



Mitchell E. Daniels, Jr.
Governor

Thomas W. Easterly
Commissioner

100 North Senate Avenue
Indianapolis, Indiana 46204
(317) 232-8603
(800) 451-6027
www.IN.gov/idem

TO: Interested Parties / Applicant
DATE: April 1, 2005
RE: Eli Lilly and Company / 157-20003-00006
FROM: Paul Dubenetzky
Chief, Permits Branch
Office of Air Quality

Notice of Decision – Approval

Please be advised that on behalf of the Commissioner of the Department of Environmental Management, I have issued a decision regarding the enclosed matter. Pursuant to 326 IAC 2, this approval was effective immediately upon submittal of the application.

If you wish to challenge this decision, IC 4-21.5-3-7 requires that you file a petition for administrative review. This petition may include a request for stay of effectiveness and must be submitted to the Office of Environmental Adjudication, 100 North Senate Avenue, Government Center North, Room 1049, Indianapolis, IN 46204, **within eighteen (18) calendar days from the mailing of this notice**. The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:

- (1) the date the document is delivered to the Office of Environmental Adjudication (OEA);
- (2) the date of the postmark on the envelope containing the document, if the document is mailed to OEA by U.S. mail; or
- (3) The date on which the document is deposited with a private carrier, as shown by receipt issued by the carrier, if the document is sent to the OEA by private carrier.

The petition must include facts demonstrating that you are either the applicant, a person aggrieved or adversely affected by the decision or otherwise entitled to review by law. Please identify the permit, decision, or other order for which you seek review by permit number, name of the applicant, location, date of this notice and all of the following:

- (1) the name and address of the person making the request;
- (2) the interest of the person making the request;
- (3) identification of any persons represented by the person making the request;
- (4) the reasons, with particularity, for the request;
- (5) the issues, with particularity, proposed for considerations at any hearing; and
- (6) identification of the terms and conditions which, in the judgment of the person making the request, would be appropriate in the case in question to satisfy the requirements of the law governing documents of the type issued by the Commissioner.

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178. Callers from within Indiana may call toll-free at 1-800-451-6027, ext. 3-0178.

Enclosures
FNPER-AM.dot 1/10/05



INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
We make Indiana a cleaner, healthier place to live.

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April 1, 2005

Mr. Stephen A. Roosz
Eli Lilly and Company, Tippecanoe Laboratories
1650 Lilly Road
Lafayette, IN 47907-9201

Re: 157-20003-00006
First Administrative Amendment to
Part 70 Permit T157-6879-00006

Dear Mr. Roosz

Eli Lilly and Company, Tippecanoe Laboratories was issued a Part 70 operation permit on February 27, 2004 for a stationary bulk pharmaceutical manufacturing plant and associated support facilities located at 1650 Lilly Road, Lafayette, IN 47907. A letter requesting a change to the permit was received on December 16, 2004. The source requested the following types of changes to the permit:

- (a) The source requested that typographical errors be corrected, that several emission unit ID numbers be revised, that redundant language be removed, and that references to emission units no longer in use be deleted. These changes to the permit qualify as either a "revision that corrects typographical errors" or a "revision to descriptive information where the revision will not trigger a new applicable requirement or violate a permit term," under 326 IAC 2-7-11, Administrative Permit Amendments.
- (b) The source requested that nine emission units, which were either inadvertently left off the original equipment list (T100-TK31B, T28-CENT3, TI0031000MS001, T46109, T69126, T63150, T47224, and 31A985DUCHT4) or added after the permit was issued (T28-TK-28HW), be added to permit as insignificant activities, since the potential uncontrolled emissions meet the exemption levels specified in 326 IAC 2-1.1-3(e)(1) or 326 IAC 2-7-1(21)(A), whichever is lower. The inclusion of these emission units in the permit each qualify as an "incorporation of an insignificant activity as defined in 326 IAC 2-7-1(21)," under 326 IAC 2-7-11, Administrative Permit Amendments.
- (c) The source requested that several conditions be revised to provide clarity to the permit requirements, to correctly incorporate requirements that are applicable, and to remove requirements that are not applicable.

The Office of Air Quality (OAQ) has determined that the following permit changes will not be made as requested by the source, with response provided:

1a. Requested Change

Condition C.18(d): change to read: Unless otherwise specified in this permit, all reports required in Section D of this permit shall be submitted within thirty (30) days of the end of the reporting period. Unless otherwise specified in this permit, all reports do require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

1b. Response to Request

Pursuant to 326 IAC 2-7-6(1), any document (including reports) required by a Part 70 permit shall contain a certification by a responsible official that meets the requirements of 326 IAC 2-7-4(f). Therefore, Condition C.18(d) will not be changed as requested.

During the application review, OAQ found additional typographical errors in the permit related to this comment that required a change to the permit (See Additional Changes below).

2a. Requested Change

Add Condition C.11(g) to read: "The permittee shall prepare and submit to IDEM, OAQ a written report of the results of the calibration gas audits and relative accuracy test audits within thirty (30) days of the end of the quarter. The report must contain the information required by 326 IAC 3-5-5(e)(2). 326 IAC 3-5-5(e)(2) is not federally enforceable." This amendment will clarify the submission requirements.

2b. Response to Request

The requirements of 326 IAC 3-5 are federally enforceable according to Condition B.3 and 326 IAC 2-1.1-9.5, because they were previously included in this FESOP (see Condition C.11(b)), which is a federally approved program that has been incorporated into our state implementation plan. The following text below will be added as C.11(g), with new language **bolded**:

(g) The permittee shall prepare and submit to IDEM, OAQ a written report of the results of the calibration gas audits and relative accuracy test audits for each calendar quarter within thirty (30) calendar days after the end of each quarter. The report must contain the information required by 326 IAC 3-5-5(e)(2).

3a. Requested Change

Add Condition C.11(h) to read: "The permittee shall prepare and submit to IDEM, OAQ a written SOP within ninety (90) days of monitor installation. The CEMS SOP should contain, at a minimum, the items described in 326 IAC 3-5-4(a). If revisions are made to the SOP, updates shall be submitted to IDEM, OAQ biennially. 326 IAC 3-5-4(a) is not federally enforceable." This amendment will provide added clarity to the requirement.

3b. Response to Request

The requirements of 326 IAC 3-5 are federally enforceable according to Condition B.3 and 326 IAC 2-1.1-9.5, because they were previously included in this Part 70 Permit (see Condition C.11(b)), which is a federally approved program that has been incorporated into our state implementation plan. The following text below will be added as C.11(h), with new language **bolded**:

(h) The permittee shall prepare and submit to IDEM, OAQ a written standard operating procedure (SOP) within ninety (90) days after monitor installation. The CEMS SOP should contain, at a minimum, the items described in 326 IAC 3-5-4(a). If revisions are made to the SOP, updates shall be submitted to IDEM, OAQ biennially.

4a. Requested Change

In E.1.1(d)(5)(G), change "to comply with E.1.1(d)(5)(i) through (ii)" should be changed "to comply with E.1.1(d)(5)(A) through (B)" to correct typographical error.

4b. Response to Request

The appropriate change to E.1.1(d)(5)(G) is as follows: change “to comply with E.1.1(d)(5)(i) through (iii)” should be changed “to comply with E.1.1(d)(5)(A) through (C)” to correct typographical error. The permit changes are as follows, with deleted language as ~~strikeouts~~ and new language **bolded**:

- (G) Open-ended valves or lines containing materials which could cause a serious safety hazard if capped or equipped with a double block and bleed system are not required to comply with E.1.1 (d)(5)(~~i~~**A**) through (~~iii~~**C**).

5. Additional Changes

In addition to the changes requested by the source, OAQ found additional typographical errors in the permit that required a change to the permit. Permit changes were made pursuant to the provisions of 326 IAC 2-7-11 and are indicated with deleted language as ~~strikeouts~~ and new language **bolded**:

- (1) Conditions D.1.18(a) and D.1.18(c), and the Quarterly Coal Characteristic and Consumption Report Form:

The reporting requirements of Condition D.1.18(a) for Boilers 1, 2, and 3 are unnecessary, since, pursuant to 326 IAC 7-2-1(c)(3), fuel combustion sources with total coal-fired heat input capacity less than one hundred (100) million British thermal units (Btus) shall submit to IDEM, OAQ, upon request reports of calendar month average sulfur content, heat content, fuel consumption, and sulfur dioxide emission rate in pounds per million Btus. Therefore, Condition D.1.18(a) and the associated Quarterly Coal Characteristic and Consumption Report Form have been deleted. The last sentence of Condition D.1.18(c) should read that “The report does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34)”. The permit changes are as follows.

D.1.18 Reporting Requirements

- ~~(a) The Permittee shall submit quarterly summary reports of the monthly coal characteristic and consumption records required by Condition D.1.12 for Boilers 1, 2 and 3.~~
- (~~ba~~) The Permittee shall submit quarterly summary reports of the monthly fuel oil characteristic and consumption records required by Condition D.1.13 for Boilers 4 and 5.
- (~~eb~~) The Permittee shall submit quarterly summary reports of the monthly natural gas and fuel oil consumption records required by Condition D.1.14 for Boiler 5.
- (~~ec~~) All reports shall be submitted to the address listed in Section C – General Reporting Requirements, of this permit, using the reporting form located at the end of this permit, or its equivalent, within thirty (30) days after the end of the quarter being reported. The report ~~does not~~ require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).

Section D.1 – Utilities Operations

Quarterly Coal Characteristic and Consumption Report

Source Name: ~~_____~~ Eli Lilly and Company, Tippecanoe Laboratories
Source Address: ~~_____~~ 1650 Lilly Road, Lafayette, Indiana 47909
Mailing Address: ~~_____~~ 1650 Lilly Road, Lafayette, Indiana 47909
Part 70 Permit No.: ~~_____~~ T157-6879-00006
Facility: ~~_____~~ Boilers 1, 2 and 3
Parameter: ~~_____~~ SO₂ emissions
Limit: ~~_____~~ 6.0 lbs/MMBtu

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(2) Conditions D.3(a) and D.3(b)

To be consistent with the source's requested changed to Conditions D.3(a) and D.3(b) to change Emission Unit ID numbers from "TXXX": to "TKXXX", Emission Unit ID numbers in Section D.4 were also changed from "TXXX": to "TKXXX". The permit changes are as follows:

SECTION D.4(a) Table, Emission Unit IDs revised as follows:

T147-TK001, T147-TK002, T147-TK003, T147-TK004, T147-TK005, T147-TK006,
T147-TK007, T147-TK008, T147-TK009, T147-TK010, T147-TK011, T147-TK012

SECTION D.4(b) Table, Emission Unit IDs revised as follows:

T3-TK47718, T3-TK56, T3-TK261, T3-TK327-1T, T3-TK330, T3-TK332-3T, T3-TK337-1T,
T3-TK338-1T, T3-TK338-2T, T3-TK341-1T, T3-TK346-1T, T3-TK353-1T, T3-TK355-1T,
T3-TK357-1T, T3-TK376-1T, T3-TK376-2T, T3-TK376-3T, T3-TK378-1T, T3-TK394,
T3-TK397-1T, T3-TK399, T40-TK050, T40-TK051, T40-TK052, T40-TK053, T40-TK055,
T40-TK060, T4-TK001, T4-TK101, T39-TK021, T39-TK022, T39-TK023, T39-TK030,
T39-TK031, T39-TK036, TK420-1T, TK434-1T

(3) Condition D.6.2(c)

D.6.1(b) should be changed to D.6.2(b) to correct typographical error. The permit changes are as follows:

D.6.2 Control Strategy for Production Equipment Exhaust Systems [40 CFR 63.1254][326 IAC 8-5-3] [326 IAC 2-2-3]

(c) Pursuant to 326 IAC 2-2-3, VOC BACT for production equipment exhaust systems not meeting the criteria of D.6.2(a) or D.6.42(b) is no controls.

(4) Condition E.1.1(d)(5)(E)

"to comply with E.1.1(d)(5)(i) through (iii)" should be changed "to comply with E.1.1(d)(5)(A) through (C)" to correct typographical error. The permit changes are as follows:

(E) Open-ended valves and lines in an emergency shutdown system which are designed to open automatically in the event of a process upset are not required to comply with E.1.1 (d)(5)(iA) through (iiiC).

(5) Part 70 Operating Permit Emergency Occurrence Report Form

The last statement of the Part 70 Operating Permit Emergency Occurrence Report Form should read: "A certification is not required for this report". The permit changes are as follows:

PART 70 OPERATING PERMIT
EMERGENCY OCCURRENCE REPORT

Source Name: Eli Lilly and Company, Tippecanoe Laboratories
Source Address: 1650 Lilly Road, Lafayette, Indiana 47909
Mailing Address: 1650 Lilly Road, Lafayette, Indiana 47909
Part 70 Permit No.: T157-6879-00006

~~Attach a signed certification to complete this report.~~
A certification is not required for this report.

All other permit changes requested by the source were made as requested (see below). Pursuant to the provisions of 326 IAC 2-7-11, the permit is hereby administratively amended as follows with deleted language as ~~strikeouts~~ and new language **bolded**:

1. Condition C.20 has been deleted as follows, because all applicable MACTs have been issued.

Part 2 MACT Application Submittal Requirement

~~C.20 Application Requirements for Section 112(j) of the Clean Air Act [40 CFR 63.52(e)] [40 CFR 63.56(a)] [40 CFR 63.9(b)] [326 IAC 2-7-12]~~

- ~~(a) The Permittee shall submit a Part 2 MACT Application in accordance with 40 CFR 63.52(e)(1). The Part 2 MACT Application shall meet the requirements of 40 CFR 63.53(b).~~
- ~~(b) Notwithstanding paragraph (a), the Permittee is not required to submit a Part 2 MACT Application if the Permittee no longer meets the applicability criteria of 40 CFR 63.50 by the application deadline in 40 CFR 63.52(e)(1). For example, the Permittee would not have to submit a Part 2 MACT Application if, by the application deadline:
 - ~~(1) The source is no longer a major source of hazardous air pollutants, as defined in 40 CFR 63.2;~~
 - ~~(2) The source no longer includes one or more units in an affected source category for which the U.S. EPA failed to promulgate an emission standard by May 15, 2002; or~~
 - ~~(3) The MACT standard or standards for the affected source categories included at the source are promulgated.~~~~
- ~~(c) Notwithstanding paragraph (a), pursuant to 40 CFR 63.56(a), the Permittee shall comply with an applicable promulgated MACT standard in accordance with the schedule provided in the MACT standard if the MACT standard is promulgated prior to the Part 2 MACT Application deadline or prior to the issuance of permit with a case-by-case Section 112(j) MACT determination. The MACT requirements include the applicable General Provisions requirements of 40 CFR 63, Subpart A. Pursuant to 40 CFR 63.9(b), the Permittee shall submit an initial notification not later than 120 days after the effective date of the MACT, unless the MACT specifies otherwise. The initial notification shall be submitted to:~~

~~Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
400 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015~~

~~and~~

~~United States Environmental Protection Agency, Region V
Director, Air and Radiation Division
77 West Jackson Boulevard
Chicago, Illinois 60604-3590~~

2. The following conditions have been revised to correct typographical errors, to revise several emission unit ID numbers, to add text that provides clarification and accuracy, or to replace incorrect text with the correct text:

D.1.8 Fuel Oil Sampling and Analysis for SO₂ [326 IAC 7-2]

- (c) Conduct a stack test for sulfur dioxide emissions from the boiler, using 40 CFR 60, Appendix A, Method 6 in accordance with the procedures in 326 IAC 3-6, which is conducted with such frequency as to generate the amount of information required by (a) or (b) above. [326 IAC 7-2-1(bd)]

SECTION D.3(a) Table, Emission Unit IDs revised as follows:

TK001, TK002, TK003, TK004, TK011, TK012, TK013, TK014, TK005, TK006, TK007, TK008, TK009, TK010, TK015, TK016, TK017, TK018, TK019, TK020, TK021, TK022, TK023, TK024, TK025, TK026, TK027, TK028, TK029, TK030, TK043, TK044, TK048, TK049, TK050

SECTION D.3(b) Table, Emission Unit IDs revised as follows:

TK121, TK122, TK123, TK123A, TK124, TK125, TK126, TK231, TK233, TK236, TK237, TK241, TK242, TK243, TK244, TK245, TK246, TK247, TK248, TK249, TK813, TK814, TK143, TK144

TK232	Waste Holding Whole Broth Storage Tank	N/A	200000	liters	None
TK234	Liquid Storage Whole Broth Storage Tank	N/A	200000	liters	None
TK235	Liquid Storage Whole Broth Storage Tank	N/A	200000	liters	None

D.3.3 Particulate Matter (PM) Emission Limitations [40 CFR 52 Subpart P]

Emission Unit Description	Emission Unit ID	Maximum Process Weight Rate (ton/hr)	Allowable PM Emission Rate (lb/hr)
<i>Building T1 – Raw Material Prep Area:</i>			
Dry Raw Material Mixers + Conveyor for Mixers	MIX001, MIX002, MCNV001	0.881	3.77, combined
<i>Building T2 – Fermentation Production Area:</i>			
Bump Tanks	TK001 – TK004	18.3	28.7, combined
Fermentor Tanks	TK005 – TK010		
Bump Tanks	TK011 – TK014		
Fermentor Tanks	TK015 – TK020		
<i>Building T2A – Fermentation Production Area:</i>			
Bump Tanks	TK021 – TK024	18.3	28.7, combined
Fermentor Tanks	TK025 – TK027, TK029 – TK030		
Fermentor Tank	TK028		
<i>Building 2C – Fermentation Production Area:</i>			
Bump Tanks	TK043 – TK044	31.6	5.5, combined
Fermentor Tanks	TK048 – TK050		

SECTION D.6(a) Table:

T100-SCR891	Process Scrubber	RTO	N/A	RTO
T100-SCR892	Process Scrubber	RTO	N/A	RTO
T100-SCR893	Process Scrubber	RTO	N/A	RTO
T100-SCR894	Process Scrubber	RTO	N/A	RTO
T100-SCR895	Process Scrubber	RTO	N/A	RTO
T100-TK11C	Process Tank	RTO	70 gal	RTO
T100-TK-30A	Process Tank	RTO	70 gal	RTO

D.9.2 Exceptions to Standards for BPM Solvent Storage Tanks [40 CFR 63.1253 and 326 IAC 2-2]

- (a) The BPM solvent storage tanks are not subject to the standards established in Condition D.9.1 (b) during periods of planned routine maintenance, as long as the planned routine maintenance activities do not exceed 240 hours per ~~year~~**365 day period**.

SECTION D.10 Table

T146-TK12	Solvent Waste Tank	RTO	19,500 gal	RTO
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D.10.2 Exceptions to Standards for BPM Waste Storage Tanks [40 CFR 63.1256(b), 40 CFR 63, and 326 IAC 2-2-3]

- (a) The BPM waste storage tanks less than 38 cubic meters are not subject to the standards established in Condition D.10.1 (b) during periods of planned routine maintenance, as long as the planned routine maintenance activities do not exceed 240 hours per ~~year~~**365 day period**.

D.12.12 Plans and Procedures [326 IAC 2-2-3, 40 CFR 63.1206, 40 CFR 63.1211, 326 IAC 2-7-5(13)]

In order to satisfy the HWC MACT Standards [40 CFR 63.1206] and the PSD BACT requirements [326 IAC 2-2-3], the Permittee shall develop and implement the following written plans, which shall be maintained in the operating record:

- (a) Operations and Maintenance (O&M) Plan – The O&M Plan shall define operations during periods of normal operation pursuant to 40 CFR 63.1206(c)(1) and (7).
- (b) **Startup, Shutdown, and Malfunction (SSM)** Plan shall be developed and implemented in accordance with 40 CFR 63.1206(c)(2), 40 CFR 63.6(e)(3), and 40 CFR 63.8(c), to ensure that the T49 liquid waste incinerator, including associated air emission control equipment and CEMS and CMS, is operated and maintained in a manner which satisfies the general duty to minimize emissions established by 40 CFR 63.6(e)(1)(i), and that all malfunctions are corrected as soon as practicable after their occurrence in order to minimize excess emissions. The SSM Plan shall contain the following information:

D.12.14 Continuous Emissions Monitoring Systems (CEMS) Operating Requirements [40 CFR 63.1209, 40 CFR 63.8, 326 IAC 2-7-24, 326 IAC 3-5, 326 IAC 2-1.1-11, 40 CFR 60, Appendix B, and 40 CFR 60, Appendix F]

- (b) SO₂ and NO_x CEMS Operation Requirements – The following requirements shall apply when the T49 Incinerator is burning waste
 - (3) The Startup, Shutdown, and Malfunction (SSM) Plan required by Condition D.12.12 (b) shall include procedures for monitoring and recording the following information during times of SO₂ or NO_x CEMS malfunction:
 - (A) When the SO₂ CEMS malfunctions, the Permittee shall monitor and record the Hydro-Sonic™ ~~scrubber~~ **equivalent** pressure drop and scrubber liquid flow rate as required by Condition D.12.15 (a)(3)(C) and (D) and the scrubber liquid pH as required by Condition D.12.15 (a)(5)(C).

D.12.15 Parametric Continuous Monitoring Systems (CMS) Requirements [40 CFR 63.8(c), 40 CFR 63.1209, and 326 IAC 2-1.1-11]

- (a) The Permittee shall operate the following CMS in accordance with the quality assurance requirements specified in 40 CFR 63.1209(d) at all times the T49 incinerator is ~~burning waste~~ **in operation**. To satisfy the HWC MACT standards [40 CFR 63.1209(b), (d), (e), (f), and (h)] and the requirements for PSD sources [326 IAC 2-1.1-11] the following parameters shall be monitored ~~when burning waste~~ **at all times the T49 incinerator is in operation. In addition, the operating parameters monitored by the following CMSs shall not exceed the established operating parameter limits at all times the T49 incinerator is burning waste:**
 - (3) Metals CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(l) and (n)], the Permittee shall install and operate CMS monitors for the following parameters:
 - (C) Hydro-Sonic™ ~~Scrubber~~ **Equivalent** Pressure Drop - Minimum hourly rolling average pressure drop across the Hydro-Sonic™ scrubber established from the average of the performance test run averages;

D.13.5 Hazardous Air Pollutant (HAP) Emission Standards [40 CFR 63.1203]

Except for periods of startup, shutdown and malfunctions, the following emission standards shall apply at all times the T49 ~~liquid waste~~ **rotary kiln** incinerator is operating:

- (d) Hydrochloric Acid/Chlorine Gas (HCl/Cl₂) and Fluorides - In order to satisfy the HWC MACT standards [40 CFR 63.1203(b)(6)], the HCl/Cl₂ emissions from the T149 rotary kiln incinerator stack exhaust shall not exceed 21 ppmvdc, expressed as HCl equivalent. In order to satisfy the PSD BACT requirements for fluorides [326 IAC 2-2-3], the T49 ~~liquid waste~~ **rotary kiln** incinerator control system shall achieve a HCl control efficiency of 98 percent or greater.

D.13.14 Continuous Emissions Monitoring Systems (CEMS) Operating Requirements [40 CFR 60, Appendix B and Appendix F, 40 CFR 63.8, 326 IAC 2-1.1-11, 326 IAC 3-5]

- (b) SO₂ and NO_x CEMS Operation Requirements – The following requirements shall apply when the T149 rotary kiln incinerator is burning waste:

- (3) The Startup, Shutdown, and Malfunction (SSM) Plan required by Condition D.13.12 (b) shall include procedures for monitoring and recording the following information during times of SO₂ or NO_x CEMS malfunction:
 - (A) When the SO₂ CEMS malfunctions, the Permittee shall monitor and record the Hydro-Sonic™ ~~scrubber~~ **equivalent** pressure drop and scrubber liquid flow rate as required by Condition D.13.15 (a)(3)(C) and (D) and the scrubber liquid pH as required by Condition D.13.15 (a)(5)(C).

D.13.15 Parametric Continuous Monitoring Systems (CMS) Requirements [40 CFR 63.8(c), 40 CFR 63.1209, and 326 IAC 2-1.1-11]

- (a) The Permittee shall operate the following CMSs in accordance with the quality assurance requirements specified in 40 CFR 63.1209(d) at all times the T149 ~~rotary kiln incinerator is burning waste~~ **in operation**. To satisfy the HWC MACT standards [40 CFR 63.1209(b), (d), (e), (f), and (h)] and the requirements for PSD sources [326 IAC 2-1.1-11], the following parameters shall be monitored ~~when burning waste~~ **at all times the T149 incinerator is in operation. In addition, the operating parameters monitored by the following CMSs shall not exceed the established operating parameter limits at all times incinerators are burning waste:**
 - (3) Metals CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(l) and (n)], the Permittee shall install and operate CMS monitors for the following parameters:
 - (C) Hydro-Sonic™ ~~Scrubber~~ **Equivalent** Pressure Drop - Minimum hourly rolling average pressure drop across the Hydro-Sonic™ scrubber established from the average of the performance test run averages;
 - (4) PM CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(m)], the Permittee shall install and operate CMS monitors for the following parameters:
 - (A) Those parameters identified in Condition D.13.15~~6~~(a)(3)(B), (C), and (D); and

D.13.19 Reporting Requirements

- (a) Quarterly Reporting Requirements
 - (1) The following streamlined quarterly reporting requirements shall satisfy the HWC MACT standards [40 CFR 63.1211], which references the MACT General Provisions [63.7-63.10], PSD BACT requirements [326 IAC 2-1.1-11], and the continuous emissions monitoring requirements [326 IAC 3-5]:
 - (C) SSM summary reports for the T49 ~~waste~~ **rotary kiln** incinerator control system, including associated CEMS and CMS equipment;

D.14.1 Control Device and Closed Vent System Standards [40 CFR 63.1253(b), (c), and (d), 63.1254(a) and (c), 63.1256(b), (e), and (h), 63.1258(b), 40 CFR 63.685(c) and (d), 63.689(b), 63.690(b), 63.693(f), 40 CFR 60.112b(a) and 60.113b(c), 326 IAC 2-2-3, and 326 IAC 8-5-3(b)]

(b) RTO Closed Vent System Inspection Standards – The following inspection standards shall apply to the RTO closed vent system (CVS), except as provided in Condition D.14.2 (b):

(1) The Permittee shall comply with the following closed vent system inspection requirements to satisfy the Pharmaceutical MACT requirements [40 CFR 63.1256(b)(3) and (e)(1) and 63.1258(h)], the Offsite Waste MACT requirements [40 CFR 63.685(g), 63.689(b), 63.690(b), 63.693(b) and (c), and 63.695(c)], and the PSD BACT requirements [326 IAC 2-2-3]:

(C) Annual visual inspections of the RTO closed vent system shall be performed for visible cracks, holes or gaps, loose connections, and broken or missing ~~limits~~**scaps**.

D.14.4 Continuous Emissions Monitoring System (CEMS) Requirements [40 CFR 60, Appendix B and Appendix F, 40 CFR 60.113b(c), 40 CFR 63.1258(b), 40 CFR 63.693(f), 40 CFR 63.8, 326 IAC 2-1.1-11, 326 IAC 2-7-24, 326 IAC 3-5]

(c) HCl CEMS Operation Requirements – The following requirements shall apply only when burning waste fume streams and represent streamlined requirements for the Pharmaceutical MACT standards for hydrogen halides and halogens [40 CFR 63.1258(b)], NESHAP General Provisions monitoring requirements [40 CFR 63.8(c)], and PSD BACT requirements for fluorides [326 IAC 2-1.1-11]:

(1) The Permittee shall install and operate the HCl CEMS in accordance with the performance and QA/QC criteria established in the *Updated Alternative Monitoring Plan for a HCl Gas Hydrogen Chloride Continuous Emission Monitoring Systems for the Regenerative Thermal Oxidizers* submitted to EPA OAQPS on August 15, 2003, as allowed by 40 CFR 63.1258(b) and 40 CFR 63.8.

