



## PART 70 PERMIT TO OPERATE

Under the authority of RSMo 643 and the Federal Clean Air Act the applicant is authorized to operate the air contaminant source(s) described below, in accordance with the laws, rules, and conditions set forth here in.

**Operating Permit Number:** OP2008-021  
**Expiration Date:** APR 22 2013  
**Installation ID:** 007-0040  
**Project Number:** 0080-0040-010

**Installation Name and Address**

Teva Pharmaceuticals USA Inc.  
5000 Snyder Drive  
Mexico, MO 65265  
Audrain County

**Parent Company's Name and Address**

Teva Pharmaceuticals USA, Inc.  
650 Cathill Road  
Sellersville, PA 18960

**Installation Description:**

Teva Pharmaceuticals USA operates a chemical manufacturing facility in Mexico, Missouri that produces derivatives of penicillin and pharmaceutical intermediates for both internal plant use and sale to other users. Emissions from the facility are primarily from the production of Amoxicillin Trihydrate, and Cephalexin USP. Teva Pharmaceuticals is a major source of volatile organic compounds (VOCs) and a source for hazardous air pollutants (HAPs); toluene, methanol, methylene chloride, and hydrogen chloride.

APR 21 2008

Effective Date

  
Director or Designee  
Department of Natural Resources

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# I. Installation Description and Equipment Listing

## INSTALLATION DESCRIPTION

Teva Pharmaceuticals USA operates a chemical manufacturing facility in Mexico, Missouri that produces derivatives of penicillin and pharmaceutical intermediates for both internal plant use and sale to other users. The primary products of this facility are Amoxicillin and Cephalexin. Dicloxacillin is also produced on a sporadic basis using the same equipment used for Amoxicillin production. Additional products Cefadroxil and Cefprozil are being manufactured in the same process equipment (600 process) as Cephalexin. Teva Pharmaceuticals is a major source of VOCs and a major source for HAPs; toluene, methanol, methylene chloride, and hydrogen chloride.

Reported Air Pollutant Emissions, tons per year							
Year	Particulate Matter ≤ Ten Microns (PM-10)	Sulfur Oxides (SO <sub>x</sub> )	Nitrogen Oxides (NO <sub>x</sub> )	Volatile Organic Compounds (VOC)	Carbon Monoxide (CO)	Lead (Pb)	Hazardous Air Pollutants (HAPs)
2006	0.30	0.02	3.69	19.52	0.47	--	3.48
2005	0.35	0.03	4.41	13.48	0.57	--	7.74
2004	0.40	0.03	5.30	23.96	4.45	--	3.36
2003	0.43	0.03	5.59	71.54	4.70	--	7.47
2002	0.83	0.15	6.57	113.85	3.62	--	3.91

## EMISSION UNITS WITH LIMITATIONS

The following list provides a description of the equipment at this installation that emits air pollutants and is identified as having unit-specific emission limitations.

Emission Unit #	Description of Emission Unit
EU 0010	2 – 8.4 MMBTU/hr boilers (Natural Gas & Fuel Oil #2)
EU 0020	18 MMBTU/hr boiler (Natural Gas & Fuel Oil #2)
EU 0030	Tank Farm Storage Tank - Methanol (24,000 gal) (EP T810)
EU 0040	14,000 gallon Methanol/Acetone Tank (EP T812)
EU 0050	Five (5) Tank Farm Storage Tanks Four (4) currently contain methanol (EP T815 – 20,000 gal, EP T823 - 20,000 gal, and EP T826 - 30,000 gal, and one Waste Methanol/Dimethylformamide (DMF) Storage Tank (EP T825 -30,000 gal.)). One (1) contains waste Methylene Chloride (EP T827 - 30,000 gal)
EU 0060	Cefalosporin Production (400 & 500 process)
EU 0070	600 Process Equipment – Cephalexin, Cefadroxil, Cefprozil
EU 0080	Methanol Distillation Column V-873 (EP-862M)
EU 0090	Toluene Distillation Column V-852 (EP-SRT)
EU 0100	Amoxicillin/Dicloxacillin Production (000/100 process) Equipment – includes two 12,000 gallon methylene chloride tanks (EP T008 and EP T010)
EU 0110	SSP Still (Methylene Chloride)
EU 0120	Waste Water Treatment Plant

## **EMISSION UNITS WITHOUT LIMITATIONS**

The following list provides a description of the equipment which does not have unit specific limitations at the time of permit issuance.

### Description of Emission Source

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244 HP Fire Water Pump (EP 1231)  
Waste Water Plant Space Heaters (EP 1400)  
Administration Building Space Heaters (EP 200)  
Cephalosporin Building Space Heaters (EP 500)  
Cephalexin Building Air Exhaust (EP CEPHB)  
Ceph G Building Air Exhaust (EP CEPHGB)  
Penicillin Building Air Exhaust (EP PENB)  
900HP @1800 rpm Emergency Electric Generator (EP G003)  
5,700 gallon Triethylamine Storage Tank (EP T030)  
5,040 gallon Fuel Oil Storage Tank – Installed 1990 (EP T1201)  
300 gallon Fuel Oil Storage Tank – Installed 1990 (EP T1202)  
300 gallon Fuel Oil Storage Tank – Installed 1990 (EP T1230)  
1000 gallon Fuel Oil Storage Tank – Installed 1992 (EP T1401)  
500 gallon Fuel Oil Day Tank – Installed 1990 (EP TG003)  
10,780 gallon HCl Storage Tank – Installed 1990 (EP T802)  
10,000 gallon Toluene Tank – Installed 1990 (EP T807)  
10,000 gallon Dimethylacetamide Tank – Installed 1990 (EP T808)  
10,000 gallon Methanol Tank (EP-T818)  
10,150 gallon HMDS Storage Tank – Installed 1990 (EP T819)  
10,000 gallon tank with Tank Farm Flexibility (Methylene Chloride)(EP T821)  
7,500 gallon Toluene Tank – Installed 1997 (EP T844)  
13,000 gallon Hexamethyldisiloxane (HMDS) Storage Tank. Year in place 1997 (EP T328 (2000))  
Bis (trimethylsilyl) oxide Storage Tank)  
20,000 Gallon Waste Sulfuric Acid Tank (EP T-1403 (2004))

## **DOCUMENTS INCORPORATED BY REFERENCE**

These documents have been incorporated by reference into this permit.

- 1) Missouri Department of Natural Resources Construction Permit # 0989-004
- 2) Missouri Department of Natural Resources Construction Permit # 0198-034
- 3) Missouri Department of Natural Resources Construction Permit # 102001-011
- 4) Missouri Department of Natural Resources Construction Permit # 082003-002
- 5) Missouri Department of Natural Resources Construction Permit # 092002-014
- 6) Notice of Compliance Report, Dated February 2004
- 7) Notice of Compliance Report, Dated February 2005
- 8) Notice of Compliance Report (Public Version), Dated January 2005, Submitted February 16, 2006
- 9) Compliance Test Results Confirmation Letter dated February 22, 2006, from Mr. Steven Feeler, Air Pollution Control Program to Mr. Don Riechart, TEVA Pharmaceuticals USA.

## II. Plant Wide Emission Limitations

The installation shall comply with each of the following emission limitations. Consult the appropriate sections in the Code of Federal Regulations (CFR) and Code of State Regulations (CSR) for the full text of the applicable requirements. All citations, unless otherwise noted, are to the regulations in effect as of the date that this permit is issued.

### PERMIT CONDITION PW001

10 CSR 10-6.075

#### Maximum Achievable Control Technology Regulations

40 CFR Part 63, Subpart GGG – Startup, Shutdown and Malfunction

#### 40 CFR Part 63, Subpart A - General Provisions

#### Emission/Operation Limitation:

- 1) 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 the Permittee follows the provisions for periods of startup, shutdown, and malfunction, as specified in §§63.1259(a)(3) and 63.1260(i). Startup, shutdown, and malfunction are defined in §63.1251. [§63.1250(g)(1)]
- 2) The provisions set forth in §63.1255 of Subpart GGG shall apply at all times except during periods of non-operation of the pharmaceutical manufacturing process unit (PMPU) (or specific portion thereof) in which the lines are drained and depressurized resulting in the cessation of the emissions to which §63.1255 of Subpart GGG applies. [§63.1250(g)(2)]
- 3) The Permittee 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. §63.1250(g)(3) does not apply if the item of equipment is malfunctioning, or if the Permittee must shut down the equipment to avoid damage due to a malfunction of the PMPU or portion thereof. [§63.1250(g)(3)]
- 4) During startups, shutdowns, and malfunctions when the emissions limitations of Subpart GGG do not apply pursuant to §§63.1250(g)(1) through (3), the Permittee shall implement, to the extent reasonably available, measures to prevent or minimize excess emissions to the extent practical. For purposes of §63.1250(g)(4), “excess emissions” means emissions in excess of those that would have occurred if there were no startup, shutdown, or malfunction and the Permittee complied with the relevant provisions of Subpart GGG. 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/or changes in the manner of operation of the source. Back-up control devices are not required, but may be used if available. [§63.1252(g)(4)]

#### Monitoring:

As specified in the Startup, Shutdown and Malfunction Plan.

#### Recordkeeping:

- 1) The Permittee shall keep copies of all records and reports required by Subpart GGG for at least five years, as specified in §63.10(b)(1). [§63.1259(a)(1)]
- 2) The Permittee shall develop and implement a written startup, shutdown, and malfunction plan as specified in §63.6(e)(3). This plan shall describe, in detail, procedures for operating and maintain the affected source during periods of startup, shutdown and malfunction and a program for corrective action for malfunctioning process, air pollution control, and monitoring equipment used to comply with Subpart GGG. The Permittee shall keep the current and superseded versions of this plan onsite, as specified in §63.6(e)(3)(v). The

Permittee shall keep the startup, shutdown and malfunction records specified in §63.1259(b)(3)(i) through (iii). Reports related to the plan shall be submitted as specified in §63.1260(i). [§63.1259(a)(3)]

- a) The Permittee shall record the occurrence and duration of each malfunction of the process operations or of air pollution control equipment used to comply with Subpart GGG, as specified in §63.6(e)(3)(iii). [§63.1259(a)(3)(i)]
- b) The Permittee shall record the occurrence and duration of each malfunction of continuous monitoring systems used to comply with Subpart GGG. [§63.1259(a)(3)(ii)]
- c) For each startup, shutdown or malfunction, the Permittee shall record all information necessary to demonstrate that the procedures specified in the affected source's startup, shutdown and malfunction plan were followed, as specified in §63.6(e)(3)(iii), and shall record all maintenance performed on the air pollution control equipment, as specified in §63.10(b)(2)(ii); alternatively, the Permittee shall record any actions taken that are not consistent with the plan, as specified in §63.6(e)(3)(iv). [§63.1259(a)(3)(iii)]

**Reporting:**

- 1) 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 §63.1260(g) instead of the schedule specified in §63.10(d)(5)(i). These reports shall include the information specified in §63.1259(a)(3)(i) through (ii) and shall contain the name, title, and signature of the Permittee or other responsible official who is certifying its accuracy. Reports are only required if a startup, shutdown, or malfunction occurred during the reporting period. Any time a Permittee takes an action that is not consistent with the procedures specified in the affected source's startup, shutdown, and malfunction plan, the Permittee shall submit an immediate startup, shutdown, and malfunction report as specified in §63.10(d)(5)(ii). [§63.1260(i)(1)]
  - a) *Submittal schedule.* Except as provided in §63.1260(g)(1)(i), (ii), and (iii), the Permittee 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 six-month period following the preceding period. [§63.1260(g)(1)]
    - i) When the administrator determines on a case-by-case basis that more frequent reporting is necessary to accurately assess the compliance status of the affected source or; [§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 the Permittee 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 §63.1260. [§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. [§63.1260(g)(1)(iii)]
- 2) Any time a Permittee takes an action that is not consistent with the procedures specified in the affected source's start-up, shutdown, and malfunction plan, the Permittee shall submit immediate startup, shutdown, and malfunction reports as specified in §63.10(d)(5)(ii). [§63.1260(i)(2)]

## PERMIT CONDITION PW002

10 CSR 10-6.075

### Maximum Achievable Control Technology Regulations

40 CFR Part 63, Subpart GGG

National Emission Standards for Pharmaceutical Production – Process Equipment Leaks

### 40 CFR Part 63, Subpart A - General Provisions

#### Emission Limitation and Monitoring Requirements:

- 1) *General Equipment Leak Requirements* [§63.1255(a)]
  - a) The provisions §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 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 Subpart GGG. [§63.1255(a)(1)]
  - b) Equipment to which the general equipment leak requirements apply shall be identified such that it can be distinguished readily from equipment that is not subject to the requirements. 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. [§63.1255(a)(7)]
  - c) When each leak is detected by visual, audible, or olfactory means, or by monitoring as described in §63.180(b) or (c), the following requirements apply: [§63.1255(a)(10)]
    - i) A weatherproof and readily visible identification, marked with the equipment identification number, shall be attached to the leaking equipment. [§63.1255(a)(10)(i)]
    - ii) The identification on a valve in light liquid or gas/vapor service may be removed after it has been monitored as specified in §63.1255(e)(7)(iii), and no leak has been detected during the follow-up monitoring. [§63.1255(a)(10)(ii)]
    - iii) The identification on equipment, except on a valve in light liquid or gas/vapor service, may be removed after it has been repaired. [§63.1255(a)(10)(iii)]
  - d) Except as provided in §63.1255(a)(11)(i), all terms in Subpart GGG that define a period of time for completion of required tasks (*e.g.*, weekly, monthly, quarterly, annual) refer to the standard calendar periods unless specified otherwise in the section or paragraph that imposes the requirement. [§63.1255(a)(11)]
    - i) If the initial compliance date does not coincide with the beginning of the standard calendar period, the Permittee may elect to utilize a period beginning on the compliance date, or may elect to comply in accordance with the provisions of §63.1255(a)(11)(ii) or (iii). [§63.1255(a)(11)(i)]
    - ii) Time periods specified in Subpart GGG for completion of required tasks may be changed by mutual agreement between the Permittee and the Administrator, as specified in subpart A of Part 63. For each time period that is changed by agreement, the revised period shall remain in effect until it is changed. A new request is not necessary for each recurring period. [§63.1255(a)(11)(ii)]
    - iii) Except as provided in §63.1255(a)(11)(i) or (ii), 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 §63.1255(a)(11)(iii)(A) or (B), as appropriate. [§63.1255(a)(11)(iii)]
      - (1) Compliance shall be required before the end of the standard calendar period within which the initial compliance date occurs if there remain at least three days for tasks that must be performed weekly, at least two weeks for tasks that must be performed monthly, at least one month for tasks

- that must be performed each quarter, or at least three months for tasks that must be performed annually or; [§63.1255(a)(11)(iii)(A)]
- (2) 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. [§63.1255(a)(11)(iii)(B)]
- iv) In all instances where a provision of Subpart GGG requires completion of a task during each of multiple successive periods, the Permittee 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. [§63.1255(a)(11)(iv)]
- e) In all cases where the provisions of Subpart GGG require the Permittee to repair leaks by a specified time after the leak is detected, it is a violation of §63.1255 to fail to take action to repair the leaks within the specified time. If action is taken to repair the leaks within the specified time, failure of that action to successfully repair the leak is not a violation of §63.1255. However, if the repairs are unsuccessful, a leak is detected and the Permittee shall take further action as required by applicable provisions of §63.1255. [§63.1255(a)(12)]
- 2) *References.* [§63.1255(b)]
- a) The Permittee shall comply with the following provisions of Subpart GGG instead of subpart H of Part 63, as specified in §63.1255(b)(2) through (4). The term “process unit” as used in subpart H of Part 63 shall be considered to be defined the same as “group of processes” for sources subject to Subpart GGG. The term “fuel gas system,” as used in subpart H of Part 63, shall not apply for the purposes of Subpart GGG. [§63.1255(b)(1)]
- b) Sections 63.160, 63.161, 63.162, 63.163, 63.167, 63.168, 63.170, 63.173, 63.175, 63.176, 63.181, and 63.182 shall not apply for the purposes of Subpart GGG. The Permittee shall comply with the provisions specified below. [§63.1255(b)(2)]
- i) For general leak requirements, the Permittee shall comply with (§63.1255(a); [§63.1255(b)(2)(i)]
- ii) For definitions, the Permittee shall comply with §63.1251; [§63.1255(b)(2)(ii)]
- iii) For pumps in light liquid service and for agitators in gas/vapor service and light liquid service the Permittee shall comply with (§63.1255(c); [§63.1255(b)(2)(iii)]
- iv) For open ended valves or lines the Permittee shall comply with §63.1255(d); [§63.1255(b)(2)(iv)]
- v) For valves in gas/vapor service and light liquid service the Permittee shall comply with §63.1255(e); [§63.1255(b)(2)(v)]
- vi) The Permittee shall comply with the recordkeeping requirements of §63.1255(g), and [§63.1255(b)(2)(vii)]
- vii) The Permittee shall comply with the reporting requirements of §63.1255(h). [§63.1255(b)(2)(viii)]
- c) The Permittee shall comply with §§63.165, 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 §63.1255(b)(2) and (4). §63.165 applies to pressure relief devices in gas/vapor service. §63.169 applies to pumps, valves, connectors, and agitators in heavy liquid service; instrumentation systems; and pressure relief devices in liquid service. §63.177 applies to general alternative means of emission limitation. §63.179 applies to alternative means of emission limitation for enclosed-vented process units. [§63.1255(b)(3)]
- d) The Permittee shall comply with §§63.171, 63.172, 63.174, 63.178, and 63.180, except as specified in §63.1255(b)(4)(i) through (vi). [§63.1255(b)(4)]
- i) §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 §63.1255(b)(4)(i)(A) through (B) exists: [§63.1255(b)(4)(i)]
- (1) The repair is technically infeasible without a process shutdown. Repair of this equipment shall occur by the end of the next scheduled process shutdown. [§63.1255(b)(4)(i)(A)]
- (2) The Permittee 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. [§63.1255(b)(4)(i)(B)]

- ii) §63.172 shall apply for closed-vent systems used to comply with §63.1255, and for control devices used to comply with §63.1255 only, except: [§63.1255(b)(4)(ii)]
  - (1) §63.172(k) and (l) shall not apply. The Permittee shall instead comply with §63.1255(f). [§63.1255(b)(4)(ii)(A)]
  - (2) Owners or operators 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. [§63.1255(b)(4)(ii)(B)]
  - (3) The requirements apply at all times, except as specified in §63.1250(g). The Permittee may not comply with the planned routine maintenance provisions in §63.1252(h). [§63.1255(b)(4)(ii)(C)]
- iii) §63.174 shall apply except: [§63.1255(b)(4)(iii)]
  - (1) §63.174(f), (g), and (h) shall not apply. Instead of §63.174(f), (g), and (h), the Permittee shall comply with §63.1255(f). §63.174(b)(3) shall not apply. Instead of §63.174(b)(3), the Permittee shall comply with §63.1255(b)(4)(iii)(B) through (F). [§63.1255(b)(4)(iii)(A)]
  - (2) If the percent leaking connectors in a group of processes was greater than or equal to 0.5 percent during the initial monitoring period, monitoring shall be performed once per year until the percent leaking connectors is less than 0.5 percent. [§63.1255(b)(4)(iii)(B)]
  - (3) If the percent leaking connectors in the group of processes was less than 0.5 percent, but equal to or greater than 0.25 percent, during the initial or last required monitoring period, the Permittee may elect to monitor once every four years. The Permittee may comply with the requirements of this paragraph by monitoring at least 40 percent of the connectors in the first two years and the remainder of the connectors within the next two years. The percent leaking connectors will be calculated for the total of all required monitoring performed during the four-year period. [§63.1255(b)(4)(iii)(C)]
  - (4) Except as provided in §63.1255(b)(4)(iii)(B), if leaking connectors comprise at least 0.5 percent but less than 1.0 percent of the connectors during the last monitoring period, the Permittee shall monitor at least once every two years for the next monitoring period. At the end of that two-year monitoring period, if the percent leaking connectors is greater than or equal to 0.5 percent, the Permittee 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, the Permittee shall monitor in accordance with §63.1255(b)(4)(iii)(C) or (F), as appropriate. [§63.1255(b)(4)(iii)(D)]
  - (5) If the Permittee determines that 1 percent or greater of the connectors in a group of processes are leaking, the Permittee shall monitor the connectors once per year. The Permittee may elect to use the provisions of §63.1255(b)(4)(iii)(C), (D), or (F), as appropriate, after a monitoring period in which less than 1 percent of the connectors are determined to be leaking. [§63.1255(b)(4)(iii)(E)]
  - (6) The Permittee may elect to perform monitoring once every eight years if the percent leaking connectors in the group of processes was less than 0.25 percent during the initial or last required monitoring period. The Permittee shall monitor at least 50 percent of the connectors in the first 4 years and the remainder of the connectors within the next 4 years. If the percent leaking connectors in the first four years is equal to or greater than 0.35 percent, the monitoring program shall revert at that time to the appropriate monitoring frequency specified in §63.1255(b)(4)(iii)(C), (D), or (E). [§63.1255(b)(4)(iii)(F)]
- iv) §63.178 shall apply except: [§63.1255(b)(4)(iv)]
  - (1) §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. [§63.1255(b)(4)(iv)(A)]
  - (2) For pumps, the phrase “at the frequencies specified in Table 1 of Subpart GGG” in §63.178(c)(3)(iii) shall mean “quarterly” for the purposes Subpart GGG. [§63.1255(b)(4)(iv)(B)]
- v) §63.180 shall apply except §63.180(b)(4)(ii)(A) through (C) shall not apply. Instead, calibration gases shall be a mixture of methane and air at a concentration of approximately, but less than, 10,000

parts per million methane for agitators; 2,000 parts per million for pumps; and 500 parts per million for all other equipment, except as provided in §63.180(b)(4)(iii). [§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 §63.1255(b)(2) and (b)(4)(i) through (v), as applicable. [§63.1255(b)(4)(vi)]

3) *Standards for Pumps in Light Liquid Service and Agitators in Gas/Vapor Service and in Light Liquid Service.* [§63.1255(c)]

a) The provisions of §63.1255 apply to each pump that is in light organic HAP liquid service, and to each agitator in organic HAP gas/vapor service or in light organic HAP liquid service. [§63.1255(c)(1)]

b) *Monitoring, Leak Definition and Visual Inspections* [§63.1255(c)(2)]

i) Each pump and agitator subject to §63.1255 shall be monitored quarterly to detect leaks by the Method 21 of 40 CFR Part 60, Appendix A in accordance with procedures established in 40 CFR §63.180(b) of subpart H except as provided in 40 CFR §§63.177, 63.178, §63.1255(f), and §63.1255(c)(5) through (9). [§63.1255(c)(2)(i)]

ii) A leak is detected if an instrument reading of 10,000 parts per million or greater for agitators and 2,000 ppm or greater for pumps is measured. The instrument reading, as determined by the method as specified in §63.180(b), that defines a leak is: [§63.1255(c)(2)(ii)(A) and (B)]

iii) *Visual Inspections.* Each pump and agitator shall be checked by visual inspection each calendar week for indications of liquids dripping from the pump or agitator seal. If there are indications of liquids dripping from the pump or agitator seal at the time of the weekly inspection, the Permittee shall follow the procedure specified in either §63.1255(c)(2)(iii)(A) or (B) prior to the next weekly inspection. [§63.1255(c)(2)(iii)]

iv) The Permittee shall monitor the pump or agitator by the method specified in §63.180(b). If the instrument reading indicates a leak as specified in §63.1255(c)(2)(ii), a leak is detected. [§63.1255(c)(2)(iii)(A)]

v) The Permittee shall eliminate the visual indications of liquids dripping. [§63.1255(c)(2)(iii)(B)]

c) *Repair provisions.* [§63.1255(c)(3)]

i) When a leak is detected pursuant to §63.1255(c)(2)(i), (c)(2)(iii)(A), (c)(5)(iv)(A), or (c)(5)(vi)(B), it shall be repaired as soon as practicable, but not later than 15 calendar days after it is detected, except as provided in §63.1255(b)(4)(i). [§63.1255(c)(3)(i)]

ii) Delay of repair of equipment for which leaks have been detected is allowed if the repair is technically infeasible without a process unit shutdown or if the Permittee determines that the repair personnel would be exposed to an immediate danger if attempting to repair without a process shutdown. Repair of such equipment shall occur by the end of the next scheduled process shutdown. [§63.1255(b)(4)(i)]

iii) 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: [§63.1255(c)(3)(ii)]

iv) Tightening of packing gland nuts. [§63.1255(c)(3)(ii)(A)]

v) Ensuring that the seal flush is operating at design pressure and temperature. [§63.1255(c)(3)(ii)(b)]

d) *Calculation of percent leakers.* [§63.1255(c)(4)]

i) The Permittee shall decide no later than the end of the first monitoring period what groups of processes will be developed. Once the Permittee has decided, all subsequent percent calculations shall be made on the same basis. [§63.1255(c)(4)(i)]

ii) If, calculated on a one-year rolling average, the greater of either 10% or three of the pumps in a group of processes leak, the Permittee shall monitor each pump once per month, until the calculated one-year rolling average value drops below 10% or three pumps, as applicable. [§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 one quarter after startup of the pump shall not count in the percent leaking pumps calculation for that one monitoring period only. [§63.1255(c)(4)(iii)]

- iv) Percent leaking pumps shall be determined by the following Equation 3 of Subpart GGG:  
[§63.1255(c)(4)(iv)]

$$\%P_L = [(P_L - P_S)/(P_T - P_S)] \times 100 \quad (\text{Eq. 3})$$

Where:

$\%P_L$  = percent leaking pumps

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

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

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

- e) *Exemptions.* Each pump or agitator equipped with a dual mechanical seal system that includes a barrier fluid system is exempt from the requirements of §63.1255(c)(1) through (c)(4)(iii), provided the following requirements are met: [§63.1255(c)(5)]
- i) Each dual mechanical seal system is: [§63.1255(c)(5)(i)]
    - (1) Operated with the barrier fluid at a pressure that is at all times greater than the pump/agitator stuffing box pressure or; [§63.1255(c)(5)(i)(A)]
    - (2) 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 §63.1255(b)(4)(ii) or; [§63.1255(c)(5)(i)(B)]
    - (3) Equipped with a closed-loop system that purges the barrier fluid into a process stream. [§63.1255(c)(5)(i)(C)]
  - ii) The barrier fluid is not in light liquid service. [§63.1255(c)(5)(ii)]
  - iii) Each barrier fluid system is equipped with a sensor that will detect failure of the seal system, the barrier fluid system, or both. [§63.1255(c)(5)(iii)]
  - iv) Each pump/agitator is checked by visual inspection each calendar week for indications of liquids dripping from the pump/agitator seal. If there are indications of liquids dripping from the pump or agitator seal at the time of the weekly inspection, the Permittee shall follow the procedures specified in either §63.1255(c)(5)(iv)(A) or (B) prior to the next required inspection. [§63.1255(c)(5)(iv)]
    - (1) The Permittee shall monitor the pump or agitator using Method 21 in accordance with the procedures specified in 40 CFR §63.180(b) of subpart H to determine if there is a leak of organic HAP in the barrier fluid. If the instrument reading indicates a leak, if an instrument reading of 10,000 parts per million or greater for agitators and 2,000 parts per million or greater for pumps is measured, as specified in §63.1255(c)(2)(ii), a leak is detected. [§63.1255(c)(5)(iv)(A)]
    - (2) The Permittee shall eliminate the visual indications of liquids dripping. [§63.1255(c)(5)(iv)(B)]
  - v) Each sensor as described in §63.1255(c)(5)(iii) is observed daily or is equipped with an alarm unless the pump is located within the boundary of an unmanned plant site. [§63.1255(c)(5)(v)]
  - vi) The Permittee 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. If indications of liquids dripping from the pump/agitator seal exceed the criteria established above, or if, based on the criteria established above, the sensor indicates failure of the seal system, the barrier fluid system, or both, a leak is detected. [§63.1255(c)(5)(vi)(A) and (B)]
  - vii) When a leak is detected pursuant to §63.1255(c)(5)(iv)(A) or (B), the leak must be repaired as specified in §63.1255(c)(3). [§63.1255(c)(5)(vii)]
- f) Any pump/agitator that is designed with no externally actuated shaft penetrating the pump/agitator housing is exempt from the requirements of §63.1255(c)(1) through (3). [§63.1255(c)(6)]

- g) Any pump/agitator equipped with a closed-vent system capable of capturing and transporting any leakage from the seal or seals back to the process or to a control device that complies with the requirements of §63.1255(b)(4)(ii) is exempt from the requirements of §63.1255(c)(2) through (5). [§63.1255(c)(7)]
  - h) Any pump/agitator that is located within the boundary of an unmanned plant site is exempt from the weekly visual inspection requirement of §63.1255(c)(2)(iii) and (c)(5)(iv), and the daily requirements of §63.1255(c)(5)(v), provided that each pump/agitator is visually inspected as often as practicable and at least monthly. [§63.1255(c)(8)]
  - i) If more than 90 percent of the pumps in a group of processes meet the criteria in either §63.1255(c)(5) or (6), the group of processes is exempt from the requirements of §63.1255(c)(4). [§63.1255(c)(9)]
- 4) *Standards: Open-Ended Valves or Lines.* [§63.1255(d)]
- a) Each open-ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve, except as provided in §63.177 and §63.1255(d)(4) through (6). 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 Permittee is not required to keep a record documenting compliance with the 1-hour requirement. [§63.1255(d)(1)(i) and (ii)]
  - b) Each open-ended valve or line equipped with a second valve shall be operated in a manner such that the valve on the process fluid end is closed before the second valve is closed. [§63.1255(d)(2)]
  - c) When a double block and bleed system is being used, the bleed valve or line may remain open during operations that require venting the line between the block valves but shall comply with §63.1255(d)(1) at all other times. [§63.1255(d)(3)]
  - d) Open-ended valves or lines in an emergency shutdown system which are designed to open automatically in the event of a process upset are exempt from the requirements of §63.1255(d)(1) through (d)(3). [§63.1255(d)(4)]
  - e) Open-ended valves or lines containing materials which would autocatalytically polymerize are exempt from the requirements of §63.1255(d)(1) through (d)(3). [§63.1255(d)(5)]
  - f) Open-ended valves or lines containing materials which could cause an explosion, serious overpressure, or other safety hazard if capped or equipped with a double block and bleed system as specified in §63.1255(d)(1) through (d)(3) are exempt from the requirements of §63.1255(d)(1) through (d)(3). [§63.1255(d)(6)]
- 5) *Standards: Valves in Gas/Vapor Service and in Light Liquid Service.* [§63.1255(e)]
- The provisions of 40 CFR 63.1255 of Subpart GGG apply to valves that are either in gas organic HAP service or in light liquid organic HAP service. A valve in gas/vapor service is a valve in organic hazardous air pollutant service containing a gas or vapor at operating conditions. A valve in light liquid service is a valve that is in organic hazardous air pollutant service and which contains a liquid at operating conditions with one or more organic compounds with a vapor pressure greater than 0.3 kilopascals at 20 °C determined by the methods described in 40 CFR 60.485(e)(1) and the total concentration of the pure organic compounds constituents having 0.3 kilopascals at 20 °C is equal to or greater than 20 percent by weight of the total process stream. [40 CFR 63.1251 – Definitions, & 63.1255(e)(1)]
- a) For existing and new affected sources, all valves subject to §63.1255 shall be monitored, except as provided in §63.1255(f) and in §63.177, by no later than one year after the compliance date. [§63.1255(e)(2)]
  - b) *Monitoring.* The Permittee shall monitor all valves, except as provided in §63.1255(f) and in §63.177, at the intervals specified in §63.1255(e)(4) and shall comply with all other provisions, except as provided in §63.1255(b)(4)(i), §§ 63.178 and 63.179. [§63.1255(e)(3)]
    - i) The valves shall be monitored to detect leaks by Method 21 in accordance with the procedures specified in 40 CFR §63.180(b) of subpart H. [§63.1255(e)(3)(i)]
    - ii) An instrument reading of 500 parts per million or greater defines a leak. [§63.1255(e)(3)(ii)]
  - c) *Subsequent monitoring frequencies.* After conducting the initial survey required in §63.1255(e)(2), the Permittee shall monitor valves for leaks at the intervals specified below: [§63.1255(e)(4)]

- i) For a group of processes with 2 percent or greater leaking valves, calculated according to §63.1255(e)(6) , the Permittee shall monitor each valve once per month, except as specified in §63.1255(e)(9). [§63.1255(e)(4)(i)]
- ii) For a group of processes with less than 2 percent leaking valves, the Permittee shall monitor each valve once each quarter, except as provided in §63.1255(e)(4)(iii) through (e)(4)(v). [§63.1255(e)(4)(ii)]
- iii) For a group of processes with less than 1 percent leaking valves, the Permittee may elect to monitor each valve once every two quarters. [§63.1255(e)(4)(iii)]
- iv) For a group of processes with less than 0.5 percent leaking valves, the Permittee may elect to monitor each valve once every four quarters. [§63.1255(e)(4)(iv)]
- v) For a group of processes with less than 0.25 percent leaking valves, the Permittee may elect to monitor each valve once every two years. [§63.1255(e)(4)(v)]
- d) *Calculation of percent leakers.* For a group of processes to which Subpart GGG applies, the Permittee may choose to subdivide the valves in the applicable group of processes and apply the provisions of §63.1255(e)(4) to each subgroup. If the Permittee elects to subdivide the valves in the applicable group of processes, then the provisions of §63.1255(e)(5)(i) through (e)(5)(viii) apply. (recordkeeping and reporting provisions under §63.1255(e)(5)(iv) through (vii) are listed in the Recordkeeping and Reporting sections, respectively). [§63.1255(e)(5)]
  - i) The overall performance of total valves in the applicable group of processes must be less than 2% leaking valves, as detected according to §63.1255(e)(3)(i) and (ii) and as calculated according to §63.1255(e)(6) (ii) and (iii). [§63.1255(e)(5)(i)]
  - ii) The initial assignment or subsequent reassignment of valves to subgroups shall be governed by the provisions of §63.1255(e)(5)(ii) (A) through (C). [§63.1255(e)(5)(ii)]
    - (1) The Permittee shall determine which valves are assigned to each subgroup. Valves with less than one 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 one year of monitoring data has been obtained. [§63.1255(e)(5)(ii)(A)]
    - (2) 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. [§63.1255(e)(5)(ii)(B)]
    - (3) 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. [§63.1255(e)(5)(ii)(C)]
  - iii) The Permittee shall determine every six 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, the Permittee shall revert to the program required in §63.1255(e)(2) through (e)(4). 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 4 of Subpart GGG: (§63.1255(e)(5)(iii))

$$\%V_{LO} = \frac{\sum_{i=1}^n (\%V_{Li} \times V_i)}{\sum_{i=1}^n V_i} \quad (Eq. 4)$$

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 §63.1255(e)(6)(ii) and (iii).

$V_i$  = number of valves in subgroup i

- iv) To determine the monitoring frequency for each subgroup, the calculation procedures of §63.1255(e)(6)(iii) shall be used. [§63.1255(e)(5)(vii)]
- v) Except for the overall performance calculations required by §63.1255(e)(5)(i) and (e)(5)(iii), each subgroup shall be treated as if it were a process for the purposes of applying the provisions of §63.1255. [§63.1255(e)(5)(viii)]
- e) The Permittee shall decide no later than the implementation date of Subpart GGG or upon revision of an operating permit how to group the processes. Once the Permittee has decided, all subsequent percentage calculations shall be made on the same basis. Percent leaking valves for each group of processes or subgroup shall be determined by the following Equation 5 of Subpart GGG: (§63.1255(e)(6)(i) and (ii))

$$\%V_L = [V_L/V_T] \times 100 \quad (\text{Eq. 5})$$

Where:

$\%V_L$  = percent leaking valves as determined through periodic monitoring required in §63.1255(e)(2) through (4).

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

- i) 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 two years) monitoring frequencies, the percent leaking valves shall be the arithmetic average of the percent leaking valves from the last three monitoring periods. [§63.1255(e)(6)(iii)]
- ii) (A) 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 §63.1255(e)(6)(iv)(B). 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. (B) If the number of nonrepairable valves exceeds 1% of the total number of valves in organic HAP service at a process, the number of nonrepairable valves exceeding 1% of the total number of valves in organic HAP service shall be included in the calculation of percent leaking valves. [§63.1255(e)(6)(iv)(A) and (B)]
- f) *Repair provisions.* [§63.1255(e)(7)]
  - i) When a leak is detected, it shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except as provided in §63.1255(b)(4)(i) stated below. [§63.1255(e)(7)(i)]
    - (1) The repair is technically infeasible without a process shutdown. Repair of this equipment shall occur by the end of the next scheduled process shutdown. [§63.1255(b)(4)(i)(A)]
    - (2) The Permittee 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. [§63.1255(b)(4)(i)(B)]
  - ii) A first attempt at repair shall be made no later than five calendar days after each leak is detected. [§63.1255(e)(7)(ii)]
  - iii) When a leak is repaired, the valve shall be monitored at least once within the first three months after its repair. Days that the valve is not in organic HAP service shall not be considered part of this three month period. The monitoring required by this paragraph is in addition to the monitoring required to satisfy the definitions of “repaired” and “first attempt at repair.” [§63.1255(e)(7)(iii)]

- (1) The monitoring shall be conducted as specified in §63.180(b) and (c) as appropriate to determine whether the valve has resumed leaking. [§63.1255(e)(7)(iii)(A)]
- (2) Periodic monitoring required by §63.1255(e)(2) through (4) may be used to satisfy the requirements of §63.1255(e)(7)(iii), if the timing of the monitoring period coincides with the time specified in §63.1255(e)(7)(iii). Alternatively, other monitoring may be performed to satisfy the requirements of §63.1255(e)(7)(iii), regardless of whether the timing of the monitoring period for periodic monitoring coincides with the time specified in §63.1255(e)(7)(iii). [§63.1255(e)(7)(iii)(B)]
- (3) If a leak is detected by monitoring that is conducted pursuant to §63.1255(e)(7)(iii), the Permittee shall follow the provisions of §63.1255(e)(7)(iii)(C)(1) and (2) to determine whether that valve must be counted as a leaking valve for purposes of §63.1255(e)(6). [§63.1255(e)(7)(iii)(C)]
  - (a) If the Permittee elects to use periodic monitoring required by §63.1255(e)(2) through (4) to satisfy the requirements of §63.1255(e)(7)(iii), then the valve shall be counted as a leaking valve. [§63.1255(e)(7)(iii)(C)(1)]
  - (b) If the Permittee elects to use other monitoring prior to the periodic monitoring required by §63.1255(e)(2) through (4) to satisfy the requirements of §63.1255(e)(7)(iii), then the valve shall be counted as a leaking valve unless it is repaired and shown by periodic monitoring not to be leaking. [§63.1255(e)(7)(iii)(C)(2)]
- g) First attempts at repair include, but are not limited to, the following practices where practicable: [§63.1255(e)(8)]
  - i) Tightening of bonnet bolts, [§63.1255(e)(8)(i)]
  - ii) Replacement of bonnet bolts, [§63.1255(e)(8)(ii)]
  - iii) Tightening of packing gland nuts, and [§63.1255(e)(8)(iii)]
  - iv) Injection of lubricant into lubricated packing. [§63.1255(e)(8)(iv)]
- h) 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 §63.1255(e)(4)(i). Instead, the Permittee shall monitor each valve in organic HAP service for leaks once each quarter, or comply with §63.1255(e)(4)(iii), (iv), or (v), except as provided in §63.1255(f). [§63.1255(e)(9)]
- 6) *Unsafe to monitor/inspect, difficult to monitor/inspect, and inaccessible equipment.* [§63.1255(f)]
  - a) 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 §63.1255(f)(1)(i) through (iv) provided the Permittee meets the requirements specified in §63.1255(f)(2), (3), or (4), 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. [§63.1255(f)(1)]
    - i) For pumps and agitators, §63.1255(c)(2), (3), and (4) do not apply. [§63.1255(f)(1)(i)]
    - ii) For valves, §63.1255(e)(2) through (7) do not apply. [§63.1255(f)(1)(ii)]
    - iii) For connectors, §63.174(b) through (e) and §63.1255(b)(4)(iii)(B) through (F) do not apply. [§63.1255(f)(1)(iii)]
    - iv) For closed-vent systems, §63.172(f)(1) and (2) and §63.172(g) do not apply. [§63.1255(f)(1)(iv)]
  - b) *Equipment that is unsafe to monitor or unsafe to inspect.* [§63.1255(f)(2)]
    - i) Valves, connectors, agitators, and pumps may be designated as unsafe to monitor if the Permittee determines that monitoring personnel would be exposed to an immediate danger as a consequence of complying with the monitoring requirements referred to in §63.1255(f)(1)(i) through (iii). [§63.1255(f)(2)(i)]
    - ii) Any part of a closed-vent system may be designated as unsafe to inspect if the Permittee determines that monitoring personnel would be exposed to an immediate danger as a consequence of complying with the monitoring requirements referred to in §63.1255(f)(1)(iv). [§63.1255(f)(2)(ii)]
    - iii) The Permittee 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. [§63.1255(f)(2)(iii)]

- iv) For any parts of a closed-vent system designated as unsafe to inspect, the Permittee 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. [§63.1255(f)(2)(iv)]
- c) *Equipment that is difficult to monitor or difficult to inspect.* [§63.1255(f)(3)]
  - i) A valve, agitator, or pump may be designated as difficult to monitor if the Permittee determines that the valve, agitator, or pump cannot be monitored without elevating the monitoring personnel more than two meters above a support surface, or it is not accessible in a safe manner when it is in organic HAP service. [§63.1255(f)(3)(i)]
  - ii) Any part of a closed-vent system may be designated as difficult to inspect if the Permittee determines that the equipment cannot be inspected without elevating the monitoring personnel more than two meters above a support surface, or it is not accessible in a safe manner when it is in organic HAP service. [§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 §63.1255(f)(3)(i) may be designated as difficult to monitor, and any parts of a closed-vent system that meet the requirements of §63.1255(f)(3)(ii) may be designated as difficult to inspect. At a new affected source, the Permittee may designate no more than 3% of valves as difficult to monitor. [§63.1255(f)(3)(iii)]
  - iv) The 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, the Permittee must have a written plan that requires inspection of the closed-vent system at least once every five years. [§63.1255(f)(3)(iv)]
- d) *Inaccessible, ceramic, or ceramic-lined connectors.* [§63.1255(f)(4)]
  - i) A connector may be designated as inaccessible if it is: [§63.1255(f)(4)(i)]
    - (1) Buried; [§63.1255(f)(4)(i)(A)]
    - (2) Insulated in a manner that prevents access to the connector by a monitor probe; [§63.1255(f)(4)(i)(B)]
    - (3) Obstructed by equipment or piping that prevents access to the connector by a monitor probe; [§63.1255(f)(4)(i)(C)]
    - (4) 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 [§63.1255(f)(4)(i)(D)]
    - (5) 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. [§63.1255(f)(4)(i)(E)]
  - 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. [§63.1255(f)(4)(ii)]
  - iii) At an existing source, any connector that meets the criteria of §63.1255(f)(4)(i) or (ii) may be designated as inaccessible. At a new affected source, the Permittee may designate no more than 3% of connectors as inaccessible. [§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 §63.1255(b)(4)(i). [§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 §63.1255(g) and (h). [§63.1255(f)(4)(v)]

**Recordkeeping:**

- 1) *Records of equipment leak detection and repair programs.* The Permittee implementing the leak detection and repair (LDAR) program specified in §63.1255 of Subpart GGG, shall implement the recordkeeping requirements in §63.1255. [§63.1259(d)]
- 2) The following recordkeeping requirements apply under §63.1255(g): [§63.1255(g)]
  - a) The Permittee of more than one group of processes subject to the provisions of §63.1255 may comply with the recordkeeping requirements for the groups of processes in one recordkeeping system if the system identifies with each record the program being implemented (e.g., quarterly monitoring) for each type of equipment. All records and information required by §63.1255 shall be maintained in a manner that can be readily accessed at the plant site. This could include physically locating the records at the plant site or accessing the records from a central location by computer at the plant site. [§63.1255(g)(1)]
  - b) *General recordkeeping.* Except as provided in §63.1255(g)(5)(i) and in §63.1255(a)(9), the following information pertaining to all equipment subject to the requirements in §63.1255 shall be recorded: [§63.1255(g)(2)]
    - i) The following apply:
      - (1) A list of identification numbers for equipment (except connectors that are subject to §63.1255(f)(4)) subject to the requirements of §63.1255. Except for equipment subject to the recordkeeping requirements in §63.1255(g)(2)(ii) through (viii), 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 §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. [§63.1255(g)(2)(i)(A)]
      - (2) A schedule for monitoring connectors subject to the provisions of §63.174(a) and valves subject to the provisions of §63.1255(e)(4). [§63.1255(g)(2)(i)(B)]
      - (3) Physical tagging of the equipment to indicate that it is in organic HAP service is not required. Equipment subject to the provisions of §63.1255 may be identified on a plant site plan, in log entries, or by other appropriate methods. [§63.1255(g)(2)(i)(C)]
    - ii) The following apply:
      - (1) A list of identification numbers for equipment that the Permittee elects to equip with a closed-vent system and control device, under the provisions of §63.1255(c)(7), §63.164(h), or §63.165(c). [§63.1255(g)(2)(ii)(A)]
      - (2) A list of identification numbers for compressors that the Permittee elects to designate as operating with an instrument reading of less than 500 parts per million above background, under the provisions of §63.164(i). [§63.1255(g)(2)(ii)(B)]
    - iii) The following requirements apply:
      - (1) A list of identification numbers for pressure relief devices subject to the provisions in §63.165(a). [§63.1255(g)(2)(iii)(A)]
      - (2) A list of identification numbers for pressure relief devices equipped with rupture disks, under the provisions of §63.165(d). [§63.1255(g)(2)(iii)(B)]
    - iv) Identification of instrumentation systems subject to the provisions of §63.1255. Individual components in an instrumentation system need not be identified. [§63.1255(g)(2)(iv)]
    - v) The following information shall be recorded for each dual mechanical seal system: [§63.1255(g)(2)(v)]
      - (1) Design criteria required by §63.1255(c)(5)(vi)(A) and §63.164(e)(2), and an explanation of the design criteria; and [§63.1255(g)(2)(v)(A)]
      - (2) Any changes to these criteria and the reasons for the changes. [§63.1255(g)(2)(v)(B)]

- vi) A list of equipment designated as unsafe to monitor/inspect or difficult to monitor/inspect under §63.1255(f) and a copy of the plan for monitoring or inspecting this equipment. [§63.1255(g)(2)(vi)]
- vii) 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 is expected to be used. [§63.1255(g)(2)(vii)]
- viii) For equipment that the Permittee 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 §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 the Permittee 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 §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. [§63.1255(g)(2)(viii)]
- c) *Records of visual inspections.* For visual inspections of equipment subject to the provisions of §63.1255(c)(2)(iii) and (c)(5)(iv), the Permittee shall document that the inspection was conducted and the date of the inspection. The Permittee shall maintain records as specified in §63.1255(g)(4) for leaking equipment identified in this inspection, except as provided in §63.1255(g)(5). These records shall be retained for two years. [§63.1255(g)(3)]
- d) *Monitoring records.* When each leak is detected as specified in §63.1255(c) and §63.164, §63.1255(e) and §63.169, and §§63.172 and 63.174, the following information shall be recorded and kept for 5 years (at least two years onsite, with the remaining three years either onsite or offsite): [§63.1255(g)(4)]
  - i) The instrument and the equipment identification number and the operator name, initials, or identification number. [§63.1255(g)(4)(i)]
  - ii) The date the leak was detected and the date of the first attempt to repair the leak. [§63.1255(g)(4)(ii)]
  - iii) The date of successful repair of the leak. [§63.1255(g)(4)(iii)]
  - iv) The maximum instrument reading measured by Method 21 of 40 CFR part 60, appendix A, after the leak is successfully repaired or determined to be nonrepairable. [§63.1255(g)(4)(iv)]
  - v) “Repair delayed” and the reason for the delay if a leak is not repaired within 15 calendar days after discovery of the leak. [§63.1255(g)(4)(v)]
    - (1) The Permittee 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 §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. [§63.1255(g)(4)(v)(A)]
    - (2) 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. [§63.1255(g)(4)(v)(B)]
- vi) If repairs were delayed, dates of process shutdowns that occur while the equipment is unrepaired. [§63.1255(g)(4)(vi)]
- 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); 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. [§63.1255(g)(4)(vii)(A) and (B)]
- viii) The date and results of the monitoring required in §63.178(c)(3)(i) for equipment added to a batch process since the last monitoring period required in §63.178(c)(3)(ii) and (iii). If no leaking equipment is found in this monitoring, the Permittee shall record that the inspection was performed. Records of the actual monitoring results are not required. [§63.1255(g)(4)(viii)]

- ix) Copies of the periodic reports as specified in §63.1255(h)(3), if records are not maintained on a computerized data base capable of generating summary reports from the records.  
[§63.1255(g)(4)(ix)]
- e) *Records of pressure tests.* The Permittee who elects to pressure test a process equipment train or supply lines between storage and processing areas to demonstrate compliance with §63.1255 is exempt from the requirements of §63.1255(g)(2), (3), (4), and (6). Instead, the Permittee shall maintain records of the following information: [§63.1255(g)(5)]
  - 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.  
[§63.1255(g)(5)(i)]
  - ii) Physical tagging of the equipment to identify that it is in organic HAP service and subject to the provisions of §63.1255 is not required. Equipment in a process subject to the provisions of §63.1255 may be identified on a plant site plan, in log entries, or by other appropriate methods.  
[§63.1255(g)(5)(ii)]
  - iii) The dates of each pressure test required in §63.178(b), the test pressure, and the pressure drop observed during the test. [§63.1255(g)(5)(iii)]
  - iv) Records of any visible, audible, or olfactory evidence of fluid loss. [§63.1255(g)(5)(iv)]
  - 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 two years: [§63.1255(g)(5)(v)]
    - (1) The date of each pressure test and the date of each leak repair attempt. [§63.1255(g)(5)(v)(A)]
    - (2) Repair methods applied in each attempt to repair the leak. [§63.1255(g)(5)(v)(B)]
    - (3) The reason for the delay of repair. [§63.1255(g)(5)(v)(C)]
    - (4) The expected date for delivery of the replacement equipment and the actual date of delivery of the replacement equipment. [§63.1255(g)(5)(v)(D)]
    - (5) The date of successful repair. [§63.1255(g)(5)(v)(E)]
- f) *Records of relief device compliance tests.* The dates and results of the monitoring following a pressure release for each pressure relief device subject to the provisions in §§63.165(a) and (b). The results shall include: [§63.1255(g)(6)]
  - i) The background level measured during each compliance test. [§63.1255(g)(6)(i)]
  - ii) The maximum instrument reading measured at each piece of equipment during each compliance test.  
[§63.1255(g)(6)(ii)]
- g) *Records for closed-vent systems.* The Permittee shall maintain records of the information specified in §63.1255(g)(7)(i) through (iii) for closed-vent systems and control devices subject to the provisions of §63.1255(b)(4)(ii). The records specified in §63.1255(g)(7)(i) shall be retained for the life of the equipment. The records specified in §63.1255(g)(7)(ii) and (g)(7)(iii) shall be retained for two years. [§63.1255(g)(7)]
  - i) The design specifications and performance demonstrations specified in §63.1255(g)(7)(i)(A) through (g)(7)(i)(D). [§63.1255(g)(7)(i)]
    - (1) Detailed schematics, design specifications of the control device, and piping and instrumentation diagrams. [§63.1255(g)(7)(i)(A)]
    - (2) The dates and descriptions of any changes in the design specifications. [§63.1255(g)(7)(i)(B)]
    - (3) A description of the parameter or parameters monitored, as required in §63.1255(b)(4)(ii), 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.  
[§63.1255(g)(7)(i)(D)]
  - ii) Records of operation of closed-vent systems and control devices. [§63.1255(g)(7)(ii)]
    - (1) Dates and durations when the closed-vent systems and control devices required in §63.1255(c) and §§63.164 through 63.166 are not operated as designed as indicated by the monitored parameters. [§63.1255(g)(7)(ii)(A)]
    - (2) Dates and durations during which the monitoring system or monitoring device is inoperative.  
[§63.1255(g)(7)(ii)(B)]

