f). Initial compliance with the emission limits is demonstrated in accordance with the

provisions of §63.1257, and continuous compliance is 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 device used to comply with the requirements in sections 63.1253, 63.1254, and 63.1256 shall comply with the requirements of Table 4 of 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 device to the atmosphere; or [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 (c)(2) of section 63.1252, owners and operators of affected sources shall comply with the requirements in paragraph (c)(1) of this section for heat exchange systems that cool process equipment or materials used in pharmaceutical manufacturing operations. [40 CFR §63.1252(c)]
 - i. The heat exchange system shall be treated according to the provisions of §63.104, except that the monitoring frequency shall be no less than quarterly. [40 CFR §63.1252(c)(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 §63.1252(c)(2)]

- d. Except as specified in paragraphs (d)(1) through (5) of section 63.1252, owners or operators of storage tanks or processes subject to the provisions of sections 63.1253 and 63.1254 may choose to comply by using emissions averaging requirements specified in section 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% for those tanks meeting the criteria of §63.1253(a)(1) and 95% 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 Sec. 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 section 63.1252, an owner or operator 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 sections 63.1253, 63.1254, 63.1255, and 63.1256. [40 CFR §63.1252(e)]
- f. Schering-Plough Las Piedras 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 section 63.1252. [40 CFR §63.1252(f)]
- g. If a combustion device is used to comply with the provisions of sections 63.1253, 63.1254, 63.1256(h) for a halogenated vent stream, then the vent stream shall be ducted to a halogen reduction device such as, but not limited to, a scrubber, before it is discharged to the atmosphere. The halogen reduction device must reduce emissions by the amounts specified in either paragraph (g)(1) or (2) of section 63.1252. [40 CFR §63.1252(g)]

- i. A halogen reduction device after the combustion control device must reduce overall emissions of hydrogen halides and halogens, as defined in §63.1251, by 95% or to a concentration less than or equal to 20 ppmv. [40 CFR §63.1252(g)(1)]
- ii. A halogen reduction device located before the combustion control device 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. Process Vents EU-VOC-PM-MACT

1. Existing sources – Schering-Plough Las Piedras must comply with the requirements in paragraphs (a)(1) and (3) or paragraphs (a)(2) and (3) of section 63.1254 for each process. [40 CFR §63.1254]
2. New sources.
 - a. Except as provided in paragraph (b)(2) of section 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% or greater by weight or controlled in accordance with any of requirements of paragraphs (a)(1)(ii)(A) through (D) of section 63.1254. [40 CFR §63.1254(b)(1)]
 - b. The actual HAP emissions from the sum of all process vents for which Schering-Plough Las Piedras is not complying with paragraph (b)(1) of section 63.1254 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 section 63.1254 shall be reduced by 93% or greater by weight, or as specified in paragraph (a)(1)(ii) of section 63.1254. Notification of changes in the compliance method shall be reported according to the procedures in §63.1260(h). [40 CFR §63.1254(a)(1)(i)]
 - b. Any one or more vents within a process may be controlled in accordance with any of the following procedures (paragraphs (a)(1)(ii)(A) through (D));
 - i. 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;

- ii. By a flare that meets the requirements of §63.11(b);
- iii. By a control device specified in §63.1257(a)(4); or
- iv. In accordance with the alternative standard specified in paragraph (c) of section 63.1254. [40 CFR §63.1254(a)(1)(ii)]

4. Individual vent emission reduction requirements.

a. Grandfathering provisions. As an alternative to the requirements in paragraph (a)(3)(i) of section 63.1254, Schering-Plough Las Piedras may comply with the provisions in paragraph (a)(3)(ii)(A), (B), or (C) of section 63.1254, if applicable. [40 CFR §63.1254(a)(3)(ii)]

i. Control device operation. If Schering-Plough Las Piedras can demonstrate that a process vent is controlled by a control device meeting the criteria specified in paragraph (a)(3)(ii)(A)(1) of section 63.1254, then the control device is required to be operated according to paragraphs (a)(3)(ii)(A)(2), (3), and (4) of section 63.1254 as follows:

- 1) The control device was installed on any process vent that met the conditions of paragraph (a)(3)(i) of section 63.1254 on or before April 2, 1997, and was operated to reduce uncontrolled emissions of total HAP by greater than or equal to 93% by weight, but less than 98% by weight. [40 CFR §63.1254(a)(3)(ii)(A)(1)];
- 2) The device must be operated to reduce inlet emissions of total HAP by 93% or by the percent reduction specified for that control device in any preconstruction permit issued pursuant to regulations approved or promulgated through rulemaking under title I (including parts C or D) of the Clean Air Act, whichever is greater. [§63.1254(a)(3)(ii)(A)(2)]. According to construction permit PFE-44-0996-1032-I-II-C of October 9, 1996, the percent reduction specified for the adsorption system with four activate carbon beds CD-SRS1 is 97%.
- 3) The device must be replaced or upgraded to achieve at least 98% reduction of HAP or meet any of the conditions specified in paragraphs (a)(1)(ii)(A) through (D) of section 63.1254 upon reconstruction or replacement. [40 CFR §63.1254(a)(3)(ii)(A)(3)]

- 4) The device must be replaced or upgraded to achieve at least 98% reduction of HAP or meet any of the conditions specified in paragraphs (a)(1)(ii)(A) through (D) of section 63.1254 by April 2, 2007, or 15 years after issuance of the preconstruction permit, whichever is later. [40 CFR §63.1254(a)(3)(ii)(A)(4)]
5. *Alternative Standard – (To comply with the standard of this section Schering-Plough Las Piedras may use one of the following alternatives).*
 - a. Schering-Plough Las Piedras may route vents from a process to a combustion control device 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. [40 CFR §63.1254(c)]
 - b. Schering-Plough Las Piedras may route emissions to a noncombustion control device that must achieve 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 §63.1254(c)]

D. Standards: Equipment Leaks (EU-FUG-MACT)

1. General Equipment Leak Requirements.
 - a. The provisions of 40 CFR §63.1255 apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems required by 40 CFR part 63, subpart GGG that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year within a 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 both this section and either of the 40 CFR part 60 or part 61, will 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 section 63.1255. [40 CFR §63.1255(a)(4)]

- d. Lines and equipment not containing process fluids are not subject to the provisions of section 63.1255. Utilities, and other nonprocess 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 section 63.1255 do not apply to bench-scale¹⁷ 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 section 63.1255 applies shall be identified such that it can be distinguished readily from equipment that is not subject to this section. 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 section 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 section 63.1255 if it is identified as required in paragraph (g)(9) of section 63.1255. [40 CFR §63.1255(a)(9)]
- i. Pursuant to 40 CFR §63.1255(a)(10), when each leak is detected by visual, audible, or olfactory means, or by monitoring as described in Sec. 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.

¹⁷ 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]

- ii. The identification on a valve in light liquid or gas/vapor service may be removed after it has been monitored as specified in paragraph (e)(7)(iii) of section 63.1255, and no leak has been detected during the follow-up monitoring.
 - 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 section 63.1255, all terms in this 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, Schering-Plough Las Piedras 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 section 63.1255.
 - ii. Time periods specified in this subpart GGG for completion of required tasks may be changed by mutual agreement between Schering-Plough Las Piedras and EQB and EPA, as specified in subpart A of this part. 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 section 63.1255, where the period specified for compliance is a standard calendar period, if the initial compliance date does not coincide with the beginning of the calendar period, compliance shall be required according to the schedule specified in paragraph (a)(11)(iii)(A) or (B) of section 63.1255, as appropriate.
 - 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 this subpart GGG requires completion of a task during each of multiple successive periods, an owner or operator may perform the required task at any time during each period, provided the task is conducted at a reasonable interval after completion of the task during the previous period.
- k. In all cases where the provisions of this subpart GGG require an owner or operator to repair leaks by a specified time after the leak is detected, it is a violation of section 63.1255 to fail to take action to repair the leaks within the specified time. If action is taken to repair the leaks within the specified time, failure of that action to successfully repair the leak is not a violation of section 63.1255. However, if the repairs are unsuccessful, a leak is detected and the owner or operator shall take further action as required by applicable provisions of section 63.1255. [40 CFR §63.1255(a)(12)]

2. References.

- a. The owner or operator of a source subject to section 63.1255 shall comply with the provisions of subpart H of part 63, as specified in paragraphs (b)(2) through (4) of section 63.1255. The term "process unit" as used in subpart H of part 63 shall be considered to be defined the same as "group of processes" for sources subject to this subpart GGG. The term "fuel gas system," as used in subpart H of part 63, shall not apply for the purposes of this 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 this subpart GGG. Schering-Plough Las Piedras shall comply with the provisions specified in paragraphs (b)(2)(i) through (viii) of section 63.1255. [40 CFR §63.1255(b)(2)]
 - i. Sections 63.160 and 63.162 shall not apply; instead, Schering-Plough Las Piedras shall comply with paragraph (a) of section 63.1255;
 - ii. Section 63.161 shall not apply; instead, Schering-Plough Las Piedras shall comply with Sec. 63.1251;
 - iii. Sections 63.163 and 63.173 shall not apply; instead, Schering-Plough Las Piedras shall comply with paragraph (c) of section 63.1255;

- iv. Section 63.167 shall not apply; instead, Schering-Plough Las Piedras shall comply with paragraph (d) of section 63.1255;
 - v. Section 63.168 shall not apply; instead Schering-Plough Las Piedras with paragraph (e) of section 63.1255;
 - vi. Section 63.170 shall not apply; instead, Schering-Plough Las Piedras shall comply with Sec. 63.1254;
 - vii. Section 63.181 shall not apply; instead, Schering-Plough Las Piedras shall comply with paragraph (g) of section 63.1255; and
 - viii. Section 63.182 shall not apply; instead Schering-Plough Las Piedras shall comply with paragraph (h) of section 63.1255.
- c. Schering-Plough Las Piedras shall comply with sections 63.164, 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, the references shall mean the sections specified in paragraphs (b)(2) and (4) of section 63.1255. Section 63.164 applies to compressors. Section 63.165 applies to pressure relief devices in gas/vapor service. Section 63.166 applies to sampling connection systems. Section 63.169 applies to pumps, valves, connectors, and agitators in heavy liquid service; instrumentation systems; and pressure relief devices 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. Schering-Plough Las Piedras 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 section 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.
 - b) Schering-Plough Las Piedras 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.