SECTION D.15 BPM CONTROL SYSTEMS – T79 FUME INCINERATOR SYSTEM OPERATIONS

Facility Description [326 IAC 2-7-5(15)]

(b) The following emission units are not subject to applicable requirements described in this D section:

The T79 control system consists of two fume incinerators, identified as **30940** and **3104**, each equipped with caustic scrubbing systems, and each exhausting to individual stacks.

D.15.1 T79 Control Device and Closed Vent System Standards [40 CFR 63.1253(b), (c), and (d), 63.1254(a) and (c), 63.1256(b), (e), and (h), 63.1258(b), 40 CFR 63.685(c) and (d), 63.689(b), 63.690(b), 63.693(f), 40 CFR 60.112b(a) and 60.113b(c), 326 IAC 2-2-3, and 326 IAC 8-5-3(b)]

(b) T79 Closed Vent System Inspection Standards – The following inspection standards shall apply to the T79 CVS, except as provided in Condition D.15.2 (b):

(1) The Permittee shall comply with the following CVS inspection requirements to satisfy the Pharmaceutical MACT requirements [40 CFR 63.1256(b)(3) and (e)(1) and 63.1258(h)], the Offsite Waste MACT requirements [40 CFR

63.685(g), 63.689(b), 63.690(b), 63.693(b) and (c), and 63.695(c)], and the PSD BACT requirements [326 IAC 2-2-3]:

- (B) Perform annual visual inspections of the T79 CVS for visible cracks, holes or gaps, loose connections, and broken or missing **limitcaps**.

D.15.7 Record Keeping and Reporting Requirements

(b) Quarterly Periodic Reporting Requirements

- (1) The following Pharmaceutical MACT reporting requirements [40 CFR 63.1260(g)], which references the MACT General Provisions [40 CFR 63.7 – 63.10], shall serve as the streamlined reporting requirements that satisfy the Offsite Waste MACT standards [40 CFR 63.697], Volatile Organic Liquid Storage Vessel requirements [40 CFR 60.115b], PSD BACT requirements [326 IAC 2-1.1-11], and continuous emission monitoring requirements [326 IAC 3-5]:

- (H) SSM summary reports for the ~~RTOT~~**T79** control system, including associated CEMS and CMS equipment.

E.1.1 LDAR Standards for BPM Process System Components [40 CFR 63.1255, 40 CFR 61 Subpart I, 326 IAC 8-5-3(b)(6), 326 IAC 2-2, CP157-4148 (Revised by this permit)]

- (b) The Permittee shall conduct an initial monitoring survey that includes the total number of each existing BPM process component type and initial monitoring as follows:

- (3) Subsequent monitoring periods shall be calendar periods, beginning October ~~22~~**4**, 2003.

- (d) The following BPM process system components in VOHAP/VOC service shall comply with design standards, shall be operated in accordance with work practice standards or shall undergo periodic LDAR monitoring in accordance with the provisions cited below. Periodic LDAR monitoring shall be performed in accordance with 40 CFR 60, Appendix A, Method 21 and 40 CFR 63.1255(b)(4)(v). The regulatory language cited by reference in this section appears in full in Appendix A.

- (3) Pressure relief devices in gas/vapor service shall be operated in accordance with the standard at 63.1255(b)(3), which requires compliance with 63.165. This section provides, generally and in part:

- (C) A rupture disk ~~is~~ satisfies conditions E.1.1 (d)(3)(**Ai**) and (**Bi**) without monitoring if it is replaced within 5 calendar days after each pressure release, except if delay of repair applies.

- (5) Open-ended valves or lines shall be operated in accordance with the standard at 63.1255(d). This section provides, generally and in part:

- (A) Each open-ended valve and line shall be equipped with a **limitcap**, blind flange, plug or second valve, which shall seal the open end at all times except when operations require fluid flow through the open-ended valve or line, or during maintenance or repair.

- (B) The **limitcap**, blind flange, plug or second valve shall be in place and closed within one hour of cessation of operations requiring fluid

flow through the open-ended valve or line, or maintenance or repair. No records are required to document compliance with this provision.

- (C) If a second valve is used, the valve on the process fluid end shall be closed before the other valve is closed.
 - (D) If a double block and bleed arrangement is used, the bleed valve may remain open during operations requiring venting the line between the block valves, but shall be closed otherwise in accordance with E.1.1 (d)(5)(iiB).
 - (F) Open-ended valves or lines containing materials, which would autocatalytically polymerize are not required to comply with E.1.1 (d)(5)(iA) through (iiiC).
- (e) As an alternative to complying with E.1.1(d), except E.1.1(d)(7), BPM process system components may comply with 63.1255(b)(4)(iv), which incorporates by reference 63.178(b) (Alternative Means of Emission Limitation: Batch Processes) as follows:
- (1) Components shall be pressure tested each time the equipment is reconfigured for production of a different product or intermediate or at least once per **calendar** year, whichever is more stringent. The pressure testing shall be conducted in accordance with 63.180(f) or (g); and

E.2.1 LDAR Standards for BPM Waste System Components [40 CFR 63.691, 326 IAC 8-5-3(b)(6), 326 IAC 2-2, CP157-4148 (Revised by this permit)]

- (b) Existing BPM waste system components in VOC/VOHAP service are covered under 40 CFR 264 and 265, Subpart BB. Data taken for purposes of Subpart BB shall satisfy the data requirements for entry into the alternate standard at 40 61.243-32. Monitoring periods are calendar periods as defined at 40 CFR 61 Subpart V and 40 CFR 264 and 265, Subpart BB.
- (d) The following BPM waste system components in VOHAP/VOC service shall comply with design standards, shall be operated in accordance with work practice standards, or shall undergo periodic LDAR monitoring in accordance with the provisions cited below. Periodic LDAR monitoring shall be performed in accordance with 40 CFR 60, Appendix A, Method 21. The regulatory language cited by reference in this section appears in full in Appendix A.
 - (3) Pressure relief devices in gas/vapor service shall be operated in accordance with the standard at 61.242-4. This section provides, generally and in part:
 - (C) A rupture disk is satisfies conditions E.2.1 (d)(3)(iA) and (iiB) without monitoring if it is replaced within 5 calendar days after each pressure release, except if delay of repair applies.
 - (D) Any pressure relief device satisfies conditions E.2.1 (d)(3)(iA) and (iiB) without monitoring if it is routed to a process or fuel gas system or equipped with a closed-vent system limitable of capturing and transporting leakage from the pressure relief device to a control device.
 - (5) Open-ended valves or lines shall be operated in accordance with the standard at 61.242-6. This section provides, generally and in part:

- (C) If a double block and bleed arrangement is used, the bleed valve may remain open during operations requiring venting the line between the block valves, but shall be closed otherwise in accordance with E.2.1 (d)(5)(~~ii~~**B**).
- (D) Open-ended valves and lines in an emergency shutdown system which are designed to open automatically in the event of a process upset are not required to comply with E.2.1 (d)(5)(~~ii~~**A**) through (~~iii~~**C**).
- (E) Open-ended valves or lines containing materials, which would autocatalytically polymerize are not required to comply with E.2.1 (d)(5)(~~ii~~**A**) through (~~iii~~**C**).
- (F) Open-ended valves or lines containing materials which could cause a serious safety hazard if capped or equipped with a double block and bleed system are not required to comply with E.2.1 (d)(5)(~~ii~~**A**) through (~~iii~~**C**).

E.2.3 Record Keeping and Reporting Requirements

- (a) Records shall be kept in accordance with 61.246, including but not limited to:
 - (7) Records for closed-vent systems and control devices, subject to E.2.1 (d)(~~8~~);
 - (9) Identification of components exempt because they are in VOC/VOHAP service for less than 300 hours per year;
 - (11) Records may be kept in one or more recordkeeping systems, providing each records is identified by process unit.

F.1.5 Nitrogen oxides (NO_x) emission limit determination

- (a) The following requirements apply to the RTOs, the T49 liquid waste incinerator, and the T149 solids-liquid waste incinerator:
 - (4) Data substitution:
 - (C) During periods of CEMS maintenance, malfunction, repair, or other periods of invalid NO_x data collection, the Permittee shall substitute the following data in lieu of actual readings from the NO_x CEMS:
 - (ii) When incinerating a waste stream, the following NO_x concentrations shall be substituted:
 - (1) RTO NO_x concentration = 912 ppmv

F.1.6 Sulfur dioxide (SO₂) emission limit determination

- (b) The following requirements apply to the T79 fume incinerators:
 - (~~4~~2) Uncontrolled SO₂ emission calculation for combustion of sulfur-containing solvents: The Permittee shall determine the mass of sulfur atoms emitted to the T79 fume incinerators [as components of solvents containing sulfur] by the BPM Support operations by using engineering calculation methods based on ideal gas law equations, stoichiometry, or mass balance. All of

the sulfur atoms shall be considered converted to SO₂ as a result of combustion in the T79 fume incinerators.

- (23) SO₂ control efficiency: The Permittee shall base SO₂ emissions on T79 scrubber control efficiency of 95%. If the compliance monitoring data is not available or indicates the scrubbers are not achieving this control efficiency, the Permittee shall use a control efficiency of zero percent (0%).
- (34) Emission calculation: The Permittee shall calculate SO₂ emissions, in tons, each calendar month by multiplying the amount of SO₂ created by combustion of the sulfur atoms in the T79 fume incinerators by the scrubber SO₂ control efficiency.
- (45) Data substitution: During periods of time when the Permittee is unable to determine natural gas usage because of auditing, calibration, maintenance, malfunction, repair, or other periods when the natural gas meters for the T79 fume incinerators are not collecting data properly, the Permittee shall determine SO₂ emissions based on a natural gas consumption rate of 0.0075 mmscf/hour [based on the nominal heat input rate of 7.626 MMBtu/hr per incinerator].

3. The following conditions have been revised to eliminate redundancy with Section C.8:

D.1.6 Testing Requirements [326 IAC 2-7-6(1), (6)]

- (a) The Permittee shall perform particulate matter performance tests for Boilers 1, 2 and 3 utilizing Methods 5 or 17 (40 CFR 60, Appendix A) for PM or other methods as approved by the Commissioner. These tests shall be repeated every third calendar year from the calendar year of the most recently completed compliance stack test. **The requirements for conducting performance tests are described in Tests shall be conducted in accordance with Section C – Performance Testing.**
- (b) No emissions testing is required for the boilers for compliance with particulate matter for boilers 4, and 5, or sulfur dioxide or nitrogen oxides emission limits established in Conditions D.1.1, D.1.2 and D.1.3, respectively, at this time. However, IDEM may require performance testing when necessary to determine compliance. **The requirements for conducting performance tests are described in Any testing shall be conducted in accordance with Section C – Performance Testing.**

D.2.3 Testing Requirements [326 IAC 2-7-6(1), (6)] [326 IAC 2-7-6(1)] [326 IAC 2-7-5(1)]

No emissions testing is required for the emission units described in this Section, at this time, but IDEM may require compliance testing at any specific time when necessary to determine if the facility is in compliance. ~~If IDEM requires testing in the future, compliance with the limitations in this Section shall be determined by performance stack tests conducted in accordance with~~ **The requirements for conducting performance tests that may be required by IDEM in the future are described in Section C – Performance Testing.**

D.3.5 Testing Requirements [326 IAC 2-7-6(1), (6)]

No emissions testing is required for the emission units described in this Section at this time, but IDEM may require compliance testing at any specific time when necessary to determine if the facility is in compliance. ~~If IDEM requires testing in the future, compliance with the limitations in this Section shall be determined by performance stack tests conducted in accordance with~~ **The requirements for conducting performance tests that may be required by IDEM in the future are described in Section C – Performance Testing.**

D.4.5 Testing Requirements [326 IAC 2-7-6(1), (6)]

No emissions testing is required for the emission units described in this Section at this time, but IDEM may require compliance testing at any specific time when necessary to determine if the facility is in compliance. ~~If IDEM requires testing in the future, compliance with the limitations in this Section shall be determined by performance stack tests conducted in accordance with~~ **The requirements for conducting performance tests that may be required by IDEM in the future are described in Section C – Performance Testing.**

4. Condition D.1.10 has been removed to eliminate redundancy with Section C.5, which states that "Except as otherwise provided by statute or rule, or in this permit, all air pollution control equipment listed in this permit and used to comply with an applicable requirement shall be operated at all times that the emission units vented to the control equipment is in operation."

D.1.10 Control Equipment Operation (Deleted)

Condition D.1.10 was deleted pursuant to Administrative Permit Amendment 157-20003-00006.

- (a) ~~The Permittee shall operate the baghouse at all times the ash handling system is in operation.~~
- (b) ~~The Permittee shall operate the multiclones at all times its associated coal-fired boiler is in operation.~~

5. The following conditions have been revised to eliminate redundancy with Section C.17:

Section D.1

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] **[326 IAC 2-7-19]**

~~Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]~~

D.1.17 Record Keeping Requirement (Deleted)

Condition D.1.17 was deleted pursuant to Administrative Permit Amendment 157-20003-00006. ~~All records shall be maintained in accordance with Section C – General Record Keeping Requirements, of this permit.~~

D.4.6 Record Keeping Requirements [40 CFR 63.1254(a)(2), 40 CFR 60.116b(b), Registration Issued November 8, 1990, and Amendment Issued November 10, 1992]

- (e) ~~All records shall be maintained in accordance with Section C – General Record Keeping Requirements, of this permit.~~

D.5.7 Record Keeping Requirements [CP 157-4363 Issued August 28, 1996 (Revised by this permit), and Amendment 157-8953 Issued November 12, 1997 (Revised by this permit)]

- (e) ~~All records shall be maintained in accordance with Section C – General Record Keeping Requirements, of this permit.~~

D.6.8 Record Keeping and Reporting Requirements

- (a) Record Keeping Requirements

- (6) ~~All records shall be maintained in accordance with Section C – General Record Keeping Requirements, of this permit.~~

D.8.5 Record Keeping and Reporting Requirements

(a) Record Keeping Requirements

~~(5) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.~~

D.9.7 Record Keeping and Reporting Requirements

(a) Record Keeping Requirements

~~(7) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.~~

D.10.7 Record Keeping and Reporting Requirements

(a) Record Keeping Requirements

~~(7) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.~~

D.11.3 Record Keeping and Reporting Requirements

(a) Record Keeping Requirements

~~(2) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.~~

D.12.17 Record keeping Requirements

(a) The Permittee shall maintain the following records ~~in accordance with Section C - General Record Keeping Requirements~~ of this permit:

D.13.18 Record keeping Requirements

(a) The Permittee shall maintain the following records ~~in accordance with Section C - General Record Keeping Requirements~~ of this permit:

D.14.9 Record Keeping and Reporting Requirements

(a) Record Keeping Requirements

The Permittee shall maintain the following records ~~in accordance with Section C - General Record Keeping Requirements~~, of this permit:

D.15.7 Record Keeping and Reporting Requirements

(a) Record Keeping Requirements

The Permittee shall maintain the following records ~~in accordance with Section C - General Record Keeping Requirements~~, of this permit:

D.16.4 Record Keeping and Reporting Requirements [CP157-4148 (Revised by this permit)]

~~(d) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.~~

D.17.6 Record keeping and Reporting Requirements

- ~~(c) All records shall be maintained in accordance with Section C – General Record Keeping Requirements, of this permit.~~

D.18.3 Record Keeping and Reporting Requirements

- ~~(b) All records shall be maintained in accordance with Section C – General Record Keeping Requirements, of this permit.~~

D.19.3 Record keeping and Reporting Requirements

- ~~(b) All records shall be maintained in accordance with Section C – General Record Keeping Requirements, of this permit.~~

E.1.3 Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)]

- (b) **Condition E.1.3(b) was deleted pursuant to Administrative Permit Amendment 157-20003-00006.** ~~All records shall be maintained in accordance with Section C – General Record Keeping Requirements, of this permit.~~

E.2.3 Record Keeping and Reporting Requirements

- (b) **Condition E.2.3(b) was deleted pursuant to Administrative Permit Amendment 157-20003-00006.** ~~All records shall be maintained in accordance with Section C – General Record Keeping Requirements, of this permit.~~

6. The following conditions have been revised to eliminate redundancy with Section C.18 and to correct the outline numbering:

D.6.8 Record Keeping and Reporting Requirements

(b) Periodic Reporting Requirements

- (1) The following streamlined quarterly reporting requirements shall satisfy the Pharmaceutical MACT standards [40 CFR 63.1256(b)] and the PSD BACT requirements [326 IAC 2-1.1-11]:
- (A) SSM summary reports for the processes.
 - (2B)** The reporting requirements for the RTO control system, and associated closed-vent system, that controls emissions from the emission units listed in this section are described in Section D.14 of this permit.
 - (3C)** The reporting requirements for the LDAR standards are described in Sections E.1 and E.2 of this permit.
- ~~(4) All reports shall be submitted to the address listed in Section C – General Reporting Requirements, of this permit, using the reporting form located at the end of this permit, or its equivalent, within thirty (30) days after the end of the quarter being reported. The report does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).~~

D.7.8 Record Keeping and Reporting Requirements

(b) Periodic Reporting Requirements

- (1) The following streamlined quarterly reporting requirements shall satisfy the Pharmaceutical MACT standards [40 CFR 63.1256(b)], Offsite Waste MACT [40 CFR 63.697(b)(3)] and the PSD BACT requirements [326 IAC 2-1.1-11]:
 - (A) SSM summary reports for the processes.
 - ~~(B2)~~ The reporting requirements for the RTO control system, T79 fume incinerator control system, and associated closed-vent systems, that control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.
 - ~~(C3)~~ The reporting requirements for the LDAR standards are described in Sections E.1 and E.2 of this permit.
- ~~(4)~~ All reports shall be submitted to the address listed in Section C — General Reporting Requirements, of this permit, using the reporting form located at the end of this permit, or its equivalent, within thirty (30) days after the end of the quarter being reported. The report requires certification by the “responsible official” as defined by 326 IAC 2-7-1(34).

D.8.5 Record Keeping and Reporting Requirements

(b) Periodic Reporting Requirements

- (1) The following streamlined quarterly reporting requirements shall satisfy the Pharmaceutical MACT standards [40 CFR 63.1256(b)] and the PSD BACT requirements [326 IAC 2-1.1-11]:
 - (A) Inspections conducted during which a leak was detected; and
 - (B) SSM summary reports for the processes.
 - ~~(2C)~~ The reporting requirements for the RTO control system, T79 fume incinerator control system, and associated closed-vent systems, that control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.
- ~~(3)~~ Reports shall be submitted to the address(es) listed in Section C — General Reporting Requirements, of this permit, using the reporting forms located at the end of this permit, or their equivalent, within thirty (30) days after the end of the reporting period. The report submitted by the Permittee does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).

D.9.7 Record Keeping and Reporting Requirements

(b) Periodic Reporting Requirements

- (1) The following streamlined quarterly reporting requirements shall satisfy the Pharmaceutical MACT standards [40 CFR 63.1256(b)] and the PSD BACT requirements [326 IAC 2-1.1-11]:
 - (A) Semiannual visual inspections conducted during which a leak was detected;

- (B) Periods of planned routine maintenance; and
 - (C) SSM summary reports for the processes.
 - (2D) The reporting requirements for the RTO control system, T79 fume incinerator control system, and associated closed-vent systems, that control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.
 - (3E) The reporting requirements for the LDAR standards are described in Section E of this permit.
- ~~(4) Reports shall be submitted to the address(es) listed in Section C — General Reporting Requirements, of this permit, using the reporting forms located at the end of this permit, or their equivalent, within thirty (30) days after the end of the reporting period. The report submitted by the Permittee does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).~~

D.10.7 Record Keeping and Reporting Requirements

(b) Quarterly Reporting Requirements

- (1) The following streamlined quarterly reporting requirements shall satisfy the Pharmaceutical MACT standards [40 CFR 63.1256(b)] and the PSD BACT requirements [326 IAC 2-1.1-11]:
 - (A) Inspections conducted during which a leak was detected;
 - (B) Periods of planned routine maintenance; and
 - (C) SSM summary reports for the processes.
 - (2D) The reporting requirements for the RTO control system and T79 fume incinerator control system used to control emissions from these emission units are described in Sections D.14 and D.15 of this permit, respectively.
 - (3E) The reporting requirements for the LDAR standards are described in Section E of this permit.
- ~~(4) Reports shall be submitted to the address(es) listed in Section C — General Reporting Requirements, of this permit, using the reporting forms located at the end of this permit, or their equivalent, within thirty (30) days after the end of the reporting period. The report submitted by the Permittee does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).~~

D.11.3 Record Keeping and Reporting Requirements

(b) Quarterly Reporting Requirements

- ~~(2) Reports shall be submitted to the address (es) listed in Section C — General Reporting Requirements, of this permit, using the reporting forms located at the end of this permit, or their equivalent, within thirty (30) days after the end of the reporting period. The report submitted by the Permittee does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).~~

D.12.18 Reporting Requirements

(a) Quarterly Reporting Requirements

- ~~(3) — The Permittee shall submit periodic reports to the address (es) listed in Section C — General Reporting Requirements, of this permit. The report submitted by the Permittee requires the certification by the “responsible official” as defined in 326 IAC 2-7-1(34).~~

D.13.19 Reporting Requirements

(a) Quarterly Reporting Requirements

- ~~(3) — The Permittee shall submit periodic reports to the address (es) listed in Section C — General Reporting Requirements, of this permit. The report submitted by the Permittee requires the certification by the “responsible official” as defined in 326 IAC 2-7-1(34).~~

D.14.9 Record Keeping and Reporting Requirements

(b) Quarterly Periodic Reports

- ~~(3) — The Permittee shall submit periodic reports to the address (es) listed in Section C — General Reporting Requirements, of this permit. The report submitted by the Permittee does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).~~

D.15.7 Record Keeping and Reporting Requirements

(b) Quarterly Periodic Reporting Requirements

- ~~(2) — The Permittee shall submit periodic reports to the address (es) listed in Section C — General Reporting Requirements, of this permit. The report submitted by the Permittee does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).~~

D.16.4 Record Keeping and Reporting Requirements [CP157-4148 (Revised by this permit)]

- ~~(e) — All reports shall be submitted to the address listed in Section C — General Reporting Requirements, of this permit, using the reporting form located at the end of this permit, or its equivalent, within thirty (30) days after the end of the quarter being reported. The report does not require certification by the “responsible official” as defined by 326 IAC 2-7-1(34).~~

D.19.3 Record keeping and Reporting Requirements

- ~~(c) — Reports shall be submitted to the address (es) listed in Section C — General Reporting Requirements, of this permit, using the reporting forms located at the end of this permit, or their equivalent, within thirty (30) days after the end of the reporting period. The report submitted by the Permittee does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).~~

E.1.3 Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)]

- ~~(d) — Reports shall be submitted to the address (es) listed in Section C — General Reporting Requirements, of this permit, using the reporting forms located at the end~~

~~of this permit, or their equivalent, within thirty (30) days after the end of the reporting period. The report submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).~~

E.2.3 Record Keeping and Reporting Requirements

~~(d) Reports shall be submitted to the address (es) listed in Section C General Reporting Requirements, of this permit, using the reporting forms located at the end of this permit, or their equivalent, within thirty (30) days after the end of the reporting period. The report submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).~~

7. Conditions D.6.6, D.7.6, D.8.3, D.9.5, D.10.5, and F.1.2 have been revised to eliminate redundancy with Conditions D.6.1(a), D.7.1(a), D.8.1(b)(2), D.9.1(b)(1), D.10.1(b), and F.1.11-F.1.12, respectively.

D.6.6 Requirements

~~With the exception of Condition D.6.1(c), the Permittee shall operate the RTO control system, and associated closed-vent system, at all times a process vent is in operation.~~

D.7.6 Requirements

(a) ~~The Permittee shall operate the RTO control system and/or T79 control system, and associated closed-vent systems, at all times a process vent is in operation. The requirements for the RTO control system and T79 control system, and associated closed-vent systems, used to control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.~~

D.8.3 Requirements

(a) ~~The Permittee shall operate the RTO control system and/or T79 control system, and associated closed-vent systems, at all times a BPM IDS containing waste equal to or greater than 500 ppmw HAP and/or 500 ppmw VOC is in operation. The compliance determination requirements for the RTO control system and T79 fume incinerator control system, and associated closed-vent systems, used to control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.~~

D.9.5 Requirements

~~The Permittee shall operate the RTO control system and/or T79 control system, and associated closed-vent systems, at all times a BPM solvent storage tank is in operation. The requirements for the RTO control system and T79 fume incinerator control system, and associated closed-vent systems, that control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.~~

D.10.5 Requirements

~~The Permittee shall operate the RTO control system and/or T79 control system, and associated closed-vent systems, at all times a BPM waste storage tank is in operation. The requirements for the RTO control system and T79 fume incinerator control system, and associated closed-vent systems, used to control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.~~

F.1.2 Site modifications and advance approval of modifications [326 IAC 2-7-5(9)]
 [326 IAC 2-7-5(16)]

(e) Notification and records

The Permittee shall notify IDEM of changes made under the flexible permit pursuant to condition F.1.12, and shall maintain records of changes pursuant to condition F.1.11.

8. The following sections have been revised to delete references to emission units that are no longer in use at the source:

SECTION D.3(b) Table

<i>Building T2 – Fermentation Production Area:</i>					
T116	Liquid Feed Tank	N/A	4000	liters	None
T117	Liquid Feed Tank	N/A	4000	liters	None
<i>Building T63 – Product Storage Area:</i>					
TK252	Whole Broth Tank	N/A	189400	liters	None

SECTION D.6(a) Table:

T27-TK49-5	Process Tank	RTO	50 gal	RTO
T27-TK49-6	Process Tank	RTO	75 gal	RTO
T28-RVD	Vacuum Dryer	RTO	NA	RTO
T28-SCR64	Process Scrubber	RTO	NA	RTO
T100-TK53A	Accumulator Tank	RTO	200 gal	RTO
T100-TK55A	Accumulator Tank	RTO	200 gal	RTO

9. The following sections have been revised to add nine emission units, each considered an insignificant activity:

SECTION D.6(a) Table:

T28-CENT3	Heinkel Centrifuge	RTO	NA	RTO
T100-TK31B	Process Tank	RTO	50 gal	RTO

SECTION D.10 Table:

Building T28:				
T28-TK-28HW*	Waste Tank	RTO	250 gal	RTO

SECTION D.16 BPM SUPPORT OPERATIONS - RESEARCH AND DEVELOPMENT OPERATIONS

Facility Description [326 IAC 2-7-5(15)]

The information describing the processes contained in the facility description boxes is descriptive information and does not constitute enforceable conditions:

- (a) The emission units listed below are insignificant activities as defined in 326 IAC 2-7-1(21), but are subject to applicable requirements described or referred to in this D section.