- (3) Dates and durations of startups and shutdowns of control devices required in §63.1255(c)(7) and §§63.164 through 63.166. [§63.1255(g)(7)(ii)(C)]
- iii) Records of inspections of closed-vent systems subject to the provisions of §63.172. [§63.1255(g)(7)(iii)]
- (1) For each inspection conducted in accordance with the provisions of §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. [§63.1255(g)(7)(iii)(A)]
- (2) For each inspection conducted in accordance with the provisions of §63.172(f)(1) or (f)(2) during which leaks were detected, the information specified in §63.1255(g)(4) shall be recorded. [§63.1255(g)(7)(iii)(B)]
- h) *Records for components in heavy liquid service.* Information, data, and analysis used to determine that a piece of equipment or process is in heavy liquid service shall be recorded. Such a determination shall include an analysis or demonstration that the process fluids do not meet the criteria of “in light liquid or gas service.” Examples of information that could document this include, but are not limited to, records of chemicals purchased for the process, analyses of process stream composition, engineering calculations, or process knowledge. [§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 §63.1255. [§63.1255(g)(9)]
- j) *Records of alternative means of compliance determination.* Owners and operators choosing to comply with the requirements of §63.179 shall maintain the following records: [§63.1255(g)(10)]
- i) Identification of the process(es) and the organic HAP they handle. [§63.1255(g)(10)(i)]
- ii) A schematic of the process, enclosure, and closed-vent system. [§63.1255(g)(10)(ii)]
- iii) A description of the system used to create a negative pressure in the enclosure to ensure that all emissions are routed to the control device. [§63.1255(g)(10)(iii)]
- 3) *Recordkeeping for Valves in Gas/Vapor Service and in Light Liquid Service* In addition to records required by §63.1255(g), the Permittee shall maintain records specified in §63.1255(e)(5)(iv)(A) through (D). [§63.1255(e)(5)(iv)]
- a) Which valves are assigned to each subgroup, [§63.1255(e)(5)(iv)(A)]
- b) Monitoring results and calculations made for each subgroup for each monitoring period, [§63.1255(e)(5)(iv)(B)]
- c) Which valves are reassigned and when they were reassigned, and [§63.1255(e)(5)(iv)(C)]
- d) The results of the semiannual overall performance calculation required in §63.1255(e)(5)(iii). [§63.1255(e)(5)(iv)(D)]

### **Reporting**

- 1) *Reporting Requirements.* [§63.1255(h)]
- a) The Permittee shall submit the reports listed in §63.1255(h)(1)(i) through (ii). [§63.1255(h)(1)]
- i) Teva Pharmaceuticals USA has successfully submitted the information specified in §63.1255(h)(2)(i) through (iii) within in the Notification of Compliance Status Reports as described in §63.1260(f). A final Notification of Compliance Status Report was submitted February 16, 2006. [§63.1255(h)(1)(i)]
- ii) Periodic reports described in §63.1255(h)(3). [§63.1255(h)(1)(ii)]
- b) *Periodic reports.* The Permittee shall submit Periodic Reports. [§63.1255(h)(3)]
- i) A report containing the information in §63.1255(h)(3)(ii), (iii), and (iv) 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 six-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. [§63.1255(h)(3)(i)]
- ii) For equipment complying with the provisions of §63.1255(b) through (g), except §63.1255(b)(4)(iv) and §63.179, the summary information listed in §63.1255(h)(3)(ii)(A) through (L) for each monitoring period during the six-month period. [§63.1255(h)(3)(ii)]

- (1) The number of valves for which leaks were detected as described in §63.1255(e)(3), the percent leakers, and the total number of valves monitored; [§63.1255(h)(3)(ii)(A)]
  - (2) The number of valves for which leaks were not repaired as required in §63.1255(e)(7), identifying the number of those that are determined nonrepairable; [§63.1255(h)(3)(ii)(B)]
  - (3) Separately, the number of pumps and agitators for which leaks were detected as described in §63.1255(c)(2), the total number of pumps and agitators monitored, and, for pumps, the percent leakers; [§63.1255(h)(3)(ii)(C)]
  - (4) Separately, the number of pumps and agitators for which leaks were not repaired as required in §63.1255(c)(3); [§63.1255(h)(3)(ii)(D)]
  - (5) The number of compressors for which leaks were detected as described in §63.164(f); [§63.1255(h)(3)(ii)(E)]
  - (6) The number of compressors for which leaks were not repaired as required in §63.164(g); [§63.1255(h)(3)(ii)(F)]
  - (7) 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; [§63.1255(h)(3)(ii)(G)]
  - (8) 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; [§63.1255(h)(3)(ii)(H)]
  - (9) The facts that explain any delay of repairs and, where appropriate, why a process shutdown was technically infeasible. [§63.1255(h)(3)(ii)(I)]
  - (10) The results of all monitoring to show compliance with §§63.164(i), 63.165(a), and 63.172(f) conducted within the semiannual reporting period. [§63.1255(h)(3)(ii)(J)]
  - (11) If applicable, the initiation of a monthly monitoring program under either §63.1255(c)(4)(ii) or §63.1255(e)(4)(i). [§63.1255(h)(3)(ii)(K)]
  - (12) If applicable, notification of a change in connector monitoring alternatives as described in §63.174(c)(1). [§63.1255(h)(3)(ii)(L)]
- iii) For owners or operators electing to meet the requirements of §63.178(b), the report shall include the information listed in §63.1255(h)(3)(iii)(A) through (E) for each process. [§63.1255(h)(3)(iii)]
- (1) Product process equipment train identification; [§63.1255(h)(3)(iii)(A)]
  - (2) The number of pressure tests conducted; [§63.1255(h)(3)(iii)(B)]
  - (3) The number of pressure tests where the equipment train failed either the retest or two consecutive pressure tests; [§63.1255(h)(3)(iii)(C)]
  - (4) The facts that explain any delay of repairs and; [§63.1255(h)(3)(iii)(D)]
  - (5) The results of all monitoring to determine compliance with §63.172(f) of Subpart H. [§63.1255(h)(3)(iii)(E)]
- iv) Any revisions to items reported in earlier Notification of Compliance Status report, if the method of compliance has changed since the last report. [§63.1255(h)(3)(iv)]
- 2) *Reporting for Valves in Gas/Vapor Service and in Light Liquid Service*
- a) In addition to the reporting requirements under §63.1255(h), the Permittee shall notify the Administrator 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. [§63.1255(e)(5)(v)]
  - b) *Semiannual reports.* In addition to the information required by §63.1255(h)(3), the Permittee shall submit in the periodic reports the information specified in §63.1255(e)(5)(vi)(A) and (B). [§63.1255(e)(5)(vi)]
    - i) Valve reassignments occurring during the reporting period, and [§63.1255(e)(5)(vi)(A)]
    - ii) Results of the semiannual overall performance calculation required by §63.1255(e)(5)(iii). [§63.1255(e)(5)(vi)(B)]

### PERMIT CONDITION PW003

10 CSR 10-6.075

#### Maximum Achievable Control Technology Regulations

40 CFR Part 63, Subpart GGG

National Emission Standards for Pharmaceutical Production – General Provisions

#### Emission Limitation:

*Control requirements for certain liquid streams in open systems within a PMPU.* [§63.1252(f)]

- 1) The Permittee shall comply with the following control requirements, for each item of equipment meeting all the criteria specified in §63.1252(f)(2) through (4) and either §63.1252(f)(5)(i) or (ii). [§63.1252(f)(1)]
  - a) For a drain or drain hub: [Table 5 of Subpart GGG]
    - i) Tightly fitting solid cover (TFSC);or
    - ii)TFSC with a vent to either a process or to a control device meeting the requirements of §63.1256(h)(2) or;
    - iii) Water seal with submerged discharge or barrier to protect discharge from wind.
  - b) For pipes: Each pipe shall have no visible gaps in joints, seals, or other emission interfaces. [Table 5 of Subpart GGG]
  - c) For tanks: Maintain a fixed roof and consider vents as process vents. A fixed roof may have openings necessary for proper venting of the tank, such as pressure/vacuum vent, j-pipe vent. [Table 5 of Subpart GGG]
  - d) For oil/water separators: [Table 5 of Subpart GGG]
    - i) Equip with a fixed roof and route vapors to a process or equip with a closed-vent system that routes vapors to a control device meeting the requirements of §63.1256(h)(2) or;
    - ii) Equip with a floating roof that meets the equipment specifications of §60.693(a)(1)(i), (a)(1)(ii), (a)(2),(a)(3), and (a)(4).
  - e) For manholes, lift stations and trenches: (Note: Manhole includes sumps and other points of access to a conveyance system) [Table 5 of Subpart GGG]
    - i) TFSC or;
    - ii) TSFC with a vent to either a process or to a control device meeting the requirements of § 63.1256(h)(2) or;
    - iii) If the manholes or lift stations or trenches are vented to the atmosphere, use a TFSC with a properly operating water seal at the entrance or exit to each item of equipment to restrict ventilation in the collection system. The vent pipe shall be at least 90 cm in length and not exceeding 10.2 cm in nominal inside diameter. The lift station shall be level controlled to minimize changes in the liquid level.
- 2) The item of equipment is of a type identified in Table 5 of Subpart GGG; [§63.1252(f)(2)]
- 3) The item of equipment is part of a PMPU, as defined in §63.1251; [§63.1252(f)(3)]
- 4) The item of equipment is controlled less stringently than in Table 5 of this subpart and the item of equipment is not otherwise exempt from controls by the provisions of Subpart GGG or subpart A of Part 63 and; [§63.1252(f)(4)]
- 5) The item of equipment: [§63.1252(f)(5)]
  - a) Is a drain, drain hub, manhole, lift station, trench, pipe, or oil/water separator that conveys water with an annual average concentration greater than or equal to 1,300 parts per million by weight (ppmw) of partially soluble HAP compounds; or an annual average concentration greater than or equal to 5,200 ppmw of partially soluble and/or soluble HAP compounds. The annual average concentration shall be determined according to the procedures in §63.1257(e)(1)(ii). [§63.1252(f)(5)(i)]
  - b) Is a tank that receives one or more streams that contain water with an annual average concentration greater than or equal to 1,300 ppmw of partially soluble HAP compounds, or greater than or equal to 5,200 ppmw of total partially soluble and/or soluble HAP compounds. The Permittee shall determine the average concentration of the stream at the inlet to the tank and according to the procedures in §63.1257(e)(1)(ii). [§63.1252(f)(5)(ii)]

**Testing Methods and Compliance Procedures:**

- 1) Where a tightly fitting solid cover is required, it shall be maintained with no visible gaps or openings, except during periods of sampling, inspection, or maintenance. [Table 5 of Subpart GGG, Footnote "a"]
- 2) *Determination of annual average concentration.* The Permittee shall determine annual average concentrations of partially soluble and/or soluble HAP compounds in accordance with the provisions specified in §63.1257(e)(1)(ii)(A), (B), or (C). The Permittee may determine annual average concentrations by process simulation. Data and other information supporting the simulation shall be reported in the Precompliance Report for approval by the administrator. The annual average concentration shall be determined either at the POD or downstream of the POD with adjustment for concentration changes made according to §63.1257(e)(1)(ii)(D). [§63.1257(e)(1)(ii)]
  - a) *Test methods.* The concentration of partially soluble HAP, soluble HAP, or total HAP shall be measured using any of the methods described in §63.1257(b)(10)(i) through (iv). [§63.1257(e)(1)(ii)(A)]
  - b) *Knowledge of the wastewater stream.* The concentration of partially soluble HAP, soluble HAP, or total HAP shall be calculated based on knowledge of the wastewater stream according to the procedures in §63.1257(e)(1)(ii)(B)(1) and (2). [§63.1257(e)(1)(ii)(B)]
    - i) *Mass balance.* The Permittee shall calculate the concentrations of HAP compounds in wastewater considering the total quantity of HAP discharged to the water, the amount of water at the POD, and the amounts of water and solvent lost to other mechanisms such as reactions, air emissions, or uptake in product or other processing materials. The quantities of HAP and water shall be based on batch sheets, manufacturing tickets, or FDA bills of materials. In cases where a chemical reaction occurs that generates or consumes HAP, the amount of HAP remaining after a reaction shall be based on stoichiometry assuming 100 percent theoretical consumption or yield, as applicable. [§63.1257(e)(1)(ii)(B)(1)]
    - ii) *Published water solubility data.* For single components in water, owners and operators may use the water solubilities published in standard reference texts at the POD temperature to determine maximum HAP concentration. [§63.1257(e)(1)(ii)(B)(2)]
  - c) *Adjustment for concentrations determined downstream of the POD.* The Permittee shall make corrections to the annual average concentration when the concentration is determined downstream of the POD at a location where: two or more wastewater streams have been mixed; one or more wastewater streams have been treated; or, losses to the atmosphere have occurred. The Permittee shall make the adjustments either to the individual data points or to the final annual average concentration. [§63.1257(e)(1)(ii)(D)]

**PERMIT CONDITION PW004**

10 CSR 10-6.075

**Maximum Achievable Control Technology Regulations**

40 CFR Part 63, Subpart GGG – Control Device Requirements

**National Emission Standards for Pharmaceutical Production - Notification of Compliance Status Report - Final Submission February 16, 2006**

**Operational and Monitoring Requirements:**

- 1) For each control device, the owner or operator shall install and operate monitoring devices and operate within the established parameter levels to ensure continued compliance with the standard. [§63.1258(b)(1)]
  - a) The Permittee shall monitor the Regenerative Thermal Oxidizer during operation for the established operating parameters listed in Attachment A. [§63.1258(h)(3)]
    - i) The temperature monitoring device must be accurate to within  $\pm 0.75$  percent of the temperature measured in degrees Celsius or  $\pm 2.5$  °C, whichever is greater. [§63.1258(b)(vii)(A)]
    - ii) The monitoring device must be calibrated annually [§63.1258(b)(vii)(B)]
  - b) The Permittee shall monitor scrubbers Y-601, Y-606 and Y-801 during operation for the established operating parameters listed in Attachment A. [§63.1258(b)(ii)]
    - i) The monitoring device used for measurement of scrubber liquid flowrate shall be certified by the manufacturer to be accurate within  $\pm 10\%$  of the design scrubber liquid flowrate. [§63.1258(b)(ii)(B)]

- ii) The monitoring device shall be calibrated annually. [§63.1258(b)(ii)(C)]
- c) The Fixed Bed Carbon Adsorber APC-018 shall be monitored during operation for the established operating parameters listed in Attachment A. [§63.1258(b)(iv)(B)]
  - i) Use a temperature monitoring device that is accurate to within  $\pm 2$  percent of the temperature measured in degrees Celsius or  $\pm 2.5$  °C, whichever is greater. [§63.1258(b)(iv)(C)]
  - ii) Use a regeneration stream flow monitoring device capable of recording the total regeneration stream flow to within  $\pm 10\%$  of the established value (i.e., accurate to within  $\pm 10\%$  of the reading). [§63.1258(b)(iv)(D)]
  - iii) Calibrate the temperature and flow monitoring devices annually. [§63.1258(b)(iv)(E)]
  - iv) Conduct an annual check for bed poisoning in accordance with manufacturer's specifications. [§63.1258(b)(iv)(F)]
- 2) To achieve the minimum 98% emission control efficiency required for the D-601 Fluid Bed Drier as required by §63.1254(a)(3)(i);
  - a) The exhaust from the D-601 Dryer will first pass through Scrubber Y-601 before entering the Regenerative Thermal Oxidizer as demonstrated on December 22, 2005, and as described in the referenced Notification of Compliance Report.
- 3) The Permittee shall perform the following to ensure proper functioning of the equipment:
  - a) If leaks or abnormal conditions are detected, the appropriate measures for remediation shall be implemented within eight hours.
  - b) All instruments and control equipment shall be calibrated, maintained and operated according to manufacturer's specifications.

**Recordkeeping and Reporting:**

The recordkeeping requirements are found in §63.1259(b) and reporting requirements are outlined in §63.1260(a).

### III. Emission Unit Specific Emission Limitations

EU0010 – EU0020 Dual Fired Boilers			
Emission Unit	Description	Manufacturer/Model #	2005 EIQ Reference #
EU0010	Two (2) - 8.4 MMBTU/hr Boilers (Natural Gas & Fuel Oil #2). Year in place 1990	Cleaver Brooks/ Two CB200 - 200	EP-BOILER

#### PERMIT CONDITION EU0010-001

10 CSR 10-3.060

#### Maximum Allowable Emissions of Particulate Matter from Fuel Burning Equipment Used for Indirect Heating

**Emissions Limitations:**

The Permittee shall not emit particulate matter in excess of 0.814 pounds per million BTU of heat input.

**Monitoring & Recordkeeping:**

The Permittee shall maintain calculations demonstrating compliance with the limit when operating at maximum potential. (See Attachment D)

**Reporting:**

The Permittee shall report to the Air Pollution Control Program, Enforcement Section, P.O. Box 176, Jefferson City, MO 65102, no later than 15 days after any exceedance of 10 CSR 10-3.060 demonstrated by the appropriate recordkeeping forms.

#### PERMIT CONDITION EU0010-002

10 CSR 10-6.260

#### Restriction of Emission of Sulfur Compounds

**Emission Limitation:**

The Permittee shall not emit in excess of eight lbs/MMBTU of sulfur dioxide averaged on any consecutive three hour time period.

**Monitoring and Recordkeeping:**

The Permittee shall maintain calculations demonstrating compliance with the limit when operating at maximum potential. (See Attachment D)

**Reporting:**

The Permittee shall report to the Air Pollution Control Program, Enforcement Section, P.O. Box 176, Jefferson City, MO 65102, no later than 15 days after any exceedance or equipment malfunction, which causes an exceedance to the aforementioned limit.

## PERMIT CONDITION EU0010-003

10 CSR 10-6.220

### Restriction of Emissions of Visible Air Contaminants

#### Emission Limitation:

- 1) No owner or other person shall cause or permit emissions to be discharged into the atmosphere from any new source any visible emissions with an opacity greater than 20%.
- 2) Exception: A person may discharge into the atmosphere from any source of emissions for a period(s) aggregating not more than six minutes in any 60 minutes air contaminants with an opacity up to 60%.

#### Monitoring:

- 1) The Permittee shall conduct a visual emission observation on this emission unit once a month using the procedures contained in U.S. EPA Test Method 22. At a minimum, the observer should be trained and knowledgeable about the effects on visibility of emissions caused by background contrast, ambient lighting, observer position relative to lighting, wind and the presence of uncombined water. Readings are only required when the emission unit is operating and when the weather conditions allow. If no visible or other significant emissions were observed using these procedures, then no further observations would be required. For emission units with visible emissions perceived or believed to exceed the applicable opacity standard, the source representative would then conduct a Method 9 observation.
- 2) Should a violation be observed, monitoring frequency will progress in the following manner:
- 3) Weekly observations shall be conducted for a minimum of eight consecutive weeks after the date of the initial violation. Should no violation of this regulation be observed during this period, then,
- 4) Observations must be made once every two weeks for a period of eight weeks. If a violation is noted, monitoring reverts to weekly. Should no violation of this regulation be observed during this period, then,
- 5) Observations must be made once per month.
- 6) If the source reverts to weekly monitoring at any time, monitoring frequency will progress in an identical manner from the initial monitoring frequency.

#### Recordkeeping:

- 1) The Permittee shall maintain records of all observation results (see Attachment F1 or F2), noting:
  - a) Whether any air emissions (except for water vapor) were visible from the emission units,
  - b) All emission units from which visible emissions occurred, and
  - c) Whether the visible emissions were normal for the process.
- 2) The Permittee shall maintain records of any equipment malfunctions. (see Attachment G)
- 3) The Permittee shall maintain records of any Method 9 test performed in accordance with this permit condition. (see Attachment H)
- 4) Attachments F1, or F2, G and H contain logs including these recordkeeping requirements. These logs, or an equivalent created by the Permittee, must be used to certify compliance with this requirement.
- 5) These records shall be made available immediately for inspection to Department of Natural Resources' personnel upon request.
- 6) All records shall be maintained for five years.

#### Reporting:

- 1) The Permittee shall report to the Air Pollution Control Program, Enforcement Section, P.O. Box 176, Jefferson City, MO 65102, no later than ten days after the Permittee determined using the Method 9 test that the emission unit(s) exceeded the opacity limit.
- 2) Reports of any deviations from monitoring, recordkeeping and reporting requirements of this permit condition shall be submitted semiannually, in the semi-annual monitoring report and annual compliance certification, as required by Section V of this permit.

<b>EU0020 – 18 MMBTU Dual Fired Boiler</b>			
Emission Unit	Description	Manufacturer/Model #	2005 EIQ Reference #
EU0020	18 MMBTU/hr Boiler (Natural Gas & Fuel Oil #2).	Cleaver Brooks	EP-BOILER

### **Permit Condition EU0020-001**

10 CSR 10-6.070

#### **New Source Performance Regulations**

40 CFR Part 60 Subpart Dc

Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units

#### **Emission Limitations:**

- 1) The Permittee shall not combust oil in EU0030 that contains greater than 0.5 weight percent sulfur. [§60.42c(d)]
- 2) The Permittee has elected to demonstrate compliance with the fuel oil sulfur limits based on a certification from the fuel supplier. [§60.42c(h)(1)]
- 3) The fuel oil sulfur limit applies at all times, including periods of startup, shutdown, and malfunction. [§60.42c(i)]

#### **Monitoring:**

The monitoring requirements of §60.46c do not apply to facilities where the owner or operator demonstrates compliance with the SO<sub>2</sub> standards based on fuel supplier certification. Therefore, there are no further monitoring requirements. [§60.46c(e)]

#### **Recordkeeping/Reporting:**

- 1) The Permittee shall keep records and submit reports as required including the following information, as applicable: [§60.48c(e)]
  - a) Calendar dates covered in the reporting period. [§60.48c(e)(1)]
  - b) If fuel supplier certification is used to demonstrate compliance, records of fuel supplier certification as described under §60.48c(f)(1). [§60.48c(e)(11)]
    - i) Fuel supplier certification for distillate oil shall include the following information: [§60.48c(f)(1)]
      - 1) The name of the oil supplier; and [§60.48c(f)(1)(i)]
      - 2) A statement from the oil supplier that the oil complies with the specifications under the definition of distillate oil in §60.41c. [§60.48c(f)(1)(ii)]
  - c) In addition to records of fuel supplier certifications, the report shall include a certified statement signed by the responsible official that the records of fuel supplier certifications submitted represent all of the fuel combusted during the reporting period. [§60.48c(e)(11)]
- 2) The Permittee shall record and maintain records of the amounts of each fuel combusted during each day. [§60.48c(g)]
- 3) All records shall be maintained for five years and shall be made available immediately for inspection to the Department of Natural Resources' personnel upon request.
- 4) The reporting period for the reports required under subpart Dc is each six-month period. All reports shall be submitted to the Missouri Department of Natural Resources and shall be postmarked by the 30th day following the end of the reporting period. [§60.48c(i)]
- 5) The Permittee shall report any deviations/exceedances of this permit condition using the semi-annual monitoring report and annual compliance certification to the Air Pollution Control Program, Enforcement Section, P.O. Box 176, Jefferson City, MO 65102, as required by Section V of this permit.