- ii. Section 63.172 shall apply for closed-vent systems used to comply with section 63.1255, and for control devices used to comply with section 63.1255 only, except:
 - a) Section 63.172(k) and (l) shall not apply. The owner or operator shall instead comply with paragraph (f) of section 63.1255. [40 CFR §63.1255(b)(4)(ii)(A)]
 - a) b) Schering-Plough Las Piedras 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 gage or other pressure measurement device 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 device is operating. [40 CFR §63.1255(b)(4)(ii)(B)]
 - c) The requirements apply at all times, except as specified in §63.1250(g). Schering-Plough Las Piedras 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), Schering-Plough Las Piedras shall comply with paragraph (f) of section 63.1255. Section 63.174(b)(3) shall not apply. Instead of §63.174(b)(3), Schering-Plough Las Piedras shall comply with paragraphs (b)(4)(iii)(B) through (F) of section 63.1255. [40 CFR §63.1255(b)(4)(iii)(A)]
 - b) If the percent leaking connectors in a group of processes was greater than or equal to 0.5% during the initial monitoring period, monitoring shall be performed once per year until the percent leaking connectors is less than 0.5%. [40 CFR §63.1255(b)(4)(iii)(B)]
 - c) If the percent leaking connectors in the group of processes was less than 0.5%, but equal to or greater than 0.25%, during the initial or last required monitoring period, Schering-Plough Las Piedras may elect to monitor once

every 4 years. An owner or operator may comply with the requirements of paragraph (b)(4)(iii)(C) of section 63.1255 by monitoring at least 40% of the connectors in the first 2 years and the remainder of the connectors within the next 2 years. The percent leaking connectors will be calculated for the total of all required monitoring performed during the 4-year period. [40 CFR §63.1255(b)(4)(iii)(C)]

- d) Except as provided in paragraph (b)(4)(iii)(B) of section 63.1255, if leaking connectors comprise at least 0.5% but less than 1.0% of the connectors during the last monitoring period, Schering-Plough Las Piedras 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, Schering-Plough Las Piedras 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, Schering-Plough Las Piedras shall monitor in accordance with paragraph (b)(4)(iii)(C) or (F) of section 63.1255, as appropriate. [40 CFR §63.1255(b)(4)(iii)(D)]
- e) If Schering-Plough Las Piedras determines that 1% or greater of the connectors in a group of processes are leaking, Schering-Plough Las Piedras shall monitor the connectors once per year. Schering-Plough Las Piedras may elect to use the provisions of paragraphs (b)(4)(iii)(C), (D) or (F) of section 63.1255, as appropriate, after a monitoring period in which less than 1% of the connectors are determined to be leaking. [40 CFR §63.1255(b)(4)(iii)(E)]
- f) Schering-Plough Las Piedras may elect to perform monitoring once every 8 years if the percent leaking connectors in the group of processes unit was less than 0.25% during the initial or last required monitoring period. Schering-Plough Las Piedras shall monitor at least 50% 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%, the monitoring program shall revert at that time to the appropriate monitoring frequency specified in paragraph (b)(4)(iii)(C), (D), or (E) of section 63.1255. [40 CFR §63.1255(b)(4)(iii)(F)]

- iv. Section 63.178 shall apply except:
 - a) Section 63.178(b), requirements for pressure testing, may be applied to all processes (not just batch processes) and to supply lines between storage and processing areas. [40 CFR §63.1255(b)(4)(iv)(A)]
 - b) For pumps, the phrase “at the frequencies specified in Table 1 of this subpart GGG” in §63.178(c)(3)(iii) shall mean “quarterly” for the purposes of this subpart GGG. [40 CFR §63.1255(b)(4)(iv)(B)]
 - v. Section 63.180 shall apply except Sec. 63.180(b)(4)(ii)(A) through (C) shall not apply. Instead calibration gases shall be a mixture of methane and air at a concentration of approximately, but less than, 10,000 parts per million (ppm) methane for agitators; 2,000 ppm for pumps; and 500 ppm for all other equipment, except as provided in section 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 section 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 this section apply to each pump that is in light organic HAP liquid service, and to each agitator in organic HAP gas/vapor service or in light organic HAP liquid service. [40 CFR §63.1255(c)(1)]
 - b. *Monitoring.* Each pump and agitator subject to section 63.1255 shall be monitored quarterly to detect leaks by the method specified in §63.180(b) except as provided in sections 63.177, 63.178, paragraph (f) of section 63.1255, and paragraphs (c)(5) through (9) of section 63.1255. [40 CFR §63.1255(c)(2)(i)]
 - c. *Leak definition.* According to 40 CFR §63.1255(c)(2)(ii), the instrument reading, as determined by the method as specified in Sec. 63.180(b), that defines a leak is:
 - i. For agitators, an instrument reading of 10,000 ppm or greater. [40 CFR §63.1255(c)(2)(ii)(A)]

- ii. For pumps, an instrument reading of 2,000 ppm or greater. [40 CFR §63.1255(c)(2)(ii)(B)]
- d. *Visual Inspections.* According to 40 CFR §63.1255(c)(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, Schering-Plough Las Piedras shall follow the procedure specified in either paragraph (c)(2)(iii)(A) or (B) of section 63.1255 prior to the next weekly inspection.
 - i. Schering-Plough Las Piedras shall monitor the pump or agitator by the method specified in 68.180(b). If the instrument reading indicates a leak as specified in paragraph (c)(2)(ii) of section 63.1255, a leak is detected. [40 CFR §63.1255(c)(2)(iii)(A)]
 - ii. Schering-Plough Las Piedras shall eliminate the visual indications of liquids dripping. [40 CFR §63.1255(c)(2)(iii)(B)]
- e. *Repair provisions.*
 - i. When a leak is detected pursuant to paragraph (c)(2)(i), (c)(2)(iii)(A), (c)(5)(iv)(A), or (c)(5)(vi)(B) of section 63.1255, it shall be repaired as soon as practicable, but not later than 15 calendar days after it is detected, except as provided in paragraph (b)(4)(i) of section 63.1255. [40 CFR §63.1255(c)(3)(i)]
 - ii. According to 40 CFR §63.1255(c)(3)(ii), a first attempt at repair shall be made no later than 5 calendar days after the leak is detected. First attempts at repair include, but are not limited to, the following practices where practicable:
 - a) Tightening of packing gland nuts.
 - b) Ensuring that the seal flush is operating at design pressure and temperature.
- f. *Calculation of percent leakers.*
 - i. Schering-Plough Las Piedras shall decide no later than the end of the first monitoring period what groups of processes will be developed. Once Schering-Plough Las Piedras has decided, all subsequent percent calculations shall be made on the same basis. [40 CFR §63.1255(c)(4)(i)]

- ii. If, calculated on a 1-year rolling average, the greater of either 10% or three of the pumps in a group of processes leak, Schering-Plough Las Piedras shall monitor each pump once per month, until the calculated 1-year rolling average value drops below 10% or three pumps, as applicable. [40 CFR §63.1255(c)(4)(ii)]
- iii. The number of pumps in a group of processes shall be the sum of all the pumps in organic HAP service, except that pumps found leaking in a continuous process within 1 quarter after startup of the pump shall not count in the percent leaking pumps calculation for that one monitoring period only. [40 CFR §63.1255(c)(4)(iii)]
- iv. According to 40 CFR §63.1255(c)(4)(iv), percent leaking pumps shall be determined by the following Equation:

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

Where:

$\%P_L$ = percent leaking pumps

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

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

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

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

- 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 device that complies with the requirements of paragraph (b)(4)(ii) of section 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, Schering-Plough Las Piedras shall follow the procedures specified in either paragraph (c)(5)(iv)(A) or (B) of section 63.1255 prior to the next required inspection. [40 CFR §63.1255(c)(5)(iv)]
 - a) Schering-Plough Las Piedras shall monitor the pump or agitator using the method specified in §63.180(b) to determine if there is a leak of organic HAP in the barrier fluid. If the instrument reading indicates a leak, as specified in paragraph (c)(2)(ii) of section 63.1255, a leak is detected. [40 CFR §63.1255(c)(5)(iv)(A)]
 - b) Schering-Plough Las Piedras shall eliminate the visual indications of liquids dripping. [40 CFR §63.1255(c)(5)(iv)(B)]
- v. Each sensor as described in paragraph (c)(5)(iii) of section 63.1255 is observed daily or is equipped with an alarm unless the pump is located within the boundary of an unmanned plant site. [40 CFR §63.1255(c)(5)(v)]
- vi. Schering-Plough Las Piedras determines, based on design considerations and operating experience, criteria applicable to the presence and frequency of drips and to the sensor that indicate failure of the seal system, the barrier fluid system, or both. [40 CFR §63.1255(c)(5)(vi)(A)]
- vii. If indications of liquids dripping from the pump/agitator seal exceed the criteria established in paragraph (c)(5)(vi)(A) of section 63.1255, or if, based on the criteria established in paragraph (c)(5)(vi)(A) of section 63.1255, the sensor indicates failure of the seal system, the barrier fluid system, or both, a leak is detected. [40 CFR §63.1255(c)(5)(vi)(B)]