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
<i>Building T71:</i>				
31A985DUCHT4	Charge Tank	Atmosphere	10 gal	None
T10031000MS001	Slurry Mill	Atmosphere	NA	None
T46109	Slurry Mill	Atmosphere	NA	None
T69126	Centrifuge	Atmosphere	5 liters	None
T63150	Plate Filter	Atmosphere	0.15 m ³	None
T44224	Filter Dryer	Atmosphere	NA	None

- 10. The following condition has been revised to clarify that these records need to be kept only when Tippecanoe Laboratories is complying with the requirements using the 98% Control Efficiency Standard:

D.6.8 Record Keeping and Reporting Requirements

- (a) Record Keeping Requirements
 - (2) Process Records - The Permittee shall maintain the following records **if the 98% Control Efficiency Emission Standard is used to demonstrate compliance with the requirements of the Pharmaceutical MACT (40 CFR Part 63, Subpart GGG):**

- 11. The following condition has been revised to include applicable requirements not previously included:

D.11.1 Standards for Small BPM Waste Containers [40 CFR 63.1256(d), 40 CFR 63.688, 326 IAC 2-2-3]

- (d) **The LDAR standards that apply to the components associated with the emission units listed in this section are described in Section E.2.**

- 12. The following condition has been revised to delete reference to 40 CFR 63.8, since it is a MACT requirement that does not apply to the BACT CO, NOx, and SO₂ monitors:

D.14.4 Continuous Emissions Monitoring System (CEMS) Requirements [40 CFR 60, Appendix B and Appendix F, 40 CFR 60.113b(c), 40 CFR 63.1258(b), 40 CFR 63.693(f), 40 CFR 63.8, 326 IAC 2-1.1-11, 326 IAC 2-7-24, 326 IAC 3-5]

- (a) CO, NOx, and SO₂ CEMS Operation Requirements –The following requirements shall apply when the RTO is burning waste fume streams:

- (1) The Permittee shall install and operate the CO, NO_x, and SO₂ CEMS in accordance with the quality assurance/quality control (QA/QC) criteria set forth in 40 CFR 60, Appendix B, ~~40 CFR 63.8,~~ and 40 CFR 60, Appendix F, Procedure 1.

13. The following condition has been revised to delete the reference "and to satisfy the monitoring for the BACT requirement [326 IAC 2-1.1-11]", since this section does not apply to the BACT monitoring:

D.14.7 Excursions [40 CFR 63.1258(b)(6), 40 CFR 63.695(e)(4), ~~326 IAC 2-1.1-11~~]

- (a) Pursuant to the Pharmaceutical MACT standards [40 CFR 63.1258(b)(7)] and the Offsite Waste MACT [40 CFR 63.695(e)(4)], ~~and to satisfy the monitoring for the BACT requirement [326 IAC 2-1.1-11],~~ excursions are defined as follows and apply to the CEMS and CMS required by Conditions D.14.4 (b) and (c), and D.14.6, respectively:

14. The following condition has been revised to delete the reference "Waste and Recovery Operations (OSWRO) MACT Standards [40 CFR 63.691]", since this reference does not apply to this section:

E.1.1 LDAR Standards for BPM Process System Components [40 CFR 63.1255, 40 CFR 61 Subpart I, 326 IAC 8-5-3(b)(6), 326 IAC 2-2, CP157-4148 (Revised by this permit)]

Except as provided in Condition E.1.2, the following LDAR standards satisfy the requirements of the Pharmaceutical Production MACT (Pharma MACT) standards [40 CFR 63.1255], ~~Offsite Waste and Recovery Operations (OSWRO) MACT Standards [40 CFR 63.691],~~ Best Available Control Technology (BACT) requirements [326 IAC 2-2-3], Reasonably Available Control Technology (RACT) LDAR requirements for synthesized pharmaceutical manufacturing operations [326 IAC 8-5-3(b)(6)], and construction permit [CP157-4148] requirements for LDAR components associated with the research and development operations in Building T71:

15. The following condition has been revised to delete the E.1.2(a)(2), since 40 CFR 63.1256 pertains to wastewater containers, which are not covered in this section:

E.1.2 Exceptions to LDAR Standards for BPM Process System Components

- (a) The following facilities are not subject to the LDAR standards under this section of the permit:
 - (2) **Condition E.1.2(a)(2) was deleted pursuant to Administrative Permit Amendment 157-20003-00006.** ~~Components on transportation equipment and containers such as railroad cars, tanker trucks and drums (40 CFR 63.1256);~~

16. The following condition has been revised to delete operations that are beyond the scope of the flexible permit as originally designed:

F.1.2 Site modifications and advance approval of modifications [326 IAC 2-7-5(9) [326 IAC 2-7-5(16)]]

- (a) Permitted modifications
 - (1) BPM Process Operations:

~~(1) Installation of new production buildings.~~

(2) BPM Support Operations:

~~(1) Installation of new solvent recovery operations, storage tanks, storage tank modules, and distillation operations.~~

17. The following condition has been deleted since it is beyond the scope of the flexible permit as originally designed:

F.1.15 Emission increases from increased utilization of ancillary equipment [326 IAC 2-2]
(Deleted)

Condition F.1.15 was deleted pursuant to Administrative Permit Amendment 157-20003-00006.~~In the event the Permittee intends to reconstruct or replace an existing pharmaceutical production building, or in the event the Permittee intends to construct a new pharmaceutical production building, the Permittee shall determine whether the planned activity will result in increased demand of support operations outside the scope of the flexible permit, such as boilers. If the planned activity will increase demand of such support operations, the Permittee shall determine the emission increases resulting from the increased demand and submit a revised PSD air quality analysis that evaluates the ambient impact of the emissions operating under the flexible permit and the ancillary support operations. Construction of the planned activity may begin only after submittal and approval of the revised PSD air quality analysis by IDEM.~~

All other conditions of the permit shall remain unchanged and in effect. Please attach a copy of this amendment and the following revised permit pages to the front of the original permit.

This decision is subject to the Indiana Administrative Orders and Procedures Act - IC 4-21.5-3-5. If you have any questions on this matter, please contact Nathan Bell, at (800) 451-6027, press 0 and ask for Nathan Bell or extension (4-3350), or dial (317) 234-3350.

Sincerely,

Original signed by

Paul Dubenetzky, Chief
Permits Branch
Office of Air Quality

Attachments
NCB

cc: File - Tippecanoe County
U.S. EPA, Region V
Tippecanoe County Health Department
Air Compliance Section Inspectors - Ray Schick and Wanda Stanfield
Compliance Data Section
Permit Tracking
Administrative and Development



Mitchell E. Daniels, Jr.
 Governor

Thomas W. Easterly
 Commissioner

100 North Senate Avenue
 Indianapolis, Indiana 46204
 (317) 232-8603
 (800) 451-6027
 www.IN.gov/idem

**PART 70 OPERATING PERMIT AND
 PREVENTION OF SIGNIFICANT DETERIORATION (PSD)
 FLEXIBLE PERMIT**

OFFICE OF AIR QUALITY

**Eli Lilly and Company
 Tippecanoe Laboratories Facility
 1650 Lilly Road
 Lafayette, Indiana 47909**

(herein known as the Permittee) is hereby authorized to operate subject to the conditions contained herein, the source described in Section A (Source Summary) of this permit.

The Permittee must comply with all conditions of this permit. Noncompliance with any provisions of this permit is grounds for enforcement action; permit termination, revocation and reissuance, or modification; or denial of a permit renewal application. Noncompliance with any provision of this permit, except any provision specifically designated as not federally enforceable, constitutes a violation of the Clean Air Act. It shall not be a defense for the Permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit. An emergency does constitute an affirmative defense in an enforcement action provided the Permittee complies with the applicable requirements set forth in Section B, Emergency Provisions.

This permit is issued in accordance with 326 IAC 2 and 40 CFR Part 70 Appendix A and contains the conditions and provisions specified in 326 IAC 2-7 as required by 42 U.S.C. 7401, et. seq. (Clean Air Act as amended by the 1990 Clean Air Act Amendments), 40 CFR Part 70.6, IC 13-15 and IC 13-17. This permit also addresses certain new source review requirements for existing equipment and is intended to fulfill the new source review procedures pursuant to 326 IAC 2-2 and 326 IAC 2-7-10.5, applicable to those conditions.

Operation Permit No.: T157-6879-00006	
Issued by: Original signed by Janet G. McCabe, Assistant Commissioner Office of Air Quality	Issuance Date: February 27, 2004 Expiration Date: February 27, 2009
First Significant Permit Modification No: 157-20216-00006	Issuance Date: January 19, 2005
First Administrative Amendment No: 157-20003-00006	Pages Affected: 29, 30, 33, 34, 37, 38-40, 42-51, 54, 57-59, 63-68, 73, 75, 80-82, 87, 88, 90, 92, 93, 95, 97, 98, 101, 102, 109, 111, 112, 114, 115, 119, 124-129, 133, 135, 136, 138, 139, 142-144, 148, 150, 152, 153, 156, 158-161, 163-165, 167-173, 176, 179, 180, 184, 187, 194, 197, 208
Issued by: Origin signed by Paul Dubenetzky, Branch Chief Office of Air Quality	Issuance Date: April 1, 2005

- (A) design, installation, and testing of all elements of the monitoring system;
and
- (B) required corrective action or compliance plan activities.
- (2) All maintenance logs, calibration checks, and other required quality assurance activities.
- (3) All records of corrective and preventive action.
- (4) A log of plant operations, including the following:
 - (A) Date of facility downtime.
 - (B) Time of commencement and completion of each downtime.
 - (C) Reason for each downtime.
- (e) In accordance with 326 IAC 3-5-7(5), the Permittee shall submit reports of continuous monitoring system instrument downtime, except for zero (0) and span checks, which shall be reported separately. The reports shall include the following:
 - (1) Date of downtime.
 - (2) Time of commencement.
 - (3) Duration of each downtime.
 - (4) Reasons for each downtime.
 - (5) Nature of system repairs and adjustments.
- (f) Except where permit conditions streamline similar applicable requirements pursuant to 326 IAC 2-7-24, nothing in this permit nor in 326 IAC 3-5 supercedes the monitoring provisions in 40 CFR Part 60 or 40 CFR Part 63.
- (g) The permittee shall prepare and submit to IDEM, OAQ a written report of the results of the calibration gas audits and relative accuracy test audits for each calendar quarter within thirty (30) calendar days after the end of each quarter. The report must contain the information required by 326 IAC 3-5-5(e)(2).
- (h) The permittee shall prepare and submit to IDEM, OAQ a written standard operating procedure (SOP) within ninety (90) days after monitor installation. The CEMS SOP should contain, at a minimum, the items described in 326 IAC 3-5-4(a). If revisions are made to the SOP, updates shall be submitted to IDEM, OAQ biennially.

Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6]

C.12 Emergency Reduction Plans [326 IAC 1-5-2] [326 IAC 1-5-3]

Pursuant to 326 IAC 1-5-2 (Emergency Reduction Plans; Submission):

- (a) The Permittee prepared and submitted written emergency reduction plans (ERPs) consistent with safe operating procedures on December 13, 2000.
- (b) Upon direct notification by IDEM, OAQ, that a specific air pollution episode level is in effect, the Permittee shall immediately put into effect the actions stipulated in the approved ERP for the appropriate episode level. [326 IAC 1-5-3]

C.13 Risk Management Plan [326 IAC 2-7-5(12)] [40 CFR 68]

If a regulated substance, as defined in 40 CFR 68, is present at a source in more than a threshold quantity, the source must comply with the applicable requirements of 40 CFR 68.

C.14 Compliance Response Plan - Preparation, Implementation, Records, and Reports [326 IAC 2-7-5] [326 IAC 2-7-6]

(a) Whenever a Testing and Monitoring condition establishes the requirement to implement a Compliance Response Plan (CRP), the Permittee shall prepare a CRP in conformance with this condition. If a Permittee is required to have an Operation, Maintenance and Monitoring (OMM) Plan (or Parametric Monitoring Plan and Start-up, Shutdown, and Malfunction (SSM) Plan) under 40 CFR 60/63, such plans shall be deemed to satisfy the requirements for a CRP for those monitoring conditions. A CRP shall be submitted to IDEM upon request. The CRP shall be prepared within ninety (90) days after issuance of this permit by the Permittee, supplemented from time to time by the Permittee, maintained on site, and comprised of:

- (1) Reasonable response steps that may be implemented in the event that a response step is needed pursuant to the requirements of Section D of this permit; and an expected timeframe for taking reasonable response steps.
- (2) If, at any time, the Permittee takes reasonable response steps that are not set forth in the Permittee's current Compliance Response Plan or Operation, Maintenance and Monitoring (OMM) Plan (or Parametric Monitoring Plan and Start-up, Shutdown, and Malfunction (SSM) Plan) and the Permittee documents such response in accordance with subsection (e) below, the Permittee shall amend its Compliance Response Plan or Operation, Maintenance and Monitoring (OMM) Plan (or Parametric Monitoring Plan and Start-up, Shutdown, and Malfunction (SSM) Plan) to include such response steps taken.

The OMM Plan (or Parametric Monitoring and SMM Plan) shall be submitted within the time frames specified by the applicable 40 CFR60/63 requirement.

(b) Reasonable response steps shall be taken when indicated by the provisions of a monitoring condition as follows:

- (1) Reasonable response steps shall be taken as set forth in the Permittee's current Compliance Response Plan or Operation, Maintenance and Monitoring (OMM) Plan (or Parametric Monitoring Plan and Start-up, Shutdown, and Malfunction (SSM) Plan); or
- (2) If none of the reasonable response steps listed in the Compliance Response Plan or Operation, Maintenance and Monitoring (OMM) Plan (or Parametric Monitoring Plan and Start-up, Shutdown, and Malfunction (SSM) Plan) is applicable or responsive to the excursion, the Permittee shall devise and implement additional response steps as expeditiously as practical. Taking such additional response steps shall not be considered a deviation from this permit so long as the Permittee documents such response steps in accordance with this condition.
- (3) If the Permittee determines that additional response steps would necessitate that the emissions unit or control device be shut down, and it will be ten (10) days or more until the unit or device will be shut down, then the Permittee shall promptly notify the IDEM, OAQ of the expected date of the shut down. The notification shall also include the status of the applicable compliance monitoring parameter with respect to normal, and the results of the response actions taken up to the time of notification.

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Indianapolis, Indiana 46206-6015

- (c) Unless otherwise specified in this permit, any notice, report, or other submission required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, on or before the date it is due.
- (d) Unless otherwise specified in this permit, all reports required in Section D of this permit shall be submitted within thirty (30) days of the end of the reporting period. All reports do require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).
- (e) The first report shall cover the period commencing on the date of issuance of this permit and ending on the last day of the reporting period. Reporting periods are based on calendar years.

Stratospheric Ozone Protection

C.19 Compliance with 40 CFR 82 and 326 IAC 22-1

The Permittee shall comply with all the applicable provisions of 40 CFR Part 82, wherever applicable to activities at the source.

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period. The averaging periods shall not be permitted for more than three (3) six (6)-minute averaging periods in a twelve (12) hour period.

D.1.5 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for the coal-fired boilers and associated multiclone control devices.

Testing and Monitoring Requirements [326 IAC 2-7-6(1), (6)] [326 IAC 2-7-5(1)]

D.1.6 Testing Requirements [326 IAC 2-7-6(1), (6)]

- (a) The Permittee shall perform particulate matter performance tests for Boilers 1, 2 and 3 utilizing Methods 5 or 17 (40 CFR 60, Appendix A) for PM or other methods as approved by the Commissioner. These tests shall be repeated every third calendar year from the calendar year of the most recently completed compliance stack test. The requirements for conducting performance tests are described in Section C – Performance Testing.
- (b) No emissions testing is required for the boilers for compliance with particulate matter for boilers 4, and 5, or sulfur dioxide or nitrogen oxides emission limits established in Conditions D.1.1, D.1.2 and D.1.3, respectively, at this time. However, IDEM may require performance testing when necessary to determine compliance. The requirements for conducting performance tests are described in Section C – Performance Testing.

D.1.7 Coal Sampling and Analysis for SO₂ [326 IAC 3-7 and 326 IAC 7-2]

The Permittee shall collect fuel sampling and analysis data on a calendar month average in accordance with one of the following methods specified in 326 IAC 3 for each of the coal-fired boilers (Boilers 1, 2 and 3):

- (a) Coal sampling and analysis shall be performed using one of the following procedures:
 - (1) Sampling and analyzing the coal according to the Permittee's Coal Sampling and Assay Plan, submitted pursuant to 326 IAC 3-7-5(a). The following minimum sampling and analysis requirements shall be met:
 - (A) The coal sample acquisition point shall be at a location where representative samples of the total coal flow to be combusted by the facility or facilities may be obtained. A single as-bunkered or as-burned sampling station may be used to represent the coal to be combusted by multiple facilities using the same stockpile feed system;
 - (B) Coal shall be sampled at least two (2) times per day and at least one (1) time per twelve (12) hour period unless no coal is bunkered during the preceding twelve (12) hour period. This permit condition satisfies the requirements of 326 IAC 3-7-2(b)(3)(B);
 - (C) Minimum sample size shall be five hundred (500) grams;
 - (D) Samples shall be composited and analyzed at the end of each calendar month;

- (E) Preparation of the coal sample, heat content analysis, and sulfur content analysis shall be determined pursuant to 326 IAC 3-7-2(c), (d), (e); or
- (2) Sample and analyze the coal pursuant to 326 IAC 3-7-2(b).
- (b) Upon written notification to IDEM by a facility owner or operator, continuous emission monitoring data collected and reported pursuant to 326 IAC 3-5-1 may be used as the means for determining compliance with the emission limitations in 326 IAC 7-1.1-2. Upon such notification, the other requirements of 326 IAC 7-2 shall not apply. [326 IAC 7-2-1(g)]

D.1.8 Fuel Oil Sampling and Analysis for SO₂ [326 IAC 7-2]

The Permittee shall utilize one of the following methods for Boilers 4 and 5 when burning fuel oil:

- (a) Provide vendor analysis of quantity, heat content and sulfur content of fuel delivered, if accompanied by a certification;
- (b) Analyze the oil sample to determine the sulfur content of the oil via the procedures in 326 IAC 3-7-4.
 - (1) Oil samples may be collected from the fuel tank immediately after the fuel tank is filled and before any oil is combusted; and
 - (2) If a partially empty fuel tank is refilled, a new sample and analysis would be required upon filling; or
- (c) Conduct a stack test for sulfur dioxide emissions from the boiler, using 40 CFR 60, Appendix A, Method 6 in accordance with the procedures in 326 IAC 3-6, which is conducted with such frequency as to generate the amount of information required by (a) or (b) above. [326 IAC 7-2-1(d)]

D.1.9 Natural Gas and Fuel Oil Consumption Monitor [326 IAC 2-2]

The Permittee shall monitor the natural gas and fuel oil usage for Boiler No. 5 on a monthly basis.

D.1.10 Control Equipment Operation (Deleted)

Condition D.1.10 was deleted pursuant to Administrative Permit Amendment 157-20003-00006.

D.1.11 Visible Emission Notations

- (a) Visible emission notations of the stack exhausts of Boilers 1, 2 and 3 shall be performed two times per day during normal daylight operations when exhausting to the atmosphere. A minimum 6-hour period shall separate the two daily readings for each boiler. A trained employee shall record whether emissions are normal or abnormal.

- (b) For processes operated continuously, “normal” means those conditions prevailing, or expected to prevail, eighty percent (80%) of the time the process is in operation, not counting startup or shutdown time.
- (c) In the case of batch or discontinuous operations, readings shall be taken during that part of the operation that would normally be expected to cause the greatest emissions.
- (d) A trained employee is an employee who has worked at the plant at least one (1) month and has been trained in the appearance and characteristics of normal visible emissions for that specific process.
- (e) The Compliance Response Plan for the boilers shall contain troubleshooting contingency and response steps for when an abnormal emission is observed.

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.1.12 Coal Characteristics and Consumption Records

The Permittee shall record the information described in items (a) through (d) below on a calendar month basis for Boilers 1, 2, and 3.

- (a) The amount (expressed in tons) of coal burned;
- (b) The average sulfur content (expressed in percentage) of coal burned;
- (c) The average heat content (expressed in Btu per pound) of the coal burned; and
- (d) The average sulfur dioxide emission rate (expressed in pounds per MMBtu).

D.1.13 Fuel Oil Characteristics and Consumption Records

The Permittee shall record the information described in item (a) through (d) below on a calendar month basis for Boiler 4, and Boiler 5:

- (a) The amount (expressed in thousands of gallons (Mgal)) of No. 2 fuel oil burned in Boilers 4 and 5;
- (b) The average sulfur content (expressed in percentage by weight) of the No. 2 fuel oil burned in Boilers 4 and 5;
- (c) The average higher heating value (expressed in Btu per gallon) of the No. 2 fuel oil burned in Boilers 4 and 5; and
- (d) The average sulfur dioxide emission rate (expressed in pounds per MMBtu) of the No. 2 fuel oil for Boilers 4 and 5.

D.1.14 Natural Gas Consumption Records

The Permittee shall maintain natural gas consumption records for Boiler 5 on a calendar month basis in accordance with Condition D.1.9.

D.1.15 Standard Operating Procedures

Pursuant to 326 IAC 3-7-5(a), the Permittee shall maintain and implement a standard operating procedure (SOP) for coal sampling, handling, analysis, quality control, quality assurance, and

data reporting of the information collected pursuant to 326 IAC 3-7-2. In addition, any revision to the SOP shall be submitted to IDEM, OAM.

D.1.16 Visible Emissions Notations

The Permittee shall record the visible emissions notations of the coal-fired boilers stack exhaust when combusting coal.

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.1.17 Record Keeping Requirement (Deleted)

Condition D.1.17 was deleted pursuant to Administrative Permit Amendment 157-20003-00006.

D.1.18 Reporting Requirements

- (a) The Permittee shall submit quarterly summary reports of the monthly fuel oil characteristic and consumption records required by Condition D.1.13 for Boilers 4 and 5.
- (b) The Permittee shall submit quarterly summary reports of the monthly natural gas and fuel oil consumption records required by Condition D.1.14 for Boiler 5.
- (c) All reports shall be submitted to the address listed in Section C – General Reporting Requirements, of this permit, using the reporting form located at the end of this permit, or its equivalent, within thirty (30) days after the end of the quarter being reported. The report does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).

Modifications and Construction Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12 and 326 IAC 2-2]

D.1.19 Modifications and Construction: Advance Approval of Permit Conditions Requirements

The emission units described in this D section are not subject to the advance approval permit conditions.

Testing and Monitoring Requirements

D.2.3 Testing Requirements [326 IAC 2-7-6(1), (6)] [326 IAC 2-7-6(1)] [326 IAC 2-7-5(1)]

No emissions testing is required for the emission units described in this Section, at this time, but IDEM may require compliance testing at any specific time when necessary to determine if the facility is in compliance. The requirements for conducting performance tests that may be required by IDEM in the future are described in Section C – Performance Testing.

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.2.4 Generator Hours of Operation

The Permittee shall record the actual hours of operation for Generator T121. The records shall report the actual hours of operation per 12-month period, rolled on a monthly basis using the reporting form located at the end of this permit, or equivalent.

D.2.5 Reporting Requirements

A quarterly report of the information specified in Condition D.2.5 shall be submitted to the address listed in Section C - General Reporting Requirements, within thirty (30) days after the end of the quarter being reported. This report submitted by the Permittee requires the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).

Modifications and Construction Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12 and 326 IAC 2-2]

D.2.6 Modifications and Construction: Advance Approval of Permit Conditions Requirements

The emission units described in this D section are not subject to the advance approval permit conditions.

SECTION D.3 FERMENTATION OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]

The information describing the processes contained in the following facility description boxes is descriptive information and does not constitute enforceable conditions:

- (a) The following emissions units are subject to applicable requirements described in this D section:

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
<i>Building T1 – Raw Material Prep Area:</i>					
MIX001*	Dry Raw Material Mixer	PV-T1-T52348	N/A	N/A	Dust Collector T52348**
MIX002*	Dry Raw Material Mixer	PV-T1-T52348	N/A	N/A	
MCNV001	Conveyor of Raw Material Mixers	PV-T1-T52348	N/A	N/A	
<i>Building T2 – Fermentation Production Area:</i>					
TK001*	Bump Tank	S-T2-FERM	5000	liters	None
TK002*	Bump Tank	S-T2-FERM	5000	liters	None
TK003*	Bump Tank	S-T2-FERM	5000	liters	None
TK004*	Bump Tank	S-T2-FERM	5000	liters	None
TK011*	Bump Tank	S-T2-FERM	5000	liters	None
TK012*	Bump Tank	S-T2-FERM	5000	liters	None
TK013*	Bump Tank	S-T2-FERM	5000	liters	None
TK014*	Bump Tank	S-T2-FERM	5000	liters	None
TK005*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T67457**
TK006*	Fermentor Tank	S-T2-FERM	60000	liters	
TK007*	Fermentor Tank	S-T2-FERM	60000	liters	
TK008*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T67458**
TK009*	Fermentor Tank	S-T2-FERM	60000	liters	
TK010*	Fermentor Tank	S-T2-FERM	60000	liters	
TK015*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T67462**
TK016*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T67463**
TK017*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T67464**
TK018*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T65689**
TK019*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T52221**
TK020*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T52228**

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
<i>Building T2A – Fermentation Production Area:</i>					
TK021*	Bump Tank	S-T2-FERM	10000	liters	None
TK022*	Bump Tank	S-T2-FERM	10000	liters	None
TK023*	Bump Tank	S-T2-FERM	10000	liters	None
TK024*	Bump Tank	S-T2-FERM	10000	liters	None
TK025*	Fermentor Tank	S-T2-FERM	120000	liters	Cyclone T67459**
TK026*	Fermentor Tank	S-T2-FERM	120000	liters	
TK027*	Fermentor Tank	S-T2-FERM	120000	liters	
TK028*	Fermentor Tank	S-T2-FERM	120000	liters	Cyclone T67696**
TK029*	Fermentor Tank	S-T2-FERM	120000	liters	Cyclone T67697**
TK030*	Fermentor Tank	S-T2-FERM	120000	liters	Cyclone T67698**
<i>Building T2C – Fermentation Production Area:</i>					
TK043*	Bump Tank	S-T2-FERM	37625	liters	Cyclone T65363**
TK044*	Bump Tank	S-T2-FERM	37625	liters	Cyclone T65364**
TK048*	Fermentor Tank	S-T2-FERM	254000	liters	Cyclone T65367**
TK049*	Fermentor Tank	S-T2-FERM	254000	liters	Cyclone T65359**
TK050*	Fermentor Tank	S-T2-FERM	254000	liters	Cyclone T65360**

* Emissions units marked with a single asterisk are insignificant activities as defined in 326 IAC 2-7-1(21)(A)-(C).
 ** All control devices are voluntary units and are not required to demonstrate compliance with any applicable regulations.