<b>EU0030 through EU0050 - Bulk Storage Tanks</b>			
Emission Unit	Description	Manufacturer/Model #	EIQ Reference # (Year)
EU0030	15,000 gallon Tank Farm Storage Tank – containing methanol, connected to a packed gas absorption column (Y-801). Year in place 1990 - 90% control	Winbco Tank Co. / Model #90108	EP T812 (2005)
EU0040	20,150 gallon Methanol or Butyl Acetate Storage Tank Connected to a Packed Gas Absorption Column (Y- 801). Year in place 1990 - 95% control	Winbco Tank Co. / Model #90124	EP T810 (2004)
EU0050	Tank Farm with Dimethylformamide, Methanol, Toluene, Isopropyl Alcohol, or Butyl Acetate Storage Tanks. 95% control Year in place 1990 - 95% control	Winbco Tank Co. / Model #90122	EP T822, EP T823, (2004) EP T815, EP T825 (2005)

**Permit Condition (EU0030 through EU0050)-001**

10 CSR 10-6.075  
 40 CFR Part 63, Subpart GGG  
**National Emission Standards for Pharmaceuticals Production**  
 40 CFR Part 63, Subpart A  
 General Provisions

**Emission Limitation:**

- 1) Storage Tank Unit EU0030 Requirements – When storing liquid that has a maximum true vapor pressure that exceeds 13.1 kPa; [§63.1253(a)]
  - a) The Permittee of a storage tank shall equip the affected storage tank with a closed-vent system meeting the conditions of §63.1252(b) with a control device that reduces inlet emissions of total HAP by 90% by weight or greater; [§63.1253(b) & (b)(1)]
- 2) Storage Tank Units EU0040 and EU0050 - When storing liquid that has a maximum true vapor pressure that exceeds 13.1 kPa; [§63.1253(a)]
  - a) The Permittee of a storage tank shall equip the affected storage tank a closed-vent system meeting the conditions of §63.1252(b) with a control device that Reduces inlet emissions of total HAP as By 95% by weight or greater.[§63.1253(c) & (§63.1253(c)(1)(i))]

**Monitoring Requirements:**

- 1) The Permittee of any existing, new, or reconstructed affected source shall provide evidence of continued compliance with the standard. [§63.1258(a)]
- 2) Monitoring for control devices. [§63.1258(b)]
  - a) Parameters to monitor. Except as specified in §63.1258(b)(1)(i), for each control device, the Permittee shall operate monitoring devices within the established parameter levels to ensure continued compliance with the standard. See Attachment A. [§63.1258(b)(1)]
    - i) Periodic verification. For control devices that control vent streams totaling less than one 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 §63.1258(b)(1)(ii) through (x). [§63.1258(b)(1)(i)]

- ii) CVS visual inspections. The Permittee shall perform monthly visual inspections of each closed vent system as specified in §63.1252(b). [§63.1258(b)(1)(xi)]
- b) Exceedances of operating parameters. An exceedance of an operating parameter is defined as one of the following: [§63.1258(b)(6)]
  - i) If the parameter, averaged over the operating day or block, is below a minimum value established during the initial compliance demonstration. [§63.1258(b)(6)(i)]
  - ii) If the parameter, averaged over the operating day or block, is above the maximum value established during the initial compliance demonstration. [§63.1258(b)(6)(ii)]
- c) Excursions. Excursions are defined by either of the two cases listed in §63.1258(b)(7)(i) or (ii). [§63.1258(b)(7)]
  - i) When the period of control device operation is four hours or greater in an operating day and monitoring data are insufficient to constitute a valid hour of data, as defined in §63.1258(b)(7)(iii), for at least 75 percent of the operating hours. [§63.1258(b)(7)(i)]
  - ii) When the period of control device operation is less than four hours in an operating day and more than one of the hours during the period of operation does not constitute a valid hour of data due to insufficient monitoring data. [§63.1258(b)(7)(ii)]
  - iii) Monitoring data are insufficient to constitute a valid hour of data, as used in §63.1258(b)(7)(i) and (ii), if measured values are unavailable for any of the required 15-minute periods within the hour. [§63.1258(b)(7)(iii)]
- d) Violations. Exceedances of parameters monitored according to the provisions of §63.1258(b)(1)(ii), (iv) through (ix), and §63.1258(b)(5)(ii)(A) and (B), or excursions as defined by §63.1258(b)(7)(i) through (iii), constitute violations of the operating limit according to §63.1258(b)(8)(i), (ii), and (iv). Exceedances of the temperature limit monitored according to the provisions of §63.1258(b)(1)(iii) or exceedances of the outlet concentrations monitored according to the provisions of §63.1258(b)(1)(x) constitute violations of the emission limit according to §63.1258(b)(8)(i), (ii), and (iv). Exceedances of the outlet concentrations monitored according to the provisions of §63.1258(b)(5) constitute violations of the emission limit according to the provisions of §63.1258(b)(8)(iii) and (iv). [§63.1258(b)(8)]
  - i) Except as provided in §63.1258(b)(8)(iv), for episodes occurring more than once per day, exceedances of established parameter limits or excursions will result in no more than one violation per operating day for each monitored item of equipment utilized in the process. [§63.1258(b)(8)(i)]
  - ii) Except as provided in §63.1258(b)(8)(iv), for control devices used for more than one process in the course of an operating day, exceedances or excursions will result in no more than one violation per operating day, per control device, for each process for which the control device is in service. [§63.1258(b)(8)(ii)]
  - iii) Except as provided in §63.1258(b)(8)(iv), exceedances of the 20 or 50 ppmv TOC outlet emission limit, averaged over the operating day, will result in no more than one violation per day per control device. Except as provided in §63.1258(b)(8)(iv), exceedances of the 20 or 50 ppmv hydrogen halide or halogen outlet emission limit, averaged over the operating day, will result in no more than one violation per day per control device. [§63.1258(b)(8)(iii)]
  - iv) Periods of time when monitoring measurements exceed the parameter values as well as periods of inadequate monitoring data do not constitute a violation if they occur during a startup, shutdown, or malfunction, and the facility follows its startup, shutdown, and malfunction plan. [§63.1258(b)(8)(iv)]
- 3) *Leak inspection provisions for vapor suppression equipment.* [§63.1258(h)]
  - a) If a closed-vent system subject to §63.1258 is also subject to the equipment leak provisions of §63.1255, the Permittee shall comply with the provisions of §63.1255 and is exempt from the requirements. See Plant-wide Condition PW002 [§63.1258(h)(9)]

**Recordkeeping:**

- 1) Records shall be maintained as specified in §63.1259(i)(4) through (9). [§63.1258(h)(8)]

- 2) Requirements of subpart A of Part 63. The Permittee of an affected source shall comply with the recordkeeping requirements in subpart A of 40 CFR Part 63 as specified in Table 1 of Subpart GGG and in §63.1259(a)(1) through (5). [§63.1259(a)]
  - a) Data retention. Each Permittee of an affected source shall keep copies of all records and reports required by Subpart GGG for at least five years, as specified in §63.10(b)(1). [§63.1259(a)(1)]
  - b) Records of applicability determinations. The Permittee of a stationary source that is not subject to Subpart GGG shall keep a record of the applicability determination, as specified in §63.10(b)(3). [§63.1259(a)(2)]
  - c) Startup, shutdown, and malfunction plan. See Plant-wide Condition PW-001. [§63.1259(a)(3)]
  - d) Application for approval of construction or reconstruction. For new affected sources, each Permittee shall comply with the provisions in §63.5 regarding construction and reconstruction, excluding the provisions specified in §63.5(d)(1)(ii)(H), (d)(2), and (d)(3)(ii). (§63.1259(a)(5))
- 3) Records of equipment operation. The Permittee must keep the following records up-to-date and readily accessible: [§63.1259(b)]
  - a) Each measurement of a control device operating parameter monitored in accordance with §63.1258. [§63.1259(b)(1)]
  - b) Number of storage tank turnovers per year, if used in an emissions average. [§63.1259(b)(7)]
  - c) A schedule or log of each operating scenario updated daily or, at a minimum, each time a different operating scenario is put into operation. [§63.1259(b)(8)]
  - d) Description of worst-case operating conditions as required in §63.1257(b)(8). [§63.1259(b)(9)]
  - e) Periods of planned routine maintenance as described in §§63.1252(h) and 63.1257(c)(5). [§63.1259(b)(10)]
  - f) If the Permittee elects to comply with §63.1253(b) or (c) by installing a floating roof (technology standard), the Permittee must keep records of each inspection and seal gap measurement in accordance with §63.123(c) through (e) as applicable. [§63.1259(b)(11)]
  - g) All maintenance performed on the air pollution control equipment. [§63.1259(b)(13)]
- 4) Records of operating scenarios. The Permittee of an affected source shall keep records of each operating scenario which demonstrates compliance with Subpart GGG. [§63.1259(c)]
- 5) Records of inspections. The Permittee shall keep records specified in §63.1259(i)(4) through (9). [§63.1259(i)]
  - a) Records identifying all parts of the vapor collection system, closed-vent system fixed roof, cover, or enclosure that are designated as unsafe to inspect in accordance with §63.1258(h)(6), an explanation of why the equipment is unsafe to inspect, and the plan for inspecting the equipment. [§63.1259(i)(4)]
  - b) Records identifying all parts of the vapor collection system, closed-vent system, fixed roof, cover, or enclosure that are designated as difficult to inspect in accordance with §63.1258(h)(7), an explanation of why the equipment is difficult to inspect, and the plan for inspecting the equipment. [§63.1259(i)(5)]
  - c) For each vapor collection system or closed-vent system that contains bypass lines that could divert a vent stream away from the control device and to the atmosphere, the Permittee shall keep a record of the information specified in either §63.1259(i)(6)(i) or (ii). [§63.1259(i)(6)]
    - i) Hourly records of whether the flow indicator specified under §63.1252(b)(1) was operating and whether a diversion was detected at any time during the hour, as well as records of the times and durations of all periods when the vent stream is diverted from the control device or the flow indicator is not operating. [§63.1259(i)(6)(i)]
    - ii) Where a seal mechanism is used to comply with §63.1252(b)(2), hourly records of flow are not required. In such cases, the Permittee shall record that the monthly visual inspection of the seals or closure mechanisms has been done, and shall record the occurrence of all periods when the seal mechanism is broken, the bypass line valve position has changed, or the key for a lock-and-key type lock has been checked out, and records of any car-seal that has broken. [§63.1259(i)(6)(ii)]
  - d) For each inspection conducted in accordance with §63.1258(h)(2) and (3) during which a leak is detected, a record of the information specified in §63.1259(i)(7)(i) through (ix). [§63.1259(i)(7)]
    - i) Identification of the leaking equipment. [§63.1259(i)(7)(i)]

- ii) The instrument identification numbers and operator name or initials, if the leak was detected using the procedures described in §63.1258(h)(3); or a record that the leak was detected by sensory observations. [§63.1259(i)(7)(ii)]
- iii) The date the leak was detected and the date of the first attempt to repair the leak. [§63.1259(i)(7)(iii)]
- iv) Maximum instrument reading measured by the method specified in §63.1258(h)(4) after the leak is successfully repaired or determined to be nonrepairable. [§63.1259(i)(7)(iv)]
- v) “Repair delayed” and the reason for the delay if a leak is not repaired within 15 calendar days after discovery of the leak. [§63.1259(i)(7)(v)]
- vi) The name, initials, or other form of identification of the Permittee (or designee) whose decision it was that repair could not be effected without a shutdown. [§63.1259(i)(7)(vi)]
- vii) The expected date of successful repair of the leak if a leak is not repaired within 15 calendar days. [§63.1259(i)(7)(vii)]
- viii) Dates of shutdowns that occur while the equipment is unrepaired. [§63.1259(i)(7)(viii)]
- ix) The date of successful repair of the leak. [§63.1259(i)(7)(ix)]
- e) For each inspection conducted in accordance with §63.1258(h)(3) during which no leaks are detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected. [§63.1259(i)(8)]
- f) For each visual inspection conducted in accordance with §63.1258(h)(2)(i)(B) or (h)(2)(iii)(B) during which no leaks are detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected. [§63.1259(i)(9)]

**Reporting:**

- 1) The Permittee of an affected source shall comply with the reporting requirements of §63.1260(b) through (l). Applicable reporting requirements of §§63.9 and 63.10 are also summarized in Table 1 of Subpart GGG. [§63.1260(a)]
- 2) Periodic reports. A Permittee shall prepare Periodic reports in accordance with §63.1260(g)(1) and (2) and submit them to the Administrator. [§63.1260(g)]
  - a) Submittal schedule. Except as provided in §63.1260(g)(1)(i), (ii), and (iii), a Permittee shall submit Periodic reports semiannually [§63.1260(g)(1)]
    - i) When the administrator determines on a case-by-case basis that more frequent reporting is necessary to accurately assess the compliance status of the affected source or; [§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 a Permittee 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 §63.1260. [§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. [§63.1260(g)(1)(iii)]
  - b) Content of Periodic report. The Permittee shall include the information in §63.1260(g)(2)(i) through (vii), as applicable. [§63.1260(g)(2)]
    - 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). [§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 information in §63.1260(g)(2)(ii)(A) through (D). [§63.1260(g)(2)(ii)]

- (1) 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. [§63.1260(g)(2)(ii)(A)]
  - (2) Duration of excursions, as defined in §63.1258(b)(7). [§63.1260(g)(2)(ii)(B)]
  - (3) Operating logs and operating scenarios for all operating scenarios for all operating days when the values are outside the levels established in the Notification of Compliance Status report or operating permit. [§63.1260(g)(2)(ii)(C)]
  - (4) When a continuous monitoring system is used, the information required in §63.10(c)(5) through (13). [§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. [§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. [§63.1260(g)(2)(iv)]
  - v) The information in §63.1260(g)(2)(v)(A) through (D) shall be stated in the Periodic report, when applicable. [§63.1260(g)(2)(v)]
    - (1) No excess emissions. [§63.1260(g)(2)(v)(A)]
    - (2) No exceedances of a parameter. [§63.1260(g)(2)(v)(B)]
    - (3) No excursions. [§63.1260(g)(2)(v)(C)]
  - vi) The information specified in §63.1260(g)(2)(vi)(A) through (C) for periods of planned routine maintenance. [§63.1260(g)(2)(vi)]
    - (1) For each storage tank subject to control requirements, periods of planned routine maintenance during which the control device does not meet the specifications of §63.1253(b) through (d). [§63.1260(g)(2)(vi)(A)]
    - (2) For a CCCD subject to §63.1252(h), periods of planned routine maintenance during the current reporting period and anticipated periods of planned routine maintenance during the next reporting period. [§63.1260(g)(2)(vi)(B)]
    - (3) Rationale for why planned routine maintenance of a CCCD subject to §63.1252(h) must be performed while a process with a vent subject to §63.1254(a)(3) will be operating, if applicable. This requirement applies only if the rationale is not in, or differs from that in, the Notification of Compliance Status report. [§63.1260(g)(2)(vi)(C)]
  - vii) Each new operating scenario which has been operated since the time period covered by the last Periodic report. For each new operating scenario, the Permittee 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. [§63.1260(g)(2)(vii)]
- 3) Notification of process change. [§63.1260(h)]
- a) Except as specified in §63.1260(h)(2), whenever a process change is made, or a change in any of the information submitted in the Notification of Compliance Status Report, the Permittee shall submit the information specified in §63.1260(h)(1)(i) through (iv) with the next Periodic report required under §63.1260(g). [§63.1260(h)(1)]
    - i) A brief description of the process change. [§63.1260(h)(1)(i)]
    - ii) A description of any modifications to standard procedures or quality assurance procedures. [§63.1260(h)(1)(ii)]
    - iii) Revisions to any of the information reported in the original Notification of Compliance Status Report under §63.1260(f). [§63.1260(h)(1)(iii)]

- iv) Information required by the Notification of Compliance Status Report under §63.1260(f) for changes involving the addition of processes or equipment. [§63.1260(h)(1)(iv)]
- b) A Permittee must submit a report 60 days before the scheduled implementation date of either of the following: [§63.1260(h)(2)]
  - i) Any change in the activity covered by the Precompliance report. [§63.1260(h)(2)(i)]
  - ii) A change in the status of a control device from small to large. [§63.1260(h)(2)(ii)]
- 4) Reports of startup, shutdown, and malfunction. See Plant-wide Condition PW-001. [§63.1260(i)]

<b>EU0060 through EU0090 - Process Equipment</b>			
Emission Unit	Description	Emission Control Device	2005 EIQ Reference #
EU0060	7 ADCA – 400-500 Process 7 - Aminodeacetyloxy penicillanic Acid (ADCA) Process (500). Year in place 1990	Regenerative Thermal Oxidizer (APC-18)	EP 400, EP 500 (2004)
EU0070	Cephalexin Process (600) – Includes Reactors, Air Dryer (vented to Scrubber Y-601 before APC-18), and Centrifuge. Other configurations are used for Cefaclor USP (650) and Cephadrine (630) production. Year in place 1990		EP 6000, 6001, 6002, 6002A, 6003, 6003A
EU0080	V-873 Methanol Distillation Column		EP-862M
EU0090	V-852 Toluene Distillation Column		EP-SRT

**Permit Conditions (EU0060 through EU0090)-001**

10 CSR 10-6.075  
**40 CFR Part 63, Subpart GGG**  
 National Emission Standards for Pharmaceuticals Production- Standards for Process Vents

**Emission Limitation:**

- 1) 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. [§63.1252(a)]
- 2) The Permittee 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 §63.1254 shall comply with the requirements of Table 4 to Subpart GGG and §63.1252(b)(1) or (2). Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and pressure relief valves needed for safety purposes are not subject to this paragraph. [§63.1252(b)]
  - a) 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; [§63.1252(b)(1)]
  - b) 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). [§63.1252(b)(2)]
- 3) *Control requirements for halogenated vent streams that are controlled by combustion devices.* If a combustion device is used to comply with the provisions of §63.1254 (process vents) 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 §63.1252(g)(1) or (2). [§63.1252(g)]

- a) 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 percent or to a concentration less than or equal to 20 ppmv. [§63.1252(g)(1)]
- b) 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. [§63.1252(g)(2)]
- 4) *Planned routine maintenance for centralized combustion control devices (CCCD)*. The Permittee may operate non-dedicated pharmaceutical manufacturing process units (PMPU's) during periods of planned routine maintenance for CCCD in accordance with the provisions specified in §63.1252(h)(2) through (6). [§63.1252(h)]
  - a) During the planned routine maintenance period, the Permittee must route emissions from process vents with organic HAP emissions greater than 15 pounds per day (lb/day) through a closed-vent system to a condenser that meets the conditions specified in §63.1252(h)(2)(i) through (iii). [§63.1252(h)(2)]
  - b) The outlet gas temperature must be less than  $-50^{\circ}\text{C}$  ( $-58^{\circ}\text{F}$ ) when the emission stream contains organic HAP with a partial pressure greater than 20 kPa (2.9 psia). [§63.1252(h)(2)(1)]
  - c) The outlet gas temperature must be less than  $-5^{\circ}\text{C}$  ( $23^{\circ}\text{F}$ ) when the emission stream contains organic HAP with a partial pressure less than or equal to 20 kPa (2.9 psia). [§63.1252(h)(2)(ii)]
  - d) The HAP partial pressures in §63.1252(h)(2)(i) and (ii) must be determined at  $25^{\circ}\text{C}$ . [§63.1252(h)(2)(iii)]
  - e) The Permittee must route HCl emissions from process vents with HCl emissions greater than 15 lb/day through a closed-vent system to a caustic scrubber, and the pH of the scrubber effluent must be maintained at or above 9. [§63.1252(h)(3)]
  - f) For the purposes of the emission calculations required in §63.1252(h)(2) and (3), the term "process vent" shall mean each vent from a unit operation. The emission calculation shall not be performed on the aggregated emission stream from multiple unit operations that are manifolded together into a common header. Once an affected process vent has been controlled in accordance with §63.1252, it is no longer subject to the requirements §63.1252 or §63.1254 during the routine maintenance period. [§63.1252(h)(4)]
  - g) The total period of planned routine maintenance, during which non-dedicated PMPU's that are normally controlled by the CCCD continue to operate, and process vent emissions are controlled as specified in §63.1252(h)(2) and (3), must not exceed 240 hours in any 365-day period. [§63.1252(h)(5)]
  - h) While being controlled as specified in §63.1252(h)(2) and (3), the process vents may not be used in emissions averaging. [§63.1252(h)(6)]
- 5) *Existing Processes*: For each process, the Permittee of an existing affected source must comply with the requirements in §63.1254(a)(1) and (3). Continuous compliance is demonstrated in accordance with the monitoring requirements described in §63.1258. [§63.1254(a)]
  - a) *Process-based emission reduction requirement*. [§63.1254(a)(1)]
    - i) Emission Units EU0060, EU0080, & EU0090 - Uncontrolled HAP emissions from the sum of all process vents within a process that are not subject to the requirements of §63.1254(a)(3) shall be reduced by 93% or greater by weight, or as specified in §63.1254(a)(1)(ii). Notification of changes in the compliance method shall be reported according to the procedures in §63.1260(h). [§63.1254(a)(1)(i)]
  - b) *Individual vent emission reduction requirements*. [§63.1254(a)(3)]
    - i) Emission unit EU0070 - Except as provided in §63.1254(a)(3)(ii), uncontrolled HAP emissions from a process vent must be reduced by 98% or in accordance with any of the procedures in §63.1254(a)(1)(ii)(A) through (D) if the uncontrolled HAP emissions from the vent exceed 25 tons per year, and the flow-weighted average flowrate (FRa) calculated using Equation 1 of Subpart GGG is less than or equal to the flowrate index (FRI) calculated using Equation 2 of Subpart GGG [§63.1254(a)(3)(i)]

$$FR_a = \frac{\sum_{i=1}^n (D_i)(FR_i)}{\sum_{i=1}^n (D_i)} \quad (Eq.1)$$

$$FRI = 0.02 * (HL) - 1,000 \quad (Eq.2)$$

Where:

FR<sub>a</sub> = flow-weighted average flowrate for the vent, scfm

D<sub>i</sub> = duration of each emission event, min

FR<sub>i</sub> = flowrate of each emission event, scfm

n = number of emission events

FRI = flowrate index, scfm

HL = annual uncontrolled HAP emissions, lb/yr, as defined in §63.1251

**Monitoring Requirements:**

- 1) The Permittee of any existing, new, or reconstructed affected source shall provide evidence of continued compliance with the standard. [§63.1258(a)]
- 2) *Monitoring for control devices.* [§63.1258(b)]
  - a) *Parameters to monitor.* Except as specified in §63.1258(b)(1)(i), for each control device, the Permittee shall operate monitoring devices within the established parameter levels to ensure continued compliance with the standard. See Attachment A. [§63.1258(b)(1)]
    - i) *Periodic verification.* For control devices that control vent streams totaling less than one 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 §63.1258(b)(1)(ii) through (x). [§63.1258(b)(1)(i)]
    - ii) *CVS visual inspections.* The Permittee shall perform monthly visual inspections of each closed vent system as specified in §63.1252(b). [§63.1258(b)(1)(xi)]
  - b) *Exceedances of operating parameters.* An exceedance of an operating parameter is defined as one of the following: [§63.1258(b)(6)]
    - i) If the parameter, averaged over the operating day or block, is below a minimum value established during the initial compliance demonstration. [§63.1258(b)(6)(i)]
    - ii) If the parameter, averaged over the operating day or block, is above the maximum value established during the initial compliance demonstration. [§63.1258(b)(6)(ii)]
  - c) *Excursions.* Excursions are defined by either of the two cases listed in §63.1258(b)(7)(i) or (ii). [§63.1258(b)(7)]
    - i) When the period of control device operation is 4 hours or greater in an operating day and monitoring data are insufficient to constitute a valid hour of data, as defined in §63.1258(b)(7)(iii), for at least 75% of the operating hours. [§63.1258(b)(7)(i)]
    - ii) When the period of control device operation is less than 4 hours in an operating day and more than one of the hours during the period of operation does not constitute a valid hour of data due to insufficient monitoring data. [§63.1258(b)(7)(ii)]
    - iii) Monitoring data are insufficient to constitute a valid hour of data, as used in §63.1258(b)(7)(i) and (ii), if measured values are unavailable for any of the required 15-minute periods within the hour. [§63.1258(b)(7)(iii)]
  - d) *Violations.* Exceedances of parameters monitored according to the provisions of §63.1258(b)(1)(ii), (iv) through (ix), and §63.1258(b)(5)(ii)(A) and (B), or excursions as defined by §63.1258(b)(7)(i) through (iii), constitute violations of the operating limit according to §63.1258(b)(8)(i), (ii), and (iv). Exceedances of the temperature limit monitored according to the provisions of §63.1258(b)(1)(iii) or exceedances of

the outlet concentrations monitored according to the provisions of §63.1258(b)(1)(x) constitute violations of the emission limit according to §63.1258(b)(8)(i), (ii), and (iv). [§63.1258(b)(8)]

- i) Except as provided in §63.1258(b)(8)(iv), for episodes occurring more than once per day, exceedances of established parameter limits or excursions will result in no more than one violation per operating day for each monitored item of equipment utilized in the process. [§63.1258(b)(8)(i)]
  - ii) Except as provided in §63.1258(b)(8)(iv), for control devices used for more than one process in the course of an operating day, exceedances or excursions will result in no more than one violation per operating day, per control device, for each process for which the control device is in service. [§63.1258(b)(8)(ii)]
  - iii) Periods of time when monitoring measurements exceed the parameter values as well as periods of inadequate monitoring data do not constitute a violation if they occur during a startup, shutdown, or malfunction, and the facility follows its startup, shutdown, and malfunction plan. [§63.1258(b)(8)(iv)]
- 3) *Leak inspection provisions for vapor suppression equipment.* [§63.1258(h)]
- a) If a closed-vent system subject to §63.1258 is also subject to the equipment leak provisions of §63.1255, the Permittee shall comply with the provisions of §63.1255 and is exempt from the requirements. See Plant-wide Condition PW002 [§63.1258(h)(9)]
- 4) *Planned routine maintenance.* During periods of planned routine maintenance when organic HAP emissions are controlled as specified in §63.1252(h)(2), the Permittee must monitor the condenser outlet gas temperature according to the procedures specified in §63.1258(b)(1)(iii). During periods of planned routine maintenance when HCl emissions are controlled as specified in §63.1252(h)(3), the Permittee must monitor the pH of the scrubber effluent once per day. [§63.1258(i)]