- viii. When a leak is detected pursuant to paragraph (c)(5)(iv)(A) or (B) of section 63.1255, the leak must be repaired as specified on paragraph (c)(3) of section 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 (c)(1) through (3) of section 63.1255. [40 CFR §63.1255(c)(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 device that complies with the requirements of paragraph (b)(4)(ii) of section 63.1255 is exempt from the requirements of paragraphs (c)(2) through (5) of section 63.1255. [40 CFR §63.1255(c)(7)]
 - 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 (c)(2)(iii) and (c)(5)(iv) of section 63.1255, and the daily requirements of paragraph (c)(5)(v) of section 63.1255, provided that each pump/agitator is visually inspected as often as practicable and at least monthly. [40 CFR §63.1255(c)(8)]
 - k. If more than 90% of the pumps in a group of processes meet the criteria in either paragraph (c)(5) or (6) of section 63.1255, the group of processes is exempt from the requirements of paragraph (c)(4) of section 63.1255. [40 CFR §63.1255(c)(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 Sec. 63.177 and paragraphs (d)(4) through (6) of section 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 section 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 section 63.1255. [40 CFR §63.1255(d)(4)]
- f. Open-ended valves or lines containing materials which would autocatalytically polymerize are exempt from the requirements of paragraphs (d)(1) through (d)(3) of section 63.1255. [40 CFR §63.1255(d)(5)]
- 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 section 63.1255 are exempt from the requirements of paragraphs (d)(1) through (d)(3) of section 63.1255. [40 CFR §63.1255(d)(6)]

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

- a. The provisions of this section 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 section 63.1255 shall be monitored, except as provided in paragraph (f) of section 63.1255 and in Sec. 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 section 63.1255 shall monitor all valves, except as provided in paragraph (f) of section 63.1255 and in Sec. 63.177, at the intervals specified in paragraph (e)(4) of section 63.1255 and shall comply with all other provisions of section 63.1255, except as provided in paragraph (b)(4)(ii) of section 63.1255, sections 63.178 and 63.179.
 - i. The valves shall be monitored to detect leaks by the method specified in Sec. 63.180(b).
 - ii. An instrument reading of 500 ppm 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 section 63.1255, Schering-Plough Las Piedras shall monitor valves for leaks at the intervals specified below:
- i. For a group of processes with 2% or greater leaking valves, calculated according to paragraph (e)(6) of section 63.1255, Schering-Plough Las Piedras shall monitor each valve once per month, except as specified in paragraph (e)(9) of section 63.1255.
 - ii. For a group of processes with less than 2% leaking valves, Schering-Plough Las Piedras shall monitor each valve once each quarter, except as provided in paragraphs (e)(4)(iii) through (e)(4)(v) of section 63.1255.
 - iii. For a group of processes with less than 1% leaking valves, Schering-Plough Las Piedras may elect to monitor each valve once every 2 quarters.
 - iv. For a group of processes with less than 0.5% leaking valves, Schering-Plough Las Piedras may elect to monitor each valve once every 4 quarters.
 - v. For a group of processes with less than 0.25% leaking valves, Schering-Plough Las Piedras 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 this subpart GGG applies, Schering-Plough Las Piedras may choose to subdivide the valves in the applicable group of processes and apply the provisions of paragraph (e)(4) of section 63.1255 to each subgroup. If Schering-Plough Las Piedras elects to subdivide the valves in the applicable group of processes, then the provisions of paragraphs (e)(5)(i) through (e)(5)(viii) of section 63.1255 apply.
- i. The overall performance of total valves in the applicable group of processes must be less than 2% leaking valves, as detected according to paragraphs (e)(3) (i) and (ii) of section 63.1255 and as calculated according to paragraphs (e)(6) (ii) and (iii) of section 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 section 63.1255.

- a) Schering-Plough Las Piedras 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 group of valves can be reassigned from a less frequently monitored subgroup to a more frequently monitored subgroup provided that the valves to be reassigned were monitored during the most recent monitoring period for the less frequently monitored subgroup. The monitoring results must be included with the less frequently monitored subgroup's monitoring event and associated next percent leaking valves calculation for that group.
 - c) Any valve or group of valves can be reassigned from a more frequently monitored subgroup to a less frequently monitored subgroup provided that the valves to be reassigned have not leaked for the period of the less frequently monitored subgroup (e.g., for the last 12 months, if the valve or group of valves is to be reassigned to a subgroup being monitored annually). Nonrepairable valves may not be reassigned to a less frequently monitored subgroup.
- iii. Schering-Plough Las Piedras shall determine every 6 months if the overall performance of total valves in the applicable group of processes is less than 2% leaking valves and so indicate the performance in the next periodic report. If the overall performance of total valves in the applicable group of processes is 2% leaking valves or greater, Schering-Plough Las Piedras shall revert to the program required in paragraphs (e)(2) through (e)(4) of section 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
process or group of processes

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

V_i = number of valves in subgroup i

n = number of subgroups

- iv. *Records.* In addition to records required by paragraph (g) of this section, the owner or operator shall maintain records specified in paragraphs (e)(5)(iv)(A) through (D) of this section.
 - 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 section 63.1255.

- v. Schering-Plough Las Piedras shall notify EQB and EPA no later than 30 days prior to the beginning of the next monitoring period of the decision to subgroup valves. The notification shall identify the participating processes and the valves assigned to each subgroup.

- vi. *Semiannual reports.* In addition to the information required by paragraph (h)(3) of section 63.1255, Schering-Plough Las Piedras shall submit in the periodic reports the information specified in paragraphs (e)(5)(vi)(A) and (B) of section 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 section 63.1255.
- vii. To determine the monitoring frequency for each subgroup, the calculation procedures of paragraph (e)(6)(iii) of section 63.1255 shall be used.
- viii. Except for the overall performance calculations required by paragraphs (e)(5)(i) and (e)(5)(iii) of section 63.1255, each subgroup shall be treated as if it were a process for the purposes of applying the provisions of section 63.1255.
- f. Schering-Plough Las Piedras shall decide no later than the implementation date of subpart GGG or upon revision of the operating permit how to group the processes. Once Schering-Plough Las Piedras 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), 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 this section.

V_L = number of valves found leaking excluding nonrepairables as provided in paragraph (e)(6)(iv)(A) of this section

V_T = total valves monitored, in a monitoring period excluding valves monitored as required by (e)(7)(iii) of this section

- 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. Nonrepairable valves shall be included in the calculation of percent leaking valves the first time the valve is identified as leaking and nonrepairable and as required to comply with paragraph (e)(6)(iv)(B) of section 63.1255. Otherwise, a number of nonrepairable valves (identified and included in the percent leaking calculation in a previous period) up to a maximum of 1% 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 nonrepairable valves exceeds 1 percent of the total number of valves in organic HAP service at a process, the number of nonrepairable 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 section 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 “repaired¹⁸” and “first attempt at repair¹⁹.” [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.

¹⁸ Repaired means that equipment is adjusted, or otherwise altered, to eliminate a 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 emissions from the equipment are below the applicable leak definition. [40 CFR §63.1251]

¹⁹ 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]

- b) Periodic monitoring required by paragraphs (e)(2) through (4) of section 63.1255 may be used to satisfy the requirements of paragraph (e)(7)(iii) of section 63.1255, if the timing of the monitoring period coincides with the time specified in paragraph (e)(7)(iii) of section 63.1255. Alternatively, other monitoring may be performed to satisfy the requirements of paragraph (e)(7)(iii) of section 63.1255, regardless of whether the timing of the monitoring period for periodic monitoring coincides with the time specified in paragraph (e)(7)(iii) of section 63.1255.
 - c) If a leak is detected by monitoring that is conducted pursuant to paragraph (e)(7)(iii) of section 63.1255, Schering-Plough Las Piedras shall follow the provisions of paragraphs (e)(7)(iii)(C)(1) and (2) of section 63.1255 to determine whether that valve must be counted as a leaking valve for purposes of paragraph (e)(6) of section 63.1255.
 - 1) If Schering-Plough Las Piedras elects to use periodic monitoring required by paragraphs (e)(2) through (4) of section 63.1255 to satisfy the requirements of paragraph (e)(7)(iii) of section 63.1255, then the valve shall be counted as a leaking valve.
 - 2) If Schering-Plough Las Piedras elects to use other monitoring prior to the periodic monitoring required by paragraphs (e)(2) through (4) of section 63.1255 to satisfy the requirements of paragraph (e)(7)(iii) of section 63.1255, then the valve shall be counted as a leaking valve unless it is repaired and shown by periodic monitoring not to be leaking.
1. 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 section 63.1255. Instead, Schering-Plough Las Piedras shall monitor each valve in organic HAP service for leaks once each quarter, or comply with paragraph (e)(4)(iii), (iv) or (v) of section 63.1255, except as provided in paragraph (f) of section 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, unsafe to inspect, difficult to monitor, difficult to inspect, or inaccessible is exempt from the monitoring requirements as specified in paragraphs (f)(1)(i) through (iv) of section 63.1255 provided Schering-Plough Las Piedras meets the requirements specified in paragraph (f)(2), (3), or (4) of section 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 section 63.1255 do not apply.
 - ii. For valves, paragraphs (e)(2) through (7) of section 63.1255 do not apply.
 - iii. For connectors, §63.174(b) through (e) and paragraphs (b)(4)(iii)(B) through (F) of section 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 Schering-Plough Las Piedras determines that monitoring personnel would be exposed to an immediate danger as a consequence of complying with the monitoring requirements referred to in paragraphs (f)(1)(i) through (iii) of section 63.1255. [40 CFR §63.1255(f)(2)(i)]
 - ii. Any part of a closed-vent system may be designated as unsafe to inspect if the owner or operator determines that monitoring personnel would be exposed to an immediate danger as a consequence of complying with the monitoring requirements