(b) The following emissions units are insignificant activities pursuant to 326 IAC 2-7-1(21)(A)-(C) and are not subject to applicable requirements described in this D section:

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
<i>Building T46 – Material Storage Area:</i>					
BIN001	Dry Raw Material Storage Bin	PV-T46-T67454	23000	liters	Baghouse T67454**
BIN002	Dry Raw Material Storage Bin	PV-T46-T67454	23000	liters	
BIN003	Dry Raw Material Storage Bin	PV-T46-T67454	23000	liters	
BIN004	Dry Raw Material Storage Bin	PV-T46-T67454	23000	liters	
BIN005	Dry Raw Material Storage Bin	PV-T46-T67455	23000	liters	Baghouse T67455**
BIN006	Dry Raw Material Storage Bin	PV-T46-T67455	23000	liters	
BIN007	Dry Raw Material Storage Bin	PV-T46-T67455	23000	liters	

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
BIN008	Dry Raw Material Storage Bin	PV-T46-T67455	23000	liters	
BIN009	Dry Raw Material Storage Bin	PV-T46-T67659	23000	liters	Baghouse T67659**
BIN010	Dry Raw Material Storage Bin	PV-T46-T67659	23000	liters	
BIN011	Dry Raw Material Storage Bin	PV-T46-T67456	23000	liters	Baghouse T67456**
BIN012	Dry Raw Material Storage Bin	PV-T46-T67456	23000	liters	
<i>Building T1 – Raw Material Prep Area:</i>					
BLO001	Railcar Pneumatic Conveyor	N/A	N/A	liters	None
DISP001	Automated Dispensing Station	PV-T1-T44984	N/A	liters	Dust Collector T44984**
DISSC001	Dispensing Scale	PV-T1-T44984	N/A	liters	
TK121	Make Up Tank	PV-T1-314512	10150	liters	Rotoclone 314512**
TK122	Make Up Tank	PV-T1-314512	10150	liters	
TK123	Make Up Tank	PV-T1-314512	2100	liters	
TK123A	Make Up Area Tank	N/A	380	liters	None
TK124	Make Up Tank	PV-T1-314512	2100	liters	Rotoclone 314512**
TSLU	Slurry Tank	N/A	3600	liters	None
TK125	Make Up Tank	PV-T1-T67489	24600	liters	Rotoclone T67489**
TK126	Make Up Tank	PV-T1-T67492	24600	liters	Rotoclone T67492**
SC001	Liquid Weigh Scale Tank	N/A	N/A	liters	None
<i>Building T1 – Liquid Storage Area:</i>					
TK231	Liquid Storage Tank	N/A	20000	liters	None
TK232	Whole Broth Storage Tank	N/A	200000	liters	None
TK233	Whole Broth Storage Tank	N/A	200000	liters	None
TK234	Whole Broth Storage Tank	N/A	200000	liters	None
TK235	Whole Broth Storage Tank	N/A	200000	liters	None
TK236	Waste Holding Tank	N/A	200000	liters	None
TK237	Liquid Storage Tank	N/A	200000	liters	None
TK241	Liquid Storage Tank	N/A	100000	liters	None
TK242	Liquid Storage Tank	N/A	100000	liters	None
TK243	Liquid Storage Tank	N/A	100000	liters	None
TK244	Liquid Storage Tank	N/A	100000	liters	None
TK245	Liquid Storage Tank	N/A	100000	liters	None
TK246	Liquid Storage Tank	N/A	100000	liters	None
TK247	Liquid Storage Tank	N/A	100000	liters	None
TK248	Liquid Storage Tank	N/A	30400	liters	None

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
TK249	Liquid Storage Tank	N/A	45300	liters	None
<i>Building T1 – Filter Room:</i>					
TK813	Lime Tank	PV-T1-316488	8600	liters	Rotoclone 316488**
TK814	Filter Room Tank (Tank 8.5)	PV-T1-316488	9600	liters	
TK143	Slurry Tank	N/A	3800	liters	None
TK144	Slurry Tank	N/A	3800	liters	None
<i>Building T63 – Product Storage Area:</i>					
TK255	Whole Broth Tank	N/A	94700	liters	None

** All control devices are voluntary units and are not required to demonstrate compliance with any applicable regulations.

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.3.1 Non-Applicability Determination of Pharmaceutical MACT Standards [40 CFR 63, Subpart GGG]

The emission units associated with the fermentation operations are not subject to the requirements of 40 CFR 63, Subpart GGG (Pharmaceutical MACT Standards) because these emission units do not process, use, or produce hazardous air pollutant (HAP) emissions in excess of 50 ppmv pursuant to 40 CFR 63.1251 (Process Vent Definition).

D.3.2 Non-Applicability Determination of State VOC Emission Standards [326 IAC 8-5-3, 326 IAC 8-1-6]

- (a) The emission units associated with the fermentation operations do not manufacture pharmaceutical products by chemical synthesis. Therefore, the emission units associated with the fermentation operations are not subject to the requirements of 326 IAC 8-5-3 (VOC Emission Limitations for Synthesized Pharmaceutical Manufacturing Operations).
- (b) The emission units associated with the fermentation operations are not subject to the requirements of 326 IAC 8-1-6 (Best Available Control Technologies for VOC Emissions) because the VOC emissions associated with each emission unit or emission project are less than 25 tons per year.

D.3.3 Particulate Matter (PM) Emission Limitations [40 CFR 52 Subpart P]

Pursuant to 40 CFR 52 Subpart P and Registration 157-3220 Issued September 3, 1993, Registration 157-4466 Issued May 8, 1995, and Registration 157-7144 Issued December 4, 1996, the emission units presented in the table below shall not exceed the following particulate matter emission rates based on the following maximum throughput rates:

Emission Unit Description	Emission Unit ID	Maximum Process Weight Rate (ton/hr)	Allowable PM Emission Rate (lb/hr)
<i>Building T1 – Raw Material Prep Area:</i>			
Dry Raw Material Mixers + Conveyor for Mixers	MIX001, MIX002, MCNV001	0.881	3.77, combined
<i>Building T2 – Fermentation Production Area:</i>			
Bump Tanks	TK001 – TK004	18.3	28.7, combined
Fermentor Tanks	TK005 – TK010		
Bump Tanks	TK011 – TK014		
Fermentor Tanks	TK015 – TK020		
<i>Building T2A – Fermentation Production Area:</i>			
Bump Tanks	TK021 – TK024	18.3	28.7, combined
Fermentor Tanks	TK025 – TK027, TK029 – TK030		
Fermentor Tank	TK028		
<i>Building 2C – Fermentation Production Area:</i>			
Bump Tanks	TK043 – TK044	31.6	5.5, combined
Fermentor Tanks	TK048 – TK050		

D.3.4 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is not required for any of the emission units or control devices described in this Section.

Testing and Monitoring Requirements [326 IAC 2-7-6(1) (6)] [326 IAC 2-7-5(1)]

D.3.5 Testing Requirements [326 IAC 2-7-6(1), (6)]

No emissions testing is required for the emission units described in this Section at this time, but IDEM may require compliance testing at any specific time when necessary to determine if the facility is in compliance. The requirements for conducting performance tests that may be required by IDEM in the future are described in Section C – Performance Testing.

Modifications and Construction Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12 and 326 IAC 2-2]

D.3.6 Modifications and Construction: Advance Approval of Permit Conditions Requirements

The emission units described in this D section are not subject to the advance approval permit conditions.

SECTION D.4 FERMENTED PRODUCTS - PURIFICATION OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]

The information describing the processes contained in the following facility description boxes is descriptive information and does not constitute enforceable conditions:

(a) The following emissions units are subject to applicable requirements described in this D section:

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
<i>Building T3 – Purification Production Area:</i>					
T3-RVD040	Rotary Vacuum Dryer	Vent	500	gallons	Dust Collector**
<i>Building T147 – Storage Tank Module:</i>					
T147-TK001	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-TK002	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-TK003	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-TK004	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-TK005	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-TK006	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-TK007	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-TK008	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-TK009	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-TK010	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-TK011	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-TK012	Storage Tank	Vent	19000	gallons	Vent Condenser**

** All control devices are voluntary units and are not required to demonstrate compliance with any applicable regulations.

(b) The following emission units are not subject to applicable requirements described in this D section:

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
<i>Building T3 – Purification Production Area:</i>					
T3-TK47718*	Azo Receiver Tank	Vent	1000	gallons	None
T3-TK56*	Vent Condensate Tank	Vent	30	gallons	None
T3-CENT001*	Stacked Plate Centrifuge	Vent	20	gallons	None
T3-CENT002*	Stacked Plate Centrifuge	Vent	20	gallons	None
T3-CENT003*	Stacked Plate Centrifuge	Vent	20	gallons	None
T3-CENT004*	Stacked Plate Centrifuge	Vent	20	gallons	None

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
T3-COL001*	East Carbon Column	Vent	200	gallons	None
T3-TK261*	Process Tank	Vent	500	gallons	None
T3-TK327-1T*	Process Tank	Vent	500	gallons	None
T3-TK330*	Process Tank	Vent	4000	gallons	None
T3-TK332-3T*	Process Tank	Vent	3000	gallons	None
T3-TK337-1T*	Process Tank - Acid tank	Vent	500	gallons	None
T3-TK338-1T*	Process Tank	Vent	500	gallons	None
T3-TK338-2T*	Process Tank	Vent	500	gallons	None
T3-TK341-1T*	Process Tank	Vent	500	gallons	None
T3-TK346-1T*	Amyl Acetate Tank	Vent	500	gallons	None
T3-TK353-1T*	Receive Amyl Acetate from EVAP305	Vent	1000	gallons	None
T3-TK355-1T*	Process Tank	Vent	1000	gallons	None
T3-TK357-1T*	Process Tank	Vent	1000	gallons	None
T3-TK376-1T*	Process Tank	Vent	2000	gallons	None
T3-TK376-2T*	Process Tank	Vent	2000	gallons	None
T3-TK376-3T*	Process Tank	Vent	2000	gallons	None
T3-TK378-1T*	Process Tank	Vent	500	gallons	None
T3-TK394*	Chemical Waste Tank	Vent	2000	gallons	None
T3-TK397-1T*	Spent Aqueous Tank	Vent	2000	gallons	None
T3-TK399*	Acid Wash Tank	Vent	500	gallons	None
T3-EVAP300*	Swenson Evaporator	Vent	400	gallons	None
T3-EVAP305	Evaporator	Vent	800	gallons	None
T3-COL002*	West Carbon Column	Vent	200	gallons	None
<i>Building T40 – Purification Production Area:</i>					
T40-TK050*	Holding Tank	Vent	750	gallons	None
T40-TK051*	Tank	Vent	2000	gallons	None
T40-TK052*	Tank	Vent	2000	gallons	None
T40-TK053*	Holding Tank	Vent	2000	gallons	None
T40-TK055	Tank	Vent	500	gallons	None
T40-TK060*	Still	Vent	2000	gallons	None
<i>Building T4 – Solvent Recovery:</i>					
T4-COL001	Distilling Column	Vent	269	cf	None
T4-TK001*	Process Tank	Vent	1985	gallons	None
T4*	Tylosin System	Vent	N/A	N/A	None
T4-TK101*	Process Tank	Condenser	25000	gallons	Vent Condenser**

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
<i>Building T39 – Product Storage:</i>					
T39-TK021*	Storage Tank	Vent	2000	gallons	None
T39-TK022*	Storage Tank	Vent	2000	gallons	None
T39-TK023*	Storage Tank	Vent	2000	gallons	None
T39-TK030*	Storage Tank	Vent	5000	gallons	None
T39-TK031*	Storage Tank	Vent	5000	gallons	None
T39-TK036*	Storage Tank	Vent	5000	gallons	None
<i>Outside Storage Tanks:</i>					
TK420-1T*	Hydrochloric Acid Tank	Scrubber Vent	12000	gallons	Acid Scrubber**
TK434-1T*	Sulfuric Acid Tank		15000	gallons	None

* Emission units marked with an asterisk are insignificant activities as defined by 326 IAC 2-7-1(21)(A)-(C).

** Control devices marked with a double asterisk are voluntary control units and are not required to demonstrate compliance with any regulations.

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.4.1 Non-Applicability Determination of Pharmaceutical MACT Standards [40 CFR 63, Subpart GGG]

Except for the T3 rotary vacuum dryer, the emission units associated with the purification operations are not subject to the requirements of 40 CFR 63, Subpart GGG (Pharmaceutical MACT Standards) because these emission units do not process, use, or produce hazardous air pollutant (HAP) emissions in excess of 50 ppmv pursuant to 40 CFR 63.1251 (Process Vent Definition).

D.4.2 Non-Applicability Determination of State VOC Emission Standards [326 IAC 8-5-3, Registration Issued November 8, 1990, and Amendment Issued November 10, 1992]

- (a) Except for the T3 rotary vacuum dryer, the emission units associated with the purification operations do not manufacture pharmaceutical products by chemical synthesis. Therefore, except for the T3 rotary vacuum dryer, these emission units are not subject to the requirements of 326 IAC 8-5-3 (VOC Emission Limitations for Synthesized Pharmaceutical Manufacturing Operations).
- (b) The T3 rotary vacuum dryer does not dry pharmaceutical products by chemical synthesis with a potential to emit equal to or greater than 15 pounds per day. Therefore, this dryer is not subject to the requirements of 326 IAC 8-5-3.

D.4.3 T3 Rotary Vacuum Dryer Process Vent Standard [40 CFR 63.1254(A)(2)]

Pursuant to 40 CFR 63 Subpart GGG (Pharmaceutical MACT Standard), undiluted and uncontrolled process vent streams equal to or greater than 50 ppmv HAP from the T3 rotary vacuum dryer shall be limited to an annual mass limit of 900 kilograms (kg) per 365-day period to comply with the individual process-based mass limit standards under 40 CFR 63.1254(a)(2)(i). The sum of process vent emissions from all uncontrolled processes generated during the

manufacturing of pharmaceutical products shall not exceed an annual mass limit of 1800 kg HAP per 365-day period pursuant to 40 CFR 63.1254(a)(2)(ii).

D.4.4 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is not required for any of the facilities or control devices described in this Section.

Testing and Monitoring Requirements [326 IAC 2-7-6(1) (6)] [326 IAC 2-7-5(1)]

D.4.5 Testing Requirements [326 IAC 2-7-6(1), (6)]

No emissions testing is required for the emission units described in this Section at this time, but IDEM may require compliance testing at any specific time when necessary to determine if the facility is in compliance. The requirements for conducting performance tests that may be required by IDEM in the future are described in Section C – Performance Testing.

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.4.6 Record Keeping Requirements [40 CFR 63.1254(a)(2), 40 CFR 60.116b(b), Registration Issued November 8, 1990, and Amendment Issued November 10, 1992]

- (a) The Permittee shall maintain in the following records of the T3 rotary vacuum dryer:
- (1) Daily rolling annual total HAP emissions from process vent streams equal to or greater than 50 ppmv from the T3 rotary vacuum dryer;
 - (2) Number of batches per year for each batch process;
 - (3) Standard batch uncontrolled and controlled emissions for each process;
 - (4) Actual uncontrolled and controlled emissions for each nonstandard batch,; and
 - (5) Record whether each batch operated was considered a standard batch.
- (b) Pursuant to 40 CFR 60.116b(b) [New Source Performance Standard for Solvent Storage Tanks], the Permittee shall maintain records of the dimensions and capacity of each storage tank associated with the T147 tank module for the life of the source.

Modifications and Construction Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12 and 326 IAC 2-2]

D.4.7 Modifications and Construction: Advance Approval of Permit Conditions Requirements

The emission units described in this D section are not subject to the advance approval permit conditions.

- (b) TRS, reduced sulfur compounds and hydrogen sulfide emissions from the transfer of bio-solids from the storage tanks to trucks shall be controlled by a vapor balance system that exhausts to the iron sponge reactor.

D.5.4 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for the iron sponge reactor system.

Testing and Monitoring Requirements [326 IAC 2-7-6(1) (6)] [326 IAC 2-7-5(1)]

D.5.5 Sampling and Analysis Requirements [CP 157-4363 Issued August 28, 1996 (Revised by this permit), and Amendment 157-8953 Issued November 12, 1997 (Revised by this permit)]

The Permittee shall measure and record the TRS outlet concentration of the air stream to the atmosphere once per calendar week using the sampling protocol and analysis methods most recently approved by IDEM.

D.5.6 Monitoring Requirements [CP 157-4363 Issued August 28, 1996 (Revised by this permit), and Amendment 157-8953 Issued November 12, 1997 (Revised by this permit)]

The Permittee shall monitor and record the pressure drop across the iron sponge reactor annubar once per day. Unless operated under conditions for which the Compliance Response Plan (CRP) specifies otherwise, the pressure drop across the operating reactor shall be maintained within the range of 0.2 and 2 inches of water column. The CRP for the iron sponge reactor system shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above-mentioned range for any one reading.

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.5.7 Record Keeping Requirements [CP 157-4363 Issued August 28, 1996 (Revised by this permit), and Amendment 157-8953 Issued November 12, 1997 (Revised by this permit)]

- (a) The Permittee shall maintain the following records:
 - (1) daily pressure drop readings across the iron sponge reactor annubar; and
 - (2) weekly analysis of the TRS outlet concentration from the iron sponge reactor.
- (b) Pursuant to 40 CFR 60.116b(b), Subpart Kb (New Source Performance Standard for Volatile Organic Liquid Storage Vessels) and CP157-4363, issued August 28, 1996, the Permittee shall keep readily accessible records of the dimensions and capacity for each bio-solids storage tank. These records shall be kept for the life of the source.

Modifications and Construction Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12 and 326 IAC 2-2]

D.5.8 Modifications and Construction: Advance Approval of Permit Conditions Requirements

The emission units described in this D section are not subject to the advance approval permit conditions.

T27-TK47-1	Process Tank	RTO	1000 gal	RTO
T27-TK47-2	Process Tank	RTO	550 gal	RTO
T27-TK47-3	Process Tank	RTO	1000 gal	RTO
T27-TK47-5	Process Tank	RTO	300 gal	RTO
T27-TK48-1	Process Tank	RTO	300 gal	RTO
T27-TK48-1A	Process Tank	RTO	1000 gal	RTO
T27-TK48-2A	Process Tank	RTO	100 gal	RTO
T27-TK48-3A	Process Tank	RTO	500 gal	RTO
T27-TK49-1	Process Tank	RTO	200 gal	RTO
T27-TK50-1	Process Tank	RTO	650 gal	RTO
T27-TK50-2	Process Tank	RTO	150 gal	RTO
T27-TK50-3	Process Tank	RTO	150 gal	RTO
T27-TK50-4	Process Tank	RTO	500 gal	RTO
T27-TK372-A	Process Tank	RTO	500 gal	RTO
T27-CENT9	Centrifuge	RTO	NA	RTO
T27-CENT16	Centrifuge	RTO	NA	RTO
T27-CENT19	Centrifuge	RTO	NA	RTO
T27-CENT30	Centrifuge	RTO	NA	RTO
T27-CENT37	Centrifuge	RTO	NA	RTO
T27-CENT38	Centrifuge	RTO	NA	RTO
T27-CENT40	Centrifuge	RTO	NA	RTO
T27-DT46-1	Process Tank	RTO		RTO
T27-RVD53-1	Process Dryer	RTO	NA	RTO
T27-RVD53-2	Process Dryer	RTO	NA	RTO
T27-SCR30-4	Process Scrubber	RTO	NA	RTO
T27-SCR33-7	Process Scrubber	RTO	NA	RTO
T27-SCR34-9	Process Scrubber	RTO	NA	RTO
T27-SCR35-10A	Process Scrubber	RTO	NA	RTO
T27-SCR35-10B	Process Scrubber	RTO	NA	RTO
T27-VC31-1	Process Condenser	RTO	NA	RTO
T27-VC32-1	Process Condenser	RTO	NA	RTO
T27-VC32-2	Process Condenser	RTO	NA	RTO
T27-VC32-3	Process Condenser	RTO	NA	RTO
T27-VC33-1	Process Condenser	RTO	NA	RTO
T27-VC33-2	Process Condenser	RTO	NA	RTO
T27-VC33-3	Process Condenser	RTO	NA	RTO
T27-VC33-4	Process Condenser	RTO	NA	RTO
T27-VC35-1	Process Condenser	RTO	NA	RTO
T27-VC35-2	Process Condenser	RTO	NA	RTO
T27-VC35-4	Process Condenser	RTO	NA	RTO
T27-VC36-1	Process Condenser	RTO	NA	RTO
T27-VC36-2	Process Condenser	RTO	NA	RTO
T27-VC36-3	Process Condenser	RTO	NA	RTO
T27-VC40	Process Condenser	RTO	NA	RTO
T27-VC40-2	Process Condenser	RTO	NA	RTO
T27-VC40-5	Process Condenser	RTO	NA	RTO

T27-VC40-7A	Process Condenser	RTO	NA	RTO
T27-VC43-1	Process Condenser	RTO	NA	RTO
T27-VC44-4	Process Condenser	RTO	NA	RTO
T27-VC45-2	Process Condenser	RTO	NA	RTO
T27-VC46-1	Process Condenser	RTO	NA	RTO
T27-VC47-1	Process Condenser	RTO	NA	RTO
T27-VC48-1	Process Condenser	RTO	NA	RTO
T27-VC48-1A	Process Condenser	RTO	NA	RTO
T27-VC49-1	Process Condenser	RTO	NA	RTO
T27-VC50-1	Process Condenser	RTO	NA	RTO
T27-VC53-1	Process Condenser	RTO	NA	RTO
T27-VC53-2	Process Condenser	RTO	NA	RTO
T27-VC53-10	Process Condenser	RTO	NA	RTO
T27-PORTVC	Portable Process Condenser	RTO	NA	RTO
<i>Building T28:</i>				
T28-CENT1	Heinkel Centrifuge	RTO	NA	RTO
T28-CENT2	Heinkel Centrifuge	RTO	NA	RTO
T28-CENT3	Heinkel Centrifuge	RTO	NA	RTO
T28-CENT15	Centrifuge	RTO	NA	RTO
T28-CENT22	Centrifuge	RTO	NA	RTO
T28-CENT24	Centrifuge	RTO	NA	RTO
T28-CENT26	Centrifuge	RTO	NA	RTO
T28-TK28-1	Process Tank	RTO	2000 gal	RTO
T28-TK28-1A	Process Tank	RTO	300 gal	RTO
T28-TK28-2	Process Tank	RTO	1000 gal	RTO
T28-TK28-3	Process Tank	RTO	2000 gal	RTO
T28-TK28-3A	Process Tank	RTO	340 gal	RTO
T28-TK28-03	Process Tank	RTO	2000 gal	RTO
T28-TK28-4	Process Tank	RTO	1000 gal	RTO
T28-TK28-5	Process Tank	RTO	1000 gal	RTO
T28-TK28-6	Process Tank	RTO	1000 gal	RTO
T28-TK28-7	Process Tank	RTO	2000 gal	RTO
T28-TK28-8	Process Tank	RTO	2000 gal	RTO
T28-TK28-9	Process Tank	RTO	1000 gal	RTO
T28-TK28-10	Process Tank	RTO	2000 gal	RTO
T28-TK28-10A	Process Tank	RTO	340 gal	RTO
T28-TK28-11	Process Tank	RTO	2000 gal	RTO
T28-TK28-12	Process Tank	RTO	2000 gal	RTO
T28-TK28-13	Process Tank	RTO	2000 gal	RTO
T28-TK28-14	Process Tank	RTO	2000 gal	RTO
T28-TK28-15	Process Tank	RTO	2000 gal	RTO
T28-TK28-16	Process Tank	RTO	2000 gal	RTO
T28-TK28-17	Process Tank	RTO	1000 gal	RTO
T28-TK28-18	Process Tank	RTO	750 gal	RTO
T28-TK28-19	Process Tank	RTO	2000 gal	RTO
T28-TK28-20	Process Tank	RTO	2000 gal	RTO

T28-TK28-21	Process Tank	RTO	2000 gal	RTO
T28-TK28-22	Process Tank	RTO	2000 gal	RTO
T28-TK28-23	Process Tank	RTO	2000 gal	RTO
T28-TK28-24	Process Tank	RTO	2000 gal	RTO
T28-TK28-25	Process Tank	RTO	1500 gal	RTO
T28-TK28-26	Process Tank	RTO	1500 gal	RTO
T28-TK28-27	Process Tank	RTO	140 gal	RTO
T28-TK28-29	Process Tank	RTO	1000 gal	RTO
T28-TK28-30	Process Tank	RTO	500 gal	RTO
T28-TK28-31	Process Tank	RTO	2000 gal	RTO
T28-TK28-32	Process Tank	RTO	2000 gal	RTO
T28-PTK1	Portable Charge Tank	RTO	300 gal	RTO
T28-PTK2	Portable Charge Tank	RTO	300 gal	RTO
T28-PTK3	Portable Charge Tank	RTO	300 gal	RTO
T28-SCR1	Process Scrubber	RTO	NA	RTO
T28-SCR2	Process Scrubber	RTO	NA	RTO
T28-SCR3	Process Scrubber	RTO	NA	RTO
T28-SCR4	Process Scrubber	RTO	NA	RTO
T28-SCR6	Process Scrubber	RTO	NA	RTO
T28-SCRTK1	Scrubber Tank	RTO	300 gal	RTO
T28-SCRTK2	Scrubber Tank	RTO	500 gal	RTO
T28-SCRTK4	Scrubber Tank	RTO	500 gal	RTO
T28-VC28-1	Process Condenser	RTO	NA	RTO
T28-VC28-3	Process Condenser	RTO	NA	RTO
T28-VC28-4	Process Condenser	RTO	NA	RTO
T28-VC28-5	Process Condenser	RTO	NA	RTO
T28-VC28-6	Process Condenser	RTO	NA	RTO
T28-VC28-8	Process Condenser	RTO	NA	RTO
T28-VC28-10	Process Condenser	RTO	NA	RTO
T28-VC28-11	Process Condenser	RTO	NA	RTO
T28-VC28-12	Process Condenser	RTO	NA	RTO
<i>Building T29:</i>				
T29-CENT1401	Heinkel Centrifuge	RTO	70 gal	RTO
T29-CENT2401	Heinkel Centrifuge	RTO	70 gal	RTO
T29-CENT3401	Heinkel Centrifuge	RTO	70 gal	RTO
T29-DRY1501	Cone Dryer	RTO	580 gal	RTO
T29-DRY2402	Filter Dryer	RTO	863 gal	RTO
T29-DRY2502	Filter Dryer	RTO	863 gal	RTO
T29-DRY3501	Cone Dryer	RTO	580 gal	RTO
T29-IBC8201	Process Tank	RTO	100 gal	RTO
T29-IBC8202	Process Tank	RTO	150 gal	RTO
T29-IBC8203	Process Tank	RTO	150 gal	RTO
T29-IBC8204	Process Tank	RTO	150 gal	RTO
T29-IBC8205	Process Tank	RTO	150 gal	RTO
T29-IBC8206	Process Tank	RTO	150 gal	RTO
T29-IBC8207	Process Tank	RTO	150 gal	RTO

T99-PD43	Pan Dryer	RTO	528 gal	RTO
T99-PD44	Pan Dryer	RTO	528 gal	RTO
T99-RVD1	Rotary Vacuum Dryer	RTO	1200 gal	RTO
T99-RVD2	Rotary Vacuum Dryer	RTO	1200 gal	RTO
T99-RVD3	Rotary Vacuum Dryer	RTO	1200 gal	RTO
T99-RVD5	Rotary Vacuum Dryer	RTO	1200 gal	RTO
T99-RVD6	Rotary Vacuum Dryer	RTO	1200 gal	RTO
T99-RVD7	Rotary Vacuum Dryer	RTO	1200 gal	RTO
T99-RVD8	Rotary Vacuum Dryer	RTO	1200 gal	RTO
T99-TK-D41	Process Tank	RTO	300 gal	RTO
T99-TK-D42	Process Tank	RTO	150 gal	RTO
T99-HE43	Process Condenser	RTO	NA	RTO
T99-HE44	Process Condenser	RTO	NA	RTO
<i>Building T100:</i>				
T100-CENT60	Centrifuge	RTO	N/A	RTO
T100-CENT61	Centrifuge	RTO	N/A	RTO
T100-CENT62	Centrifuge	RTO	N/A	RTO
T100-CENT63	Centrifuge	RTO	N/A	RTO
T100-CENT64	Centrifuge	RTO	N/A	RTO
T100-CENT65	Centrifuge	RTO	N/A	RTO
T100-CENT66	Centrifuge	RTO	N/A	RTO
T100-CENT67	Centrifuge	RTO	N/A	RTO
T100-CENT68	Centrifuge	RTO	N/A	RTO
T100-CENT69	Centrifuge	RTO	N/A	RTO
T100-CENT70	Centrifuge	RTO	N/A	RTO
T100-TK1	Process Tank	RTO	2000 gal	RTO
T100-TK1C	Process Tank	RTO	N/A	RTO
T100-TK2	Process Tank	RTO	4000 gal	RTO
T100-TK3	Process Tank	RTO	2000 gal	RTO
T100-TK4	Process Tank	RTO	2000 gal	RTO
T100-TK5	Process Tank	RTO	2000 gal	RTO
T100-TK6	Process Tank	RTO	2000 gal	RTO
T100-TK7	Process Tank	RTO	4000 gal	RTO
T100-TK8	Process Tank	RTO	4000 gal	RTO
T100-TK8C	Process Tank	RTO	30 gal	RTO
T100-TK9	Process Tank	RTO	4000 gal	RTO
T100-TK10	Process Tank	RTO	4000 gal	RTO
T100-TK11	Process Tank	RTO	4000 gal	RTO
T100-TK12	Process Tank	RTO	4000 gal	RTO
T100-TK13	Process Tank	RTO	3300 Gal	RTO
T100-TK14	Process Tank	RTO	4000 gal	RTO
T100-TK15	Process Tank	RTO	2000 gal	RTO
T100-TK16	Process Tank	RTO	2000 gal	RTO
T100-TK17	Process Tank	RTO	2000 gal	RTO
T100-TK18	Process Tank	RTO	2000 gal	RTO
T100-TK20	Process Tank	RTO	4000 gal	RTO