**Recordkeeping:**

- 1) *Requirements of subpart A of Part 63.* The Permittee of an affected source shall comply with the recordkeeping requirements in subpart A of 40 CFR Part 63 as specified in Table 1 of Subpart GGG and in §63.1259(a)(1) through (5). [§63.1259(a)]
  - a) *Data retention.* Each Permittee of an affected source shall keep copies of all records and reports required by Subpart GGG for at least 5 years, as specified in § 63.10(b)(1). [§63.1259(a)(1)]
  - b) *Records of applicability determinations.* The Permittee of a stationary source that is not subject to Subpart GGG shall keep a record of the applicability determination, as specified in §63.10(b)(3). [§63.1259(a)(2)]
  - c) *Startup, shutdown, and malfunction plan.* See Plant-wide Condition PW001. [§63.1259(a)(3)]
  - d) *Application for approval of construction or reconstruction.* For new affected sources, each Permittee shall comply with the provisions in §63.5 regarding construction and reconstruction, excluding the provisions specified in §63.5(d)(1)(ii)(H), (d)(2), and (d)(3)(ii). [§63.1259(a)(5)]
- 2) *Records of equipment operation.* The Permittee must keep the following records up-to-date and readily accessible: [§63.1259(b)]
  - a) Each measurement of a control device operating parameter monitored in accordance with §63.1258. [§63.1259(b)(1)]
  - b) Records of the following, as appropriate: [§63.1259(b)(5)]
    - i) For processes that are in compliance with the percent reduction requirements of §63.1254(a)(1) and that contain vents controlled to less than the percent reduction requirement, the records specified in §63.1259(b)(5)(i)(A) through (C) are required. [§63.1259(b)(5)(i)]
      - (1) Standard batch uncontrolled and controlled emissions for each process; [§63.1259(b)(5)(i)(A)]
      - (2) Actual uncontrolled and controlled emissions for each nonstandard batch and; [§63.1259(b)(5)(i)(B)]
      - (3) A record whether each batch operated was considered a standard batch. [§63.1259(b)(5)(i)(C)]
- 3) *Records of operating scenarios.* The Permittee of an affected source shall keep records of each operating scenario which demonstrates compliance with Subpart GGG. [§63.1259(c)]
- 4) *Records of inspections.* The Permittee shall keep records specified in §63.1259(i)(4) through (9). [§63.1259(i)]

- a) Records identifying all parts of the vapor collection system and closed-vent system that are designated as unsafe to inspect in accordance with §63.1258(h)(6), an explanation of why the equipment is unsafe to inspect, and the plan for inspecting the equipment. [§63.1259(i)(4)]
- b) Records identifying all parts of the vapor collection system and closed-vent system that are designated as difficult to inspect in accordance with §63.1258(h)(7), an explanation of why the equipment is difficult to inspect, and the plan for inspecting the equipment. [§63.1259(i)(5)]
- c) For each vapor collection system or closed-vent system that contains bypass lines that could divert a vent stream away from the control device and to the atmosphere, the Permittee shall keep a record of the information specified in either §63.1259(i)(6)(i) or (ii). [§63.1259(i)(6)]
  - i) Hourly records of whether the flow indicator specified under §63.1252(b)(1) was operating and whether a diversion was detected at any time during the hour, as well as records of the times and durations of all periods when the vent stream is diverted from the control device or the flow indicator is not operating. [§63.1259(i)(6)(i)]
  - ii) Where a seal mechanism is used to comply with §63.1252(b)(2), hourly records of flow are not required. In such cases, the Permittee shall record that the monthly visual inspection of the seals or closure mechanisms has been done, and shall record the occurrence of all periods when the seal mechanism is broken, the bypass line valve position has changed, or the key for a lock-and-key type lock has been checked out, and records of any car-seal that has broken. [§63.1259(i)(6)(ii)]
- d) For each inspection conducted in accordance with §63.1258(h)(2) and (3) during which a leak is detected, a record of the information specified in §63.1259(i)(7)(i) through (ix). [§63.1259(i)(7)]
  - i) Identification of the leaking equipment. [§63.1259(i)(7)(i)]
  - ii) The instrument identification numbers and operator name or initials, if the leak was detected using the procedures described in §63.1258(h)(3); or a record that the leak was detected by sensory observations. [§63.1259(i)(7)(ii)]
  - iii) The date the leak was detected and the date of the first attempt to repair the leak. [§63.1259(i)(7)(iii)]
  - iv) Maximum instrument reading measured by the method specified in §63.1258(h)(4) after the leak is successfully repaired or determined to be nonrepairable. [§63.1259(i)(7)(iv)]
  - v) "Repair delayed" and the reason for the delay if a leak is not repaired within 15 calendar days after discovery of the leak. [§63.1259(i)(7)(v)]
  - vi) The name, initials, or other form of identification of the Permittee (or designee) whose decision it was that repair could not be effected without a shutdown. [§63.1259(i)(7)(vi)]
  - vii) The expected date of successful repair of the leak if a leak is not repaired within 15 calendar days. [§63.1259(i)(7)(vii)]
  - viii) Dates of shutdowns that occur while the equipment is unrepaired. [§63.1259(i)(7)(viii)]
  - ix) The date of successful repair of the leak. [§63.1259(i)(7)(ix)]
- e) For each inspection conducted in accordance with §63.1258(h)(3) during which no leaks are detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected. [§63.1259(i)(8)]
- f) For each visual inspection conducted in accordance with §63.1258(h)(2)(i)(B) or (h)(2)(iii)(B) during which no leaks are detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected. [§63.1259(i)(9)]

### **Reporting**

- 1) The Permittee of an affected source shall comply with the reporting requirements of §63.1260(b) through (l). Applicable reporting requirements of §§63.9 and 63.10 are also summarized in Table 1 of Subpart GGG. [§63.1260(a)]
- 2) *Periodic reports.* A Permittee shall prepare Periodic reports in accordance with §63.1260(g)(1) and (2) and submit them to the administrator. [§63.1260(g)]
  - a) *Submittal schedule.* Except as provided in §63.1260(g)(1)(i), (ii), and (iii), a Permittee 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. [§63.1260(g)(1)]
- i) When the administrator determines on a case-by-case basis that more frequent reporting is necessary to accurately assess the compliance status of the affected source or; [§63.1260(g)(1)(i)]
  - ii) When a new operating scenario has been operated since the last report, in which case quarterly reports shall be submitted. [§63.1260(g)(1)(iii)]
- 3) *Content of Periodic report.* The Permittee shall include the information in §63.1260(g)(2)(i) through (vii), as applicable. [§63.1260(g)(2)]
- a) Each Periodic report must include the information in §63.10(e)(3)(vi)(A) through (I) and (K) through (M). [§63.1260(g)(2)(i)]
  - b) 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 percent or greater of the total operating time for the reporting period, the Periodic report must include the information in §63.1260(g)(2)(ii)(A) through (D). [§63.1260(g)(2)(ii)]
    - i) 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. [§63.1260(g)(2)(ii)(A)]
    - ii) Duration of excursions, as defined in §63.1258(b)(7). [§63.1260(g)(2)(ii)(B)]
    - iii) 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. [§63.1260(g)(2)(ii)(C)]
  - c) 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. [§63.1260(g)(2)(iii)]
  - d) 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. [§63.1260(g)(2)(iv)]
  - e) The information in §63.1260(g)(2)(v)(A) through (D) shall be stated in the Periodic report, when applicable. [§63.1260(g)(2)(v)]
    - i) No excess emissions. [§63.1260(g)(2)(v)(A)]
    - ii) No exceedances of a parameter. [§63.1260(g)(2)(v)(B)]
    - iii) No excursions. [§63.1260(g)(2)(v)(C)]
  - f) The information specified in §63.1260(g)(2)(vi)(B) through (C) for periods of planned routine maintenance. [§63.1260(g)(2)(vi)]
    - i) For a CCCD subject to §63.1252(h), periods of planned routine maintenance during the current reporting period and anticipated periods of planned routine maintenance during the next reporting period. [§63.1260(g)(2)(vi)(B)]
    - ii) Rationale for why planned routine maintenance of a CCCD subject to §63.1252(h) must be performed while a process with a vent subject to §63.1254(a)(3) will be operating, if applicable. This requirement applies only if the rationale is not in, or differs from that in, the Notification of Compliance Status report. [§63.1260(g)(2)(vi)(C)]
    - iii) Each new operating scenario which has been operated since the time period covered by the last Periodic report. For each new operating scenario, the Permittee 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. [§63.1260(g)(2)(vii)]
- 4) Except as specified in §63.1260(h)(2), whenever a process change is made, or a change in any of the information submitted in the Notification of Compliance Status Report, the Permittee shall submit the

information specified in §63.1260(h)(1)(i) through (iv) with the next Periodic report required under §63.1260(g). [§63.1260(h)(1)]

- a) A brief description of the process change. [§63.1260(h)(1)(i)]
  - b) A description of any modifications to standard procedures or quality assurance procedures. [§63.1260(h)(1)(ii)]
  - c) Revisions to any of the information reported in the original Notification of Compliance Status Report under §63.1260(f). [§63.1260(h)(1)(iii)]
  - d) Information required by the Notification of Compliance Status Report under §63.1260(f) for changes involving the addition of processes or equipment. [§63.1260(h)(1)(iv)]
- 5) A Permittee must submit a report 60 days before the scheduled implementation date of either of the following: (§63.1260(h)(2))
- a) Any change in the activity covered by the Precompliance report. [§63.1260(h)(2)(i)]
  - b) A change in the status of a control device from small to large. [§63.1260(h)(2)(ii)]
- 6) *Reports of startup, shutdown, and malfunction.* See Plant-wide Condition PW-001. [§63.1260(i)]

**Permit Condition EU0060-002 through EU0090-002**

10 CSR 10-6.060

**Construction Permits Required**

MDNR Construction Permit #082003-002

**Operation Limitations:**

The Permittee shall control emissions from the following list of equipment using a regenerative thermal oxidizer (RTO-1) as specified in the permit application. The regenerative thermal oxidizer must be in use at all times when the following list of equipment is in operation.

Emission Point	Description
400A	7-ADCA Process Reactors
500A	7-ADCA Process Reactors
6001	Cephalexin Reactors
6002	Cephalexin Reactors
600D	Cephalexin Dryer
862M	Methanol Recovery Still
SRT	Toluene Recovery Still
400	7-ADCA Process Vent
500	7-ADCA Process Vent

**Monitoring, Recordkeeping and Reporting:**

See Plantwide Condition PW004

**Permit Condition EU0060-003**

10 CSR 10-6.060

**Construction Permits Required**

MDNR Construction Permit #0989-004

**Operation Limitations:**

- 1) The Permittee shall not produce in excess of 1379 batches of 7-ADCA per consecutive 12 month period.
- 2) The Permittee shall operate and maintain all emission control equipment as specified by the manufacturer during operation of this facility.

**Monitoring and Recordkeeping:**

- 1) The Permittee shall keep quarterly records of the amount of solvents purchased and the amount of solvents shipped off-site.
- 2) The Permittee shall keep quarterly records of the number of 7-ADCA batches produced in each quarter as well as the 12 month rolling total.
- 3) Attachment B contains a log for solvent recordkeeping. Attachment C contains a log for production recordkeeping. These logs, or ones similar created by the Permittee shall be used to demonstrate compliance with this condition.
- 4) All records shall be maintained in either electronic or paper form for a minimum of two years.
- 5) Records shall be made available immediately to Missouri Department of Natural Resources' personnel upon request.

**Reporting:**

The Permittee shall report to the Air Pollution Control Program, Enforcement Section, P.O. Box 176, Jefferson City, MO 65102, no later than 15 days after the quarter end when recordkeeping indicates any exceedance of the aforementioned limit.

**Permit Condition EU0070-003**

10 CSR 10-6.060

**Construction Permits Required**

MDNR Construction Permit #0989-004

**Operation Limitations:**

- 1) The construction permit outlines that the Permittee shall not produce in excess of 641 batches of Cephalexin per any consecutive 12 month period. This limit has been adjusted according to permit condition EU0070-005.
- 2) The Permittee shall operate and maintain all emission control equipment as specified by the manufacturer during operation of this facility.

**Monitoring and Recordkeeping:**

- 1) The Permittee shall keep quarterly records of the amount of solvents purchased and the amount of solvents shipped off-site.
- 2) The Permittee shall keep quarterly records of the number of Cephalexin batches produced in each quarter as well as the 12 month rolling total.
- 3) Attachment B contains a log for solvent recordkeeping. Attachment C contains a log for production recordkeeping. These logs, or similar ones created by the Permittee, shall be used to demonstrate compliance with this condition.
- 4) All records shall be maintained in either electronic or paper form for a minimum of five (5) years.
- 5) Records shall be made available immediately to Missouri Department of Natural Resources' personnel upon request.

**Reporting:**

The Permittee shall report to the Air Pollution Control Program, Enforcement Section, P.O. Box 176, Jefferson City, MO 65102, only after an exceedance of Permit Condition EU0080-005.

**Permit Condition EU0070-004**

10 CSR 10-6.060

**Construction Permits Required**

MDNR Construction Permit #1298-010

**Operation Limitations:**

If a continuing situation of demonstrated nuisance odors exists in violation of 10 CSR 10-3.090, Restriction of Emission of Odors, the director may require Teva Pharmaceuticals USA to submit a corrective action plan within ten days adequate to timely and significantly mitigate the odors. Teva Pharmaceuticals USA shall implement any such plan immediately upon its approval by the director. Failure to either submit or implement such a plan shall be a violation of the permit.

**Permit Condition EU0070-005**

10 CSR 10-6.060  
**Construction Permits Required**  
 MDNR Construction Permit #102001-011

**Emission Limitations:**

- 1) The Permittee shall not emit in excess of 40.0 tons of volatile organic compounds (VOC) per consecutive 12 month period from the additional 285 batches of cephalexin allowed by the above referenced construction permit.
- 2) The Permittee shall not discharge hazardous air pollutants (HAPs) other than methanol and toluene, which primarily comprise the above VOC(s), from the cephalexin process.

**Monitoring and Recordkeeping:**

- 1) The Permittee shall keep monthly records of the number of cephalexin batches produced and the VOC emitted in each month above the previous 641 batch limit as well as the 12 month rolling total.
- 2) Attachment E contains a log of these recordkeeping requirements. This log, or one similar created by the Permittee shall be used to demonstrate compliance with this condition.
- 3) The Permittee shall keep Material Safety Data Sheets (MSDS) available for all materials used in the process.
- 4) All records shall be maintained in either electronic or paper form for a minimum of five years.
- 5) Records shall be made available immediately to Missouri Department of Natural Resources' personnel upon request.

**Reporting:**

The Permittee shall report to the Air Pollution Control Program, Enforcement Section, P.O. Box 176, Jefferson City, MO 65102, no later than ten days after the end of the month that the records indicate any exceedance of the VOC limit.

<b>EU0100 &amp; EU0110 - Process Equipment</b>			
Emission Unit	Description	Control Equipment	2006 EIQ Reference #
EU0100	Amoxicillin – 000 Process Amoxicillin Trihydrate Process (000) – Includes reactors and two (2) methylene chloride tanks. 100 Process - Operation in conjunction with PMPU 000 producing Amoxicillin and Dicloxacillin.	Fixed Bed Carbon Adsorber (APC –018)	EP-000 EP-100 EP-T008 EP-T010
EU0110	SSP Still (Methylene Chloride)		V001 EP-T011

**Permit Conditions (EU0100 through EU0110)-001**  
 10 CSR 10-6.075

**40 CFR Part 63, Subpart GGG**  
 National Emission Standards for Pharmaceuticals Production- Standards for Process Vents

**Emission Limitation:**

- 1) 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. [§63.1252(a)]
- 2) The Permittee 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 §63.1254 shall comply with the requirements of Table 4 to Subpart GGG and §63.1252(b)(1) or (2). Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and pressure relief valves needed for safety purposes are not subject to this paragraph. [§63.1252(b)]
  - a) 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; [§63.1252(b)(1)]
  - b) 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). [§63.1252(b)(2)]
- 3) *Existing Processes:* For each process, the Permittee of an existing affected source must comply with the requirements in §63.1254(a)(1) and (3). Continuous compliance is demonstrated in accordance with the monitoring requirements described in §63.1258. [§63.1254(a)]
  - a) *Process-based emission reduction requirement.* [§63.1254(a)(1)]
    - i) Uncontrolled HAP emissions from the sum of all process vents within a process that are not subject to the requirements of §63.1254(a)(3) shall be reduced by 93% or greater by weight, or as specified in §63.1254(a)(1)(ii). Notification of changes in the compliance method shall be reported according to the procedures in §63.1260(h). [§63.1254(a)(1)(i)]

**Monitoring Requirements:**

- 1) The Permittee of any existing, new, or reconstructed affected source shall provide evidence of continued compliance with the standard. [§63.1258(a)]
  - a) *Monitoring for control devices.* [§63.1258(b)]
    - i) *Parameters to monitor.* Except as specified in §63.1258(b)(1)(i), for each control device, the Permittee shall operate monitoring devices within the established parameter levels to ensure continued compliance with the standard. See Attachment A. [§63.1258(b)(1)]
    - b) *Periodic verification.* 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 §63.1258(b)(1)(ii) through (x). [§63.1258(b)(1)(i)]
- 2) *CVS visual inspections.* The Permittee shall perform monthly visual inspections of each closed vent system as specified in §63.1252(b). [§63.1258(b)(1)(xi)]
  - a) *Exceedances of operating parameters.* An exceedance of an operating parameter is defined as one of the following: [§63.1258(b)(6)]
    - i) If the parameter, averaged over the operating day or block, is below a minimum value established during the initial compliance demonstration. [§63.1258(b)(6)(i)]
    - ii) If the parameter, averaged over the operating day or block, is above the maximum value established during the initial compliance demonstration. [§63.1258(b)(6)(ii)]
  - b) *Excursions.* Excursions are defined by either of the two cases listed in §63.1258(b)(7)(i) or (ii). [§63.1258(b)(7)]

- i) When the period of control device operation is 4 hours or greater in an operating day and monitoring data are insufficient to constitute a valid hour of data, as defined in §63.1258(b)(7)(iii), for at least 75 percent of the operating hours. [§63.1258(b)(7)(i)]
- ii) When the period of control device operation is less than 4 hours in an operating day and more than one of the hours during the period of operation does not constitute a valid hour of data due to insufficient monitoring data. [§63.1258(b)(7)(ii)]
- iii) Monitoring data are insufficient to constitute a valid hour of data, as used in §63.1258(b)(7)(i) and (ii), if measured values are unavailable for any of the required 15-minute periods within the hour. [§63.1258(b)(7)(iii)]
- c) *Violations.* Exceedances of parameters monitored according to the provisions of §63.1258(b)(1)(ii), (iv) through (ix), and §63.1258(b)(5)(ii)(A) and (B), or excursions as defined by §63.1258(b)(7)(i) through (iii), constitute violations of the operating limit according to §63.1258(b)(8)(i), (ii), and (iv). Exceedances of the temperature limit monitored according to the provisions of §63.1258(b)(1)(iii) or exceedances of the outlet concentrations monitored according to the provisions of §63.1258(b)(1)(x) constitute violations of the emission limit according to §63.1258(b)(8)(i), (ii), and (iv). [§63.1258(b)(8)]
  - i) Except as provided in §63.1258(b)(8)(iv), for episodes occurring more than once per day, exceedances of established parameter limits or excursions will result in no more than one violation per operating day for each monitored item of equipment utilized in the process. [§63.1258(b)(8)(i)]
  - ii) Except as provided in §63.1258(b)(8)(iv), for control devices used for more than one process in the course of an operating day, exceedances or excursions will result in no more than one violation per operating day, per control device, for each process for which the control device is in service. [§63.1258(b)(8)(ii)]
  - iii) Periods of time when monitoring measurements exceed the parameter values as well as periods of inadequate monitoring data do not constitute a violation if they occur during a startup, shutdown, or malfunction, and the facility follows its startup, shutdown, and malfunction plan. [§63.1258(b)(8)(iv)]
- 3) *Leak inspection provisions for vapor suppression equipment.* [§63.1258(h)]
  - a) If a closed-vent system subject to §63.1258 is also subject to the equipment leak provisions of §63.1255, the Permittee shall comply with the provisions of §63.1255 and is exempt from the requirements. See Plant-wide Condition PW002 [§63.1258(h)(9)]
- 4) *Planned routine maintenance.* During periods of planned routine maintenance when organic HAP emissions are controlled as specified in §63.1252(h)(2), the Permittee must monitor the condenser outlet gas temperature according to the procedures specified in §63.1258(b)(1)(iii). During periods of planned routine maintenance when HCl emissions are controlled as specified in §63.1252(h)(3), the Permittee must monitor the pH of the scrubber effluent once per day. [§63.1258(i)]

**Recordkeeping:**

- 1) Records shall be maintained as specified in §63.1259(i)(4) through (9). [§63.1258(h)(8)]
- 2) *Requirements of subpart A of Part 63.* The Permittee of an affected source shall comply with the recordkeeping requirements in subpart A of 40 CFR Part 63 as specified in Table 1 of Subpart GGG and in §63.1259(a)(1) through (5). [§63.1259(a)]
  - a) *Data retention.* Each Permittee of an affected source shall keep copies of all records and reports required by Subpart GGG for at least 5 years, as specified in §63.10(b)(1). [§63.1259(a)(1)]
  - b) *Records of applicability determinations.* The Permittee of a stationary source that is not subject to Subpart GGG shall keep a record of the applicability determination, as specified in §63.10(b)(3). [§63.1259(a)(2)]
  - c) *Startup, shutdown, and malfunction plan.* See Plant-wide Condition PW001. [§63.1259(a)(3)]
  - d) *Application for approval of construction or reconstruction.* For new affected sources, each Permittee shall comply with the provisions in §63.5 regarding construction and reconstruction, excluding the provisions specified in §63.5(d)(1)(ii)(H), (d)(2), and (d)(3)(ii). [§63.1259(a)(5)]
- 3) *Records of equipment operation.* The Permittee must keep the following records up-to-date and readily accessible: [§63.1259(b)]

- a) For purposes of compliance with the annual mass limits of §63.1254(b)(2), daily records of the rolling annual total emissions. [§63.1259(b)(4)]
  - b) Records of the following, as appropriate: [§63.1259(b)(5)]
    - i) For processes in compliance with the annual mass limits of §63.1254(a)(2), the following records are required: [§63.1259(b)(5)(ii)]
      - (1) The number of batches per year for each batch process; [§63.1259(b)(5)(ii)(A)]
      - (2) The operating hours per year for continuous processes; [§63.1259(b)(5)(ii)(B)]
      - (3) Standard batch uncontrolled and controlled emissions for each process; [§63.1259(b)(5)(ii)(C)]
      - (4) Actual controlled emissions for each batch operated during periods of planned routine maintenance of a CCCD, calculated according to §63.1258(c). [§63.1259(b)(5)(ii)(D)]
      - (5) Actual uncontrolled and controlled emissions for each nonstandard batch; [§63.1259(b)(5)(ii)(E)]
      - (6) A record whether each batch operated was considered a standard batch. [§63.1259(b)(5)(ii)(F)]
  - c) A schedule or log of each operating scenario updated daily or, at a minimum, each time a different operating scenario is put into operation. [§63.1259(b)(8)]
  - d) Description of worst-case operating conditions as required in §63.1257(b)(8). [§63.1259(b)(9)]
  - e) Periods of planned routine maintenance as described in §§63.1252(h) and 63.1257(c)(5). [§63.1259(b)(10)]
  - f) All maintenance performed on the air pollution control equipment. [§63.1259(b)(13)]
- 4) *Records of operating scenarios.* The Permittee of an affected source shall keep records of each operating scenario which demonstrates compliance with Subpart GGG. [§63.1259(c)]
- 5) *Records of inspections.* The Permittee shall keep records specified in §63.1259(i)(4) through (9). [§63.1259(i)]
- a) Records identifying all parts of the vapor collection system and closed-vent system that are designated as unsafe to inspect in accordance with §63.1258(h)(6), an explanation of why the equipment is unsafe to inspect, and the plan for inspecting the equipment. [§63.1259(i)(4)]
  - b) Records identifying all parts of the vapor collection system and closed-vent system that are designated as difficult to inspect in accordance with §63.1258(h)(7), an explanation of why the equipment is difficult to inspect, and the plan for inspecting the equipment. [§63.1259(i)(5)]
  - c) For each vapor collection system or closed-vent system that contains bypass lines that could divert a vent stream away from the control device and to the atmosphere, the Permittee shall keep a record of the information specified in either §63.1259(i)(6)(i) or (ii). [§63.1259(i)(6)]
    - i) Hourly records of whether the flow indicator specified under §63.1252(b)(1) was operating and whether a diversion was detected at any time during the hour, as well as records of the times and durations of all periods when the vent stream is diverted from the control device or the flow indicator is not operating. [§63.1259(i)(6)(i)]
    - ii) Where a seal mechanism is used to comply with §63.1252(b)(2), hourly records of flow are not required. In such cases, the Permittee shall record that the monthly visual inspection of the seals or closure mechanisms has been done, and shall record the occurrence of all periods when the seal mechanism is broken, the bypass line valve position has changed, or the key for a lock-and-key type lock has been checked out, and records of any car-seal that has broken. [§63.1259(i)(6)(ii)]
  - d) For each inspection conducted in accordance with §63.1258(h)(2) and (3) during which a leak is detected, a record of the information specified in §63.1259(i)(7)(i) through (ix). [§63.1259(i)(7)]
    - i) Identification of the leaking equipment. [§63.1259(i)(7)(i)]
    - ii) The instrument identification numbers and operator name or initials, if the leak was detected using the procedures described in §63.1258(h)(3); or a record that the leak was detected by sensory observations. [§63.1259(i)(7)(ii)]
    - iii) The date the leak was detected and the date of the first attempt to repair the leak. [§63.1259(i)(7)(iii)]
    - iv) Maximum instrument reading measured by the method specified in §63.1258(h)(4) after the leak is successfully repaired or determined to be nonrepairable. [§63.1259(i)(7)(iv)]
    - v) “Repair delayed” and the reason for the delay if a leak is not repaired within 15 calendar days after discovery of the leak. [§63.1259(i)(7)(v)]