referred to in paragraph (f)(1)(iv) of section 63.1255. [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, Schering-Plough Las Piedras 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 Schering-Plough Las Piedras 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 Schering-Plough Las Piedras determines that the equipment cannot be inspected without elevating the monitoring personnel more than 2 meters above a support surface, or it is not accessible in a safe manner when it is in organic HAP service. [40 CFR §63.1255(f)(3)(ii)]
- iii. At an existing source, any valve, agitator or pump within a group of processes that meets the criteria of paragraph (f)(3)(i) of section 63.1255 may be designated as difficult to monitor, and any parts of a closed-vent system that meet the requirements of paragraph (f)(3)(ii) section 63.1255 may be designated as difficult to inspect. At a new affected source, Schering-Plough Las Piedras may designate no more than 3% 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, Schering-Plough Las Piedras 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 equipment by a monitor probe;
 - c) Obstructed by equipment or piping that prevents access to the connector by a monitor probe;
 - d) Unable to be reached from a wheeled scissor-lift or hydraulic-type scaffold which would allow access to equipment up to 7.6 meters (25 feet) above the ground; or
 - e) Not able to be accessed at any time in a safe manner to perform monitoring. Unsafe access includes, but is not limited to, the use of a wheeled scissor-lift on unstable or uneven terrain, the use of a motorized man-lift basket in areas where an ignition potential exists, or access would require near proximity to hazards such as electrical lines, or would risk damage to equipment.
- ii. A connector may be designated as inaccessible if it would require elevating the monitoring personnel more than 2 meters above a permanent support surface or would require the erection of scaffold. [40 CFR §63.1255(f)(4)(ii)]
- iii. At an existing source, any connector that meets the criteria of paragraph (f)(4)(i) or (ii) of section 63.1255 may be designated as inaccessible. At a new affected source, Schering-Plough Las Piedras may designate no more than 3% of connectors as inaccessible. [40 CFR §63.1255(f)(4)(iii)]
- iv. If any inaccessible, ceramic, or ceramic-lined connector is observed by visual, audible, olfactory, or other means to be leaking, the leak shall be repaired as soon as practicable, but no

later than 15 calendar days after the leak is detected, except as provided in paragraph (b)(4)(i) of section 63.1255. [40 CFR §63.1255(f)(4)(iv)]

- v. Any connector that is inaccessible or that is ceramic or ceramic-lined is exempt from the recordkeeping and reporting requirements of paragraphs (g) and (h) of section 63.1255. [40 CFR §63.1255(f)(4)(v)]

2. *Recordkeeping Requirements.*

- a. An owner or operator of more than one group of processes subject to the provisions of section 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 section 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 section 63.1255 and in paragraph (a)(9) of section 63.1255, the following information pertaining to all equipment subject to the requirements in section 63.1255 shall be recorded:
 - i. A list of identification numbers for equipment (except connectors that are subject to paragraph (f)(4) of section 63.1255) subject to the requirements of section 63.1255. Except for equipment subject to the recordkeeping requirements in paragraphs (g)(2)(ii) through (viii) of section 63.1255, equipment need not be individually identified if, for a particular type of equipment, all items of that equipment in a designated area or length of pipe subject to the provisions of section 63.1255 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.

- 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 section 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 section 63.1255 may be identified on a plant site plan, in log entries, or by other appropriate methods. [40 CFR §63.1255(g)(2)(i)(C)]
- iv. A list of identification numbers for equipment that Schering-Plough Las Piedras elects to equip with a closed-vent system and control device, under the provisions of paragraph (c)(7) of section 63.1255, §63.164(h), or §63.165(c). [40 CFR §63.1255(g)(2)(ii)(A)]
- v. A list of identification numbers for compressors that the owner or operator elects to designate as operating with an instrument reading of less than 500 ppm above background, under the provisions of §63.164(i). [40 CFR §63.1255(g)(2)(ii)(B)]
- vi. A list of identification numbers for pressure relief devices subject to the provisions in §63.165(a). [40 CFR §63.1255(g)(2)(iii)(A)]
- vii. A list of identification numbers for pressure relief devices equipped with rupture disks, under the provisions of §63.165(d). [40 CFR §63.1255(g)(2)(iii)(B)]
- viii. Identification of instrumentation systems subject to the provisions of section 63.1255. Individual components in an instrumentation system need not be identified. [40 CFR §63.1255(g)(2)(iv)]
- ix. 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 (c)(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.
- x. A list of equipment designated as unsafe to monitor/inspect or difficult to monitor/inspect under paragraph (f) of section 63.1255

and a copy of the plan for monitoring or inspecting this equipment.
[40 CFR §63.1255(g)(2)(vi)]

- xi. A list of connectors removed from and added to the process, 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 are expected to be used. [40 CFR §63.1255(g)(2)(vii)]
 - xii. For equipment that Schering-Plough Las Piedras elects to monitor as provided under §63.178(c), a list of equipment added to batch product processes since the last monitoring period required in sections 63.178(c)(3)(ii) and (iii). This list must be completed for each type of equipment within 90 calendar days, or by the next Periodic Report, following the end of the monitoring period for the type of equipment monitored, whichever is later. Also, if Schering-Plough Las Piedras elects to adjust monitoring frequency by the time in use, as provided in §63.178(c)(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 section 63.1255 are required. Examples of suitable documentation are records of time in use for individual pieces of equipment or average time in use for the process unit. [40 CFR §63.1255(g)(2)(viii)]
- c. *Records of visual inspections.* For visual inspections of equipment subject to the provisions of paragraphs (c)(2)(iii) and (c)(5)(iv) of section 63.1255, Schering-Plough Las Piedras shall document that the inspection was conducted and the date of the inspection. Schering-Plough Las Piedras shall maintain records as specified in paragraph (g)(4) of section 63.1255 for leaking equipment identified in this inspection, except as provided in paragraph (g)(5) of section 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 (c) of section 63.1255 and section 63.164, paragraph (e) of section 63.1255 and section 63.169, and sections 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 nonrepairable.
- 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) Schering-Plough Las Piedras may 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 section 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 unrepaired.
- vii. If the alternative in §63.174(c)(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 §63.174(c)(1)(i) and (c)(2)(ii). If identification of disturbed connectors is made by location, then all connectors within the designated location shall be monitored.
- ix. The date and results of the monitoring required in §63.178(c)(3)(i) for equipment added to a batch process since the last monitoring period required in sections 63.178(c)(3)(ii) and (iii). If no leaking equipment is found in this monitoring, Schering-Plough Las

Piedras 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 section 63.1255, if records are not maintained on a computerized data base capable of generating summary reports from the records.

- e. *Records of pressure tests.* According to 40 CFR §63.1255(g)(5), the owner or operator who elects to pressure test a process equipment train or supply lines between storage and processing areas to demonstrate compliance with this section is exempt from the requirements of paragraphs (g)(2), (3), (4), and (6) of section 63.1255. Instead, the owner or operator shall maintain records of the following information:
 - i. The identification of each product, or product code, produced during the calendar year. It is not necessary to identify individual items of equipment in the process equipment train.
 - ii. Physical tagging of the equipment to identify that it is in organic HAP service and subject to the provisions of section 63.1255 is not required. Equipment in a process subject to the provisions of this section may be identified on a plant site plan, in log entries, or by other appropriate methods.
 - iii. The dates of each pressure test required in section 63.178(b), the test pressure, and the pressure drop observed during the test.
 - iv. Records of any visible, audible, or olfactory evidence of fluid loss.
 - v. When a process equipment train does not pass two consecutive pressure tests, the following information shall be recorded in a log and kept for 2 years:
 - a) The date of each pressure test and the date of each leak repair attempt.
 - b) Repair methods applied in each attempt to repair the leak.
 - c) The reason for the delay of repair.
 - d) The expected date for delivery of the replacement equipment and the actual date of delivery of the replacement equipment.
 - e) The date of successful repair.