T100-TK21	Process Tank	RTO	4000 gal	RTO
T100-TK22	Process Tank	RTO	2000 gal	RTO
T100-TK24	Process Tank	RTO	4000 gal	RTO
T100-TK25	Process Tank	RTO	4000 gal	RTO
T100-TK26	Process Tank	RTO	4000 gal	RTO
T100-TK27	Process Tank	RTO	4000 gal	RTO
T100-TK28	Process Tank	RTO	4000 gal	RTO
T100-TK29	Process Tank	RTO	4000 gal	RTO
T100-TK30	Process Tank	RTO	4000 gal	RTO
T100-TK-30A	Process Tank	RTO	70 gal	RTO
T100-TK31	Process Tank	RTO	4000 gal	RTO
T100-TK31B	Process Tank	RTO	50 gal	RTO
T100-TK32	Process Tank	RTO	4000 gal	RTO
T100-TK33	Process Tank	RTO	1000 gal	RTO
T100-TK34	Process Tank	RTO	1000 gal	RTO
T100-TK35	Process Tank	RTO	1000 gal	RTO
T100-TK36	Process Tank	RTO	1000 gal	RTO
T100-TK37	Process Tank	RTO	1000 gal	RTO
T100-TK38	Process Tank	RTO	1000 gal	RTO
T100	Portable Process Tank	RTO	N/A	RTO
T100	Portable Process Tank	RTO	N/A	RTO
T100-PTK1	Portable Cleaning Tank	RTO	150 gal	RTO
T100-HE1	Process Condenser	RTO	N/A	RTO
T100-HE1C	Process Condenser		N/A	
T100-HE2	Process Condenser	RTO	N/A	RTO
T100-HE4	Process Condenser	RTO	N/A	RTO
T100-HE6	Process Condenser	RTO	N/A	RTO
T100-HE7	Process Condenser	RTO	N/A	RTO
T100-HE8	Process Condenser	RTO	N/A	RTO
T100-HE11	Process Condenser	RTO	N/A	RTO
T100-HE12	Process Condenser	RTO	N/A	RTO
T100-HE13	Process Condenser	RTO	N/A	RTO
T100-HE14	Process Condenser	RTO	N/A	RTO
T100-HE14B	Process Condenser	RTO	N/A	RTO
T100-HE16	Process Condenser	RTO	N/A	RTO
T100-HE21A	Process Condenser	RTO	N/A	RTO
T100-HE21B	Process Condenser	RTO	N/A	RTO
T100-HE26	Process Condenser	RTO	N/A	RTO
T100-HE28	Process Condenser	RTO	N/A	RTO
T100-HE31	Process Condenser	RTO	N/A	RTO
T100-TK14A	Accumulator Tank	RTO	50 gal	RTO
T100-TK21A	Accumulator Tank	RTO	50 gal	RTO
T100-TK39	CIP Tank	RTO	500 gal	RTO
T100-SCR80	Process Scrubber	RTO	N/A	RTO
T100-SCR81	Process Scrubber	RTO	N/A	RTO
T100-SCR82	Process Scrubber	RTO	N/A	RTO
T100-SCR83	Process Scrubber	RTO	N/A	RTO
T100-SCR84	Process Scrubber	RTO	N/A	RTO

T100-SCR85	Process Scrubber	RTO	N/A	RTO
T100-TK82	Scrubber Holding Tank	RTO	1000 gal	RTO
T100-TK83	Scrubber Holding Tank	RTO	1000 gal	RTO
T100-TK84	Scrubber Holding Tank	RTO	1000 gal	RTO
T100-TK85	Scrubber Holding Tank	RTO	1000 gal	RTO

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.6.1 Standards for BPM Process Vents [40 CFR 63.1254, 326 IAC 2-2-3, and 326 IAC 8-5-3]

The following streamlined standards for the BPM process operations satisfy the Maximum Achievable Control Technology Standards for Pharmaceutical Production Operations (Pharmaceutical MACT) for process vents [40 CFR 63.1254], Prevention of Significant Deterioration Best Available Control Technology (PSD BACT) requirements [326 IAC 2-2-3] and Reasonably Available Control Technology (RACT) requirements for synthesized pharmaceutical manufacturing operations [326 IAC 8-5-3]:

- (a) With the exception of Conditions D.6.1(c) and D.6.2, the Permittee shall route the vapors from each operating BPM process vent containing undiluted and uncontrolled process vent streams equal to or greater than 50 ppmv HAP, 50 ppmv VOC, or 15 pounds per day VOC through a closed-vent system to the RTO control system. The operation, inspection and maintenance requirements for the RTO control system, and its closed-vent system, used to control emissions from these emission units are described in Section D.14 of this permit.
- (b) The Permittee shall cover all in-process tanks, having an exposed liquid surface containing VOC greater than 15 pounds per day unless production, sampling, maintenance, or inspection procedures require operator access.
- (c) The Permittee is not required to control emissions from BPM process vents in accordance with (a) of this section, if it would result in a safety hazard, as long as the sum of the uncontrolled BPM process vent streams within an individual BPM process does not exceed an annual mass limit of 900 kilograms (2000 pounds) of HAP per 365-day period and the sum of all uncontrolled process vent emissions generated during the manufacturing of pharmaceutical products do not exceed an annual mass limit of 1800 kilograms (4000 pounds) of HAP per 365-day period.
- (d) The Permittee shall enclose all centrifuges, rotary vacuum filters, and other filters having an exposed liquid surface, where the liquid contains VOC and exerts a total vapor pressure of 0.5 pounds per square inch or more at 20°C.

D.6.2 Control Strategy for Production Equipment Exhaust Systems [40 CFR 63.1254][326 IAC 8-5-3][326 IAC 2-2-3]

- (a) Pursuant to 40 CFR 63.1254, production equipment exhaust systems containing undiluted and uncontrolled exhaust streams with HAP concentrations greater than fifty (50) ppm, HAP shall be routed to the RTO control system. The operation, inspection, and maintenance requirements for the RTO control system, and its closed - vent system, used to control emissions from these emission units are described in Section D.14 of this permit.
- (b) Pursuant to 326 IAC 8-5-3(b)(2), VOC emissions from production equipment exhaust systems shall not exceed thirty-three (33) pounds per day. If uncontrolled VOC emissions from a production equipment exhaust system would exceed thirty three (33) pounds per day, then the Permittee shall route VOC emissions from that production equipment exhaust system to the RTO control system. The operation, inspection, and maintenance requirements for the RTO control system, and its closed vent system, used to control emissions from these emission units are described in Section D.14 of this permit.

- (c) Pursuant to 326 IAC 2-2-3, VOC BACT for production equipment exhaust systems not meeting the criteria of D.6.2(a) or D.6.2(b) is no controls. If the process affiliated with a production equipment exhaust system that is not routed to the RTO control system is modified in a manner that causes the criteria in Condition D.6.2(a) or D.6.2(b) to apply, the Permittee shall connect the production equipment exhaust system to the RTO control system before beginning any operations that would cause D.6.2(a) or D.6.2(b) to be applicable.

D.6.3 Leak Detection and Repair (LDAR) Standards [326 IAC 2-2-3, 326 IAC 8-5-3, and 40 CFR 63.1255]

The LDAR standards that apply to components associated with the BPM production operations are described in Sections E.1 and E.2 of this permit.

D.6.4 Heat Exchange System Requirements [326 IAC 2-2-3 and 40 CFR 63.1252(c)(2)]

- (a) The Permittee shall inspect the physical integrity of heat exchange systems that use water to cool process equipment or materials used in pharmaceutical manufacturing operations in accordance with the following current good manufacturing practice (CGMP) requirements of 21 CFR 211 to satisfy the streamlined standards of the Pharmaceutical MACT for heat exchange systems [40 CFR 63.1252(c)(2)] and the PSD BACT requirements [326 IAC 2-2-3]:
 - (1) Assignment of responsibility for maintaining equipment;
 - (2) Maintenance schedules; and
 - (3) Description in sufficient detail of the methods, equipment, and materials used in maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper maintenance.

D.6.5 Startup, Shutdown and Malfunction Requirements [326 IAC 2-2-3, 40 CFR 63.1259(a)(3), and 40 CFR 63.6(e) and 63.8(c)]

The NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e) and 63.8(c)] shall be used to satisfy the Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)], and PSD BACT requirements [326 IAC 2-1.1-11].

- (a) Pursuant to 40 CFR 63.6(e)(3), the Permittee shall develop an SSM Plan to ensure that processes are operated and maintained in a manner which satisfies the general duty to minimize emissions established by 40 CFR 63.6(e)(1)(i), and that all malfunctions are corrected as soon as practicable after their occurrence in order to minimize excess emissions. The SSM Plan shall contain the following information:
 - (1) Detailed plans and/or procedures for operating and maintaining the process during periods of SSM; and
 - (2) Corrective action program for malfunctioning processes.
- (b) The startup, shutdown and malfunction (SSM) requirements for the RTO control system, and associated closed-vent system, are described in Section D.14 of this permit.

Testing and Monitoring Requirements [326 IAC 2-7-6(1) (6)] [326 IAC 2-7-5(1)]

D.6.6 Requirements

The requirements for the RTO control system, and its associated closed-vent system, used to control emissions from the emission units listed in this section are described in Section D.14 of this permit.

D.6.7 Monitoring Requirements

The monitoring requirements for the RTO control system, and its associated closed-vent system, used to control emissions from the applicable emission units listed in this section are described in Section D.14 of this permit.

Record Keeping and Reporting [326 IAC 2-7-5(3) and 326 IAC 2-7-19]

D.6.8 Record Keeping and Reporting Requirements

(a) Record Keeping Requirements

- (1) RTO Control System Records - The record keeping and reporting requirements for the RTO control system, and associated closed-vent systems, used to control emissions from the emission units listed in this section are described in Section D.14 of this permit.
- (2) Process Records - The Permittee shall maintain the following records if the 98% Control Efficiency Emission Standard is used to demonstrate compliance with the requirements of the Pharmaceutical MACT (40 CFR Part 63, Subpart GGG):
 - (A) Daily rolling annual total HAP emissions;
 - (B) Number of batches per year for each batch process;
 - (C) Standard batch uncontrolled and controlled emissions for each process;
 - (D) Actual uncontrolled and controlled emissions for each nonstandard batch; and
 - (E) Record whether each batch operated was considered a standard batch.
- (3) Heat Exchange System Records - Maintenance records, including the date, time, and sign off or initials of the individual who completed the task, of all heat exchange systems that use water to cool process equipment or materials used in pharmaceutical manufacturing operations. The Permittee shall track the heat exchange systems that use water to cool process equipment or materials used in pharmaceutical manufacturing operations in an operating scenario maintained in the On-Site Implementation Log (OSIL).
- (4) LDAR Records - The record keeping and reporting requirements for the LDAR standards are described in Sections E.1 and E.2 of this permit.
- (5) SSM Records - The Permittee shall maintain the following records:
 - (A) Records of the current and superseded versions of SSM Plan.
 - (B) Occurrence/duration records of each process malfunction.
 - (C) Information to demonstrate conformance with each SSM is consistent with the procedures in the SSM Plan.
 - (D) Records of actions taken during each SSM when different from SSM Plan.

(b) Periodic Reporting Requirements

- (1) The following streamlined quarterly reporting requirements shall satisfy the Pharmaceutical MACT standards [40 CFR 63.1256(b)] and the PSD BACT requirements [326 IAC 2-1.1-11]:
 - (A) SSM summary reports for the processes.
 - (B) The reporting requirements for the RTO control system, and associated closed-vent system, that controls emissions from the emission units listed in this section are described in Section D.14 of this permit.
 - (C) The reporting requirements for the LDAR standards are described in Sections E.1 and E.2 of this permit.

(c) Immediate Reporting Requirements

The reporting requirements in the NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e)(3)] shall be used to satisfy the reporting requirements under the Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)], and PSD BACT requirements [326 IAC 2-1.1-11].

- (1) Any time an action taken by the Permittee during an SSM event of a process is not consistent with the procedures specified in the SSM Plan, the Permittee shall report the actions taken for that event. The immediate report shall be submitted to the agency via a telephone call or facsimile within 2 working days after commencing actions inconsistent with the plan.
- (2) Within 7 working days after the end of an SSM event of a process where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):
 - (A) Name, title and signature of responsible official certifying accuracy;
 - (B) Explanation of the circumstances for the event;
 - (C) Reason for not following the SSM Plan; and
 - (D) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred.

Testing and Monitoring Requirements [326 IAC 2-7-6(1) (6)] [326 IAC 2-7-5(1)]

D.7.6 Requirements

- (a) The requirements for the RTO control system and T79 control system, and associated closed-vent systems, used to control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.
- (b) The following streamlined requirements for the solvent recovery columns that treat off-site waste shall satisfy the Offsite Waste MACT standards [40 CFR 63.684(d) and (e)] and the PSD BACT requirements [326 IAC 2-1.1-11]:
 - (1) An initial and annual demonstration shall be performed within 30 days after first time an owner or operator begins using the treatment process to manage a new off-site material stream equal to or greater than 500 ppmw VOHAP or VOC in accordance with the requirements of either § 63.683(b)(1)(ii) or § 63.683(b)(2)(ii).
 - (2) The Permittee shall establish solvent recovery column temperature limits for each off-site waste material stream equal to or greater than 500 ppmw VOHAP or VOC. The Permittee shall monitor the temperature as follows:
 - (A) The Permittee shall install and operate the temperature CMS in accordance with 40 CFR 63.8(c).
 - (B) Each CMS shall be in continuous operation when the solvent recovery column is receiving off-site waste streams equal to or greater than 500 ppmw VOHAP or VOC, except for system malfunctions (breakdowns, out of control periods, and associated repairs), maintenance periods, calibration checks and zero (low-level) and high-level calibration drift adjustments.
 - (C) Continuous operation is defined as the collection of at least one measurement for each successive 15-minute period.

D.7.7 Monitoring Requirements

The monitoring requirements for the RTO control system and T79 control system, and associated closed-vent systems, used to control emissions from the applicable emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3) and 326 IAC 2-7-19]

D.7.8 Record Keeping and Reporting Requirements

- (a) Record Keeping Requirements
 - (1) RTO Control System and T79 Control System Records - The record keeping requirements for the RTO control system and T79 control system, and associated closed-vent systems, used to control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.

- (1) The following streamlined quarterly reporting requirements shall satisfy the Pharmaceutical MACT standards [40 CFR 63.1256(b)], Offsite Waste MACT [40 CFR 63.697(b)(3)] and the PSD BACT requirements [326 IAC 2-1.1-11]:
 - (A) SSM summary reports for the processes.
 - (B) The reporting requirements for the RTO control system, T79 fume incinerator control system, and associated closed-vent systems, that control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.
 - (C) The reporting requirements for the LDAR standards are described in Sections E.1 and E.2 of this permit.

(c) Immediate Reporting Requirements

The reporting requirements in the NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e)(3)] shall be used to satisfy the reporting requirements under the Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)], Offsite Waste MACT standards [40 CFR 63.697(b)(3), and PSD BACT requirements [326 IAC 2-1.1-11].

- (1) Any time an action taken by the Permittee during an SSM event of a process is not consistent with the procedures specified in the SSM Plan, the Permittee shall report the actions taken for that event. The immediate report shall be submitted to the agency via a telephone call or facsimile within 2 working days after commencing actions inconsistent with the plan.
- (2) Within 7 working days after the end of an SSM event of a process where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):
 - (A) Name, title and signature of responsible official certifying accuracy;
 - (B) Explanation of the circumstances of the event;
 - (C) Reason for not following the SSM Plan; and
 - (D) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred.

Modifications and Construction Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12 and 326 IAC 2-2]

D.7.9 Modifications and Construction: Advance Approval of Permit Conditions

- (a) The Permittee may modify any existing emission units listed in this section of the permit without obtaining a source modification approval (otherwise required by 326 IAC 2-7-

- (b) The startup, shutdown and malfunction (SSM) requirements for the RTO control system or T79 control system, are described in Sections D.14 and D.15 of this permit, respectively.

Testing and Monitoring Requirements [326 IAC 2-7-6(1) (6)] [326 IAC 2-7-5(1)]

D.8.3 Requirements

- (a) The compliance determination requirements for the RTO control system and T79 fume incinerator control system, and associated closed-vent systems, used to control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.
- (b) The Permittee shall utilize engineering knowledge of the waste stream constituents such as material balances to demonstrate the average VOHAP and/or VOC concentration is less than 500 ppmw for each BPM IDS that is not controlled in accordance with D.8.3 (a).

D.8.4 Monitoring Requirements

The monitoring requirements for the RTO control system and T79 fume incinerator control system, and associated closed-vent systems, used to control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.

Record Keeping and Reporting Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12 and 326 IAC 2-2]

D.8.5 Record Keeping and Reporting Requirements

- (a) Record Keeping Requirements
 - (1) RTO Control System and T79 Control System Records - The record keeping requirements for the RTO control system and T79 fume incinerator control system, and associated closed-vent systems, that control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.
 - (2) Inspection and Maintenance Records - The Permittee shall maintain the following records:
 - (A) Identification and explanation of all BPM IDS covers unsafe to inspect, including a plan for when these IDS covers will be inspected;
 - (B) Identification and explanation of all BPM IDS covers difficult to inspect, including a plan for when these IDS covers will be inspected;
 - (C) Visual inspection log of BPM IDSs, including the date of inspection and a statement that no leaks were detected, if applicable;
 - (D) One-time Method 21 inspection log of each BPM IDS cover, including the date of inspection and a statement that no leaks were detected, if applicable;

- (E) Information on each BPM IDS cover inspection during which a leak is detected, including:
 - (i) Instrument identification numbers, operator name or initials, and identification of the equipment;
 - (ii) Date the leak was detected and the date of the first attempt to repair the leak;
 - (iii) Maximum instrument reading measured after leak is successfully repaired or determined to be nonrepairable;
 - (iv) Reason for any delay of repair if leak not repaired within 15 calendar days after discovery of the leak;
 - (v) Name, initials, or other form of identification of person whose decision it was that repair could not be effected without a shutdown;
 - (vi) Expected date of successful repair of leak if leak not required within 15 calendar days after discovery of leak;
 - (vii) Dates of shutdowns that occur while the equipment is unrepaired; and
 - (viii) Date of successful repair of the leak.
- (F) Documentation of a decision to use a delay of repair due to unavailability of parts shall include a description of the failure, the reason additional time was necessary (including a statement of why replacement parts were not kept onsite and when delivery from the manufacturer is scheduled), and the date when the repair was completed.
- (1) SSM Records - The Permittee shall maintain the following records:
 - (i) Records of the current and superseded versions of SSM Plan.
 - (ii) Occurrence/duration records of each process malfunction.
 - (iii) Information to demonstrate conformance with each SSM are consistent with the procedures in the SSM Plan.
 - (iv) Records of actions taken during each SSM when different from SSM Plan.
- (4) IDS Waste Stream Records - The Permittee shall identify each IDS not controlled by the RTO or T79 control system and maintain documentation to support the average waste stream constituents of VOHAP and/or VOC concentration are less than 500 ppmw.
- (b) Periodic Reporting Requirements

- (1) The following streamlined quarterly reporting requirements shall satisfy the Pharmaceutical MACT standards [40 CFR 63.1256(b)] and the PSD BACT requirements [326 IAC 2-1.1-11]:
 - (A) Inspections conducted during which a leak was detected; and
 - (B) SSM summary reports for the processes.
 - (C) The reporting requirements for the RTO control system, T79 fume incinerator control system, and associated closed-vent systems, that control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.

(c) Immediate Reporting Requirements

The reporting requirements in the NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e)(3)] shall be used to satisfy the reporting requirements under the Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)], Offsite Waste MACT standards [40 CFR 63.697(b)(3), and PSD BACT requirements [326 IAC 2-1.1-11].

- (1) Any time an action taken by the Permittee during an SSM event of a process is not consistent with the procedures specified in the SSM Plan, the Permittee shall report the actions taken for that event. The immediate report shall be submitted to the agency via a telephone call or facsimile within 2 working days after commencing actions inconsistent with the plan.
- (2) Within 7 working days after the end of an SSM event of a process where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):
 - (A) Name, title and signature of responsible official certifying accuracy;
 - (B) Explanation of the circumstances for the event;
 - (C) Reason for not following the SSM Plan; and
 - (D) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred.

Modifications and Construction Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12 and 326 IAC 2-2]

D.8.6 Modifications and Construction: Advance Approval of Permit Conditions

- (a) The Permittee may modify any existing emission units listed in this section of the permit without obtaining a source modification approval (otherwise required by 326 IAC 2-7-10.5), a Title V permit modification (otherwise required by 326 IAC 2-7-12), or a Prevention of Significant Deterioration permit (otherwise required by 326 IAC 2-2),

(c) Inspection Standards:

- (1) The Permittee shall conduct one-time Method 21 inspections of the fixed roof for each existing BPM solvent storage tank not operated under negative pressure and not already subject to LDAR within 150 days of the issuance date of this permit, and for each new BPM solvent storage tank not operated under negative pressure and not subject to LDAR within 150 days upon startup.
- (2) The Permittee shall conduct semiannual visual inspections on each BPM solvent storage tank for visible, audible, or olfactory indications of leaks.
- (3) The Permittee shall initiate repair of any leak on a BPM solvent storage tank no later than 5 calendar days after identification, and complete the repair within 15 days after identification, unless:
 - (i) The repair is technically infeasible without a shutdown of an operation or process; or
 - (ii) It is determined that emissions resulting from immediate repair would be greater than the fugitive emissions likely to result from delay or repair.

Repairs delayed due to either of the causes described in (A) or (B) shall be completed by the end of the next shutdown.

D.9.2 Exceptions to Standards for BPM Solvent Storage Tanks [40 CFR 63.1253 and 326 IAC 2-2]

- (a) The BPM solvent storage tanks are not subject to the standards established in Condition D.9.1 (b) during periods of planned routine maintenance, as long as the planned routine maintenance activities do not exceed 240 hours per 365 day period.
- (b) BPM solvent storage tanks storing VOC/VOHAP with a vapor pressure less than 3.5 kPa are not subject to the requirements of D.9.1 (b)(1) and (c).
- (c) BPM solvent storage tanks that are unsafe or difficult to inspect are not subject to the requirements of D.9.1(c).

D.9.3 Leak Detection and Repair (LDAR) Standards [40 CFR 63.1255 and 326 IAC 2-2]

The LDAR standards that apply to components associated with the emission units listed in this section are described in Sections E.1 and E.2 of this permit.

D.9.4 Startup, Shutdown and Malfunction Requirements [40 CFR 63.1259(a)(3), 326 IAC 2-2-3, 40 CFR 63.6(e) and 40 CFR 63.8(c)]

The NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e) and 63.8(c)] shall be used to satisfy the Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)], and PSD BACT requirements [326 IAC 2-1.1-11].

- (a) Pursuant to 40 CFR 63.6(e)(3), the Permittee shall develop an SSM Plan to ensure that processes are operated and maintained in a manner which satisfies the general duty to minimize emissions established by 40 CFR 63.6(e)(1)(i), and that all malfunctions are corrected as soon as practicable after their occurrence in order to minimize excess emissions. The SSM Plan shall contain the following information:

- (1) Detailed plans and/or procedures for operating and maintaining the process during periods of SSM; and
 - (2) Corrective action program for malfunctioning processes.
- (b) The startup, shutdown and malfunction (SSM) requirements for the RTO control system or T79 control system, are described in Sections D.14 and D.15 of this permit, respectively.

Testing and Monitoring Requirements [326 IAC 2-7-6(1) (6)] [326 IAC 2-7-5(1)]

D.9.5 Requirements

The requirements for the RTO control system and T79 fume incinerator control system, and associated closed-vent systems, that control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.

D.9.6 Monitoring Requirements

The monitoring requirements for the RTO control system, T79 fume incinerator control system, and associated closed-vent systems, that control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.

Record Keeping and Reporting Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12, 326 IAC 2-2, 40 CFR 60.7, 40 CFR 60 Subpart Kb, and 40 CFR 63 Subpart GGG]

D.9.7 Record Keeping and Reporting Requirements

- (a) Record Keeping Requirements
- (1) The record keeping requirements for the RTO control system, T79 fume incinerator control system, and associated closed-vent systems, that control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.
 - (2) Inspection and Maintenance Records - The Permittee shall maintain the following records:
 - (A) Identification and explanation of all BPM solvent storage tanks unsafe to inspect, including a plan for when these tanks will be inspected;
 - (B) Identification and explanation of all BPM solvent storage tanks difficult to inspect, including a plan for when these tanks will be inspected;
 - (C) Visual inspection log of BPM solvent storage tanks, including the date of inspection and a statement that no leaks were detected, if applicable;
 - (D) One-time Method 21 inspection log of each BPM solvent storage tank, including the date of inspection and a statement that no leaks were detected, if applicable;
 - (E) Information on each BPM solvent storage tank inspection during which a leak is detected, including:

(b) Periodic Reporting Requirements

- (1) The following streamlined quarterly reporting requirements shall satisfy the Pharmaceutical MACT standards [40 CFR 63.1256(b)] and the PSD BACT requirements [326 IAC 2-1.1-11]:
 - (A) Semiannual visual inspections conducted during which a leak was detected;
 - (B) Periods of planned routine maintenance; and
 - (C) SSM summary reports for the processes.
 - (D) The reporting requirements for the RTO control system, T79 fume incinerator control system, and associated closed-vent systems, that control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.
 - (E) The reporting requirements for the LDAR standards are described in Section E of this permit.

(c) Immediate Reporting Requirements

The reporting requirements in the NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e)(3)] shall be used to satisfy the reporting requirements under the Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)] and PSD BACT requirements [326 IAC 2-1.1-11].