- vi) The name, initials, or other form of identification of the Permittee (or designee) whose decision it was that repair could not be effected without a shutdown. [§63.1259(i)(7)(vi)]
- vii) The expected date of successful repair of the leak if a leak is not repaired within 15 calendar days. [§63.1259(i)(7)(vii)]
- viii) Dates of shutdowns that occur while the equipment is unrepaired. (§63.1259(i)(7)(viii))
- ix) The date of successful repair of the leak. [§63.1259(i)(7)(ix)]
- e) For each inspection conducted in accordance with §63.1258(h)(3) during which no leaks are detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected. [§63.1259(i)(8)]
- f) For each visual inspection conducted in accordance with §63.1258(h)(2)(i)(B) or (h)(2)(iii)(B) during which no leaks are detected, a record that the inspection was performed, the date of the inspection, and a statement that no leaks were detected. [§63.1259(i)(9)]

**Reporting:**

- 1) The Permittee of an affected source shall comply with the reporting requirements of §63.1260(b) through (l). Applicable reporting requirements of §§63.9 and 63.10 are also summarized in Table 1 of Subpart GGG. [§63.1260(a)]
- 2) *Periodic reports.* A Permittee shall prepare Periodic reports in accordance with §63.1260(g)(1) and (2) and submit them to the administrator. [§63.1260(g)]
  - a) *Submittal schedule.* Except as provided in §63.1260(g)(1)(i), (ii), and (iii), a Permittee 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. [§63.1260(g)(1)]
    - i) When the Administrator determines on a case-by-case basis that more frequent reporting is necessary to accurately assess the compliance status of the affected source or; [§63.1260(g)(1)(i)]
    - ii) When a new operating scenario has been operated since the last report, in which case quarterly reports shall be submitted. [§63.1260(g)(1)(iii)]
  - b) *Content of Periodic report.* The Permittee shall include the information in §63.1260(g)(2)(i) through (vii), as applicable. [§63.1260(g)(2)]
    - 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). [§63.1260(g)(2)(i)]
    - ii) 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. [§63.1260(g)(2)(iii)]
    - iii) 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. [§63.1260(g)(2)(iv)]
    - iv) The information in §63.1260(g)(2)(v)(A) through (D) shall be stated in the Periodic report, when applicable. [§63.1260(g)(2)(v)]
      - (1) No excess emissions. [§63.1260(g)(2)(v)(A)]
      - (2) No exceedances of a parameter. [§63.1260(g)(2)(v)(B)]
      - (3) No excursions. [§63.1260(g)(2)(v)(C)]
    - v) The information specified in §63.1260(g)(2)(vi)(B) through (C) for periods of planned routine maintenance. [§63.1260(g)(2)(vi)]
      - (1) For a CCCD subject to §63.1252(h), periods of planned routine maintenance during the current reporting period and anticipated periods of planned routine maintenance during the next reporting period. [§63.1260(g)(2)(vi)(B)]

- (2) Rationale for why planned routine maintenance of a CCCD subject to §63.1252(h) must be performed while a process with a vent subject to §63.1254(a)(3) will be operating, if applicable. This requirement applies only if the rationale is not in, or differs from that in, the Notification of Compliance Status report. [§63.1260(g)(2)(vi)(C)]
- vi) Each new operating scenario which has been operated since the time period covered by the last Periodic report. For each new operating scenario, the Permittee 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. [§63.1260(g)(2)(vii)]
- 3) *Notification of process change.* [§63.1260(h)]
  - a) Except as specified in §63.1260(h)(2), whenever a process change is made, or a change in any of the information submitted in the Notification of Compliance Status Report, the Permittee shall submit the information specified in §63.1260(h)(1)(i) through (iv) with the next Periodic report required under §63.1260(g). [§63.1260(h)(1)]
    - i) A brief description of the process change. [§63.1260(h)(1)(i)]
    - ii) A description of any modifications to standard procedures or quality assurance procedures. [§63.1260(h)(1)(ii)]
    - iii) Revisions to any of the information reported in the original Notification of Compliance Status Report under §63.1260(f). [§63.1260(h)(1)(iii)]
    - iv) Information required by the Notification of Compliance Status Report under §63.1260(f) for changes involving the addition of processes or equipment. [§63.1260(h)(1)(iv)]
  - b) A Permittee must submit a report 60 days before the scheduled implementation date of either of the following: [§63.1260(h)(2)]
    - i) Any change in the activity covered by the Precompliance report. [§63.1260(h)(2)(i)]
    - ii) A change in the status of a control device from small to large. [§63.1260(h)(2)(ii)]
- 4) *Reports of startup, shutdown, and malfunction.* See Plant-wide Condition PW-001. [§63.1260(i)]

**Permit Condition EU0100-002**

10 CSR 10-6.060

**Construction Permits Required**

MDNR Construction Permits #0198-034 & 092002-014

**Operation Limitations:**

The Permittee shall operate and maintain the activated carbon adsorption system to minimize incidences of excess emissions. An incidence of excess emissions occurs when breakthrough is detected while the unit is in operation controlling the process.

**Monitoring:**

- 1) The Permittee shall monitor the adsorption system with a breakthrough monitor.
- 2) The Permittee shall annually verify the control efficiency of the activated carbon adsorption system.

**Recordkeeping:**

- 1) The Permittee shall maintain a record of all incidences of excess emissions associated with the activated carbon adsorption system. Records shall include: 1) date, start time, and duration of incident; 2) probable cause; 3) corrective action(s) taken to mitigate the incident and minimize recurrence; and 4) estimate of excess emissions resulting from incident.
- 2) All records of the control efficiency verifications shall be kept for the life of the system.

**Reporting:**

The Permittee shall report to the Air Pollution Control Program, Enforcement Section, P.O. Box 176, Jefferson City, MO 65102, no later than ten days after any incident of excess emissions.

<b>EU0120 – Waste Water Treatment Plant</b>			
Emission Unit	Description	Manufacturer/Model #	2005 EIQ Reference #
EU0120	Waste Water Treatment Plant.	N/A	EP WWTP

**Permit Condition EU0120-001**

10 CSR 10-6.075

**40 CFR Part 63 Subpart GGG**

National Emission Standards for Pharmaceuticals Production – Wastewater Treatment

**Emission Limitations:**

- 1) Per §63.1256(g)(11), the owner or operator must reduce, by destruction, the mass of partially soluble and soluble HAP compounds by 95% or greater entering the biological treatment unit.
- 2) Compliance shall be determined using procedures specified in §63.1257(e)(2)(iii)(E).

**Operation Limitations:**

All handling operations from the point of determination to the biological treatment unit are subject to the regulations outlined in §63.1256(b) through (f).

**Monitoring:**

- 1) The Permittee shall comply with the monitoring requirements applicable to the waste water transportation and treatment system as specified in §63.1258.
- 2) Per §63.1258(g), the Permittee shall monitor TSS, BOD, and biomass at a frequency and with a method approved by the Missouri Department of Natural Resources.
- 3) Exception: the Permittee may request to monitor other parameters. This request shall be submitted in the Precompliance report according to the procedures specified in §63.1260(e).

**Recordkeeping:**

- 1) The Permittee shall maintain records as required by §63.1259.
- 2) The Permittee shall develop and implement a written startup, shutdown, and malfunction plan as specified in §63.6(e)(3). The current and superseded versions of this plan shall be kept onsite.
- 3) The Permittee shall record the occurrence and duration of any malfunction of the treatment operations, air pollution control equipment, and monitoring systems.
- 4) The Permittee shall maintain records of all inspections and maintenance performed on the air pollution control equipment, and any wastewater handling or storage equipment prior to the biological unit.
- 5) The Permittee shall maintain all records for a minimum of five (5) years.

**Reporting:**

- 1) The Permittee shall submit periodic reports semiannually as required by §63.1260(g). The first report shall be submitted no later than November 15, 2003 or 240 days after the Notification of Compliance. Each subsequent report shall cover a six (6) month period or as specified in paragraph (g). Each report shall include information as outlined in §63.1260(g) as well as any process modifications as described in §63.1260(h).
- 2) Each report shall include the compiled information for all the applicable units at the facility.
- 3) The above reports and any other reports required by §63.1260 shall be submitted to the Air Pollution Control Program, Enforcement Section, P.O. Box 176, Jefferson City, MO 65101.
- 4) For incidences of excess emissions, reports shall be no later than ten days after the incident.

***This permit condition is enforceable after the compliance date for an existing affected source (October 21, 2002) set forth in §63.1250(f).***

## IV. Core Permit Requirements

The installation shall comply with each of the following requirements. Consult the appropriate sections in the Code of Federal Regulations (CFR) and Code of State Regulations (CSR) for the full text of the applicable requirements. All citations, unless otherwise noted, are to the regulations in effect as of the date that this permit is issued.

### **10 CSR 10-6.050 Start-up, Shutdown and Malfunction Conditions**

- 1) In the event of a malfunction, which results in excess emissions that exceed one hour, the Permittee shall submit to the director within two business days, in writing, the following information:
  - a) Name and location of installation;
  - b) Name and telephone number of person responsible for the installation;
  - c) Name of the person who first discovered the malfunction and precise time and date that the malfunction was discovered.
  - d) Identity of the equipment causing the excess emissions;
  - e) Time and duration of the period of excess emissions;
  - f) Cause of the excess emissions;
  - g) Air pollutants involved;
  - h) Best estimate of the magnitude of the excess emissions expressed in the units of the applicable requirement and the operating data and calculations used in estimating the magnitude;
  - i) Measures taken to mitigate the extent and duration of the excess emissions; and
  - j) Measures taken to remedy the situation that caused the excess emissions and the measures taken or planned to prevent the recurrence of these situations.
- 2) The Permittee shall submit the paragraph 1 information list to the director in writing at least ten days prior to any maintenance, start-up or shutdown, which is expected to cause an excessive release of emissions that exceed one hour. If notice of the event cannot be given ten days prior to the planned occurrence, it shall be given as soon as practicable prior to the release. If an unplanned excess release of emissions exceeding one hour occurs during maintenance, start-up or shutdown, the director shall be notified verbally as soon as practical during normal working hours and no later than the close of business of the following working day. A written notice shall follow within ten working days.
- 3) Upon receipt of a notice of excess emissions issued by an agency holding a certificate of authority under section 643.140, RSMo, the Permittee may provide information showing that the excess emissions were the consequence of a malfunction, start-up or shutdown. The information, at a minimum, should be the paragraph 1 list and shall be submitted not later than 15 days after receipt of the notice of excess emissions. Based upon information submitted by the Permittee or any other pertinent information available, the director or the commission shall make a determination whether the excess emissions constitute a malfunction, start-up or shutdown and whether the nature, extent and duration of the excess emissions warrant enforcement action under section 643.080 or 643.151, RSMo.
- 4) Nothing in this rule shall be construed to limit the authority of the director or commission to take appropriate action, under sections 643.080, 643.090 and 643.151, RSMo to enforce the provisions of the Air Conservation Law and the corresponding rule.
- 5) Compliance with this rule does not automatically absolve the Permittee of liability for the excess emissions reported.

### **10 CSR 10-6.060 Construction Permits Required**

The Permittee shall not commence construction, modification, or major modification of any installation subject to this rule, begin operation after that construction, modification, or major modification, or begin operation of any installation which has been shut down longer than five years without first obtaining a permit from the permitting authority.

### **10 CSR 10-6.065 Operating Permits**

The Permittee shall file a complete application for renewal of this operating permit at least six months before the date of permit expiration. In no event shall this time be greater than eighteen months.

[10 CSR 10-6.065(6)(B)1.A(V)] The Permittee shall retain the most current operating permit issued to this installation on-site. [10 CSR 10-6.065(6)(C)1.C(II)] The Permittee shall immediately make such permit available to any Missouri Department of Natural Resources' personnel upon request. [10 CSR 10-6.065(6)(C)3.B]

### **10 CSR 10-6.110 Submission of Emission Data, Emission Fees and Process Information**

- 1) The Permittee shall complete and submit an Emission Inventory Questionnaire (EIQ) in accordance with the requirements outlined in this rule.
- 2) The Permittee shall pay an annual emission fee per ton of regulated air pollutant emitted according to the schedule in the rule. This fee is an emission fee assessed under authority of RSMo. 643.079 to satisfy the requirements of the Federal Clean Air Act, Title V.
- 3) The fees shall be due April 1 each year for emissions produced during the previous calendar year. The fees shall be payable to the Department of Natural Resources and shall be accompanied by the EIQ form or equivalent approved by the director.

### **10 CSR 10-6.130 Controlling Emissions During Episodes of High Air Pollution Potential**

This rule specifies the conditions that establish an air pollution alert (yellow/orange/red/purple), or emergency (maroon) and the associated procedures and emission reduction objectives for dealing with each. The Permittee shall submit an appropriate emergency plan if required by the director.

### **10 CSR 10-6.150 Circumvention**

The Permittee shall not cause or permit the installation or use of any device or any other means which, without resulting in reduction in the total amount of air contaminant emitted, conceals or dilutes an emission or air contaminant which violates a rule of the Missouri Air Conservation Commission.

### **10 CSR 10-6.170 Restriction of Particulate Matter to the Ambient Air Beyond the Premises of Origin**

- 1) The Permittee shall not cause or allow to occur any handling, transporting or storing of any material; construction, repair, cleaning or demolition of a building or its appurtenances; construction or use of a road, driveway or open area; or operation of a commercial or industrial installation without applying reasonable measures as may be required to prevent, or in a manner which allows or may allow, fugitive particulate matter emissions to go beyond the premises of origin in quantities that the particulate matter may be found on surfaces beyond the property line of origin. The nature or origin of the particulate matter shall be determined to a reasonable degree of certainty by a technique proven to be accurate and approved by the director.
- 2) The Permittee shall not cause nor allow to occur any fugitive particulate matter emissions to remain visible in the ambient air beyond the property line of origin.

- 3) Should it be determined that noncompliance has occurred, the director may require reasonable control measures as may be necessary. These measures may include, but are not limited to, the following:
  - a) Revision of procedures involving construction, repair, cleaning and demolition of buildings and their appurtenances that produce particulate matter emissions;
  - b) Paving or frequent cleaning of roads, driveways and parking lots;
  - c) Application of dust-free surfaces;
  - d) Application of water; and
  - e) Planting and maintenance of vegetative ground cover.

#### **10 CSR 10-6.180 Measurement of Emissions of Air Contaminants**

- 1) The director may require any person responsible for the source of emission of air contaminants to make or have made tests to determine the quantity or nature, or both, of emission of air contaminants from the source. The director may specify testing methods to be used in accordance with good professional practice. The director may observe the testing. All tests shall be performed by qualified personnel.
- 2) The director may conduct tests of emissions of air contaminants from any source. Upon request of the director, the person responsible for the source to be tested shall provide necessary ports in stacks or ducts and other safe and proper sampling and testing facilities, exclusive of instruments and sensing devices as may be necessary for proper determination of the emission of air contaminants.
- 3) The director shall be given a copy of the test results in writing and signed by the person responsible for the tests.

#### **10 CSR 10-3.030 Open Burning Restrictions**

- 1) The Permittee shall not conduct, cause, permit or allow a salvage operation, the disposal of trade wastes or burning of refuse by open burning.
- 2) Exception - Open burning of trade waste or vegetation may be permitted only when it can be shown that open burning is the only feasible method of disposal or an emergency exists which requires open burning.
- 3) Any person intending to engage in open burning shall file a request to do so with the director. The request shall include the following:
  - a) The name, address and telephone number of the person submitting the application; The type of business or activity involved; A description of the proposed equipment and operating practices, the type, quantity and composition of trade wastes and expected composition and amount of air contaminants to be released to the atmosphere where known;
  - b) The schedule of burning operations;
  - c) The exact location where open burning will be used to dispose of the trade wastes;
  - d) Reasons why no method other than open burning is feasible; and
  - e) Evidence that the proposed open burning has been approved by the fire control authority which has jurisdiction.
- 4) Upon approval of the open burning permit application by the director, the person may proceed with the operation under the terms of the open burning permit. Be aware that such approval shall not exempt Teva Pharmaceuticals USA Inc. from the provisions of any other law, ordinance or regulation.
- 5) The Permittee shall maintain files with letters from the director approving the open burning operation and previous Department of Natural Resources' inspection reports.

**10 CSR 10-6.080 Emission Standards for Hazardous Air Pollutants and 40 CFR Part 61  
Subpart M National Emission Standard for Asbestos**

- 1) The Permittee shall follow the procedures and requirements of 40 CFR Part 61, Subpart M for any activities occurring at this installation which would be subject to provisions for 40 CFR Part 61, Subpart M, National Emission Standard for Asbestos.
- 2) The Permittee shall conduct monitoring to demonstrate compliance with registration, certification, notification, and Abatement Procedures and Practices standards as specified in 40 CFR Part 61, Subpart M.

**10 CSR 10-6.250 Asbestos Abatement Projects – Certification, Accreditation, and Business  
Exemption Requirements**

The Permittee shall conduct all asbestos abatement projects within the procedures established for certification and accreditation by 10 CSR 10-6.250. This rule requires individuals who work in asbestos abatement projects to be certified by the Missouri Department of Natural Resources' Air Pollution Control Program. This rule requires training providers who offer training for asbestos abatement occupations to be accredited by the Missouri Department of Natural Resources' Air Pollution Control Program. This rule requires persons who hold exemption status from certain requirements of this rule to allow the department to monitor training provided to employees. Each individual who works in asbestos abatement projects must first obtain certification for the appropriate occupation from the department. Each person who offers training for asbestos abatement occupations must first obtain accreditation from the department. Certain business entities that meet the requirements for state-approved exemption status must allow the department to monitor training classes provided to employees who perform asbestos abatement.

**Title VI – 40 CFR Part 82 Protection of Stratospheric Ozone**

- 1) The Permittee shall comply with the standards for labeling of products using ozone-depleting substances pursuant to 40 CFR Part 82, Subpart E:
  - a) All containers in which a class I or class II substance is stored or transported, all products containing a class I substance, and all products directly manufactured with a class I substance must bear the required warning statement if it is being introduced into interstate commerce pursuant to §82.106.
  - b) The placement of the required warning statement must comply with the requirements pursuant to §82.108.
  - c) The form of the label bearing the required warning statement must comply with the requirements pursuant to §82.110.
  - d) No person may modify, remove, or interfere with the required warning statement except as described in §82.112.
- 2) The Permittee shall comply with the standards for recycling and emissions reduction pursuant to 40 CFR Part 82, Subpart F, except as provided for motor vehicle air conditioners (MVACs) in Subpart B:
  - a) Persons opening appliances for maintenance, service, repair, or disposal must comply with the required practices pursuant to §82.156.
  - b) Equipment used during the maintenance, service, repair, or disposal of appliances must comply with the standards for recycling and recovery equipment pursuant to §82.158.
  - c) Persons performing maintenance, service, repair, or disposal of appliances must be certified by an approved technician certification program pursuant to §82.161.

- d) Persons disposing of small appliances, MVACs, and MVAC-like appliances must comply with recordkeeping requirements pursuant to §82.166. (“MVAC-like” appliance as defined at §82.152).
  - e) Persons owning commercial or industrial process refrigeration equipment must comply with the leak repair requirements pursuant to §82.156.
  - f) 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.
- 3) If the Permittee manufactures, transforms, imports, or exports a class I or class II substance, the Permittee is subject to all the requirements as specified in 40 CFR Part 82, Subpart A, Production and Consumption Controls.
  - 4) If the Permittee performs a service on motor (fleet) vehicles when this service involves ozone-depleting substance refrigerant (or regulated substitute substance) in the motor vehicle air conditioner (MVAC), the Permittee is subject to all the applicable requirements as specified in 40 CFR part 82, Subpart B, Servicing of Motor Vehicle Air conditioners. The term “motor vehicle” as used in Subpart B does not include a vehicle in which final assembly of the vehicle has not been completed. The term “MVAC” as used in Subpart B does not include the air-tight sealed refrigeration system used as refrigerated cargo, or system used on passenger buses using HCFC-22 refrigerant.

The Permittee shall be allowed to switch from any ozone-depleting substance to any alternative that is listed in the Significant New Alternatives Program (SNAP) promulgated pursuant to 40 CFR Part 82, Subpart G, Significant New Alternatives Policy Program. *Federal Only - 40 CFR part 82*

#### **10 CSR 10-6.280 Compliance Monitoring Usage**

- 1) The Permittee is not prohibited from using the following in addition to any specified compliance methods for the purpose of submission of compliance certificates:
  - a) Monitoring methods outlined in 40 CFR Part 64;
  - b) Monitoring method(s) approved for the Permittee pursuant to 10 CSR 10-6.065, “Operating Permits”, and incorporated into an operating permit; and
  - c) Any other monitoring methods approved by the director.
- 2) Any credible evidence may be used for the purpose of establishing whether a Permittee has violated or is in violation of any such plan or other applicable requirement. Information from the use of the following methods is presumptively credible evidence of whether a violation has occurred by a Permittee:
  - a) Monitoring methods outlined in 40 CFR Part 64;
  - b) A monitoring method approved for the Permittee pursuant to 10 CSR 10-6.065, “Operating Permits”, and incorporated into an operating permit; and
  - c) Compliance test methods specified in the rule cited as the authority for the emission limitations.
- 3) The following testing, monitoring or information gathering methods are presumptively credible testing, monitoring, or information gathering methods:
  - a) Applicable monitoring or testing methods, cited in:
    - i) 10 CSR 10-6.030, “Sampling Methods for Air Pollution Sources”;
    - ii) 10 CSR 10-6.040, “Reference Methods”;
    - iii) 10 CSR 10-6.070, “New Source Performance Standards”;
    - iv) 10 CSR 10-6.080, “Emission Standards for Hazardous Air Pollutants”;
  - b) Other testing, monitoring, or information gathering methods, if approved by the director, that produce information comparable to that produced by any method listed above.

## V. General Permit Requirements

The installation shall comply with each of the following requirements. Consult the appropriate sections in the Code of Federal Regulations (CFR) and Code of State Regulations (CSR) for the full text of the applicable requirements. All citations, unless otherwise noted, are to the regulations in effect as of the date that this permit is issued.

### **10 CSR 10-6.065(6)(C)1.B Permit Duration**

This permit is issued for a term of five years, commencing on the date of issuance. This permit will expire at the end of this period unless renewed.

### **10 CSR 10-6.065(6)(C)1.C General Recordkeeping and Reporting Requirements**

- 1) Recordkeeping
  - a) All required monitoring data and support information shall be retained for a period of at least five years from the date of the monitoring sample, measurement, report or application.
  - b) Copies of all current operating and construction permits issued to this installation shall be kept on-site for as long as the permits are in effect. Copies of these permits shall be made immediately available to any Missouri Department of Natural Resources' personnel upon request.
- 2) Reporting
  - a) All reports shall be submitted to the Air Pollution Control Program, Enforcement Section, P. O. Box 176, Jefferson City, MO 65102.
  - b) The Permittee shall submit a report of all required monitoring by:
    - i) October 1st for monitoring which covers the January through June time period, and
    - ii) April 1st for monitoring which covers the July through December time period.
    - iii) Exception. Monitoring requirements which require reporting more frequently than semi annually shall report no later than 30 days after the end of the calendar quarter in which the measurements were taken.
  - c) Each report shall identify any deviations from emission limitations, monitoring, recordkeeping, reporting, or any other requirements of the permit, this includes deviations or Part 64 exceedances.
  - d) Submit supplemental reports as required or as needed. Supplemental reports are required no later than ten days after any exceedance of any applicable rule, regulation or other restriction. All reports of deviations shall identify the cause or probable cause of the deviations and any corrective actions or preventative measures taken.
    - i) Notice of any deviation resulting from an emergency (or upset) condition as defined in paragraph (6)(C)7.A of 10 CSR 10-6.065 (Emergency Provisions) shall be submitted to the permitting authority either verbally or in writing within two working days after the date on which the emission limitation is exceeded due to the emergency, if the Permittee wishes to assert an affirmative defense. The affirmative defense of emergency shall be demonstrated through properly signed, contemporaneous operating logs, or other relevant evidence that indicate an emergency occurred and the Permittee can identify the cause(s) of the emergency. The permitted installation must show that it was operated properly at the time and that during the period of the emergency the Permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards or requirements in the permit. The notice must contain a description of the emergency, the steps taken to mitigate emissions, and the corrective actions taken.
    - ii) Any deviation that poses an imminent and substantial danger to public health, safety or the environment shall be reported as soon as practicable.