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

- g. *Records for closed-vent systems.* According to el 40 CFR §63.1255(g)(7), Schering-Plough Las Piedras shall maintain records of the information specified in paragraphs (g)(7)(i) through (iii) of section 63.1255 for closed-vent systems and control devices subject to the provisions of paragraph (b)(4)(ii) of section 63.1255. The records specified in paragraph (g)(7)(i) of section 63.1255 shall be retained for the life of the equipment. The records specified in paragraphs (g)(7)(ii) and (g)(7)(iii) of section 63.1255 shall be retained for 2 years.
 - i. The design specifications and performance demonstrations specified in paragraphs (g)(7)(i)(A) through (g)(7)(i)(D) of section 63.1255.
 - a) Detailed schematics, design specifications of the control device, and piping and instrumentation diagrams.
 - b) The dates and descriptions of any changes in the design specifications.
 - c) The flare design (i.e., steam assisted, air assisted, or nonassisted) and the results of the compliance demonstration required by §63.11(b).
 - d) A description of the parameter or parameters monitored, as required in paragraph (b)(4)(ii) of section 63.1255, to ensure that control devices are operated and maintained in conformance with their design and an explanation of why that parameter (or parameters) was selected for the monitoring.
 - ii. Records of operation of closed-vent systems and control devices.

- a) Dates and durations when the closed-vent systems and control devices required in paragraph (c) of section 63.1255 and sections 63.164 through 63.166 are not operated as designed as indicated by the monitored parameters, including periods when a flare pilot light system does not have a flame.
 - b) Dates and durations during which the monitoring system or monitoring device is inoperative.
 - c) Dates and durations of startups and shutdowns of control devices required in paragraph (c)(7) of section 63.1255 and sections 63.164 through 63.166.
- iii. Records of inspections of closed-vent systems subject to the provisions of §63.172.
 - a) For each inspection conducted in accordance with the provisions of section 63.172(f)(1) or (f)(2) during which no leaks were detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected.
 - b) For each inspection conducted in accordance with the provisions of section 63.172(f)(1) or (f)(2) during which leaks were detected, the information specified in paragraph (g)(4) of section 63.1255 shall be recorded.
- h. *Records for components in heavy liquid service.* Information, data, and analysis used to determine that a piece of equipment or process is in heavy liquid service shall be recorded. Such a determination shall include an analysis or demonstration that the process fluids do not meet the criteria of “in light liquid or gas service.” Examples of information that could document this include, but are not limited to, records of chemicals purchased for the process, analyses of process stream composition, engineering calculations, or process knowledge. [40 CFR §63.1255(g)(8)]
- i. *Records of exempt components.* Identification, either by list, location (area or group) of equipment in organic HAP service less than 300 hours per year subject to the provisions of section 63.1255. [40 CFR §63.1255(g)(9)]
- j. *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 section 63.179 shall maintain the following records:

- i. Identification of the process(es) and the organic HAP they handle.
- ii. A schematic of the process, enclosure, and closed-vent system.
- iii. A description of the system used to create a negative pressure in the enclosure to ensure that all emissions are routed to the control device.

3. *Reporting Requirements.*

- a. According to 40 CFR §63.1255(h)(1), each owner or operator of a source subject to section 63.1255 shall submit the reports listed in paragraphs (h)(1)(i) through (ii) of section 63.1255.
 - i. A Notification of Compliance Status Report described in paragraph (h)(2) of section 63.1255,
 - ii. Periodic Reports described in paragraph (h)(3) of section 63.1255, and
- b. *Notification of compliance status report.* According to 40 CFR §63.1255(h)(2), each owner or operator of a source subject to section 63.1255 shall submit the information specified in paragraphs (h)(2)(i) through (iii) of section 63.1255 in the Notification of Compliance Status Report described in section 63.1260(f).
 - i. The notification shall provide the information listed in paragraphs (h)(2)(i)(A) through (C) of section 63.1255 for each process subject to the requirements of paragraphs (b) through (g) of section 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 section 63.1255 for each process subject to

the requirements of paragraph (b)(4)(iv) of section 63.1255 and section 63.178(b).

- a) Products or product codes subject to the provisions of this section, and
 - b) Planned schedule for pressure testing when equipment is configured for production of products subject to the provisions of this section.
- iii. The notification shall provide the information listed in paragraphs (h)(2)(iii)(A) and (B) of section 63.1255 for each process subject to the requirements in section 63.179.
- a) Process identification.
 - b) A description of the system used to create a negative pressure in the enclosure and the control device used to comply with the requirements of paragraph (b)(4)(ii) of section 63.1255.
- iv. Any change in the information submitted under paragraph (h) of section 63.1255 shall be provided to the EQB and EPA as a part of subsequent Periodic Reports. Section 63.9(j) shall not apply to the Notification of Compliance Status Report described in this paragraph (h)(2).
- c. *Periodic reports.* According to 40 CFR §63.1255(h)(3), the owner or operator of a source subject to section 63.1255 shall submit Periodic Reports.
- i. A report containing the information in paragraphs (h)(3)(ii), (h)(3)(iii), and (h)(3)(iv) of section 63.1255 shall be submitted semiannually. The first report shall be submitted no later than 240 days after the Notification of Compliance Status Report is due and shall cover the 6-month period beginning on the date the Notification of Compliance Status Report is due. Each subsequent report shall cover the 6-month period following the preceding period.
 - ii. For equipment complying with the provisions of paragraphs (b) through (g) of section 63.1255, except paragraph (b)(4)(iv) of §63.1255 and §63.179, the summary information listed in paragraphs (h)(3)(ii)(A) through (L) of section 63.1255 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 section 63.1255, the percent leakers, and the total number of valves monitored;
- b) The number of valves for which leaks were not repaired as required in paragraph (e)(7) of section 63.1255, identifying the number of those that are determined nonrepairable;
- c) Separately, the number of pumps and agitators for which leaks were detected as described in paragraph (c)(2) of section 63.1255, the total number of pumps and agitators monitored, and, for the percent leakers;
- d) Separately, the number of pumps and agitators for which leaks were not repaired as required in paragraph (c)(3) of section 63.1255;
- e) The number of compressors for which leaks were detected as described in §63.164(f);
- f) The number of compressors for which leaks were not repaired as required in §63.164(g);
- g) 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;
- h) The number of connectors for which leaks were not repaired as required in §63.174(d), identifying the number of those that are determined nonrepairable;
- i) The facts that explain any delay of repairs and, where appropriate, why a process shutdown was technically infeasible.
- j) The results of all monitoring to show compliance with sections 63.164(i), 63.165(a), and 63.172(f) conducted within the semiannual reporting period.
- k) If applicable, the initiation of a monthly monitoring program under either paragraph (c)(4)(ii) or paragraph (e)(4)(i) of section 63.1255.

- l) If applicable, notification of a change in connector monitoring alternatives as described in §63.174(c)(1).
- iii. For owners or operators electing to meet the requirements of §63.178(b), the report shall include the information listed in paragraphs (h)(3)(iii)(A) through (E) of paragraph (h)(iii) of section 63.1255 for each process.
 - a) Product process equipment train identification;
 - b) The number of pressure tests conducted;
 - c) The number of pressure tests where the equipment train failed either the retest or two consecutive pressure tests;
 - d) The facts that explain any delay of repairs; and;
 - e) The results of all monitoring to determine compliance with §63.172(f) of subpart H.
- iv. Any revisions to items reported in earlier Notification of Compliance Status Report, if the method of compliance has changed since the last report.

9. *Monitoring Requirements*

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

10. *Reporting Requirements*

- a. *Reports of LDAR programs.* According to section 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. The owner or operator of an affected source subject to the provisions of this part shall maintain files of all information (including all reports and notifications) required by this part

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)]

E. Test Methods

1. Except as specified in paragraph (a)(5) of section 63.1257, the procedures specified in paragraphs (c), (d), (e), and (f) of section 63.1257 are required to demonstrate initial compliance with sections 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 section 63.1257. The provisions in paragraph (a)(5) of this section are used to demonstrate initial compliance with the alternative standards specified in sections 63.1253(d) and 63.1254(c). The provisions in paragraph (a)(6) of this section are used to comply with the outlet concentration requirements specified in sections 63.1253(c), 63.1254 (a)(2)(i) and (a)(3)(ii)(B), 63.1254(b)(i) and 63.1256(h)(2). [40 CFR §63.1257(a)]
2. To demonstrate that a control device meets the required control efficiency, a design evaluation must address the composition and organic HAP concentration of the vent stream entering the control device. A design evaluation also must address other vent stream characteristics and control device operating parameters as specified in any one of paragraphs (a)(1) (i) through (vi) of section 63.1257, depending on the type of control device that is used. If the vent stream is not the only inlet to the control device, the efficiency demonstration also must consider all other vapors, gases, and liquids, other than fuels, received by the control device. [40 CFR §63.1257(a)(1)]
3. An owner or operator using any control device specified in paragraphs (a)(4)(i) through (iv) of section 63.1257 is exempt from the initial compliance provisions in paragraphs (c), (d), and (e) of section 63.1257. [40 CFR §63.1257(a)(4)]
4. Schering-Plough Las Piedras shall use the test methods specified in paragraphs (b)(1) through (10) of section 63.1257 when testing is conducted to measure emissions from an affected source. [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 section 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 section 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)]

F. 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 section 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 device 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 section 63.1258, for each control device, Schering-Plough Las Piedras shall install and operate monitoring devices and operate within the established parameter levels to ensure continued compliance with the standard. Monitoring parameters are specified for control scenarios in Table 4 of subpart GGG and in paragraphs (b)(1)(ii) through (xi) of section 63.1258 and in the following paragraphs:
 - a. For control devices that control vent streams totaling less than 1 ton/yr HAP emissions, before control, monitoring shall consist of a daily verification that the device is operating properly. If the control device 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 section 63.1258. [40 CFR §63.1258(b)(1)(i)]
 - b. Regenerative carbon adsorbers – For the regenerative carbon adsorber CDSRS1, Schering-Plough Las Piedras shall comply with the provisions in paragraphs (b)(1)(iv)(A) through (F) of section 63.1258 [40 CFR §63.1258(b)(1)(iv)];
 - i. Schering-Plough Las Piedras shall establish the regeneration cycle characteristics of unit CDSRS1 under worst-case conditions, as defined in §63.1257(b)(8)(i) and specified as follows [40 CFR §63.1258(b)(1)(iv)(A)]:

- a) Minimum regeneration frequency (i.e., operating time since last regeneration). According to the manufacturer specifications²⁰ this frequency is established as 41 minutes between regenerations operating four glatts simultaneously.
 - a) Minimum temperature to which the bed is heated during regeneration. Schering-Plough Las Piedras established²¹ the minimum temperature at 185°F.
 - b) Maximum temperature to which the bed is cooled, measured within 15 minutes of completing the cooling phase. Schering-Plough Las Piedras established¹⁴ the maximum temperature at 157.2°F.
 - c) Minimum regeneration stream flow. Schering-Plough Las Piedras established¹⁴ this flow at 10,000 pounds per hour.
- ii. Schering-Plough Las Piedras shall prepare and maintain a record of the regeneration cycle characteristics of unit CDSRS1 specified in paragraphs (b)(1)(iv)(B)(1) through (4) of section 63.1258 for each regeneration cycle as specified in condition 2.b.i.a) through d) as follows [40 CFR §63.1258(b)(1)(iv)(B)];
- a) Regeneration frequency (operating time since end of last regeneration);
 - b) Temperature to which the bed is heated during regeneration;
 - c) Temperature to which the bed is cooled, measured within 15 minutes of the completion of the cooling phase; and
 - d) Regeneration stream flow.
- iii. Schering-Plough Las Piedras shall provide a temperature indicator to monitor the temperature in unit CDSRS1. This temperature indicator shall be accurate to within $\pm 2\%$ of the temperature measured in degrees Celsius or $\pm 2.5^\circ\text{C}$, whichever is greater. [40 CFR §63.1258(b)(1)(iv)(C)]
- iv. Schering-Plough Las Piedras shall provide a flow meter to monitor the regeneration flow in unit CDSRS1 capable of recording the

²⁰ Vendor Data for Carbon Adsorption System, Barnebey & Sutcliffe Corporation of March 15, 1999.

²¹ Notification of Compliance Status Report, March 2003.

total regeneration stream flow to within $\pm 10\%$ of the established value (i.e., accurate to within $\pm 10\%$ of the reading). [40 CFR §63.1258(b)(1)(iv)(D)]

- v. The temperature and flow monitoring devices of unit CDSRS1 shall be calibrated annually (every 12 months) and Schering-Plough Las Piedras shall keep the records and documents of calibrations available at any time at the facility for inspection of EQB personnel. [40 CFR §63.1258(b)(1)(iv)(E)]
 - vi. Schering-Plough Las Piedras shall perform an annual check to the carbon bed of unit CDSRS1 for bed poisoning in accordance with manufacturer's specifications. Schering-Plough Las Piedras shall keep the records and documents of calibrations available at any time at the facility for inspection of EQB personnel. [40 CFR §63.1258(b)(1)(iv)(F)]
- c. *Continuous emission monitor* – As an alternative to the parameters specified in paragraphs (b)(1)(ii) through (ix) of section 63.1258, Schering-Plough Las Piedras may monitor and record the outlet HAP concentration or both the outlet TOC concentration and outlet hydrogen halide and halogen concentration every 15 minutes during the period in which the control device is functioning in achieving the HAP removal required by subpart GGG. The HAP or TOC monitor must meet the requirements of Performance Specification 8 or 9 of appendix B of part 60 and must be installed, calibrated, and maintained, according to §63.8. As part of the QA/QC Plan, calibration of the device must include, at a minimum, quarterly cylinder gas audits. [40 CFR §63.1258(b)(1)(x)]
- d. *CVS visual inspections* - Schering-Plough Las Piedras shall perform monthly visual inspections of each closed vent system as specified in §63.1252(b). [40 CFR §63.1258(b)(1)(xi)]
3. Averaging periods for parametric monitoring levels shall be established according to paragraphs (b)(2)(i) through (iii) of section 63.1258. [40 CFR §63.1258(b)(2)]
4. *Procedures for setting parameter levels for control devices used to control emissions.*
- a. *Small control devices* - Except as provided in paragraph (b)(1)(i) of section 63.1258, for devices 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 monitoring 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 devices* - For devices 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. Schering-Plough Las Piedras may establish the parametric monitoring 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 the level indicates proper operation of the control device shall be provided in the Precompliance report. [40 CFR §63.1258(b)(3)(ii)(C)]

- c. *Parameters for control devices controlling batch process vents.* For devices controlling batch process vents alone or in combination with other streams, the parameter level(s) shall be established in accordance with the following paragraphs:
 - i. If more than one batch emission episode has been selected to be controlled, a single level for the batch process(es) shall be determined from the initial compliance demonstration. [40 CFR §63.1258(b)(3)(iii)(A)]
 - ii. Instead of establishing a single level for the batch process(es), as described in paragraph (b)(3)(iii)(A) of section 63.1258, Schering-Plough Las Piedras may establish separate levels for each batch emission episode, selected to be controlled. If separate monitoring levels are established, Schering-Plough Las Piedras must provide a record indicating at what point in the daily schedule or log of processes required to be recorded per the requirements of §63.1259(b)(9) the parameter being monitored changes levels and must record at least one reading of the new parameter level, even if

the duration of monitoring for the new parameter is less than 15-minutes. [40 CFR §63.1258(b)(3)(iii)(B)]

5. Schering-Plough Las Piedras may request approval to monitor parameters other than those required by paragraphs (b)(1)(ii) through (ix) of section 63.1258. The request shall be submitted according to the procedures specified in §63.8(f) or included in the Precompliance report. [40 CFR §63.1258(b)(4)]
6. *Monitoring for the alternative standards.*
 - a. For control devices that are used to comply with the provisions of §63.1253(d) or 63.1254(c), Schering-Plough Las Piedras shall monitor and record the outlet TOC concentration and the outlet hydrogen halide and halogen concentration every 15 minutes during the period in which the device is functioning in achieving the HAP removal required by this subpart using CEMS as specified in paragraphs (b)(5)(i)(A) through (D) of section 63.1258. [40 CFR §63.1258(b)(5)(i)]
 - b. An owner or operator complying with the alternative standard using control devices in which supplemental gases are added to the vents or manifolds must either correct for supplemental gases as specified in §63.1257(a)(3) or comply with the requirements of paragraph (b)(5)(ii)(A) or (B) of section 63.1258. If Schering-Plough Las Piedras corrects for supplemental gases as specified in §63.1257(a)(3)(ii) for noncombustion control devices, the flow rates must be evaluated as specified in paragraph (b)(5)(ii)(C) of section 63.1258. [40 CFR §63.1258(b)(5)(ii)]
7. The owner or operator of any affected source complying with the provisions of §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), Schering-Plough Las Piedras must calculate controlled emissions assuming the HAP emissions are reduced by 93%. For any owner or operator opting to switch compliance strategy from the 93% 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)]
8. The owner or operator of any affected source complying with the requirements of §63.1255 of subpart GGG shall meet the monitoring requirements described §63.1255 of subpart GGG. [40 CFR §63.1258(d)]
9. 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)]

10. 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 this section, as applicable, for all processes and storage tanks included in the emissions average. [40 CFR §63.1258(f)]
11. Inspection and monitoring of waste management units and treatment processes.
 - a. For each wastewater tank, surface impoundment, container, individual drain system, and oil-water separator that receives, manages, or treats wastewater, a residual removed from wastewater, a recycled wastewater, or a recycled residual removed from wastewater, the owner or operator shall comply with the inspection requirements specified in Table 7 of subpart. [40 CFR §63.1258(g)(1)]
12. Leak inspection provisions for vapor suppression equipment.
 - a. Except as provided in paragraph (h)(9) and (10) of section 63.1258, for each vapor collection system, closed-vent system, fixed roof, cover, or enclosure required to comply with this section, Schering-Plough Las Piedras shall comply with the requirements of paragraphs (h)(2) through (8) of section 63.1258. [40 CFR §63.1258(h)(1)]
 - b. Schering-Plough Las Piedras shall comply with the provisions of section 63.1255 and is exempt from the requirements of section 63.1258 if a closed-vent system subject to section 63.1258 is also subject to the equipment leak provisions of section 63.1255. [40 CFR §63.1258(h)(9)]
 - c. Instead of complying with the provisions of paragraphs (h)(2) through (8) of section 63.1258, Schering-Plough Las Piedras 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 device 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 device is operating. [40 CFR §63.1258(h)(10)]

G. Recordkeeping Requirements

1. Schering-Plough Las Piedras 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 section 63.1259. [40 CFR §63.1259(a)]

2. Schering-Plough Las Piedras must keep the records specified in paragraphs (b)(1) through (13) of section 63.1259 up-to-date and readily accessible. [40 CFR §63.1259(b)]
3. Schering-Plough Las Piedras shall keep records of each operating scenario which demonstrates compliance with subpart GGG. [40 CFR §63.1259(c)]
4. The owner or operator of any affected source implementing the LDAR program specified in §63.1255 of subpart GGG, shall implement the recordkeeping requirements in §63.1255 of subpart GGG. [40 CFR §63.1259(d)]
5. The owner or operator of any affected source 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. Schering-Plough Las Piedras shall keep records specified in paragraphs (i)(1) through (9) of section 63.1259 as applicable. [40 CFR §63.1259(i)].