- (1) Any time an action taken by the Permittee during an SSM event of the process is not consistent with the procedures specified in the SSM Plan, the Permittee shall report the actions taken for that event. The immediate report shall be submitted to the agency via a telephone call or facsimile within 2 working days after commencing actions inconsistent with the plan.
- (2) Within 7 working days after the end of an SSM event of the process where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):
 - (A) Name, title and signature of responsible official certifying accuracy;
 - (B) Explanation of the circumstances for the event;
 - (C) Reason for not following the SSM Plan; and

SECTION D.10 BPM SUPPORT OPERATIONS – WASTE TANK CONDITIONS

Facility Description [326 IAC 2-7-5(15)]

The information describing the processes contained in the following facility description boxes is descriptive information and does not constitute enforceable conditions:

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
<i>Building T27:</i>				
T27-TK53-10*	Waste Tank	RTO	500 gal	RTO
<i>Building T28:</i>				
T28-TK-28HW*	Waste Tank	RTO	250 gal	RTO
<i>Building T29:</i>				
T29-TK7902*	Waste Tank	RTO	1000 gal	RTO
<i>Building T31:</i>				
T31-TK609*	Waste Tank	RTO	100 gal	RTO
T31-TK669*	Waste Tank	RTO	100 gal	RTO
<i>Building T31A:</i>				
T31A-TK451K*	Waste Tank	RTO	100 gal	RTO
T31A-TK688*	Waste Tank	RTO	125 gal	RTO
<i>Building T99:</i>				
T99-TK-1B*	Waste Tank	RTO	100 gal	RTO
T99-TK-7B*	Waste Tank	RTO	210 gal	RTO
T99-TK-8B*	Waste Tank	RTO	210 gal	RTO
T99-TK-D45A*	Waste Tank	RTO	100 gal	RTO
<i>Building T100:</i>				
T100-TK-10A*	Waste Tank	RTO	200 gal	RTO
T100-TK-48*	Waste Tank	RTO	3300 gal	RTO
<i>Building T79:</i>				
T79-TK301*	Equalization Tank	T79 - 321 stream	50,000 gal	T79 Incinerator
T79-TK302*	Equalization Tank	T79 - 321 stream	50,000 gal	T79 Incinerator
T79-TK303*	Neutralization Tank	T79 - 321 stream	5,000 gal	T79 Incinerator
<i>Tank Module Building T140:</i>				
T140-TK3122	Waste Tank	T79 Incinerator	38,425 gal	T79 Incinerator
T140-TK3123	Waste Tank	T79 Incinerator	38,425 gal	T79 Incinerator
T140-TK3124	Waste Tank	T79 Incinerator	38,425 gal	T79 Incinerator
T140-TK3125	Waste Tank	T79 Incinerator	38,425 gal	T79 Incinerator
T140-TK3126	Waste Tank	T79 Incinerator	38,425 gal	T79 Incinerator
T140-TK3227*	Waste Tank	T79 -324 stream	18,130 gal	T79 Incinerator
T140-TK3228*	Waste Tank	T79 - 324 stream	18,130 gal	T79 Incinerator
T140-TK3229*	Waste Tank	T79 - 324 stream	500 gal	T79 Incinerator
<i>Tank Module Building T142:</i>				
T142-TK01	Waste Tank	T79 or RTO	19,500 gal	T79 or RTO
T142-TK02	Waste Tank	T79 or RTO	19,500 gal	T79 or RTO

T142-TK03	Waste Tank	T79 or RTO	19,500 gal	T79 or RTO
T142-TK04	Waste Tank	T79 or RTO	19,500 gal	T79 or RTO
T142-TK05	Waste Tank	T79 or RTO	19,500 gal	T79 or RTO
T142-TK06	Waste Tank	T79 or RTO	19,500 gal	T79 or RTO
T142-TK07	Waste Tank	T79 or RTO	19,500 gal	T79 or RTO
T142-TK08	Waste Tank	T79 or RTO	19,500 gal	T79 or RTO
T142-TK09	Waste Tank	T79 or RTO	19,500 gal	T79 or RTO
T142-TK10	Waste Tank	T79 or RTO	19,500 gal	T79 or RTO
T142-TK11	Waste Tank	T79 or RTO	19,500 gal	T79 or RTO
T142-TK12	Waste Tank	T79 or RTO	19,500 gal	T79 or RTO
<i>Tank Module Building T143:</i>				
T143-TK02*	Waste Tank	T79 - 325 stream	19,500 gal	T79 Incinerator
T143-TK06*	Waste Tank	T79 - 325 stream	19,500 gal	T79 Incinerator
T143-TK08	Waste Tank	T79 Incinerator	19,500 gal	T79 Incinerator
T143-TK10*	Waste Tank	T79 - 325 stream	19,500 gal	T79 Incinerator
T143-TK15*	Waste Tank	T79 - 325 stream	19,500 gal	T79 Incinerator
T143-TK56*	Knock Out Pot	T79 Incinerator	45 gal	T79 Incinerator
<i>Tank Module Building T145:</i>				
T145-TK76*	Knock Out Pot	T79 Incinerator	45 gal	T79 Incinerator
T145-TK77*	Knock Out Pot	T79 Incinerator	45 gal	T79 Incinerator
<i>Tank Module Building T146:</i>				
T146-TK23	Waste Tank	RTO	19,000 gal	RTO
T146-TK24	Waste Tank	RTO	19,000 gal	RTO
T146-TK11*	Waste Tank	RTO	18,644 gal	RTO
T146-TK20*	Waste Tank	RTO	18,644 gal	RTO
T146-TK21*	Waste Tank	RTO	18,644 gal	RTO
T146-TK12	Waste Tank	RTO	19,500 gal	RTO
T146-TK56*	Knock Out Pot	RTO	45 gal	RTO
<i>T48 Tank Farm:</i>				
T48-TK3207*	Waste Tank	T79 - 324 stream	102,759 gal	T79 Incinerator
T48-TK3208*	Waste Tank	T79 - 324 stream	102,759 gal	T79 Incinerator
T48-TK3209*	Waste Tank	T79 - 324 stream	102,759 gal	T79 Incinerator
T48-TK3211*	Waste Tank	T79 - 324 stream	260,650 gal	T79 Incinerator
T48-TK3212*	Waste Tank	T79 - 324 stream	260,650 gal	T79 Incinerator

* Emission units marked with an asterisk are insignificant activities as defined by 326 IAC 2-7-1(21)(A)-(C).

Repairs delayed due to either of the causes described in (A) or (B) shall be completed by the end of the next shutdown.

D.10.2 Exceptions to Standards for BPM Waste Storage Tanks [40 CFR 63.1256(b), 40 CFR 63, and 326 IAC 2-2-3]

- (a) The BPM waste storage tanks less than 38 cubic meters are not subject to the standards established in Condition D.10.1 (b) during periods of planned routine maintenance, as long as the planned routine maintenance activities do not exceed 240 hours per 365 day period.
- (b) BPM waste storage tanks storing VOC/VOHAP with a vapor pressure less than 3.5 kPa are not subject to the requirements of D.10.1 (b)(1) and (c).
- (c) BPM waste storage tanks that are unsafe or difficult to inspect are not subject to the requirements of D.10.1(c).

D.10.3 Leak Detection and Repair (LDAR) Standards [40 CFR 61, Subpart V and 326 IAC 2-2-3]

The LDAR standards that apply to components associated with the BPM waste storage tanks are described in Section E.2 of this permit.

D.10.4 Startup, Shutdown and Malfunction Requirements [40 CFR 63.1259(a)(3), 40 CFR 63.697(b)(3), 326 IAC 2-2-3, 40 CFR 63.6(e) and 40 CFR 63.8(c)]

The NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e) and 63.8(c)] shall be used to satisfy the Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)], Offsite Waste MACT [40 CFR 63.697(b)(3)], and PSD BACT requirements [326 IAC 2-1.1-11].

- (a) Pursuant to 40 CFR 63.6(e)(3), the Permittee shall develop an SSM Plan to ensure that processes are operated and maintained in a manner which satisfies the general duty to minimize emissions established by 40 CFR 63.6(e)(1)(i), and that all malfunctions are corrected as soon as practicable after their occurrence in order to minimize excess emissions. The SSM Plan shall contain the following information:
 - (1) Detailed plans and/or procedures for operating and maintaining the process during periods of SSM; and
 - (2) Corrective action program for malfunctioning processes.
- (b) The startup, shutdown and malfunction (SSM) requirements for the RTO control system or T79 control system, via its associated closed vent system, are described in Sections D.14 and D.15 of this permit, respectively.

Testing and Monitoring Requirements [326 IAC 2-7-6(1) (6)] [326 IAC 2-7-5(1)]

D.10.5 Requirements

The requirements for the RTO control system and T79 fume incinerator control system, and associated closed-vent systems, used to control emissions from the emission units listed in this section are described in Sections D.14 and D.15 of this permit, respectively.

- (v) Name, initials, or other form of identification of person whose decision it was that repair could not be effected without a shutdown;
 - (vi) Expected date of successful repair of leak if leak not required within 15 calendar days after discovery of leak;
 - (vii) Dates of shutdowns that occur while the equipment is unrepaired; and
 - (viii) Date of successful repair of the leak.
 - (F) Periods of planned routine maintenance; and
 - (G) Records of BPM waste storage tanks storing VOC/VOHAP with a vapor pressure less than 3.5 kPa.
- (3) SSM Records - The Permittee shall maintain the following records:
- (A) Records of the current and superseded versions of SSM Plan.
 - (B) Occurrence/duration records of each process malfunction.
 - (C) Information to demonstrate conformance with each SSM are consistent with the procedures in the SSM Plan.
 - (D) Records of actions taken during each SSM when different from SSM Plan.
- (4) LDAR Records - The record keeping requirements for the LDAR standards are described in Section E of this permit.
- (5) Storage Tank Records - Pursuant to New Source Performance Standard for Volatile Organic Liquid Storage Vessels (40 CFR 60.116b(a) and (b)), the Permittee shall, for the life of the source, keep readily accessible records of the dimensions and capacity for all applicable BPM waste storage tanks.
- (6) Operating Plan – Pursuant to 40 CFR 60.115b, the Permittee shall, for the life of the source, maintain a copy of the operating plan required by 40 CFR 60.113b for all tanks with design capacity greater than or equal to 75 cubic meters.
- (b) Quarterly Reporting Requirements
- (1) The following streamlined quarterly reporting requirements shall satisfy the Pharmaceutical MACT standards [40 CFR 63.1256(b)] and the PSD BACT requirements [326 IAC 2-1.1-11]:
- (A) Inspections conducted during which a leak was detected;
 - (B) Periods of planned routine maintenance; and

- (C) SSM summary reports for the processes.
- (D) The reporting requirements for the RTO control system and T79 fume incinerator control system used to control emissions from these emission units are described in Sections D.14 and D.15 of this permit, respectively.
- (E) The reporting requirements for the LDAR standards are described in Section E of this permit.

(c) Immediate Reporting Requirements

The reporting requirements in the NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e)(3)] shall be used to satisfy the reporting requirements under the Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)], Offsite Waste MACT standards [40 CFR 63.697(b)(3), and PSD BACT requirements [326 IAC 2-1.1-11].

- (1) Any time an action taken by the Permittee during an SSM event of a process is not consistent with the procedures specified in the SSM Plan, the Permittee shall report the actions taken for that event. The immediate report shall be submitted to the agency via a telephone call or facsimile within 2 working days after commencing actions inconsistent with the plan.
- (2) Within 7 working days after the end of an SSM event of a process where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):
 - (A) Name, title and signature of responsible official certifying accuracy;
 - (B) Explanation of the circumstances for the event;
 - (C) Reason for not following the SSM Plan; and
 - (D) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred.

Modifications and Construction Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12 and 326 IAC 2-2]

D.10.8 Modifications and Construction: Advance approval of permit conditions

- (a) The Permittee may modify any existing emission units listed in this section of the permit without obtaining a source modification approval (otherwise required by 326 IAC 2-7-10.5), a Title V permit modification (otherwise required by 326 IAC 2-7-12), or a Prevention of Significant Deterioration permit (otherwise required by 326 IAC 2-2), provided the modified emission units are subject to the same applicable requirements listed in this D section, and the Permittee shall comply with the Change Management and Flexible Permit provisions in Section F.1 of this permit.

- (c) Inspection Standards:
 - (1) Initial and semiannual visual inspections shall be conducted for improper work practices and control equipment failures.
 - (2) Inspections that are unsafe or difficult to inspect are not subject to the inspection requirements of D.11.1(c)(1).
 - (3) The Permittee shall attempt to repair any defect within 24 hours after detection of the defective container and complete the repair within 5 calendar days after detection. If repair of a defect cannot be completed within 5 calendar days, then the waste shall be removed from the container and the container shall not be used to manage waste until the defect is repaired.
- (d) The LDAR standards that apply to the components associated with the emission units listed in this section are described in Section E.2.

D.11.2 Standards for Large BPM Waste Containers [40 CFR 63.1256(d), 40 CFR 63.688, 326 IAC 2-2-3, 326 IAC 2-7-24]

The following standards represent the streamlined requirements of the Pharmaceutical MACT Standards under 40 CFR 63.1256(d), OSWRO MACT Standards under 40 CFR 63.688, and Best Available Control Technology (BACT) requirements under 326 IAC 2-2-3:

- (a) Definition Standards:
 - (1) A large BPM waste container is defined as any portable unit containing VOC/VOHAP material at concentrations greater than 500 ppmw with a storage capacity of greater than 0.42 cubic meters (110.5 gallons).
- (b) Operational Standards:
 - (1) The cover and all openings on each large BPM waste container shall be maintained in the closed position, and without leaks, except when adding material, removing material, accessing material for non-transfer-related routine activities, opening from a pressure relief device, and opening of a safety device.
 - (2) A submerged fill pipe shall be used when pumping BPM liquid waste into a large BPM waste container. The submerged fill pipe outlet shall extend to no more than 6 inches or within two fill pipe diameters of the bottom of the container while the container is being filled.
- (c) Inspection Standards:
 - (1) One-time Method 21 inspections shall be conducted on each new large BPM waste container within 150 days upon first onsite usage.
 - (2) Initial and semiannual visual inspections shall be conducted for:
 - (A) Improper work practices;
 - (B) Control equipment failures; and
 - (C) Visible, audible, or olfactory indications of leaks.
 - (3) Inspections that are unsafe or difficult to inspect are not subject to the inspection requirements of D.11.2(c)(1) and (2).

- (4) The Permittee shall attempt to repair any defect within 24 hours after detection of the defective container and complete the repair within 5 calendar days after detection. If repair of a defect cannot be completed within 5 calendar days, then the waste shall be removed from the container and the container shall not be used to manage waste until the defect is repaired.

Record Keeping and Reporting Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12 and 326 IAC 2-2]

D.11.3 Record Keeping and Reporting Requirements

(a) Record Keeping Requirements

- (1) The Permittee shall maintain the following records for inspections required by Conditions D.11.1 and D.11.2:
 - (A) Identification and explanation of all containers unsafe to inspect, including a plan for when these containers will be inspected;
 - (B) Identification and explanation of all containers difficult to inspect, including a plan for when these containers will be inspected;
 - (C) Visual inspection log of BPM waste containers, including the date of inspection and a statement that no leaks were detected, if applicable;
 - (D) One-time Method 21 inspection log of each large BPM waste container, including the date of inspection and a statement that no leaks were detected, if applicable;
 - (E) Information on each BPM waste container inspection during which a leak is detected, including:
 - (i) Instrument identification numbers (for Method 21 inspections only), operator name or initials, and identification of the equipment;
 - (ii) Date the leak was detected and the date of the first attempt to repair the leak; and
 - (iii) Date of successful repair of the leak or date material removed from container.

(b) Quarterly Reporting Requirements

- (1) The Permittee shall include the inspection records specified in D.11.3 (a)(5) for each inspection conducted during which a leak was detected in the next quarterly report.

D.12.12 Plans and Procedures [326 IAC 2-2-3, 40 CFR 63.1206, 40 CFR 63.1211, 326 IAC 2-7-5(13)]

In order to satisfy the HWC MACT Standards [40 CFR 63.1206] and the PSD BACT requirements [326 IAC 2-2-3], the Permittee shall develop and implement the following written plans, which shall be maintained in the operating record:

- (a) Operations and Maintenance (O&M) Plan – The O&M Plan shall define operations during periods of normal operation pursuant to 40 CFR 63.1206(c)(1) and (7).
- (b) Startup, Shutdown, and Malfunction (SSM) Plan shall be developed and implemented in accordance with 40 CFR 63.1206(c)(2), 40 CFR 63.6(e)(3), and 40 CFR 63.8(c), to ensure that the T49 liquid waste incinerator, including associated air emission control equipment and CEMS and CMS, is operated and maintained in a manner which satisfies the general duty to minimize emissions established by 40 CFR 63.6(e)(1)(i), and that all malfunctions are corrected as soon as practicable after their occurrence in order to minimize excess emissions. The SSM Plan shall contain the following information:
 - (1) Detailed procedures for operating and maintaining the T49 liquid waste incinerator system, including associated CEMS and CMS equipment, during periods of startup, shutdown, and malfunction; and
 - (2) Corrective action program for malfunctioning process, air pollution control, CEMS, and CMS equipment.
- (c) Feedstream Analysis Plan -The Feedstream Analysis Plan shall be developed and implemented in accordance with 40 CFR 63.1209(c)(2) for those parameters with feed rate limits defined in Condition D.12.15.
- (d) Continuous Emissions Monitoring System (CEMS) Standard Operating Procedures (SOP) – The Permittee shall prepare and implement a SOP that provides step-by-step procedures and operations of the CEMS in accordance with 326 IAC 3-5-4(a)(9) – Preventive maintenance procedures and corrective maintenance procedures that include those procedures taken to ensure continuous operation and to minimize malfunctions.

Testing and Monitoring Requirements [326 IAC 2-7-6(1) (6)] [326 IAC 2-7-5(1)]

D.12.13 Performance Test Requirements [40 CFR 63.1207, 326 IAC 2-1.1-11, 326 IAC 3-6]

The following streamlined performance test requirements shall satisfy the NESHAP General Provisions [40 CFR 63.7], the HWC MACT requirements [40 CFR 63.1207 and 63.1209], the PSD BACT requirements for VOC and fluorides [326 IAC 2-1.1-11] and the State emission testing requirements [326 IAC 3-6]:

- (a) Initial Comprehensive Performance Test Requirements:
 - (1) The Permittee shall submit a notification of intention to conduct a comprehensive performance test and CMS performance evaluation and a site-specific test plan and CMS performance evaluation test plan at least one year before the performance test and performance evaluation are scheduled to begin.
 - (2) The Permittee shall perform initial comprehensive performance tests within 6 months after the HWC MACT compliance date unless an exemption is granted pursuant to 40 CFR 63.1207(e)(3).

- (1) Pursuant to 40 CFR 63.1207(d)(4)(ii), no confirmatory performance tests shall be required until the U.S. EPA promulgates permanent replacement standards pursuant to the Settlement Agreement noticed in the Federal Register on November 16, 2001.
- (2) Upon promulgation of the permanent replacement standards, the Permittee shall comply with the subsequent comprehensive testing requirements established.

D.12.14 Continuous Emissions Monitoring Systems (CEMS) Operating Requirements [40 CFR 63.1209, 40 CFR 63.8, 326 IAC 2-7-24, 326 IAC 3-5, 326 IAC 2-1.1-11, 40 CFR 60, Appendix B, and 40 CFR 60, Appendix F]

- (a) CO and O₂ CEMS Operation Requirements – The following provisions shall be applied at all times the T49 incinerator is in operation and represent the streamlined requirements of the HWC MACT standards for CO and HC [40 CFR 63.1209(a), (d), (e), (f), and (h)], PSD BACT requirements for CO and VOC [326 IAC 2-1.1-11], and the emission monitoring requirements for MACT and PSD sources [326 IAC 3-5-1(b) and (d)]:
 - (1) The Permittee shall install and operate the CO and O₂ CEMS in accordance with the QA requirements of the HWC MACT standards [40 CFR 63, Appendix to Subpart EEE], the applicable QC and performance evaluation requirements of 40 CFR 63.1209(d), and the applicable performance specification requirements of 40 CFR 60, Appendix B.
 - (2) The CEMS shall be installed and operational upon certification of the DOC for the HWC MACT.
 - (3) Continuous operation is defined as the collection of at least one measurement for each successive 15-second period.
- (b) SO₂ and NO_x CEMS Operation Requirements – The following requirements shall apply when the T49 Incinerator is burning waste
 - (1) The Permittee shall install and operate the SO₂ and NO_x CEMS in accordance with the QA/QC criteria set forth in 40 CFR 60, Appendix B and 40 CFR 60, Appendix F, Procedure 1.
 - (2) Continuous operation is defined as the collection of at least one measurement for each successive 15-minute period.
 - (3) The Startup, Shutdown, and Malfunction (SSM) Plan required by Condition D.12.12 (b) shall include procedures for monitoring and recording the following information during times of SO₂ or NO_x CEMS malfunction:
 - (A) When the SO₂ CEMS malfunctions, the Permittee shall monitor and record the Hydro-Sonic™ equivalent pressure drop and scrubber liquid flow rate as required by Condition D.12.15 (a)(3)(C) and (D) and the scrubber liquid pH as required by Condition D.12.15 (a)(5)(C).
 - (B) When the NO_x CEMS malfunctions, the Permittee shall monitor and record the combustion chamber temperature, combustion air flow rate, and primary and secondary waste feed rates as required by Condition D.12.15 (a)(1), and assess NO_x emissions, using waste testing, waste shipment and process knowledge, to determine whether the quantity of nitrogen fed into the incinerator during that time could have exceeded the worst case 24-hour daily average nitrogen feed rate of 1,650 pounds per hour that formed the basis of the NO_x BACT limit.

D.12.15 Parametric Continuous Monitoring Systems (CMS) Requirements [40 CFR 63.8(c), 40 CFR 63.1209, and 326 IAC 2-1.1-11]

- (a) The Permittee shall operate the following CMS in accordance with the quality assurance requirements specified in 40 CFR 63.1209(d) at all times the T49 incinerator is in operation. To satisfy the HWC MACT standards [40 CFR 63.1209(b), (d), (e), (f), and (h)] and the requirements for PSD sources [326 IAC 2-1.1-11] the following parameters shall be monitored at all times the T49 incinerator is in operation. In addition, the operating parameters monitored by the following CMSs shall not exceed the established operating parameter limits at all times the T49 incinerator is burning waste:
- (1) Dioxin/Furan CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(k)], the Permittee shall install and operate CMS monitors for the following parameters:
- (A) Combustion Chamber Temperature - Minimum rolling hourly average combustion chamber temperature established from the average temperature measured during the three DRE test runs;
 - (B) Combustion Air Flow Rate - Maximum hourly rolling average combustion air flow rate established from the average of the maximum hourly rolling average for each performance test run; and
 - (C) Primary Waste Feed Rate – Maximum hourly rolling average primary waste feed rate as established from the average of the maximum hourly rolling averages for each performance test run.
 - (D) Secondary Waste Feed Rate - Maximum hourly rolling average secondary waste feed rate as established from the average of the maximum hourly rolling averages for each performance test run.
- (2) DRE Standard CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(j)], the Permittee shall install and operate CMS monitors for those parameters identified in Condition D.12.15 (a)(1).
- (3) Metals CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(l) and (n)], the Permittee shall install and operate CMS monitors for the following parameters:
- (A) Waste Feed Rate - Maximum 12-hour rolling average feed rates for total Hg, semi-volatile metals (cadmium and lead) and low volatile metals (arsenic, beryllium, and chromium) in all waste feedstreams established from the average of the hourly rolling averages for each performance test run and approved extrapolation techniques;
 - (B) Scrubber Liquids Solid Content - Maximum 12-hour rolling average solids content of the scrubber liquid using a continuous monitoring system established from the average of the performance test run averages. This parameter does not apply to mercury;
 - (C) Hydro-Sonic™ Equivalent Pressure Drop - Minimum hourly rolling average pressure drop across the Hydro-Sonic™ scrubber established from the average of the performance test run averages;
 - (D) Scrubber Liquid Flow Rate - Minimum hourly rolling average scrubber liquid flow rate established from the average of the performance test run averages; and

- (c) Monitoring data are insufficient to constitute a valid hour of data if measured values are unavailable for any of the required 15-minute periods within the hour.

(1) Record Keeping and Reporting Requirement [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.12.17 Record keeping Requirements

- (a) The Permittee shall maintain the following records:
- (1) Notifications, reports, and other documents, such as the Documentation of Compliance, as required by 40 CFR 63.1200, 63.1211(c), and 63.10(b) and (c).
- (2) All data recorded by continuous monitoring systems (CMS), including continuous emission monitoring systems (CEMS), required by Conditions D.12.14 and D.12.15;
- (3) Documentation that a change will not adversely affect compliance with the emission standards or operating requirements as required by 40 CFR 63.1206(b)(5)(ii);
- (4) Records of the estimated hazardous waste residence time as required by 40 CFR 63.1206(b)(11);
- (5) Plans and procedures as required by Condition D.12.12;
- (6) Documentation of the results of the investigation, corrective measures taken, and evaluation of excessive exceedances during malfunctions as required by 40 CFR 63.1206(c)(2)(v)(A);
- (7) Corrective Measures for any AWFCO that results in an exceedance of an applicable emission standard or operating parameter limit as required by 40 CFR 63.1206(c)(3)(v);
- (8) Documentation of the results of the AWFCO operability testing as required by Condition D.12.10 (b) and 40 CFR 63.1206(c)(3)(vii);
- (9) Daily visual inspection records of the T49 liquid waste incinerator to ensure the combustion zone is sealed as required by Condition D.12.10 (a) and 40 CFR 63.1206(c)(5);
- (10) A copy of the Operator Certification and Training Program required by Condition D.12.11 and 40 CFR 63.1206(c)(6);
- (11) Documentation of the changes in modes of operation as required by 40 CFR 63.1209(q); and
- (12) For days when Condition D.12.16 requires that CEMS data must be supplemented, the documentation of the information required by Condition D.12.14 (b)(3).

D.12.18 Reporting Requirements

- (a) Quarterly Reporting Requirements

- (1) The following streamlined quarterly reporting requirements shall satisfy the HWC MACT standards [40 CFR 63.1211], which references the MACT General Provisions [63.7-63.10], PSD BACT requirements [326 IAC 2-1.1-11], and the continuous emissions monitoring requirements [326 IAC 3-5]:
 - (A) Reports shall be submitted within 30 days following the reporting period using the reporting forms located at the end of this permit, or their equivalent;
 - (B) Summary reports of excess emissions, parameter exceedances, and monitor downtime including information specified in 63.10(c)(5)-(c)(13);
 - (C) SSM summary reports for the T49 waste incinerator control system, including associated CEMS and CMS equipment;
 - (D) Excessive exceedances report, if applicable, as required by 40 CFR 63.1206(c)(3)(vi); and
 - (2) In addition to the requirements described in (a)(1) of this condition, the Permittee shall report the following information for the NO_x and SO₂ CEMS to satisfy the PSD BACT requirements [326 IAC 2-1.1-11]:
 - (A) A list of days when condition D.12.16 requires that CEMS data must be supplemented that provides:
 - (B) A detailed report for each day when condition D.12.16 requires that CEMS data must be supplemented:
 - (i) the information required by Condition D.12.14 (b)(3), and
 - (ii) an analysis of whether that information indicates continuous compliance with the limit established in Condition D.12.3 or D.12.4, and if the NO_x CEMS malfunctions for greater than six continuous hours, an assessment of NO_x emissions using waste testing, waste shipment, and process knowledge whether the quantity of nitrogen fed into the incinerator during that time could have exceeded the worst case 24-hour daily average nitrogen feed rate of 1,650 pounds per hour that formed the basis of the NO_x BACT limit.
- (b) Immediate Reporting Requirements
- (1) The Permittee shall submit any revision to the SSM Plan that may significantly increase emissions of hazardous air pollutants to the Administrator for approval within 5 days after making a change to the plan to satisfy the reporting requirements under the HWC MACT standards [40 CFR 63.1206(c)(2)(ii)(C)].
 - (2) The reporting requirements in the NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e)(3)] shall be used to satisfy the reporting requirements under the HWC MACT standards [40 CFR 63.1206(c)(2)] and PSD BACT requirements [326 IAC 2-1.1-11].