- iii) Any other deviations identified in the permit as requiring more frequent reporting than the Permittee's semiannual report shall be reported on the schedule specified in this permit, and no later than ten days after any exceedance of any applicable rule, regulation, or other restriction.
- e) Every report submitted shall be certified by the responsible official, except that, if a report of a deviation must be submitted within ten days after the deviation, the report may be submitted without a certification if the report is resubmitted with an appropriate certification within ten days after that, together with any corrected or supplemental information required concerning the deviation.
- f) The Permittee may request confidential treatment of information submitted in any report of deviation.

#### **10 CSR 10-6.065(6)(C)1.D Risk Management Plan Under Section 112(r)**

The Permittee shall comply with the requirements of 40 CFR Part 68, Accidental Release Prevention Requirements. If the Permittee has more than a threshold quantity of a regulated substance in process, as determined by 40 CFR Section 68.115, the Permittee shall submit a Risk Management Plan in accordance with 40 CFR Part 68 no later than the latest of the following dates:

- 1) June 21, 1999;
- 2) Three years after the date on which a regulated substance is first listed under 40 CFR Section 68.130; or
- 3) The date on which a regulated substance is first present above a threshold quantity in a process.

#### **10 CSR 10-6.065(6)(C)1.F Severability Clause**

In the event of a successful challenge to any part of this permit, all uncontested permit conditions shall continue to be in force. All terms and conditions of this permit remain in effect pending any administrative or judicial challenge to any portion of the permit. If any provision of this permit is invalidated, the Permittee shall comply with all other provisions of the permit.

#### **10 CSR 10-6.065(6)(C)1.G General Requirements**

- 1) The Permittee must comply with all of the terms and conditions of this permit. Any noncompliance with a permit condition constitutes a violation and is grounds for enforcement action, permit termination, permit revocation and re-issuance, permit modification or denial of a permit renewal application.
- 2) The Permittee may not use as a defense in an enforcement action that it would have been necessary for the Permittee to halt or reduce the permitted activity in order to maintain compliance with the conditions of the permit
- 3) The permit may be modified, revoked, reopened, reissued or terminated for cause. Except as provided for minor permit modifications, the filing of an application or request for a permit modification, revocation and reissuance, or termination, or the filing of a notification of planned changes or anticipated noncompliance, does not stay any permit condition.
- 4) This permit does not convey any property rights of any sort, nor grant any exclusive privilege.
- 5) The Permittee shall furnish to the Air Pollution Control Program, upon receipt of a written request and within a reasonable time, any information that the Air Pollution Control Program reasonably may require to determine whether cause exists for modifying, reopening, reissuing or revoking the permit or to determine compliance with the permit. Upon request, the Permittee also shall furnish to the Air Pollution Control Program copies of records required to be kept by the Permittee. The

Permittee may make a claim of confidentiality for any information or records submitted pursuant to 10 CSR 10-6.065(6)(C)1.

#### **10 CSR 10-6.065(6)(C)1.H Incentive Programs Not Requiring Permit Revisions**

No permit revision will be required for any installation changes made under any approved economic incentive, marketable permit, emissions trading, or other similar programs or processes provided for in this permit.

#### **10 CSR 10-6.065(6)(C)1.I Reasonably Anticipated Operating Scenarios**

The permit includes terms and conditions for reasonably anticipated operating scenarios identified by the applicant.

#### **10 CSR 10-6.065(6)(C)3 Compliance Requirements**

- 1) Any document (including reports) required to be submitted under this permit shall contain a certification signed by the responsible official.
- 2) Upon presentation of credentials and other documents as may be required by law, the Permittee shall allow authorized officials of the Missouri Department of Natural Resources, or their authorized agents, to perform the following (subject to the installation's right to seek confidential treatment of information submitted to, or obtained by, the Air Pollution Control Program):
  - a) Enter upon the premises where a permitted installation is located or an emissions-related activity is conducted, or where records must be kept under the conditions of this permit;
  - b) Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;
  - c) Inspect, at reasonable times and using reasonable safety practices, any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under this permit; and
  - d) As authorized by the Missouri Air Conservation Law, Chapter 643, RSMo or the Act, sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with the terms of this permit, and all applicable requirements as outlined in this permit.
- 3) All progress reports required under an applicable schedule of compliance shall be submitted semiannually (or more frequently if specified in the applicable requirement). These progress reports shall contain the following:
  - a) Dates for achieving the activities, milestones or compliance required in the schedule of compliance, and dates when these activities, milestones or compliance were achieved, and
  - b) An explanation of why any dates in the schedule of compliance were not or will not be met, and any preventative or corrective measures adopted.
- 4) The Permittee shall submit an annual certification that it is in compliance with all of the federally enforceable terms and conditions contained in this permit, including emissions limitations, standards, or work practices. These certifications shall be submitted annually by April 1st, unless the applicable requirement specifies more frequent submission. These certifications shall be submitted to EPA Region VII, 901 North 5th Street, Kansas City, Kansas 66101, as well as the Air Pollution Control Program, Enforcement Section, P.O. Box 176, Jefferson City, MO 65102. All deviations and Part 64 exceedances and excursions must be included in the compliance certifications. The compliance certification shall include the following:
  - a) The identification of each term or condition of the permit that is the basis of the certification;
  - b) The current compliance status, as shown by monitoring data and other information reasonably available to the installation;

- c) Whether compliance was continuous or intermittent;
- d) The method(s) used for determining the compliance status of the installation, both currently and over the reporting period; and
- e) Such other facts as the Air Pollution Control Program will require in order to determine the compliance status of this installation.

#### **10 CSR 10-6.065(6)(C)6 Permit Shield**

- 1) Compliance with the conditions of this permit shall be deemed compliance with all applicable requirements as of the date that this permit is issued, provided that:
  - a) The application requirements are included and specifically identified in this permit, or
  - b) The permitting authority, in acting on the permit revision or permit application, determines in writing that other requirements, as specifically identified in the permit, are not applicable to the installation, and this permit expressly includes that determination or a concise summary of it.
- 2) Be aware that there are exceptions to this permit protection. The permit shield does not affect the following:
  - a) The provisions of section 303 of the Act or section 643.090, RSMo concerning emergency orders,
  - b) Liability for any violation of an applicable requirement which occurred prior to, or was existing at, the time of permit issuance,
  - c) The applicable requirements of the acid rain program,
  - d) The authority of the Environmental Protection Agency and the Air Pollution Control Program of the Missouri Department of Natural Resources to obtain information, or
  - e) Any other permit or extra-permit provisions, terms or conditions expressly excluded from the permit shield provisions.

#### **10 CSR 10-6.065(6)(C)7 Emergency Provisions**

- 1) An emergency or upset as defined in 10 CSR 10-6.065(6)(C)7.A shall constitute an affirmative defense to an enforcement action brought for noncompliance with technology-based emissions limitations. To establish an emergency- or upset-based defense, the Permittee must demonstrate, through properly signed, contemporaneous operating logs or other relevant evidence, the following:
  - a) That an emergency or upset occurred and that the Permittee can identify the source of the emergency or upset,
  - b) That the installation was being operated properly,
  - c) That the Permittee took all reasonable steps to minimize emissions that exceeded technology-based emissions limitations or requirements in this permit, and
  - d) That the Permittee submitted notice of the emergency to the Air Pollution Control Program within two working days of the time when emission limitations were exceeded due to the emergency. This notice must contain a description of the emergency, any steps taken to mitigate emissions, and any corrective actions taken.
- 2) Be aware that an emergency or upset shall not include noncompliance caused by improperly designed equipment, lack of preventative maintenance, careless or improper operation, or operator error.

#### **10 CSR 10-6.065(6)(C)8 Operational Flexibility**

An installation that has been issued a Part 70 operating permit is not required to apply for or obtain a permit revision in order to make any of the changes to the permitted installation described below if the changes are not Title I modifications, the changes do not cause emissions to exceed emissions allowable

under the permit, and the changes do not result in the emission of any air contaminant not previously emitted. The Permittee shall notify the Air Pollution Control Program, Enforcement Section, P.O. Box 176, Jefferson City, MO 65102, as well as EPA Region VII, 901 North 5th Street, Kansas City, Kansas 66101, at least seven days in advance of these changes, except as allowed for emergency or upset conditions. Emissions allowable under the permit means a federally enforceable permit term or condition determined at issuance to be required by an applicable requirement that establishes an emissions limit (including a work practice standard) or a federally enforceable emissions cap that the source has assumed to avoid an applicable requirement to which the source would otherwise be subject.

- 1) Section 502(b)(10) changes. Changes that, under section 502(b)(10) of the Act, contravene an express permit term may be made without a permit revision, except for changes that would violate applicable requirements of the Act or contravene federally enforceable monitoring (including test methods), recordkeeping, reporting or compliance requirements of the permit.
  - a) Before making a change under this provision, The Permittee shall provide advance written notice to the Air Pollution Control Program, Enforcement Section, P.O. Box 176, Jefferson City, MO 65102, as well as EPA Region VII, 901 North 5th Street, Kansas City, Kansas 66101, describing the changes to be made, the date on which the change will occur, and any changes in emission and any permit terms and conditions that are affected. The Permittee shall maintain a copy of the notice with the permit, and the Air Pollution Control Program shall place a copy with the permit in the public file. Written notice shall be provided to the EPA and the Air Pollution Control Program as above at least seven days before the change is to be made. If less than seven days notice is provided because of a need to respond more quickly to these unanticipated conditions, the Permittee shall provide notice to the EPA and the Air Pollution Control Program as soon as possible after learning of the need to make the change.
  - b) The permit shield shall not apply to these changes.

#### **10 CSR 10-6.065(6)(C)9 Off-Permit Changes**

- 1) Except as noted below, the Permittee may make any change in its permitted operations, activities or emissions that is not addressed in, constrained by or prohibited by this permit without obtaining a permit revision. Insignificant activities listed in the application, but not otherwise addressed in or prohibited by this permit, shall not be considered to be constrained by this permit for purposes of the off-permit provisions of this section. Off-permit changes shall be subject to the following requirements and restrictions:
  - a) The change must meet all applicable requirements of the Act and may not violate any existing permit term or condition; the Permittee may not change a permitted installation without a permit revision if this change is subject to any requirements under Title IV of the Act or is a Title I modification;
  - b) The Permittee must provide written notice of the change to the Air Pollution Control Program, Enforcement Section, P.O. Box 176, Jefferson City, MO 65102, as well as EPA Region VII, 901 North 5th Street, Kansas City, Kansas 66101, no later than the next annual emissions report. This notice shall not be required for changes that are insignificant activities under 10 CSR 10-6.065(6)(B)3. This written notice shall describe each change, including the date, any change in emissions, pollutants emitted and any applicable requirement that would apply as a result of the change.
  - c) The Permittee shall keep a record describing all changes made at the installation that result in emissions of a regulated air pollutant subject to an applicable requirement and the emissions resulting from these changes; and
  - d) The permit shield shall not apply to these changes.

### **10 CSR 10-6.020(2)(R)12 Responsible Official**

The application utilized in the preparation of this permit was signed by Mr. George Svokos, Vice President, Missouri Operations. On March 23, 2007, the Air Pollution Control Program was informed that Mr. Raaj Kumar is now the responsible official. If this person terminates employment, or is reassigned different duties such that a different person becomes the responsible person to represent and bind the installation in environmental permitting affairs, the owner or operator of this air contaminant source shall notify the director of the Air Pollution Control Program of the change. Said notification shall be in writing and shall be submitted within 30 days of the change. The notification shall include the name and title of the new person assigned by the source owner or operator to represent and bind the installation in environmental permitting affairs. All representations, agreement to terms and conditions and covenants made by the former responsible person that were used in the establishment of limiting permit conditions on this permit will continue to be binding on the installation until such time that a revision to this permit is obtained that would change said representations, agreements and covenants.

### **10 CSR 10-6.065(6)(E)6 Reopening-Permit for Cause**

This permit may be reopened for cause if:

- 1) The Missouri Department of Natural Resources receives notice from the Environmental Protection Agency (EPA) that a petition for disapproval of a permit pursuant to 40 CFR § 70.8(d) has been granted, provided that the reopening may be stayed pending judicial review of that determination,
- 2) Missouri Department of Natural Resources or EPA determines that the permit contains a material mistake or that inaccurate statements were made which resulted in establishing the emissions limitation standards or other terms of the permit,
- 3) Additional applicable requirements under the Act become applicable to the installation; however, reopening on this ground is not required if—
  - a) The permit has a remaining term of less than three years;
  - b) The effective date of the requirement is later than the date on which the permit is due to expire;or
  - c) The additional applicable requirements are implemented in a general permit that is applicable to the installation and the installation receives authorization for coverage under that general permit,
- 4) The installation is an affected source under the acid rain program and additional requirements (including excess emissions requirements), become applicable to that source, provided that, upon approval by EPA, excess emissions offset plans shall be deemed to be incorporated into the permit; or
- 5) Missouri Department of Natural Resources or EPA determines that the permit must be reopened and revised to assure compliance with applicable requirements.

### **10 CSR 10-6.065(6)(E)1.C Statement of Basis**

This permit is accompanied by a statement setting forth the legal and factual basis for the draft permit conditions (including references to applicable statutory or regulatory provisions). This Statement of Basis, while referenced by the permit, is not an actual part of the permit.

## **VI. Attachments**

Attachments follow.

**Attachment A**  
**Control Equipment Monitoring Parameters for 40 CFR Subpart GGG Compliance**

Device	Compliance Parameters	Compliance Value
<b>Regenerative Thermal Oxidizer (RTO)</b> § 63.1258(b)(vii) The RTO controls emissions from the following processes: PMPU 400, PMPU 600, V-873 Methanol Distillation Column (EP-862M), V-852 Toluene Distillation Column (EP-SRT)	Chamber Temp <sup>1</sup>	1550 F
<b>Y-601 Scrubber</b> § 63.1258(b)(ii)(B) Counter current packed bed tower utilizing water Y-601 scrubber is used in series with the RTO (APC-18) to achieve the required 98% removal efficiency required for Fluid Bed Drier (D-601) per §63.1254(a)(3)(i).	Minimum Scrubber Liquor Flow <sup>2</sup>	60 GPM
<b>Y-606 Acid Gas Scrubber</b> § 63.1258(b)(ii)(B) Counter current packed bed tower utilizing water Y-606 controls emissions from HCL charge vessels in PMPUs 400,500,600	Minimum Scrubber Liquor Flow <sup>2</sup>	2.85 GPM
<b>Y-801 Tank Farm Scrubber</b> § 63.1258(b)(ii) (B) Counter current packed bed tower utilizing water Y-801 controls emissions for the methanol, sulfuric acid, and hydrochloric acid tanks	Minimum Scrubber Liquor Flow <sup>2</sup>	6 GPM
<b>Fixed Bed Carbon Adsorber (FBCA)</b> (§63.1258(b)(1)(iv)) FCBA controls emissions from PMPUs 000 & 100 (including Tanks T008, and T010) and the SSP Batch Distillation Unit	Minimum Regeneration Frequency <sup>4</sup> Minimum Regeneration Bed Temperature <sup>3</sup> Maximum Bed Cooling Temperature <sup>3</sup> Minimum Regeneration Steam Flow <sup>3</sup>	Every 12 hrs or upon detected breakthrough <sup>5</sup> 200°F 110°F 350 pounds per Regeneration Cycle

<sup>1</sup>Annual Calibration of monitoring device required per §63.1258(b)(vii)(B).

<sup>2</sup>Annual Calibration of Scrubber Liquor Flowmeter required per §63.1258(b)(ii)(C).

<sup>3</sup>Calibrate the temperature and flow monitoring devices annually per §63.1258(b)(1)(iv)(E).

<sup>4</sup>Conduct annual check for bed poisoning in accordance with manufacturer's specifications per §63.1258(b)(1)(iv)(F).

<sup>5</sup>Breakthrough occurs when the THC Analyzer detects 100 ppmv in the FBCA exhaust stream.





### Attachment D Demonstration of Compliance with 10 CSR 3.060 and 10 CSR 10-6.260

This following tables demonstrate that the listed emission units are in compliance with 10 CSR 10-3.060, *Restriction of Emission of Particulate Matter from Fuel Burning Equipment Used for Indirect Heating*.

Emission Unit ID #	Fuel	Emission Factor	Source	Conversion Factors	Emission Factor (lb/MMBtu)	Emission Limit (lb/MMBtu)	Is EU in compliance?
EU0010	Natural Gas	7.6 lb /10 <sup>6</sup> scf	AP-42 Table 1.4-2	1050 MMBtu /10 <sup>6</sup> scf	0.007	0.286	YES
	Fuel Oil #2	2 lb /10 <sup>3</sup> gal	AP-42 Table 1.3-1	140 MMBtu /10 <sup>3</sup> gal	0.014	0.286	YES

<sup>1</sup>PM emission factor converted 7.6 lb/scf to lb/MMBtu by dividing by 1050 mmBTU/10<sup>6</sup> scf for Natural Gas.

<sup>1</sup>SO<sub>2</sub> emission factor converted 2 lb/10<sup>3</sup> gal to lb/MMBtu by dividing by 137 mmBTU/10<sup>3</sup> gal for Diesel Fuel.

This following calculations demonstrate that the listed emission units are in compliance with 10 CSR 10-6.260 - *Restriction of Emissions of Sulfur Compounds*

Emission Unit	Emission Unit Description		<sup>1</sup> Calculated Maximum SO <sub>2</sub> Emissions	SO <sub>2</sub> Emissions Limit	<sup>1</sup> Calculated Maximum SO <sub>3</sub> Emissions	SO <sub>3</sub> Emissions Limit
EU0010	Two (2) - 8.4 MMBtu/hr Boilers	Fuel Oil #2	133 ppmv	500 ppmv	11.08 mg/m <sup>3</sup>	35 mg/m <sup>3</sup>
		Natural Gas	153 ppmv	500 ppmv	<sup>2</sup> Insignificant	35 mg/m <sup>3</sup>

<sup>1</sup>The supporting calculations and further detail can be found in the Statement of Basis

<sup>2</sup>AP-42 has no emission factor for SO<sub>3</sub> in Table 1.4-2, as the natural gas emission factor for SO<sub>2</sub> is based on 100% fuel sulfur conversion to SO<sub>2</sub>.

Emission Unit	Emission Unit Description		SO <sub>2</sub> Emission Factor (lb/MMBtu) <sup>1</sup>	SO <sub>2</sub> Emissions (lb/MMBtu)	SO <sub>2</sub> Limit (lb/MMBtu)
EU0010	Two (2) - 8.4 MMBtu/hr Boilers	Natural Gas	0.0006 AP42 Tbl 1.4-2 (07/98)	0.0006	8
		Fuel Oil #2	0.52 AP42 Tbl 1.3-1 (09/98)	0.52	8

<sup>1</sup>SO<sub>2</sub> emission factor converted 0.6 lb/scf to lb/MMBtu by dividing by 1050 mmBTU/10<sup>6</sup> scf for Natural Gas.

<sup>1</sup>SO<sub>2</sub> emission factor converted 71 lb/10<sup>3</sup> gal to lb/MMBtu by dividing by 137 mmBTU/10<sup>3</sup> gal for Diesel Fuel.

**Attachment E**

Cephalexin Process Recordkeeping Log for Volatile Organic Compound Emission Limitation For Year:

Month	[A] Batches in Month	[B] [A] - 641 or zero	[C] VOC Emission Factor (tons/batch)	[D] Monthly VOC Emissions (tons) [A]*[C]	[E] VOC from Extra Batches (tons) [B]*[C]	[F] Total Year to Date VOC Emissions (tons)	[G] Total Year to Date Extra VOC Emissions (tons)	Signature & Date
January			0.139					
February			0.139					
March			0.139					
April			0.139					
May			0.139					
June			0.139					
July			0.139					
August			0.139					
September			0.139					
October			0.139					
November			0.139					
December			0.139					
Yearly Totals			x			x	x	x

Note: Year to date total of VOC emissions (column G) for all Cephalexin batches beyond batch 641 shall not exceed 40.0 tons. This equates to a maximum of 285 batches over and above the 641 batches as permitted in the original construction permit, MDNR Construction Permit #0989-004.







### Attachment H

Method 9 Opacity Emission Observations	
Company	Observer
Location	Observer Certification Date
Date	Emission Unit
Time	Control Device

Hour	Min.	Seconds				Steam Plume (check if applicable)		Comments
		0	15	30	45	Attached	Detached	
	0							
	1							
	2							
	3							
	4							
	5							
	6							
	7							
	8							
	9							
	10							
	11							
	12							
	13							
	14							
	15							
	16							
	17							
	18							

SUMMARY OF AVERAGE OPACITY				
Set Number	Time		Opacity	
	Start	End	Sum	Average

Readings ranged from \_\_\_\_\_ to \_\_\_\_\_ % opacity.  
 Was the emission unit in compliance at the time of evaluation? \_\_\_\_\_  
 YES NO Signature of Observer \_\_\_\_\_

## STATEMENT OF BASIS

### Permit Reference Documents

These documents were relied upon in the preparation of the operating permit. Because they are not incorporated by reference, they are not an official part of the operating permit.

- 1) Part 70 Operating Permit Application, received September 6, 1996; revised August 28, 1997;
- 2) 2005 Emissions Inventory Questionnaire, received March 31, 2006;
- 3) U.S. EPA document AP-42, *Compilation of Air Pollutant Emission Factors*; Volume I, Stationary Point and Area Sources, Fifth Edition.
- 4) EPA's Pharmaceutical MACT Rule Assistant (<http://icode.trintegral.net/rules/pharmact/appl.cfm>);
- 5) MDNR Construction Permit # 1292-012
- 6) MDNR Construction Permit # 0395-002
- 7) MDNR Construction Permit # 0797-032
- 8) MDNR Construction Permit # 0597-013
- 9) MDNR Construction Permit # 0198-024
- 10) Comments/corrections from Mr. Don Reichert, TEVA Pharmaceuticals, in an email dated March 23, 2007.

### Applicable Requirements Included in the Operating Permit but Not in the Application

*In the operating permit application, the installation indicated they were not subject to the following regulation(s). However, in the review of the application, the agency has determined that the installation is subject to the following regulation(s) for the reasons stated.*

#### 10 CSR 10-6.075, *Maximum Achievable Control Technology*,

The standard for pharmaceuticals production, 40 CFR 63 GGG, was not promulgated at the time of application but the facility is subject to the rule, therefore, it is included in the operating permit. The facility has since demonstrated compliance with GGG, and the established monitoring parameters for demonstrating continuous compliance are also incorporated into this permit.

#### 10 CSR 10-6.180, *Measurement of Emissions of Air Contaminants*,

This rule has been included in the operating permit in order to provide citing for the allowance of requests for emissions data results. On past forms issued by the Air Pollution Control Program, including the application for this permit, it was automatically marked as an administrative rule not required to be listed as an applicable requirement. It is no longer judged to be solely administrative and is, therefore, included in the operating permit.

#### 10 CSR 10-6.260, *Restriction of Emission of Sulfur Compounds*

This rule had not been created at the time of application; however, it has been determined to be applicable to the installation and, therefore, has been included in the operating permit.

### Other Air Regulations Determined Not to Apply to the Operating Permit

The Air Pollution Control Program has determined the following requirements to not be applicable to this installation at this time for the reasons stated.

#### 10 CSR 10-6.100, *Alternate Emission Limits*

This rule is not applicable because the installation is in an ozone attainment area.

## Construction Permit Revisions

### CONSTRUCTION PERMIT HISTORY

Permit Number	Description
0989-004	Construction of a pharmaceutical production facility
1292-012	Increase Dane salt production and alter boiler operation
0395-002	Install solvent recovery (distillation) systems, operational changes
0797-032	Cephalosporin G expansion (2 reactors, 2 receivers, 2 holding tanks)
0597-013	Install two new dual fuel boilers and Tank Farm Flexibility
0198-024	Install bis-trimethylsilylurea manufacturing process
0198-034	Install amoxicillin trihydrate manufacturing process
1298-010	Install Cefaclor manufacturing process within existing equipment
0399-010	Install Cephalexin recovery equipment
102001-011	Modification of the Cephalexin process to increase production
092002-014	Modification to the existing Amoxicillin manufacturing process for increased production
022003-014	Modification to existing equipment to recover Cephalexin Monohydrate USP(Bulk) from the mother liquors
82003-002	Installation of the Regenerative Thermal Oxidizer

The following revisions were made to construction permits for this installation:

- 1) MDNR Construction Permit #0989-004  
The recordkeeping retention requirement was changed from two (2) years to five (5) years to conform to the requirements of 10 CSR 10-6.065(6)(C)1.C, and as listed in Section V of this permit.
- 2) MDNR Construction Permit # 1292-012  
Special Conditions were not included because the Dane Salt line is inactive.
- 3) MDNR Construction Permit # 0395-002  
Unit is decommissioned; Special Conditions were not included in the permit.
- 4) MDNR Construction Permit # 0597-013  
No special conditions contained in this permit. Boilers not in service.
- 5) MDNR Construction Permit # 0797-032  
Special Conditions were not included because the PMPU 300 line is inactive per Notice of Compliance Report submissions
- 6) MDNR Construction Permit # 0198-024  
Special Conditions were not included because the bis-trimethylsilylurea (PMPU 325) production line is inactive per Notice of Compliance Report submissions.
- 7) MDNR Construction Permit #0399-010  
Special Condition was a historical performance testing requirement, and not included in this permit.
- 8) MDNR Construction Permit 102001-011  
Special Condition #3: "The exit air flow rate from stack S-606 shall be maintained at 2,500 standard cubic feet per minute." was removed because the control device configuration for PMPU 600 has since changed.
- 9) MDNR Construction Permit # 22003-014  
Permit #22003-014 has no special conditions, and the carbon canisters were replaced by the Regenerative Thermal Oxidizer in MDNR Construction Permit #82003-002.
- 10) MDNR Construction Permit #82003-002:  
The recordkeeping and reporting conditions outlined in Subpart GGG and in PW004 satisfy the Special Conditions 2.B and 2.C in permit MDNR Construction Permit #82003-002. The record retention on site for five years is also met (§63.1259(i)).