H. Reporting Requirements

1. Schering-Plough Las Piedras shall comply with the following reporting requirements. Applicable reporting requirements of §63.9 and 63.10 are also summarized in Table 1 of subpart GGG. [40 CFR §63.1260(a)]
2. Schering-Plough Las Piedras 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 EQB and 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 EQB or EPA to conduct a performance evaluation for a continuous monitoring system shall notify EQB and EPA of the date of the performance evaluation as specified in §63.8(e)(2). [40 CFR §63.1260(d)]
5. For new sources, the Precompliance report shall be submitted to EQB and EPA with the application for approval of construction or reconstruction. If the request is denied, Schering-Plough Las Piedras must still be in compliance with the standard by the compliance date. To change any of the information submitted in the report, Schering-Plough Las Piedras shall notify EQB and EPA 90 days before

the planned change is to be implemented. The Precompliance report shall include: [40 CFR §63.1260(e)]

- a. Requests for approval to use alternative monitoring parameters or requests to set monitoring 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 control devices subject to §63.1258(b)(1)(i) are operating as designed. [40 CFR §63.1260(e)(2)]
 - c. A description of test conditions, and the corresponding monitoring 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)(C). [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 monitoring devices, monitoring frequencies, and the values of monitored 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 devices. [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. Schering-Plough Las Piedras shall prepare Periodic reports in accordance with the following and submit them to EQB and EPA:
- a. Except as provided in paragraphs (g)(1)(i), (ii), and (iii) of section 63.1260, Schering-Plough Las Piedras 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 EQB or 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 monitored according to the provisions of §63.1258(b)(1)(iii) or an exceedance of the outlet concentration monitored according to the provisions of §63.1258(b)(1)(x) or (b)(5). Once an affected source reports quarterly, the affected source shall follow a quarterly reporting format until a request to reduce reporting frequency is approved. If an owner or operator submits a request to reduce the frequency of reporting, the provisions in §63.10(e)(3)(ii) and (iii) shall apply, except that the phrase "excess emissions and continuous monitoring system performance report and/or summary report" shall mean "Periodic report" for the purposes of section 63.1260. [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.* Schering-Plough Las Piedras shall include the following information, 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 monitoring 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% or greater of the total operating time for the reporting period, or the total continuous monitoring system downtime for the reporting period is 5% or greater of the total operating time for the reporting period, the Periodic report must include the following information:
 - a) Monitoring data, including 15-minute monitoring values as well as daily average values of monitored 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)]
 - b) Duration of excursions, as defined in §63.1258(b)(7). [40 CFR §63.1260(g)(2)(ii)(B)]
 - c) 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)(C)]
 - d) When a continuous monitoring system is used, the information required in §63.10(c)(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 device 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 section 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)]
 - c) No excursions. [40 CFR §63.1260(g)(2)(v)(C)]
 - d) No continuous monitoring system has been inoperative, out of control, repaired, or adjusted. [40 CFR §63.1260(g)(2)(v)(D)]
- vi. The information specified in paragraphs (g)(2)(vi)(A) through (C) of section 63.1260 for periods of planned routine maintenance. [40 CFR §63.1260(g)(2)(vi)]
- vii. Each new operating scenario which has been operated since the time period covered by the last Periodic report. For each new operating scenario, Schering-Plough Las Piedras shall provide verification that the operating conditions for any associated control or treatment device 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)]
- viii. If Schering-Plough Las Piedras elects to comply with the provisions of §63.1253(b) or (c) by installing a floating roof, Schering-Plough Las Piedras 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. Schering-Plough Las Piedras shall submit the information specified in paragraphs (h)(1)(i) through (iv) of section 63.1260 with the next Periodic report required under §63.1260(g) whenever a process change is made, or a change in any of the information submitted in the Notification of Compliance Status Report, except as specified in paragraph (h)(2) of section 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 section 63.1260. [40 CFR §63.1260(h)(1)(iii)]
 - iv. Information required by the Notification of Compliance Status Report under paragraph (f) of section 63.1260 for changes involving the addition of processes or equipment. [40 CFR §63.1260(h)(1)(iv)]
 - b. Schering-Plough Las Piedras 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 Precompliance report.
 - ii. A change in the status of a control device from small to large.
9. Reports of startup, shutdown, and malfunction. Schering-Plough Las Piedras shall prepare startup, shutdown, and malfunction reports as specified in paragraphs (i)(1) and (2) of section 63.1260 as follows:
 - a. If actions taken by Schering-Plough Las Piedras during a startup, shutdown, or malfunction of an affected source (including actions to correct a malfunction) are consistent with the procedures specified in the source's startup, shutdown, and malfunction plan, Schering-Plough Las Piedras shall state this fact in a startup, shutdown, or malfunction 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 startup, shutdown, and malfunction

reports shall be submitted on the same schedule as the periodic reports required under paragraph (g) of section 63.1260 instead of the schedule specified in §63.10(d)(5)(i). Reports are only required if a startup, shutdown, or malfunction occurred during the reporting period. [40 CFR §63.1260(i)(1)]

- b. Any time Schering-Plough Las Piedras takes an action that is not consistent with the procedures specified in the affected source's startup, shutdown, and malfunction plan, Schering-Plough Las Piedras shall submit immediate startup, shutdown, and malfunction 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 §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 sections 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. Schering-Plough Las Piedras shall notify EQB and EPA of the planned date of a performance test at least 60 days before the test in accordance with §63.7(b). Schering-Plough Las Piedras 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. Schering-Plough Las Piedras may submit to EQB and EPA a request for an extension of compliance in accordance with §63.1250(f)(4). [40 CFR §63.1260(m)]

Section IX - Insignificant Emission Units

The following activities will be considered insignificant as long as Schering-Plough Las Piedras complies with the descriptions indicated below.

Emission Unit ID	Capacity	Description (Basis for exemption)
Two storm water storage tanks	45,000 gal	Appendix B.3.i.(A) of the RCAP
Two fire pump water storage tank	250,000 gal	
One domestic potable water tank	100,000 gal	
Compressed air/distillates of air		Appendix B.3.i.(A) of the RCAP
Office activities		Appendix B.3.ii. (A) and (D) of the RCAP
Maintenance activities		Appendix B.3.1.(B), (E), (H), (I) and B.3.xviii of the RCAP
Bathroom and locker room ventilation and maintenance		Appendix B.3.ii.(C) of the RCAP
First aid or emergency medical care		Appendix B.3.ii.(F) of the RCAP
Laundry operations that service uniforms or other clothing used at the facility (uniforms storage room)		Appendix B.3.ii.(G) of the RCAP
Food preparation to service facility cafeterias and dining rooms		Appendix B.3.ii.(J) of the RCAP

Emission Unit ID	Capacity	Description (Basis for exemption)
Water treatment equipment, including sewers and sewer manholes if the VOC concentration is <3,500 ppb by weight.		Appendix B.3.ii.(L) of the RCAP. (Estimated 0.91 tpy of VOC using USEPA WATER8 Program)
Methylene chloride rework tank	5,000 gal	Appendix B.3.ii.(N) of the RCAP - Tanks with storage capacity of less than 10,000 gallons.
Methanol tank	5,000 gal	
Methylene chloride QC tank	7,000 gal	
Two fire pumps	230 hp	Appendix B.2. of the RCAP
Research trials that will last for 30 days or less, prior a 15 days notice and which will result in VOC emissions of less than 3 pounds per hour (3 lbs/hr) or 15 pounds per day (15 lbs/day).		Appendix B.3.ix. of the RCAP
Training activities to respond to fire, explosions, required under the contingency plan and safety and involves the use and combustion of fuels and chemicals as part of the training.		Appendix B.3.xvi. of the RCAP
Safety devices (rupture discs for gas handling systems, <i>safety valves</i>)		Appendix B.3.xix.; xxxxi of the RCAP
Air contaminant and test equipment		Appendix B.3.xx. of the RCAP

Emission Unit ID	Capacity	Description (Basis for exemption)
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
Air compressors and pumps		Appendix B.3.xxiii. of the RCAP
Non-routine clean out of tanks and equipment for the purpose of worker entry or in preparation for maintenance or decommissioning.		Appendix B.3.xxvi. of the RCAP
Sampling connections and systems used exclusively to withdraw materials for testing and analysis including air contaminant detectors and vent lines.		Appendix B.3.xxvii. of the RCAP
Solvent storage cabinet (containers covered)		Appendix B.3.xxviii. of the RCAP
Cooling ponds		Appendix B.3.xxix. of the RCAP
Equipment for steam cleaning or brushing dust off equipment		Appendix B.3.xxx. of the RCAP
Process raw water treatment (e.g. phosphate)		Appendix B.3.xxxii. of the RCAP
Water-cooling tower except for systems including contact process water or water treatment with chromium-based chemicals.		Appendix B.3.xxxiii. of the RCAP
Spill collection tanks		Appendix B.3.xxxiv. of the RCAP