D.13.4 Oxides of Nitrogen (NO_x) Emission Standards [326 IAC 2-2-3]

In order to satisfy the PSD BACT requirements [326 IAC 2-2-3], the T149 rotary kiln incinerator shall be equipped with selective non-catalytic reduction (SNCR) equipment to control NO_x emissions. The NO_x emissions from the incinerator stack exhaust shall not exceed 170 ppmv dry corrected to 7% oxygen, expressed as NO₂, averaged over a 24-hour daily period when burning waste streams.

D.13.5 Hazardous Air Pollutant (HAP) Emission Standards [40 CFR 63.1203]

Except for periods of startup, shutdown and malfunctions, the following emission standards shall apply at all times the T49 rotary kiln incinerator is operating:

- (a) Mercury – Pursuant to the HWC MACT standards [40 CFR 63.1203(b)(2)], the mercury emissions from the T149 rotary kiln incinerator stack exhaust shall not exceed 45 ug/dscm, corrected to 7% oxygen.
- (b) Lead and Cadmium – Pursuant to the HWC MACT standards [40 CFR 63.1203(b)(3)], the total semi-volatile metals (lead and cadmium) emissions from the T149 rotary kiln incinerator stack exhaust shall not exceed 120 ug/dscm, corrected to 7 percent oxygen.
- (c) Arsenic, Beryllium, and Chromium – Pursuant to the HWC MACT standards [40 CFR 63.1203(b)(4)], the total low volatile metals (arsenic, beryllium, and chromium) emissions from the T149 rotary kiln incinerator stack exhaust shall not exceed 97 ug/dscm, corrected to 7 percent oxygen.
- (d) Hydrochloric Acid/Chlorine Gas (HCl/Cl₂) and Fluorides - In order to satisfy the HWC MACT standards [40 CFR 63.1203(b)(6)], the HCl/Cl₂ emissions from the T149 rotary kiln incinerator stack exhaust shall not exceed 21 ppmvdc, expressed as HCl equivalent. In order to satisfy the PSD BACT requirements for fluorides [326 IAC 2-2-3], the T49 rotary kiln incinerator control system shall achieve a HCl control efficiency of 98 percent or greater.
- (e) Dioxin/Furans – Pursuant to HWC MACT standards [40 CFR 63.1203(b)(1)], the dioxin/furan emissions from the T149 rotary kiln incinerator stack exhaust shall not exceed 0.20 ng TEQ/dscm, corrected to 7 percent oxygen.
- (f) Principle Organic Hazardous Constituents (POHCs) – Pursuant to the HWC MACT standards [40 CFR 63.1203(c)(1) and (2)], the Permittee shall comply with the following requirements:
 - (1) The destruction and removal efficiency (DRE) for each principle organic hazardous constituent (POHC), excluding dioxin-listed hazardous wastes F020, F021, F022, F023, F026, or F027 shall be at least 99.99 percent.
 - (2) Dioxin-listed hazardous wastes F020, F021, F022, F023, F026, or F027 shall not be burned in the T149 rotary kiln incinerator.

D.13.6 Carbon Monoxide (CO) Emission Standards [326 IAC 2-2-3, 40 CFR Part 52, Subpart P, and 40 CFR 63.1203]

- (a) In order to satisfy the HWC MACT standards [40 CFR 63.1203(b)(5)(i)] and the PSD BACT requirements [326 IAC 2-2-3], the CO emissions from the T149 rotary kiln incinerator stack exhaust, as monitored by a continuous emissions monitoring system (CEMS), shall not exceed 100 ppmv dry corrected to 7% oxygen, averaged over an

- (2) Upon promulgation of the permanent replacement standards, the Permittee shall comply with the subsequent comprehensive testing requirements established.
- (a) Confirmatory Performance Tests
 - (1) Pursuant to 40 CFR 63.1207(d)(4)(ii), no confirmatory performance tests shall be required until the U.S. EPA promulgates permanent replacement standards pursuant to the Settlement Agreement noticed in the Federal Register on November 16, 2001.
 - (2) Upon promulgation of the permanent replacement standards, the Permittee shall comply with the subsequent comprehensive testing requirements established.

D.13.14 Continuous Emissions Monitoring Systems (CEMS) Operating Requirements [40 CFR 60, Appendix B and Appendix F, 40 CFR 63.8, 326 IAC 2-1.1-11, 326 IAC 3-5]

- (a) CO and O₂ CEMS Operation Requirements – The following requirements shall be applied at all times the T149 rotary kiln incinerator is in operation and represent the streamlined requirements of the HWC MACT standards for CO and HC [40 CFR 63.1209(a), (d), (e), (f), and (h)], PSD BACT requirements for CO and VOC [326 IAC 2-1.1-11], and the emission monitoring requirements for MACT and PSD sources [326 IAC 3-5-1(b) and (d)]:
 - (3) The Permittee shall install and operate the CO and O₂ CEMS in accordance with the QA requirements of the HWC MACT standards [40 CFR 63, Appendix to Subpart EEE], the applicable QC and performance evaluation requirements of 40 CFR 63.1209(d), and the applicable performance specification requirements of 40 CFR 60, Appendix B.
 - (4) The CEMS shall be installed and operational upon certification of the DOC for the HWC MACT.
 - (3) Continuous operation is defined as the collection of at least one measurement for each successive 15-second period, regardless of startup, shutdown and malfunction.
- (b) SO₂ and NO_x CEMS Operation Requirements – The following requirements shall apply when the T149 rotary kiln incinerator is burning waste:
 - (1) The Permittee shall install and operate the SO₂ and NO_x CEMS in accordance with the QA/QC criteria set forth in 40 CFR 60, Appendix B and 40 CFR 60, Appendix F, Procedure 1.
 - (2) Continuous operation is defined as the collection of at least one measurement for each successive 15-minute period.
 - (3) The Startup, Shutdown, and Malfunction (SSM) Plan required by Condition D.13.12 (b) shall include procedures for monitoring and recording the following information during times of SO₂ or NO_x CEMS malfunction:
 - (A) When the SO₂ CEMS malfunctions, the Permittee shall monitor and record the Hydro-Sonic™ equivalent pressure drop and scrubber liquid flow rate as required by Condition D.13.15 (a)(3)(C) and (D) and the scrubber liquid pH as required by Condition D.13.15 (a)(5)(C).

- (B) When the NO_x CEMS malfunctions, the Permittee shall monitor and record the combustion chamber temperature, combustion air flow rate, and primary and secondary waste feed rates as required by Condition D.13.15 (a)(1), and assess NO_x emissions, using waste testing, waste shipment and process knowledge, to determine whether the quantity of nitrogen fed into the incinerator during that time could have exceeded the worst case 24-hour daily average nitrogen feed rate of 1,379 pounds per hour that formed the basis of the NO_x BACT limit.

D.13.15 Parametric Continuous Monitoring Systems (CMS) Requirements [40 CFR 63.8(c), 40 CFR 63.1209, and 326 IAC 2-1.1-11]

- (a) The Permittee shall operate the following CMSs in accordance with the quality assurance requirements specified in 40 CFR 63.1209(d) at all times the T149 incinerator is in operation. To satisfy the HWC MACT standards [40 CFR 63.1209(b), (d), (e), (f), and (h)] and the requirements for PSD sources [326 IAC 2-1.1-11], the following parameters shall be monitored at all times the T149 incinerator is in operation. In addition, the operating parameters monitored by the following CMSs shall not exceed the established operating parameter limits at all times incinerators are burning waste:
- (1) Dioxin/Furan CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(k)], the Permittee shall install and operate CMS monitors for the following parameters:
- (A) Combustion Chamber Temperature - Minimum rolling hourly average combustion chamber temperature established from the average temperature measured during the three DRE test runs;
- (B) Flue Gas Flow Rate - Maximum hourly rolling average flue gas flow rate established from the average of the maximum hourly rolling average for each performance test run; and
- (C) Primary Waste Feed Rate – Maximum hourly rolling average primary waste feed rate as established from the average of the maximum hourly rolling averages for each performance test run.
- (D) Secondary Waste Feed Rate - Maximum hourly rolling average secondary waste feed rate as established from the average of the maximum hourly rolling averages for each performance test run.
- (2) DRE Standard CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(j)], the Permittee shall install and operate CMS monitors for those parameters identified in Condition D.13.16 (a)(1).
- (3) Metals CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(l) and (n)], the Permittee shall install and operate CMS monitors for the following parameters:
- (A) Waste Feed Rate - Maximum 12-hour rolling average feed rates for total Hg, semi-volatile metals (cadmium and lead) and low volatile metals (arsenic, beryllium, and chromium) in all waste feedstreams established from the average of the hourly rolling averages for each performance test run and approved extrapolation techniques;
- (B) Scrubber Liquids Solid Content - Maximum 12-hour rolling average solids content of the scrubber liquid using a continuous monitoring system established from the average of the performance test run averages. This parameter does not apply to mercury;

- (C) Hydro-Sonic™ Equivalent Pressure Drop - Minimum hourly rolling average pressure drop across the Hydro-Sonic™ scrubber established from the average of the performance test run averages;
 - (D) Scrubber Liquid Flow Rate - Minimum hourly rolling average scrubber liquid flow rate established from the average of the performance test run averages; and
 - (E) Flue Gas Flow Rate - Maximum hourly rolling average flue gas flow rate, the maximum production rate, or another surrogate parameter for gas residence time, established from the average of the maximum hourly rolling averages for each test run.
- (4) PM CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(m)], the Permittee shall install and operate CMS monitors for the following parameters:
- (A) Those parameters identified in Condition D.13.15(a)(3)(B), (C), and (D); and
 - (B) Ash Feed Rate - Maximum 12-hour average ash feed rate established from the average of the test run averages.
- (5) HCl/Cl₂ and Fluorides CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(o)] and compliance monitoring requirements for PSD sources [326 IAC 2-1.1-11], the Permittee shall install and operate CMS monitors for the following parameters:
- (A) Those parameters identified in Condition D.13.16 (a)(3)(C), (D) and (E).
 - (B) Waste Feed Rate - Maximum 12-hour rolling average feed rates for chlorine (organic and inorganic) in all waste feedstreams established from the average of the performance test run averages. [40 CFR 63.1209(o)(1)]
 - (C) Scrubber Liquid pH - Minimum hourly rolling average scrubber liquid pH established from the average of the performance test run averages. [40 CFR 63.1209(o)(3)(iv)]
- (b) Continuous operation is defined as the collection of at least one measurement for each successive 15-second period, regardless of startup, shutdown and malfunction.
- (c) Pursuant to the HWC MACT standards [40 CFR 63.1209(a)(5)] and the compliance monitoring methods for PSD sources [326 IAC 2-1.1-11], the Permittee may petition the Administrator to use CEMS for compliance monitoring in lieu of compliance with the operating parameter limits established in (a) of this condition.
- (d) If applicable, the Permittee may document compliance using the waiver provisions of 40 CFR 63.1207(m) in lieu of complying with (a) and (c) of this condition.

D.13.16 Fuel Oil Sampling and Analysis for SO₂ [326 IAC 2-1.1-11] [326 IAC 3-7-4]

Pursuant to 326 IAC 3-7-4, the Permittee shall maintain sampling and analysis certification records of the fuel oil sulfur content in accordance with approved ASTM methods.

D.13.17 Minimum Data Requirements – SO₂ and NO_x Compliance [326 IAC 2-1.1-11]

The following defines when CEMS data must be supplemented with data required by condition D.13.14 (b)(3), D.13.18 (a)(13), and D.13.19 (a)(2):

- (a) When the period of incinerator operation (i.e., receiving waste streams) is 4 hours or greater in an operating day and monitoring data are insufficient to constitute a valid hour of data for at least 75 percent of the operating hours, or
- (b) When the period of incinerator operation (i.e., receiving waste streams) 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.
- (c) Monitoring data are insufficient to constitute a valid hour of data if measured values are unavailable for any of the required 15-minute periods within the hour.

(2) Record Keeping and Reporting Requirement [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.13.18 Record keeping Requirements

- (a) The Permittee shall maintain the following records:
 - (1) Notifications, reports, and other documents, such as the Documentation of Compliance, as required by 40 CFR 63.1200, 63.1211(c), and 63.10(b) and (c).
 - (2) All data recorded by continuous monitoring systems (CMS), including continuous emission monitoring systems (CEMS), required by Conditions D.13.14, D.13.15, and D.13.17;
 - (3) Documentation that a change will not adversely affect compliance with the emission standards or operating requirements as required by 40 CFR 63.1206(b)(5)(ii);
 - (4) Records of the estimated hazardous waste residence time as required by 40 CFR 63.1206(b)(11);
 - (5) Plans and procedures as required by Condition D.13.12;
 - (6) Documentation of the results of the investigation, corrective measures taken, and evaluation of excessive exceedances during malfunctions as required by 40 CFR 63.1206(c)(2)(v)(A);
 - (7) Corrective Measures for any AWFCO that results in an exceedance of an applicable emission standard or operating parameter limit as required by 40 CFR 63.1206(c)(3)(v);
 - (8) Documentation and results of the AWFCO operability testing as required by Condition D.13.10 (b) and 40 CFR 63.1206(c)(3)(vii);
 - (9) Corrective measures for any ESV opening as required by 40 CFR 63.1206(c)(4)(iii);

- (10) Daily visual inspection records of the T149 rotary kiln incinerator to ensure the combustion zone is sealed as required by Condition D.13.10 (a) and 40 CFR 63.1206(c)(5);
 - (11) A copy of the Operator Certification and Training Program required by Condition D.13.11 and 40 CFR 63.1206(c)(6); and
 - (12) Documentation of the changes in modes of operation as required by 40 CFR 63.1209(q).
 - (13) For days when condition D.13.17 requires that CEMS data must be supplemented, the documentation of the information required by Condition D.13.14 (b)(3).
- (b) The record keeping and reporting requirements for the LDAR standards are described in Section E.2 of this permit.
- (c) The Permittee shall maintain quarterly records of all fuel oil used in the T149 rotary kiln incinerator on a calendar month average basis, for the following:
- (1) Sulfur content;
 - (2) Heat content;
 - (3) Fuel consumption; and
 - (4) Sulfur dioxide emission rate in pounds per MMBtu.

D.13.19 Reporting Requirements

- (a) Quarterly Reporting Requirements
- (1) The following streamlined quarterly reporting requirements shall satisfy the HWC MACT standards [40 CFR 63.1211], which references the MACT General Provisions [63.7-63.10], PSD BACT requirements [326 IAC 2-1.1-11], and the continuous emissions monitoring requirements [326 IAC 3-5]:
 - (A) Reports shall be submitted within 30 days following the reporting period using the reporting forms located at the end of this permit, or their equivalent;
 - (B) Summary reports of excess emissions, parameter exceedances, and monitor downtime including information specified in 63.10(c)(5)-(c)(13);
 - (C) SSM summary reports for the T49 rotary kiln incinerator control system, including associated CEMS and CMS equipment;
 - (D) Excessive exceedances report, if applicable, as required by 40 CFR 63.1206(c)(3)(vi); and
 - (E) Emergency safety vent opening reports as require by 40 CFR 63.1206(c)(4)(iv); and
 - (2) In addition to the requirements described in (a)(1) of this condition, the Permittee shall report the following information for the NO_x and SO₂ CEMS to satisfy the PSD BACT requirements [326 IAC 2-1.1-11]:

- (A) A list of days when condition D.13.17 requires that CEMS data must be supplemented
 - (B) A detailed report for each day when condition D.13.17 requires that CEMS data must be supplemented that provides:
 - (i) the information required by Condition D.13.14 (b)(3), and
 - (ii) an analysis of whether that information indicates continuous compliance with the limit established in Condition D.13.3 or D.13.4, and if the NOx CEMS malfunctions for greater than six continuous hours, an assessment of NOx emissions using waste testing, waste shipment, and process knowledge whether the quantity of nitrogen fed into the incinerator during that time could have exceeded the worst case 24-hour daily average nitrogen feed rate of 1,379 pounds per hour that formed the basis of the NOx BACT limit.
- (b) Immediate Reporting Requirements
- (1) The Permittee shall submit any revision to the SSM Plan that may significantly increase emissions of hazardous air pollutants to the Administrator for approval within 5 days after making a change to the plan to satisfy the reporting requirements under the HWC MACT standards [40 CFR 63.1206(c)(2)(ii)(C)].
 - (2) The reporting requirements in the NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e)(3)] shall be used to satisfy the reporting requirements under the HWC MACT standards [40 CFR 63.1206(c)(2)] and PSD BACT requirements [326 IAC 2-1.1-11].
 - (A) The Permittee shall report all actions taken during T149 incinerator system SSM event that results in an exceedance of a relevant emission standard when those actions are inconsistent with the procedures specified in the SSM Plan. The immediate report shall be submitted to the agency via a telephone call or facsimile within 2 working days after commencing actions inconsistent with the plan.
 - (B) Within 7 working days after the end of an SSM event where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):
 - (i) Name, title and signature of responsible official certifying accuracy;
 - (ii) Explanation of the circumstances of the event;
 - (iii) Reason for not following the SSM Plan; and
 - (iv) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred.

- (iii) The 24-hour daily average scrubber liquid recirculation flow rate of the caustic scrubbing system shall not be less than the value established from a compliant stack test; and
- (iv) The 24-hour daily average scrubber caustic flow rate of the caustic scrubbing system shall not exceed the value established from a compliant stack test.

The Permittee shall conduct a performance test for HCl before the control efficiency monitoring approach is used to assess compliance with this control efficiency standard.

- (b) RTO Closed Vent System Inspection Standards – The following inspection standards shall apply to the RTO closed vent system (CVS), except as provided in Condition D.14.2 (b):

- (1) The Permittee shall comply with the following closed vent system inspection requirements to satisfy the Pharmaceutical MACT requirements [40 CFR 63.1256(b)(3) and (e)(1) and 63.1258(h)], the Offsite Waste MACT requirements [40 CFR 63.685(g), 63.689(b), 63.690(b), 63.693(b) and (c), and 63.695(c)], and the PSD BACT requirements [326 IAC 2-2-3]:
 - (A) Initial one-time Method 21 inspections shall be conducted on new portions of the RTO closed vent system not operated under negative pressure within 150 days after startup, if not subject to the LDAR requirements established in Section E of this permit.
 - (B) Portions of the CVS that are operated under negative pressure shall be equipped with a pressure gauge or other pressure measurement/detection. The data output must be viewable from a readily accessible location to verify that negative pressure is being maintained when waste fume streams are going to the control system.
 - (C) Annual visual inspections of the RTO closed vent system shall be performed for visible cracks, holes or gaps, loose connections, and broken or missing caps.
 - (D) Repair of any leak detected on the RTO closed vent system shall be initiated no later than 5 calendar days after identification, and completed within 15 days after identification, unless:
 - (i) The repair is technically infeasible without a shutdown of an operation or process; or
 - (ii) It is determined that emissions resulting from immediate repair would be greater than the fugitive emissions likely to result from delay of repair.

Repairs delayed due to either of the causes described in (A) or (B) shall be completed by the end of the next shutdown.

- (2) The Permittee shall monitor each bypass line on the RTO closed vent system to satisfy the Pharmaceutical MACT requirements [40 CFR 63.1252(b), 63.1253(b) and (c), and 63.1258(b)], the Offsite Waste MACT requirements [40 CFR 63.685(g), 63.689(b), 63.690(b), and 63.693(c)], and the PSD BACT requirements [326 IAC 2-2-3] using one of the following methods:

Testing and Monitoring Requirements [326 IAC 2-7-6(1) (6)] [326 IAC 2-7-5(1)]

D.14.4 Continuous Emissions Monitoring System (CEMS) Requirements [40 CFR 60, Appendix B and Appendix F, 40 CFR 60.113b(c), 40 CFR 63.1258(b), 40 CFR 63.693(f), 40 CFR 63.8, 326 IAC 2-1.1-11, 326 IAC 2-7-24, 326 IAC 3-5]

- (a) CO, NO_x, and SO₂ CEMS Operation Requirements –The following requirements shall apply when the RTO is burning waste fume streams:
- (1) The Permittee shall install and operate the CO, NO_x, and SO₂ CEMS in accordance with the quality assurance/quality control (QA/QC) criteria set forth in 40 CFR 60, Appendix B, and 40 CFR 60, Appendix F, Procedure 1.
 - (2) Continuous operation is defined as the collection of at least one measurement for each successive 15-minute period.
 - (3) The Startup, Shutdown, and Malfunction (SSM) Plan required by Condition D.14.3 (b) shall include procedures for monitoring and recording the following information during times of CO or SO₂ or NO_x CEMS malfunction:
 - (A) When the SO₂ CEMS malfunctions, the Permittee shall monitor and record the scrubber liquid recirculation flow rate and caustic flow rate as required by Condition D.14.6(b)(1) (A) and (B) respectively and the scrubber liquid pH as required by Condition D.14.6 (b)(1)(C).
 - (B) When CO CEMS malfunctions, the Permittee shall monitor and record the RTO combustion chamber temperature, and exhaust airflow rate from the RTO as required by D.14.6 (a)(1) and (3), respectively.
 - (C) When the NO_x CEMS malfunctions, the Permittee shall monitor and record the combustion chamber temperature and exhaust airflow rate from the RTO as required by D.14.6 (a) (1) and (3), and assess NO_x emissions, using process knowledge, to determine whether the quantity of nitrogen fed into the RTOs during that time could have exceeded the worst case 24-hour daily average nitrogen feed rate of 1, 085 pounds per hour that formed the basis of the NO_x BACT limit.
- (b) TOC CEMS Operation Requirements –The following requirements shall apply only when burning waste fume streams and represent the streamlined requirements of the Pharmaceutical MACT standards [40 CFR 63.1258(b)], Offsite Waste MACT standards [40 CFR 63.693(f)], NESHAP General Provisions monitoring requirements [40 CFR 63.8(c)], NSPS Volatile Organic Liquid Storage Vessel requirements [40 CFR 60.113b(c)], PSD BACT requirements for VOCs [326 IAC 2-1.1-11], and emission monitoring requirements for MACT and PSD sources [326 IAC 3-5-1(b) and (d)]:
- (1) The Permittee shall install and operate the CEMS in accordance with the QA/QC criteria set forth in 40 CFR 60, Appendix B, 40 CFR 63.1258(b)(1)(x), and 40 CFR 63.8.
 - (2) Continuous operation is defined as the collection of at least one measurement for each successive 15-minute period.
- (c) HCl CEMS Operation Requirements – The following requirements shall apply only when burning waste fume streams and represent streamlined requirements for the Pharmaceutical MACT standards for hydrogen halides and halogens [40 CFR

63.1258(b)], NESHAP General Provisions monitoring requirements [40 CFR 63.8(c)], and PSD BACT requirements for fluorides [326 IAC 2-1.1-11]:

- (1) The Permittee shall install and operate the HCl CEMS in accordance with the performance and QA/QC criteria established in the *Updated Alternative Monitoring Plan for Hydrogen Chloride Continuous Emission Monitoring Systems for the Regenerative Thermal Oxidizers* submitted to EPA OAQPS on August 15, 2003, as allowed by 40 CFR 63.1258(b) and 40 CFR 63.8.
- (2) Continuous operation is defined as the collection of at least one measurement for each successive 15-minute period.
- (d) CEMS Standard Operating Procedures (SOP) - The Permittee shall prepare and implement an SOP that provides step-by-step procedures and operations in accordance with 326 IAC 3-5-4(a) (9) – Preventive maintenance procedures and corrective maintenance procedures that include those procedures taken to ensure continuous operation and to minimize malfunctions.

D.14.5 Performance Testing Requirements [40 CFR 60.113b(c), 40 CFR 63.7, 40 CFR 63.1257(b), (c), and (d) and 63.1258(b)(3), 40 CFR 63.693(f), 326 IAC 3-6-3(c), 326 IAC 2-7-24, and 326 IAC 2-1.1-11]

(a) Initial Comprehensive Performance Test Requirements:

- (1) VOC/VOHAP – When applying the control efficiency standard, the following streamlined requirements shall apply only when burning waste fume streams to satisfy the Pharmaceutical MACT standards [40 CFR 63.1257(b), (c), and (d) and 63.1258(b)], Offsite Waste MACT standards [40 CFR 63.693(f)], Volatile Organic Liquid Storage Vessel requirements [40 CFR 60.113b(c)], PSD BACT requirements [326 IAC 2-1.1-11], and emission testing requirements for MACT sources [326 IAC 3-6-3(c)]:
 - (A) Prior to applying the control efficiency emission standard, the Permittee shall conduct an initial performance test in accordance with the methods set forth in 40 CFR 63.1257.
 - (B) The Permittee shall submit a notification of the performance test and a site-specific test plan at least 60 days in advance of the intended performance test date.
 - (C) The operating parameters defined in Condition D.14.1 (a)(4)(B) shall be monitored during the performance test to establish the 24-hour daily average parametric limits, according to the requirements of 40 CFR 63.1258(b)(3).
 - (D) The Permittee shall submit the performance test reports, and upon request, the CMS performance evaluation, within 45 days following the test. The Permittee is allowed an extension if a reasonable explanation is provided within 40 days following the test.
- (2) Hydrogen Halide/Halogen – When applying the control efficiency standard, the following requirements shall apply only when burning waste fume streams to satisfy the Pharmaceutical MACT standards [40 CFR 63.1258(b)] and the PSD BACT requirements for fluorides [326 IAC 2-1.1-11]:

- (A) Scrubber liquid pH monitor;
 - (B) Scrubber liquid recirculation flow rate monitor; and
 - (C) Scrubber caustic flow rate monitor.
- (2) Continuous operation is defined as the collection of at least one measurement for each successive 15-minute period.
- (c) CMS Standard Operating Procedure (SOP) – The Permittee shall prepare and implement a SOP for the CMS units in accordance with 40 CFR 63.8(d).

D.14.7 Excursions [40 CFR 63.1258(b)(6), 40 CFR 63.695(e)(4)]

- (a) Pursuant to the Pharmaceutical MACT standards [40 CFR 63.1258(b)(7)] and the Offsite Waste MACT [40 CFR 63.695(e)(4)], excursions are defined as follows and apply to the CEMS and CMS required by Conditions D.14.4 (b) and (c), and D.14.6, respectively:
- (1) When the period of control device operation (i.e., receiving waste fume streams) is 4 hours or greater in an operating day and monitoring data are insufficient to constitute a valid hour of data for at least 75 percent of the operating hours.
 - (2) When the period of control device operation (i.e., receiving waste fume streams) 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.
- (b) A valid hour requires at least one data point for each 15-minute period in the operating hour.

D.14.8 Minimum Data Requirements – SO₂, CO, and NO_x Compliance [326 IAC 2-1.1-11]

The following defines when CEMS data must be supplemented with data required by conditions D.14.4 (a)(3), D.14.9 (a)(1)(L), and D.14.9 (b)(2):

- (a) When the period of RTO operation (i.e., receiving waste streams) is 4 hours or greater in an operating day and monitoring data are insufficient to constitute a valid hour of data for at least 75 percent of the operating hours, or
- (b) When the period of RTO operation (i.e., receiving waste streams) 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.
- (c) Monitoring data are insufficient to constitute a valid hour of data if measured values are unavailable for any of the required 15-minute periods within the hour.