11) MDNR Construction Permit #82003-002: has listed emission points to have emissions controlled by the RTO. The following table has the original list from the CP, with justification for excluding certain units from the list, and updating emission point names to the present. The sentence “The regenerative thermal oxidizer shall be operated and maintained in accordance with the manufacturer's specifications.” was removed due to the requirements mentioned in item #2 above.

Emission Point 2002	Description	Emission Point last reported (if different)	<sup>1</sup> Status in 2006
3001	Cephalosporin-G Process Reactors		PMPU 300 is no longer in operation.
3002	Cephalosporin-G Process (expansion) Reactors		
3003	Cephalosporin-G Process (expansion) Reactors		
400A	7-ADCA Process Reactors	EP-400(2004)	Operational
500A	7-ADCA Process Reactors	EP-500(2004)	Operational
6001	Cephalexin Reactors		Operational
6002	Cephalexin Reactors		Operational
600D	CEPHALEXIN DRYER - 600 PROCESS AIR DRYER	Incorporated into EP 6001 and EP-6002	Operational
862M	Methanol Recovery Still	EP-862M(2005)	Operational
R325-326	Bis-trimethylsilylurea Reactors		PMPU 325 is no longer in operation.
SRT	Toluene Recovery Still	EP-SRT(2005)	Operational
400	7-ADCA Process Vent	EP-400(2004)	Operational
500	7-ADCA Process Vent	EP-500(2004)	Operational

<sup>1</sup>From Notice of Compliance Report submitted to the AIR POLLUTION CONTROL PROGRAM dated February 2005.

**New Source Performance Standards (NSPS) Applicability**

40 CFR 60, Subpart Dc *Performance Standards for Small Industrial-Commercial-Institutional Steam Generating Units* applies to the boiler EU0030, but does not apply to the boiler EU0010, because EU0010 has a maximum hourly design rate of less than 10 MMBTU/hr.

40 CFR 60, Subpart Kb *Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commences After July 23, 1984*. 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 (§63.1258), recordkeeping (§63.1259), and reporting (§63.1260) provisions of Subpart GGG. [§63.1250(h)(3)]

**Maximum Available Control Technology (MACT) Applicability**

The following is a list illustrating the process operating status as reported in the Notice of Compliance Report submittals:

Process	Status as of February 2006
000 PROCESS	In operation
SSP Batch Distillation Unit	In operation
PMPU 100	In operation in conjunction with PMPU 000 producing Amoxicillin and Dicloxacillin since approximately 5/1/2004
PMPU 200 Pen G Sulfoxide Production	The Pen G Sulfoxide process is aqueous. No HAPs or VOCs are used in the process.
PMPU 300 Cephalosporin G Production	PMPU 300 is no longer in operation. There are no emissions from this PMPU.
PMPU 325 Scenario: BSU Production	PMPU 325 is no longer in operation. There are no emissions from this PMPU.
PMPU 400 (7-ADCA Process)	In operation
PMPU 600	In operation
V852 Distillation Unit	In operation
V-873 Distillation Unit	In operation

#### 40 CFR 63, Subparts F & G

The National Emissions Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry do not apply to Teva Pharmaceuticals USA because they do not manufacture any of the chemicals listed in Table 1 of Subpart F as a primary product.

#### 40 CFR 63, Subparts H & I

The National Emissions Standards for Organic Hazardous Air Pollutants of Certain Process Subject to the Negotiated Regulated for Equipment Leaks (Subpart I) applies to the amoxicillin process because of the methylene chloride used in the process. Subpart H (National Emissions Standards for Organic Hazardous Air Pollutants for Equipment Leaks) also applies to the process because all processes subject to subpart I are also subject to subpart H. Teva has elected to meet the requirements of Subpart I through implementation of the equipment leak provisions in §63.1255. §63.1255(b) has provisions to compensate for regulatory overlap with Subpart H, and were included in the permit. (*see plant-wide condition PW002*).

#### 40 CFR 63 Subpart GGG

The National Emissions Standards for Pharmaceuticals Productions (Subpart GGG) applies to Teva Pharmaceuticals USA. Teva demonstrated compliance with the requirements of Subpart GGG on December 22, 2005, and submitted the final Notice of Compliance Status Report on February 16, 2006. The following table was compiled from information submitted in the Notice of Compliance report submittals and illustrates the process vents subject to 40 CFR 63 Subpart GGG and the corresponding emission control requirements.

Process Vents:PMPU 400: 7-ADCA Process			Classified existing source per § 63.1250	
Equipment Tag	Service	Control Device	Control Requirement	Reference
R-401	Reactor	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)
R-407	Reactor	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)
R-410	Reactor	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)
T-420	Tank	None; contents emit <50 ppm HAP		
V-401	Vessel	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)
V-402	Vessel	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)

<b>Process Vents:PMPU 600: Cephalexin Production</b>			<b>Classified existing source per § 63.1250</b>	
<u>Equipment Tag</u>	<u>Service</u>	<u>Control Device</u>	<u>Control Requirement</u>	<u>Reference</u>
D-601	Fluid Bed Drier	Regenerative Thermal Oxidizer	98.00%	§63.1254(a)(3)(i) <sup>1</sup>
N-601	Centrifuge	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)
N-602	Centrifuge	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)
R-303	Reactor	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)
R-605	Reactor	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)
R-601	Reactor	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)
R-602	Reactor	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)
R-604	Reactor	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)
T-417	Tank	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)
T-616	Tank	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)

<sup>1</sup>§63.1254(a)(3)(i) applies to tag D-601 because of Fluid Bed Dryer PTE > 25 ton/year

<b>Process Vents: V-852: Distillation Unit, Toluene Recovery</b>			<b>Classified existing source per § 63.1250</b>	
<u>Equipment Tag</u>	<u>Service</u>	<u>Control Device</u>	<u>Control Requirement</u>	<u>Reference</u>
E-862	Condenser	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)
V-843	Bottoms receiver	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)
V-846	Transfer tank	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)

<b>Process Vents:V-873: Distillation Unit, Methanol Recovery</b>			<b>Classified existing source per § 63.1250</b>	
<u>Equipment Tag</u>	<u>Service</u>	<u>Control Device</u>	<u>Control Requirement</u>	<u>Reference</u>
E-878	Condenser	Regenerative Thermal Oxidizer	93.00%	§63.1254(a)(1)(i)

<b>Process Vents:000 and 100 Process – Both Production Scenarios</b>			<b>Classified existing source per §63.1250</b>	
<u>Equipment Tag</u>	<u>Service</u>	<u>Control Device</u>	<u>Control Requirement</u> <sup>1</sup>	<u>Control Reference</u>
R-005	6-APA Slurry Tank	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
T-002	Mix Tank	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
R-001	Mixed Anhydride Reactor	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
R-002	Mixed Anhydride Reactor	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
R-101/ R-102	Dicloxacillin Reactor	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
R-105	Phase Separation Vessel	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
R-107	Crystallization Reactor	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
R-003	Crystallization Reactor	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
R-004	Crystallization Reactor	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
R-201	Crystall. Product Feed	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
N-001	Centrifuge	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
N-002	Centrifuge	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)

N-003	Centrifuge	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
N-101	Centrifuge	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
N-201	Centrifuge	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
T-155	Mother Liquor Tank	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
T-005	Mother Liquor Tank	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
T-027	Mother Liquor Tank	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
T-001	Pivaloyl Chloride Tank	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
D-001	Fluid Bed Dryer	<sup>2</sup> Scrubbers present but not required: effluent contains < 50 ppm HAP		
D-201	Fluid Bed Dryer	<sup>2</sup> None: effluent contains < 50 ppm HAP		
T-040	NaOH Tank	<sup>2</sup> None < 50 ppm HAP		
T-020	HCl Load Tank	<sup>2</sup> None < 50 ppm HAP		
<b>Dedicated Storage Tanks:</b>				
T-008	MeCl <sub>2</sub> (reclaim & new)	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
T-010	MeCl <sub>2</sub> (spent)	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
T-007	Acetone (reclaim & new)	None: Acetone not HAP		
T-009	Acetone (spent)	None: Acetone not HAP		
T-030	Triethylamine (new)	None: Triethylamine Vapor Pressure <13.1 Kpa @ max op Temp		

<sup>1</sup>This control requirement is for both operating scenarios.

<sup>2</sup>Waste stream contains <50 ppm HAP per the Notice of Compliance Report, date stamped by the Air Pollution Control Program on February 20, 2004. From the definition of “Process vents” in GGG; Emission streams that are undiluted and uncontrolled containing less than 50 ppmv HAP, as determined through process knowledge that no HAP are present in the emission stream or using an engineering assessment as discussed in §63.1257(d)(2)(ii), test data using Methods 18 of 40 CFR part 60, appendix A, or any other test method that has been validated according to the procedures in Method 301 of appendix A of this part, are not considered process vents.

<b>Process Vents: SSP Batch Distillation Unit –Methylene Chloride Scenario<sup>1</sup></b>			<b>Classified New Source per §63.1250</b>	
<b>Equipment Tag</b>	<b>Service</b>	<b>Control Device</b>	<b>Control Requirement</b>	<b>Control Reference</b>
V-001 Feed	Spent MeCl <sub>2</sub> Feed Tank	Primary Condensor E-002	93.00%	§63.1254(a)(1)(i)
V-001	Distillation Column	Primary Condensor E-002	93.00%	§63.1254(a)(1)(i)
V-028	MeCl <sub>2</sub> Condensate Decanter	Vent Condensor E-004	93.00%	§63.1254(a)(1)(i)
T-011	Recovered MeCl <sub>2</sub> Receiver	Vent Condensor E-004	93.00%	§63.1254(a)(1)(i)
T-024	First Cut MeCl <sub>2</sub> Receiver	Vent Condensor E-004	93.00%	§63.1254(a)(1)(i)
E-002	Primary Condenser <sup>2</sup>	Vent Condensor E-004	93.00%	§63.1254(a)(1)(i)
E-003	Secondary Condenser <sup>2</sup>	Vent Condensor E-004	93.00%	§63.1254(a)(1)(i)
E-004	Vent Condenser <sup>2</sup>	Fixed Bed Regenerative Carbon Adsorber	93.00%	§63.1254(a)(1)(i)
V-028	Acetone Condensate Recanter	Vent Condensor E-004	93.00%	§63.1254(a)(1)(i)
T-012	Recovered Acetone Receiver	Vent Condensor E-004	93.00%	§63.1254(a)(1)(i)
T-013	First Cut Receiver	Vent Condensor E-004	93.00%	§63.1254(a)(1)(i)

<sup>1</sup>Waste stream contains <50 ppm HAP under Acetone Distillation Mode scenario 2 as described in the Notice of Compliance Report, date stamped by the APCP on February 20, 2004

<sup>2</sup>Vent Condensers E002, E003, and E004 are installed in series with the stream exiting the system at E004, which is ducted to the carbon adsorber.

§63.1250(b) *New source applicability*: An affected source for which construction or reconstruction commenced after April 2, 1997, and the standard was applicable at the time of construction or reconstruction; §63.1250(a)(ii) defines Subpart GGG applicability as to facilities that are major for HAPs, which at the time processes 100/000 were constructed, the facility was not major for HAPs.

The following was excerpted from the EPA’s Pharmaceutical MACT Rule Assistant:

A storage tank is **not** subject to the Pharmaceutical Production MACT **unless** the following four conditions below are true:

- The storage tanks or vessels store organic HAP-containing materials (ex. raw material feedstocks or used solvents for the purpose of solvent recovery), and,
- The storage tanks have a capacity of at least 38 m<sup>3</sup>, and,
- The storage tanks store materials with a total HAP maximum true vapor pressure greater than or equal to 13.1 kPa, and ,
- The storage tank is part of a PMPU subject to the MACT.

Storage tanks at pharmaceutical manufacturing operations that do not meet the four criteria above are still subject to minor recordkeeping and reporting requirements. All applicability determinations must be reported in the Initial Notification of Compliance status report, per §63.1260(f)(1).

Reference: Chapter 4, p.4-2 - *Compliance Assistance Tool for Clean Air Act Regulations: Subpart GGG of 40 CFR NESHAPS for Source Category Pharmaceutical Production (August 2002)* from the U.S. EPA Office of Enforcement and Compliance Assurance (OECA).

Tank Subpart GGG applicability determinations in this permit were performed based upon the Notice of Compliance submittals. Whenever a process change is made, or a change in any of the information submitted in the Notification of Compliance Status Report (NOCSR), the facility is required by §63.1260(h) to submit updated information about the changes made, and revisions to the NOCSR (*as required by §63.1260(f)*) with the next Periodic report. (*See Permit Condition (EU0030 through EU0050) – 001*)

#### 40 CFR 63 Subpart GGG Bulk Storage Tank Applicability

Tanks Subject to 40 CFR 63 Subpart GGG		Tank Capacity (m <sup>3</sup> )	Control Device <sup>3</sup>	40 CFR 63 Subpart GGG Option	Required Removal Efficiency	Part 70 Emission Unit	Kb Apply?
EP T812	Methanol	53.00	Y-801	§63.1253(b)(1) <sup>1</sup>	90.00%	EU0040	No
EP T810	Methanol	75.71	Y-801	§63.1253(c)(1) <sup>2</sup>	95.00%	EU0050	Yes
EP T815	Methanol	75.71	Y-801	§63.1253(c)(1) <sup>2</sup>	95.00%		Yes
EP T822	Methanol	75.71	Y-801	§63.1253(c)(1) <sup>2</sup>	95.00%		Yes
EP T823	Methanol	75.71	Y-801	§63.1253(c)(1) <sup>2</sup>	95.00%		Yes
EP T825	Waste Methanol/DMF	113.56	Y-801	§63.1253(c)(1) <sup>2</sup>	95.00%		Yes
EP T826	Methanol	113.56	Y-801	§63.1253(c)(1) <sup>2</sup>	95.00%		Yes
EP T008	Methylene chloride tank	45.42	APC-18	§63.1253(c)(1) <sup>4</sup>	93.00%	EU0100	No
EP T010	Methylene chloride tank	45.42	APC-18	§63.1253(c)(1) <sup>4</sup>	93.00%		No

<sup>1</sup>A storage tank with a design capacity ≥ 38 m<sup>3</sup> (10038.54 gallon) but < 75 m<sup>3</sup> (19812.9 gallon) storing a liquid for which the maximum true vapor pressure of total HAP is ≥ 13.1 kPa. **(subject to requirements of paragraph §63.1253(b))**

<sup>2</sup>A storage tank with a design capacity  $\geq 75 \text{ m}^3$  (19812.9 gallon) storing a liquid for which the maximum true vapor pressure of total HAP is  $\geq 13.1 \text{ kPa}$ . **(subject to the requirements of paragraph §63.1253(c))**

<sup>3</sup>Y-801 is the Tank Farm Scrubber, APC-18 is the Fixed Bed Regenerative Carbon Adsorber as both are referred to in the notice of compliance status reports.

<sup>4</sup>Tanks T008 and T010 are dedicated to the Process 000 and comply with GGG by treating the tanks as process vents and achieving an emissions removal efficiency of at least 93%.

Dimethylformamide (DMF) vapor pressure: is 2.6 mm Hg at 20 C. Table uses the vapor pressure of methanol as a worse case scenario for applicability purposes.

**Scenarios for Applicability Due to Tank Capacity**

Storage Vessel	Capacity (1000 gal)	Applicability of GGG Tank Storage Standards (§63.1253)	GGG Control Requirements When Subject
T328	13	Tanks are subject when liquid stored has a maximum true vapor pressure $\geq 13.1 \text{ kPa}$	90% Control Required
T810	20.15		95% Control Required
T812	15.0		90% Control Required
T814	39.0		95% Control Required
T815	39.0		
T820	20.0		
T822	20.0		
T823	20.0		
T824	30.0		
T825	30.0		
T826	30.0		
T827	30.0		
T1403	20.0		

**40 CFR 63 Subpart PPP**

Teva does not manufacture polyether polyol and is not subject to Subpart PPP

**Compliance Assurance Monitoring (CAM) Applicability**

40 CFR Part 64, *Compliance Assurance Monitoring (CAM)*

40 CFR Part 64 is not applicable because §64.2(1)(i) states that an exemption exists for have subject units that have emission limitations or standards proposed by the administrator after November 15, 1990 pursuant to section 111 or 112 of the Act.

40 CFR Part 64 is not applicable because §64.2(b)(1)(vi) exempts units with pre-control HAP emissions greater than 25 tons per year, that have “Emission limitations or standards for which a part 70 or 71 permit specifies a continuous compliance determination method, as defined in §64.1.

From §64.1:

*Continuous compliance determination method* means a method, specified by the applicable standard or an applicable permit condition, which:

- 1) Is used to determine compliance with an emission limitation or standard on a continuous basis, consistent with the averaging period established for the emission limitation or standard; and
- 2) Provides data either in units of the standard or correlated directly with the compliance limit.

The monitoring parameters established from the compliance demonstration of 40 CFR Subpart GGG provide a continuous compliance determination method as described above by definition in §64.1. For these reasons the D-601 Dryer, which is the only unit with pre-control emission levels of greater than 25 ton per year of HAP, is exempt from 40 CFR Part 64 applicability.

**Other Regulatory Determinations**

<b>Tanks listed as Emission Units Without Specific Limitations</b>			
Storage Vessel	Product Stored	Max True Vapor Pressure (kPa)	Capacity (1000 gal)
T328	Hexamethyldisiloxane	2.7	13.0
T802	<sup>1</sup> HCl (33 wt%)	10.24	10.0
T807	Toluene	3.7	10.0
T808	C <sub>4</sub> H <sub>9</sub> NO	0.4	10.0
T813	MeOH	16.4	10.0
T814	Toluene	3.7	39.0
T818	MeOH	16.4	10.0
T819	Hexamethyldisiloxane	4.3	10.15
T820	Toluene	3.7	20.0
T821	MeCl <sub>2</sub>	56.5	10.0
T824	Toluene	3.7	30.0
T827	Toluene	3.7	30.0
T1403	<sup>2</sup> Waste	<3.7	20.0

<sup>1</sup>HCL 33 wt % solution vapor pressure at 30 C was obtained from Appendix 1, Table A-2, Hydrochloric Acid Guidance Document located on EPA’s Toxic Release Inventory website.

<sup>2</sup>Hazardous waste tank contains Sulfuric Acid with approximately >580 ppm of saturated toluene.

The following table gives reasoning for each emission unit’s exclusion from specific permit conditions.

Emission Unit	Reason for Permit Condition Exclusion
Fire Water Pump	MDNR defined insignificant activity
Space Heaters	MDNR defined insignificant activity
Building Vents	No HAPs released
Emergency Electric Generator	MDNR defined insignificant activity
VOL Storage Tanks	Must be at least 75 m <sup>3</sup> (19812.9 gallon) for regulation under Subpart Kb, or Volume ≥ 38 m <sup>3</sup> (10,038.54 gallon) & MTVP ≥ 13.1 kPa for GGG applicability.
Other Storage Tanks	Small non-volatile organic liquid and inorganic storage tanks (that are not part of PMPU) and not defined as VOL Storage Tanks (above), are not specifically limited by this permit.

**10 CSR 10-3.060 - Maximum Allowable Emissions of Particulate Matter from Fuel Burning Equipment Used for Indirect Heating**

Emission unit EU0030 is subject to 40 CFR 60 Subpart Dc and therefore exempt from this rule by 10 CSR 10-3.060(3)(E). However, indirect heat input values from sources that are subject to New Source Performance

Standards were used in the calculation of the installation's total heat input (Q) to demonstrate compliance in Attachment D of this permit.

Emission Unit ID #	MHDR (MMBtu/hr)	2006 EIQ Reference #
Space Heating (No ID)	54.4	EP-NATGAS
Boiler SB-1 (No ID)	3.0	EP-BOILER
*EU0010	16.8	EP-BOILER
EU0020	18	EP-BOILER
<b>Total Heat Input (Q)</b>	<b>90.54</b>	

\* (EU0010 consists of 2 boilers each rated at 8.4 MMBtu/hr)

Allowable PM emission limitation for new indirect heating source having a total intermediate capacity between ten (10) MMBtu and two thousand (2000) MMBtu;  $E = 1.31(Q)^{-0.338} = 1.31(90.54)^{-0.338} = 0.286 \text{ lb/MMBtu}$

10 CSR 10-6.260 - *Restriction of Emission of Sulfur Compounds*

Emission unit EU0030 is subject to 40 CFR 60 Subpart Dc and therefore exempt from this rule by §6.260(1)(A).

Supporting Calculations for Attachment D - 10 CSR 10-6.260, *Restriction of Emission of Sulfur Compounds Compliance Demonstration*

For maximum SO<sub>2</sub> emissions from natural gas combustion in the boiler (ppmv):

$$\text{Natural gas SO}_2 \text{ emission factor (lbs/MMBtu)} = \frac{0.6 \text{ lbs}/10^6 \text{ scf}}{1020 \text{ MMBtu}/10^6 \text{ scf}} = 5.88 \times 10^{-4} \text{ lb/MMBtu}$$

(AP - 42 Table 1.4 - 2(7/98))

$$\text{ppmv SO}_2 = \left( \frac{5.88 \text{E} - 4 \text{ lb}}{\text{MMBtu}} \right) \times \left( \frac{\text{MMBtu}}{10,610 \text{ wscf}} \right) \times \left( \frac{\text{ppmw}}{1.667 \text{E}^{-7} \text{ lb/scf}} \right) \times \left( \frac{0.45 \text{ ppmv}}{\text{ppmw}} \right) = 153.3 \text{ ppmv}$$

For maximum SO<sub>2</sub> emissions from Fuel Oil #2 combustion in the boiler (ppmv):

$$\text{Distillate Oil SO}_2 \text{ emission factor (lbs/MMBtu)} = \frac{142(0.5) \text{ lbs}/10^3 \text{ gal}}{140 \text{ MMBtu}/10^3 \text{ gal}} = 0.51 \text{ lb/MMBtu}$$

(AP - 42 Table 1.3 - 1(9/98))

$$\text{ppmv SO}_2 = \left( \frac{0.507 \text{ lb}}{\text{MMBtu}} \right) \times \left( \frac{\text{MMBtu}}{10,320 \text{ wscf}} \right) \times \left( \frac{\text{ppmw}}{1.660 \text{E}^{-7} \text{ lb/scf}} \right) \times \left( \frac{0.45 \text{ ppmv}}{\text{ppmw}} \right) = 133.22 \text{ ppmv}$$

(Appendix A – 7 to Part 60)

SO<sub>3</sub> (35-mg/m<sup>3</sup>) Limit - For maximum SO<sub>3</sub> emissions from Fuel Oil #2 combustion in the boiler (mg/m<sup>3</sup>):

$$\text{Distillate Oil SO}_3 \text{ emission factor (lbs/MMBtu)} = \frac{1 \text{ lbs}/10^3 \text{ gal}}{140 \text{ MMBtu}/10^3 \text{ gal}} = 7.14 \times 10^{-3} \text{ lbs/MMBtu}$$

(AP - 42 Table 1.3 - 1(9/98))

$$\text{SO}_3 \left( \frac{\text{mg}}{\text{m}^3} \right) = \left( \frac{7.14\text{E} - 03 \text{ lb}}{\text{MMBtu}} \right) \times \left( \frac{\text{MMBtu}}{10,320 \text{ wscf}} \right) \times \left( 1.603 \times 10^7 \frac{\text{mg} \cdot \text{ft}^3}{\text{lb} \cdot \text{m}^3} \right) = 11.08 \frac{\text{mg}}{\text{m}^3} \text{SO}_3$$

10 CSR 10-6.350, *Emission Limitations and Emissions Trading of Oxides of Nitrogen*

This rule applies to any fossil fuel fired electric generating unit that serves a generator with a nameplate capacity of greater than twenty-five megawatts. There are no emission units at the installation that meet the applicability criteria of this rule.

**Other Regulations Not Cited in the Operating Permit or the Above Statement of Basis**

Any regulation which is not specifically listed in either the Operating Permit or in the above Statement of Basis does not appear, based on this review, to be an applicable requirement for this installation for one or more of the following reasons:

- 1) The specific pollutant regulated by that rule is not emitted by the installation;
- 2) The installation is not in the source category regulated by that rule;
- 3) The installation is not in the county or specific area that is regulated under the authority of that rule;
- 4) The installation does not contain the type of emission unit which is regulated by that rule;
- 5) The rule is only for administrative purposes.

Should a later determination conclude that the installation is subject to one or more of the regulations cited in this Statement of Basis or other regulations which were not cited, the installation shall determine and demonstrate, to the Air Pollution Control Program's satisfaction, the installation's compliance with that regulation(s). If the installation is not in compliance with a regulation which was not previously cited, the installation shall submit to the Air Pollution Control Program a schedule for achieving compliance for that regulation(s).

Prepared by:

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