Emission Unit ID	Capacity	Description (Basis for exemption)
Steam vents and leaks from boilers and steam distribution systems		Appendix B.3.xxxxv. of the RCAP
Boiler water treatment operations except those involving use of hydrazide.		Appendix B.3.xxxxvi. of the RCAP
Herbicide mixing and application activities not involving herbicide manufacture		Appendix B.3.xxxxvii. of the RCAP
Portable or mobile containers		Appendix B.3.xxxxviii. of the RCAP
Vents or stacks for sewer lines or enclosed areas required for safety or by code		Appendix B.3.xxxx. of the RCAP
Pump seals		Appendix B.3.xxxxix. of the RCAP
Storage of substances in closed drums, barrels, or bottles		Appendix B.3.xxxxiv. of the RCAP
Refrigeration systems		Appendix B.3.xxxxv. of the RCAP
Distillate fuel oil No.2 storage tanks	30,000 gal	Rule 206(F)(3) and Appendix B.3.ii.(P) of the RCAP
	200,000 gal	
	500 gal	
Pressurized storage tank		
Accelacotta coating machine area connected to the 4,000 CFM dust collectors (efficiency of 99.8%)		Appendix B.3.ii.(P) of the RCAP

Section X - Permit Shield

As specified under Rule 603(D) of the RCAP, compliance with the conditions of the permit shall be deemed compliance with any applicable requirement as of the date of permit issuance, but only if such applicable requirement is included and specifically identified in the permit. Moreover, Schering-Plough Las Piedras shall be deemed in compliance with any other requirement specifically identified in the permit as **Non Applicable**. Moreover, according to 40 CFR §63.6(e)(3)(ix) none of the procedures specified by the startup, shutdown, and malfunction plan for an affected source shall be deemed to fall within the permit shield provision in section 504(f) of the Act.

(1) Non Applicable Requirements

Non applicable requirements		
State	Federal	Reason
---	Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) (40 CFR part 60, subpart Kb)	See Section VIII, Part (2) of the Permit
---	Standards of Performance of Small Industrial-Commercial-Institutional Steam Generating Units (40 CFR part 60, subpart Dc)	See Section VIII, Part (2) of the Permit

(2) Reasons for Non Applicability

Coding for Non Applicability	
Code	Reason
40 CFR part 60, subpart Kb	It is not applicable for vessels with capacities greater than or equal to 151 m ³ storing a liquid with a maximum true vapor pressure less than 3.5 kPa or with a capacity greater than or equal to 75 m ³ but less than 151 m ³ storing a liquid with a maximum true vapor pressure less than 15 kPa.
40 CFR part 60, subpart Dc	It is not applicable for steam generating units (boilers) constructed before June 9, 1989.

Section XI - Permit Approval

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

In San Juan, Puerto Rico, **February 6, 2006.**

ENVIRONMENTAL QUALITY BOARD

/s/

Julio I. Rodríguez Colón
Alternate Member

/s/

Carlos W. López-Freytes
President

APPENDIXES

Appendix I - Definitions and Abbreviations

A. Definitions:

1. Act – Clean Air Act, as amended, 42 U.S. 7401, et seq.
2. Responsible Official- see definition of responsible official, as established in the EQB Regulation for the Control of Atmospheric Pollution, (1995).
3. Regulations – Regulations for the Control of Atmospheric Pollution of the Environmental Quality Board.
4. Permittee – person or establishment to whom EQB has issued an operating permit for an emission source covered by Title V.
5. Title V – Title V of the Federal Clean Air Act (42 U.S.C. 7661).

B. Abbreviations

ASTM	American Society for Testing and Materials
Btu	British thermal unit
CEMS	Continuous Emission Monitoring Systems
CFR	Code of Federal Regulations
CGMP	Current Good Manufacturing Practices
CMS	Continuous Monitoring Systems
CO	Carbon Monoxide
CVS	Closed Vent System
EPA	Environmental Protection Agency
EQB	Environmental Quality Board
GPH	Gallons per hour
HAP	Hazardous Atmospheric Pollutants
LSFO	Low Sulfur Fuel Oil
MACT	Maximum Available Control Technology

Mg	Milligrams
NAAQS	National Ambient Air Quality Standards
NESHAP	National Emission Standards for Hazardous Air Pollutants
NO _x	Nitrogen oxides
NSPS	New Source Performance Standards
OSHA	Occupational Safety & Health Administration
P2	Pollution Prevention
PM	Particulate Matter
PMPU	Pharmaceutical Manufacturing Process Unit
PM ₁₀	Particulate matter with a size less than or equal to 10 micrometers in aerodynamic mass median diameter
QA/QC	Quality Assurance/ Quality Control
RCAP	Regulation for the Control of Atmospheric Pollution of the Environmental Quality Board
SIC	Standard Industrial Classification
SOP	Standard Operating Procedures
SO ₂	Sulfur dioxide
TOC	Total Organic Compounds
VOC	Volatile Organic Compounds

C. Notification Addresses

Compliance Notifications and Permit Modifications

Environmental Quality Board
 Air Quality Area
 P.O. Box 11488
 Santurce, PR 00910

Appendix II – Combustion Devices Description

Source	Power (hp)	Consumption Rate (gph)	Hours of Operation (hours/year)	Sulfur percent by weight in diesel
EPBO1	300	*90.0	*Global consumption limit of 3,153,600 gallons per year.	0.5
EPBO2	300	*90.0		0.5
EPBO3	300	*90.0		0.5
EPBO4	300	*90.0		0.5
EPBO5	300	*90.0		0.5
EUCO1	21.02 MMBtu/hr	70	8,760	0.5
EPGEN1	1500	82.2	*Global consumption limit of 958,074 gallons per year.	0.5
EPGEN2	1500	82.2		0.5
EPGEN3	1500	70.0		0.5
EPGEN4	2682	141.0		
Fire pump 1	230	14	500	0.5
Fire pump 2	230	14	500	0.5

Appendix III – Emission Sources with Fuel Input Capacities that exceeds 8 MMBtu/hr

Source	Stack	Capacity (MMBtu/hr)	Stack Coordinates (km)		Permitted % S	Parameters	
			X	Y		High (feet)	Exit Temperature (°F)
*Three Boilers (EPBO1, EPBO2 and EPBO5)	1	12.73 each (300 hp)	211.049	39.072	0.5	45	450
Catalytic Oxidizer	2	21.02	211.046	39.112	0.5	41	500
*Two Boilers (EPBO3 and EPBO4)	3	12.73 each	211.071	29.072	0.5	45	450

Appendix IV – Control Devices Description

Emission Point	Control Device ID	Controlled Pollutant	Control Device				Basis of Estimate ²²
			Type	Manufacturer/ Model	Efficiency (%)		
					Design	Actual	
EU-VOC-PM-MACT	CDSRS1	VOC, HAP	Activated carbon adsorber	Barnebey & Sutcliffe	97	>93	A
EPCOAT1	CDCBA1	VOC, HAP	Activated carbon adsorber	MET-PRO	90	>80	B
EU-PM-VOC-NON-MACT	CDCO1	VOC, HAP	Catalytic Oxidizer	MET-PRO	97	>90	B
EPGL1	CDDC1	PM, PM ₁₀	Filter	Torit	99.8	>95	B
EPGL2	CDDC2	PM, PM ₁₀	Filter	Torit	99.8	>95	B
EPGL3	CDDC3	PM, PM ₁₀	Filter	Torit	99.8	>95	B
EPGRAN1	CDDC4	PM, PM ₁₀	Filter	Torit	99.8	>95	B
EPMFG1, MFG2, MFG3, MFG8	CDDC5	PM, PM ₁₀	Filter	Torit	99.8	>95	B
EMFG4, EMFG5	CDDC6	PM, PM ₁₀	Filter	Torit	99.8	>95	B
EPCOAT1	CDDC7	PM, PM ₁₀	Filter	Torit	99.8	>95	B

²² Basis of Estimate

A Stack Test

B Manufacturer Specifications

Emission Point	Control Device ID	Controlled Pollutant	Control Device				Basis of Estimate ²²
			Type	Manufacturer/Model	Efficiency (%)		
					Design	Actual	
EPMFG6	CDDC8	PM, PM ₁₀	Filter	Torit	99.8	>95	B
EPGRAN2	CDDC9	PM, PM ₁₀	Filter	Torit	99.8	>95	B
EPGL4	CDDC10	PM, PM ₁₀	Filter	Torit	99.8	>95	B
EPMFG7	CDDC11	PM, PM ₁₀	Filter	Torit	99.8	>95	B
Insignificant	CDDC12	PM, PM ₁₀	Filter	Torit	99.8	>95	B
EPGL5	CDDC13	PM, PM ₁₀	Filter	Torit	99.8	>95	B
EPGL6	CDDC14	PM, PM ₁₀	Filter	Torit	99.8	>95	B
EPGL7	CDDC15	PM, PM ₁₀	Filter	Torit	99.8	>95	B
EPGL8	CDDC16	PM, PM ₁₀	Filter	Torit	99.8	>95	B
Insignificant	CDDC17	PM, PM ₁₀	Filter	Torit	99.8	>95	B
Insignificant	CDDC18	PM, PM ₁₀	Filter	Torit	99.8	>95	B
Insignificant	CDDC19	PM, PM ₁₀	Filter	Torit	99.8	>95	B
EPGL9	CDDC20	PM, PM ₁₀	Filter	Torit	99.8	>95	B
Insignificant	CDDC21	PM, PM ₁₀	Filter	Torit	99.8	>95	B
Insignificant	CDDC22	PM, PM ₁₀	Filter	Torit	99.8	>95	B