Record Keeping and Reporting Requirement [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.14.9 Record Keeping and Reporting Requirements

- (a) Record Keeping Requirements

The Permittee shall maintain the following records:

- (1) Control Device (RTO) Records – The following streamlined record keeping requirements satisfy the Pharmaceutical MACT requirements [40 CFR 63.1259], the Offsite Waste MACT standards [40 CFR 63.696], Volatile Organic Liquid Storage Vessel requirements [40 CFR 60.115b], PSD BACT requirements [326 IAC 2-1.1-11 and 326 IAC 2-7-5(3)], and the continuous emission monitoring and performance testing requirements [326 IAC 3-5 and 3-6]:
 - (A) Log of the operating scenario (i.e., concentration standard or control efficiency standard) applied to satisfy the VOC/VOHAP and hydrogen halide and halogen emission standards required by Conditions D.14.1 (a)(4) and D.14.1 (a)(5) in an On-Site Implementation Log (OSIL);
 - (B) Records of the current and superseded versions of SSM Plan;
 - (C) Description of worst-case operating conditions, if complying with control efficiency standard;
 - (D) Results of control device performance tests and CMS performance evaluations, if complying with control efficiency standard;
 - (E) Records of all required CMS and CEMS data;
 - (F) Records of each CMS and CEMS calibration checks;
 - (G) Maintenance records for each control device, CMS, and CEMS;
 - (H) Occurrence/duration records of each control device malfunction, CMS malfunction, and CEMS malfunction;
 - (I) Information to demonstrate conformance with each SSM is consistent with procedures in the SSM Plan;
 - (J) Records of actions taken during each SSM when different from SSM Plan; and
 - (K) Record of the current standard operating procedure (SOP) for the RTO CEMS and CMS units.
 - (L) For days when condition D.14.8 requires that CEMS data must be supplemented, the documentation of the information required by Condition D.14.4 (a)(3).
- (2) Closed Vent System (RTO CVS) Records – The following streamlined record keeping requirements satisfy the Pharmaceutical MACT requirements [40 CFR 63.1259], the Offsite Waste MACT standards [40 CFR 63.696], Volatile Organic Liquid Storage Vessel requirements [40 CFR 60.115b], PSD BACT requirements [326 IAC 2-1.1-11 and 326 IAC 2-7-5(3)], and the continuous emission monitoring and performance testing requirements [326 IAC 3-5 and 3-6]:
 - (A) Hourly records of bypass flow indicator operating status and the time and duration of all diversions detected by the bypass flow indicator, if complying via this method;

daily average nitrogen feed rate of 1,085 pounds per hour that formed the basis of the NO_x BACT limit.

(c) Immediate Reporting Requirements

The reporting requirements in the NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e)(3)] shall be used to satisfy the reporting requirements under the Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)], Offsite Waste MACT standards [40 CFR 63.697(b)(3)], and PSD BACT requirements [326 IAC 2-1.1-11].

- (1) The Permittee shall report all actions taken during an RTO system SSM event that results in an exceedance of a relevant emission standard when those actions are inconsistent with the procedures specified in the SSM Plan. The immediate report shall be submitted to the agency via a telephone call or facsimile within 2 working days after commencing actions inconsistent with the plan.
- (2) Within 7 working days after the end of an SSM event where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):
 - (A) Name, title and signature of responsible official certifying accuracy;
 - (B) Explanation of the circumstances of the event;
 - (C) Reason for not following the SSM Plan; and
 - (D) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred.

Modifications and Construction Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12 and 326 IAC 2-2]

D.14.10 Modifications and Construction: Advance approval of permit conditions

- (a) The Permittee may modify any existing emission units listed in this section of the permit without obtaining a source modification approval (otherwise required by 326 IAC 2-7-10.5), a Title V permit modification (otherwise required by 326 IAC 2-7-12), or a Prevention of Significant Deterioration permit (otherwise required by 326 IAC 2-2), provided the modified emission units are subject to the same applicable requirements listed in this D section, and the Permittee shall comply with the Change Management and Flexible Permit provisions in Section F.1 of this permit.
- (b) The Permittee may construct and install new emission units comparable in function to the emission units listed in this D section without obtaining a source modification approval (otherwise required by 326 IAC 2-7-10.5), a Title V permit modification (otherwise required by 326 IAC 2-7-12), or a Prevention of Significant Deterioration permit (otherwise required by 326 IAC 2-2), provided the new emission units are subject to the same applicable requirements listed in this D section, and the Permittee shall comply with the Change Management and Flexible Permit provisions in Section F.1 of this permit.

SECTION D.15 BPM CONTROL SYSTEMS – T79 FUME INCINERATOR SYSTEM OPERATIONS

Facility Description [326 IAC 2-7-5(15)]

The information describing the processes contained in the following facility description is descriptive information and does not constitute enforceable conditions:

(a) The following emissions units are subject to applicable requirements described in this D section:

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
T79-INC309	Fume Incinerator	T79-INC309	7.6 MMBtu/hr	Scrubber (313)
T79-INC310	Fume Incinerator	T79-INC310	7.6 MMBtu/hr	Scrubber (314)

(b) The following emission units are not subject to applicable requirements described in this D section:

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
T79-COL304	Air Stripper Column	T79 Incinerator	4,400 gallons	T79 Incinerator
T79-COL305	Air Stripper Column	T79 Incinerator	4,400 gallons	T79 Incinerator

The T79 control system consists of two fume incinerators, identified as 309 and 310, each equipped with caustic scrubbing systems, and each exhausting to individual stacks.

The closed vent system (CVS) associated with the T79 control system begins at the outlet of the production building roof fans exhausting to the T79 fume transport system and at the outlet side of the tank conservation vents of those tank modules exhausting to the T79 fume transport system and ends at the entrance of the T79 control system.

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.15.1 T79 Control Device and Closed Vent System Standards [40 CFR 63.1253(b), (c), and (d), 63.1254(a) and (c), 63.1256(b), (e), and (h), 63.1258(b), 40 CFR 63.685(c) and (d), 63.689(b), 63.690(b), 63.693(f), 40 CFR 60.112b(a) and 60.113b(c), 326 IAC 2-2-3, and 326 IAC 8-5-3(b)]

(a) T79 Control Device Standards – The T79 control device standards shall apply at all times the unit is burning waste fume streams, except as provided in Condition D.15.2 (a):

(1) VOC/VOHAP Emission Standards – In order to satisfy the Pharmaceutical MACT requirements [40 CFR 63.1253(b), (c), and (d), 63.1254(a) and (c), and 63.1256(b), (e) and (h), and 63.1258(b)], the Offsite Waste and Recovery Operations MACT requirements [40 CFR 63.685(c) and (d), 63.689(b), 63.690(b), and 63.693(f)], the PSD BACT requirements [326 IAC 2-2-3], the Synthetic Pharmaceutical RACT requirements [326 IAC 8-5-3(b)], and the New Source Performance Standards for Volatile Organic Liquid Storage Vessel requirements [40 CFR 60.112b(a) and 60.113b(c)], the Permittee shall meet the following streamlined VOC/VOHAP emission standards:

- (A) The VOC/VOHAP emissions shall be reduced by a control efficiency of 98% or more at the outlet of the T79 control system;
- (B) The T79 combustion chamber shall maintain a minimum 24-hour daily average temperature established from a compliant stack test.

- (2) Hydrogen halide and halogen Emission Standards – In order to satisfy the Pharmaceutical MACT requirements [40 CFR 63.1253(b), (c), and (d), 63.1254(a) and (c), 63.1256(b), (e) and (h), and 63.1258(b)] and PSD BACT requirements for fluorides [326 IAC 2-2-3], the Permittee shall meet the following streamlined hydrogen halide and halogen (including hydrogen fluoride) emission standards:
- (C) The HCl/Cl₂ emissions shall be reduced by a control efficiency of 98% or more at the outlet of the T79 system; and
 - (B) The T79 caustic scrubber system shall maintain the following parametric conditions established from a compliant stack test:
 - (i) Minimum 24-hour daily average scrubber liquid pH;
 - (ii) Minimum 24-hour daily average scrubber liquid recirculation flow rate; and
 - (iii) Maximum 24-hour daily average scrubber caustic flow rate.
- (b) T79 Closed Vent System Inspection Standards – The following inspection standards shall apply to the T79 CVS, except as provided in Condition D.15.2 (b):
- (1) The Permittee shall comply with the following CVS inspection requirements to satisfy the Pharmaceutical MACT requirements [40 CFR 63.1256(b)(3) and (e)(1) and 63.1258(h)], the Offsite Waste MACT requirements [40 CFR 63.685(g), 63.689(b), 63.690(b), 63.693(b) and (c), and 63.695(c)], and the PSD BACT requirements [326 IAC 2-2-3]:
- (A) Conduct an initial one-time Method 21 inspection on new portions of the T79 CVS not operated under negative pressure and not subject to LDAR within 150 days after startup. Portions of the T79 CVS that are operated under negative pressure shall be equipped with a pressure gauge or other pressure measurement/detection. The data output from the must be viewable from a readily accessible location to verify that negative pressure is being maintained when waste fume streams are going to the control system.
 - (B) Perform annual visual inspections of the T79 CVS for visible cracks, holes or gaps, loose connections, and broken or missing caps.
 - (C) Initiate repair of any leak detected on the T79 CVS no later than 5 calendar days after identification, and complete the repair within 15 days after identification, unless:
 - (i) The repair is technically infeasible without a shutdown of an operation or process; or
 - (ii) It is determined that emissions resulting from immediate repair would be greater than the fugitive emissions likely to result from delay of repair.

Repairs delayed due to either of the causes described in (A) or (B) shall be completed by the end of the next shutdown.

- (1) When the period of control device operation (i.e., receiving waste fume streams) is 4 hours or greater in an operating day and monitoring data are insufficient to constitute a valid hour of data for at least 75 percent of the operating hours.
 - (2) When the period of control device operation (i.e., receiving waste fume streams) 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.
- (b) A valid hour requires at least one data point for each 15-minute period in the operating hour.

Record Keeping and Reporting Requirement [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.15.7 Record Keeping and Reporting Requirements

(a) Record Keeping Requirements

The Permittee shall maintain the following records:

- (1) Control Device (T79) Records – The Pharmaceutical MACT record keeping requirements [40 CFR 63.1259] shall serve as the streamlined requirement that satisfies the Offsite Waste MACT standards [40 CFR 63.696], Volatile Organic Liquid Storage Vessel requirements [40 CFR 60.115b], PSD BACT requirements [326 IAC 2-1.1-11], and continuous emission monitoring and performance testing requirements [326 IAC 3-5 and 3-6]:
 - (A) Records of the current and superseded versions of SSM Plan;
 - (B) Description of worst-case operating conditions;
 - (C) Results of control device performance tests and CMS performance evaluations;
 - (D) Records of all required CMS data;
 - (E) Records of each CMS calibration checks;
 - (F) Maintenance records for each control device and CMSs;
 - (G) Occurrence/duration records of each control device malfunction and CMS malfunction;
 - (H) Information to demonstrate conformance with each SSM are consistent with procedures in the SSM Plan;
 - (I) Records of actions taken during each SSM when different from SSM Plan; and
 - (J) Record of the current standard operating procedure (SOP) for the T79 CMS units.
- (2) Closed Vent System (T79 CVS) Records – The Pharmaceutical MACT record keeping requirements [40 CFR 63.1259] shall serve as the streamlined requirement that satisfies the Offsite Waste MACT standards [40 CFR 63.696],

- (iii) Record of reason for any delay of repair, name of person responsible for decision, expected date of repair, dates of shutdowns when repair is made and date of successful repair of leak.

(b) Quarterly Periodic Reporting Requirements

- (1) The following Pharmaceutical MACT reporting requirements [40 CFR 63.1260(g)], which references the MACT General Provisions [40 CFR 63.7 – 63.10], shall serve as the streamlined reporting requirements that satisfy the Offsite Waste MACT standards [40 CFR 63.697], Volatile Organic Liquid Storage Vessel requirements [40 CFR 60.115b], PSD BACT requirements [326 IAC 2-1.1-11], and continuous emission monitoring requirements [326 IAC 3-5]:
 - (A) Reports shall be submitted within 30 days following the reporting period using the reporting forms located at the end of this permit, or their equivalent;
 - (B) If total duration of excess emissions, parameter exceedances, or excursions is 1% or greater of total operating time or total CMS downtime is greater than 5% for reporting period, include:
 - (i) 15-minute data and daily averages for all operating days out of range;
 - (ii) duration of excursions; and
 - (iii) operating logs and scenarios for all operating days out of range;
 - (C) Summary reports of excess emissions, parameter exceedances, and monitor downtime including information specified in 63.10(c)(5)-(c)(13);
 - (D) Report, when applicable, no excess emissions, no exceedances, no excursions, and no CMS has been inoperative, out of control, repaired or adjusted;
 - (E) CVS bypass lines with flow indicator: report all periods when vent stream is diverted from control device through bypass line;
 - (F) CVS with bypass lines without flow indicator: report periods which seal mechanism is broken, position has changed or key to unlock bypass line valve was checked out;
 - (G) Report each new operating scenario that has been operated since last report;
 - (H) SSM summary reports for the T79 control system, including associated CEMS and CMS equipment.

(c) Immediate Reporting Requirements

SECTION D.16 BPM SUPPORT OPERATIONS – RESEARCH AND DEVELOPMENT OPERATIONS

Facility Description [326 IAC 2-7-5(15)]

The information describing the processes contained in the facility description boxes is descriptive information and does not constitute enforceable conditions:

- (a) The emission units listed below are insignificant activities as defined in 326 IAC 2-7-1(21), but are subject to applicable requirements described or referred to in this D section.

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
<i>Building T71:</i>				
31A985DUCHT4	Charge Tank	Atmosphere	10 gal	None
TI0031000MS001	Slurry Mill	Atmosphere	NA	None
T46109	Slurry Mill	Atmosphere	NA	None
T69126	Centrifuge	Atmosphere	5 liters	None
T63150	Plate Filter	Atmosphere	0.15 m ³	None
T44224	Filter Dryer	Atmosphere	NA	None
T71-TK5700	Waste Tank	Atmosphere	1000 gallons	None
T71-TK9601	Portable Process Tank	Atmosphere	50 gallons	None
T71-TK9602	Portable Process Tank	Atmosphere	50 gallons	None
T71-TK9605	Portable Process Tank	Atmosphere	30 gallons	None
T71-TK9606	Portable Process Tank	Atmosphere	50 gallons	None
T71-TK9609	Portable Process Tank	Atmosphere	30 gallons	None
T71-TK9610	Portable Process Tank	Atmosphere	50 gallons	None
T71-TK9611	Portable Process Tank	Atmosphere	50 gallons	None
T71-TK9612	Portable Process Tank	Atmosphere	50 gallons	None
T71-TK9613	Condensate Collection Tank	Atmosphere	10 gallons	None
T71-TK9614	Condensate Collection Tank	Atmosphere	10 gallons	None
T71-TK9615	Condensate Collection Tank	Atmosphere	10 gallons	None
T71-TK9616	Condensate Collection Tank	Atmosphere	10 gallons	None
T71-TK9617	Condensate Collection Tank	Atmosphere	20 gallons	None
T71-TK9623	Charge Tank	Atmosphere	10 gallons	None
T71-TK9624	Charge Tank	Atmosphere	10 gallons	None
T71-TK9625	Charge Tank	Atmosphere	10 gallons	None
T71-TK9626	Charge Tank	Atmosphere	10 gallons	None
T71-RVD9801	Rotary Vacuum Dryer	Atmosphere	3 cubic feet	None
T71-FLT9901	Single-Plate Filter	Atmosphere	N/A	None
T71-FLT9902	Multi-Plate Filter	Atmosphere	N/A	None

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.16.1 Non-Applicability Determination [40 CFR 63, Subpart GGG and 326 IAC 8-5-3]

- (a) The emission units listed above are not subject to the requirements of 40 CFR 63, Subpart GGG (Pharmaceutical MACT Standards) because these operations are research and development facilities that are exempt pursuant to 40 CFR 63.1250(d) and 63.1251.
- (b) The emission units listed above are not subject to the requirements of 326 IAC 8-5-3 because the potential to emit VOC of any facility is less than 15 pounds per day.

D.16.2 Emission Standards [CP157-4148]

The sulfur dioxide (SO₂) emissions from the emission units in Building T71 shall not exceed 16.7 tons per year to avoid the requirements of 326 IAC 2-2 (Prevention of Significant Deterioration). This emission limit correlates to a maximum sulfur containing compound (SCC) usage rate of 521 lbmoles equivalent per twelve consecutive month period using the following equivalency:

$$1 \text{ lbmole SCC equivalent} = 1 \text{ lb mole SO}_2$$

D.16.3 Leak Detection and Repair (LDAR) for Fugitive Emissions [CP157-4148 (Revised by this permit)]

The LDAR standards that apply to components associated with the process operations in Building T71 are described in Section E.1 of this permit and the waste tank in T71 are described in Section E.2 of this permit.

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3) and 326 IAC 2-7-19]

D.16.4 Record Keeping and Reporting Requirements [CP157-4148 (Revised by this permit)]

- (a) The Permittee shall maintain SCC usage records on a calendar month basis to document compliance with the limitations established in Condition D.16.2.
- (b) The Permittee shall submit quarterly summary reports of the monthly SCC usage records.
- (c) The record keeping and reporting requirements for the LDAR standards are described in Sections E.1 and E.2 of this permit.

Modifications and Construction Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12 and 326 IAC 2-2]

D.16.5 Modifications and Construction: Advance Approval of Permit Conditions Requirements

The emission units described in this D section are not subject to the advance approval permit conditions.

- (c) Transfer of affected wastewater streams for offsite treatment – The performance standards for offsite disposal of affected wastewater are described in Section D.19 of this permit.

Testing and Monitoring Requirements [326 IAC 2-7-6(1) (6)] [326 IAC 2-7-5(1)]

D.17.5 Testing and Monitoring Requirements

The requirements for the storage, transfer and treatment of the affected wastewater are described in Sections D.8, D.10, D.11, D.12, D.13, D.18 and D.19 of this permit.

Record Keeping and Reporting Requirements

D.17.6 Record keeping and Reporting Requirements

- (a) The following record keeping and reporting requirements apply to the maintenance wastewater plan required under 40 CFR 63.1256(a)(4)(iv) and 63.6(e)(3):
 - (1) Maintain record of original maintenance wastewater plan for the life of the affected source or until the affected source is no longer subject to the provisions of this rule;
 - (2) Maintain updated versions of the maintenance wastewater plan, as necessary;
 - (3) Maintain records for each instance the plan was implemented and whether the plan was followed; and
 - (4) Record and report all instances within 2 working days after commencing actions inconsistent with the SSM plan followed by a written letter within 7 working days after the end of the event.
- (b) Each POD as defined in Condition D.17.1 (b) shall be identified and its wastewater HAP concentration documented in the On-Site Implementation Log (OSIL) as required by 40 CFR 63.1259(b)(6) and 40 CFR 63.1251 – Operating Scenario.

- (2) Wastewater streams containing combined partially soluble HAPs greater than 1300 ppmw.
- (b) Pursuant to the Pharmaceutical MACT standards for wastewater [40 CFR 63.1251 and 40 CFR 63.1256(g)(10)], the Permittee shall maintain a minimum mixed liquor volatile suspended solids (biomass) concentration of 1 kg/cubic meter (942 mg/l) of the mixed liquor in the enhanced biological treatment system.

Testing and Monitoring Requirements [326 IAC 2-7-6(1) (6)] [326 IAC 2-7-5(1)]

D.18.2 Sampling and Analysis Requirements [40 CFR 63.1258(g)(2)]

Pursuant to the Pharmaceutical MACT standards [40 CFR 63.1258(g)(2)], the Permittee shall measure the following parameters for each enhanced biological treatment unit in use at least once per week and record the weekly average data:

- (a) Total suspended solids (TSS), chemical oxygen demand (COD); and
- (b) Biomass (VSS) concentration.

Recordkeeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.18.3 Record Keeping and Reporting Requirements

- (a) The Permittee shall maintain the sampling and analysis records required by Condition D.18.2 in accordance with the Pharmaceutical MACT record keeping requirements [40 CFR 63.1259(b)(1)].

Modifications and Construction Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12 and 326 IAC 2-2]

D.18.4 Modifications and Construction: Advance Approval of Permit Conditions Requirements

The emission units described in this D section are not subject to the advance approval permit conditions.

SECTION D.19 BPM SUPPORT OPERATIONS – TRANSFER OF AFFECTED WASTEWATER FOR OFFSITE TREATMENT CONDITIONS

Facility Description [326 IAC 2-7-5(15)]

The information in this facility description section does not constitute enforceable conditions. The transfer of affected wastewater for offsite treatment relates to either of the following situations:

- (a) Shipment of affected wastewater generated onsite to an offsite treatment facility; or
- (b) Receipt of an offsite affected wastewater to be treated onsite.

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.19.1 Shipment of Affected Wastewater to an Offsite Treatment Facility [40 CFR 63.1256(a)(5)]

- (a) Pursuant to the Pharmaceutical MACT standards for wastewater [40 CFR 63.1256(a)(5)(i)(B)], the Permittee shall include a notice with each shipment of affected wastewater or residual removed from affected wastewater to an offsite treatment facility. The notice shall state that the affected wastewater or residual contains organic HAP must be treated in accordance with the treatment requirements of the Pharmaceutical MACT standards. When the transport is continuous or ongoing, the notice shall be submitted to the treatment operator initially and whenever there is a change in the required treatment.
- (b) Pursuant to the Pharmaceutical MACT standards for wastewater [40 CFR 63.1256(a)(5)(ii)], the Permittee shall not transfer the affected wastewater or residual unless the transferee has submitted to the EPA a written certification that the transferee will manage and treat any affected wastewater or residual removed from affected wastewater received from a source subject to the requirements of this subpart in accordance with the treatment requirements of the Pharmaceutical MACT standards.

D.19.2 Receipt of Offsite Affected Wastewater for Onsite Treatment [40 CFR 63.1256(a)(5)]

- (a) Where the Permittee is the transferee, the Permittee shall submit to EPA a written certification that it will manage and treat any affected wastewater or residual removed from affected wastewater received from a source subject to the requirements of this subpart in accordance with the treatment requirements of the Pharmaceutical MACT standards for wastewater [40 CFR 63.1256(a)(5)(ii) and (iv)].
- (b) The Permittee may revoke its certification as allowed under 40 CFR 63.1256(a)(5)(iii).

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.19.3 Record keeping and Reporting Requirements

- (a) The Permittee shall keep records of all notifications required by Conditions D.19.1 and D.19.2 in accordance with 40 CFR 63.1259(g).

Modifications and Construction Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12 and 326 IAC 2-2]

D.19.4 Modifications and Construction: Advance Approval of Permit Conditions

The emission units described in this D section are not subject to the advance approval permit conditions.

SECTION E.1 LEAK DETECTION AND REPAIR (LDAR) CONDITIONS FOR BPM PROCESS SYSTEM COMPONENTS

Facility Description [326 IAC 2-7-5(15)]

The following facility description of LDAR components subject to this permit section is descriptive information and does not constitute enforceable conditions:

- (a) BPM process systems consist of process operations and non-waste storage serving bulk pharmaceutical manufacturing operations. LDAR applies to BPM process system components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves and lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems intended to operate in volatile organic hazardous air pollutant and/or volatile organic compound (VOHAP/VOC) service for 300 hours or more during the calendar year. In VOHAP/VOC service means that a piece or equipment either contains or contacts a fluid (liquid or gas) that is at least 5 percent by weight VOHAP/VOC.
- (b) LDAR BPM process system components are located from the point at which raw material serving the BPM operations is unloaded at the plant site to the point of determination (POD) or point where waste exits the pharmaceutical manufacturing process unit (PMPU). The closed-vent systems not used to control emissions from LDAR components are not subject to the conditions of this section, but instead are subject to the conditions in Sections D.14, and D.15, as applicable.

Emission Limitations and Standards [326 IAC 2-7-5(1)]

E.1.1 LDAR Standards for BPM Process System Components [40 CFR 63.1255, 40 CFR 61 Subpart I, 326 IAC 8-5-3(b)(6), 326 IAC 2-2, CP157-4148 (Revised by this permit)]

Except as provided in Condition E.1.2, the following LDAR standards satisfy the requirements of the Pharmaceutical Production MACT (Pharma MACT) standards [40 CFR 63.1255], Best Available Control Technology (BACT) requirements [326 IAC 2-2-3], Reasonably Available Control Technology (RACT) LDAR requirements for synthesized pharmaceutical manufacturing operations [326 IAC 8-5-3(b)(6)], and construction permit [CP157-4148] requirements for LDAR components associated with the research and development operations in Building T71:

- (a) The Permittee shall implement the LDAR program under 40 CFR 63.1255 for all BPM process system component types listed in item (a) of the facility description section from the point at which raw material serving BPM is unloaded at the plant site to the point of determination (POD) or point where waste exits the pharmaceutical manufacturing process unit (PMPU).
- (b) The Permittee shall conduct an initial monitoring survey that includes the total number of each existing BPM process component type and initial monitoring as follows:
 - (1) Existing BPM process system components in VOHAP service shall be initially monitored between October 21, 2002 and October 21, 2003.
 - (2) Existing BPM process system components in VOC service shall be initially monitored for purposes of this permit between October 21, 2002 and October 21, 2003.
 - (3) Subsequent monitoring periods shall be calendar periods, beginning October 22, 2003.

- (C) A rupture disk satisfies conditions E.1.1 (d)(3)(A) and (B) without monitoring if it is replaced within 5 calendar days after each pressure release, except if delay of repair applies.
 - (D) Any pressure relief device satisfies conditions E.1.1 (d)(3)(i) and (ii) without monitoring if it is routed to a process or fuel gas system or equipped with a closed-vent system limitable of capturing and transporting leakage from the pressure relief device to a control device.
- (4) Sampling connection systems shall be operated in accordance with the standard at 63.1255(b)(3), which requires compliance with 63.166. This section provides, generally and in part:
- (A) Gases displaced during filling of a sample container are not required to be captured or collected.
 - (B) Each sampling connection system shall be equipped with a closed-purge, closed-loop or closed-vent system, which shall:
 - (i) Return the purged process fluid directly to the process line;
 - (ii) Collect and recycle the purged process fluid to a process;
 - (iii) Be designed and operated to capture and transport the purged process fluid to a control device;
 - (iv) Collect, store, and transport the purged process fluid to a SOCFI/HON waste management unit (40 CFR Part 63, Subpart G) operated according to the provisions which apply to Group 1 wastewater streams, or to a treatment, storage, or disposal facility subject to regulation under 40 CFR Part 262, 264, 265 or 266 (a RCRA unit), or, if the purged fluids are not hazardous waste, to a facility with an appropriate State permit to manage municipal or industrial solid waste; or
 - (v) In-situ sampling systems, and sampling systems without purges, have no other obligations under this section.
- (5) Open-ended valves or lines shall be operated in accordance with the standard at 63.1255(d). This section provides, generally and in part:
- (A) Each open-ended valve and line shall be equipped with a cap, blind flange, plug or second valve, which shall seal the open end at all times except when operations require fluid flow through the open-ended valve or line, or during maintenance or repair.
 - (B) The cap, blind flange, plug or second valve shall be in place and closed within one hour of cessation of operations requiring fluid flow through the open-ended valve or line, or maintenance or repair. No records are required to document compliance with this provision.
 - (C) If a second valve is used, the valve on the process fluid end shall be closed before the other valve is closed.
 - (D) If a double block and bleed arrangement is used, the bleed valve may remain open during operations requiring venting the line between the

- block valves, but shall be closed otherwise in accordance with E.1.1 (d)(5)(B).
- (E) Open-ended valves and lines in an emergency shutdown system which are designed to open automatically in the event of a process upset are not required to comply with E.1.1 (d)(5)(A) through (C).
 - (F) Open-ended valves or lines containing materials, which would autocatalytically polymerize are not required to comply with E.1.1 (d)(5)(A) through (C).
 - (G) Open-ended valves or lines containing materials which could cause a serious safety hazard if capped or equipped with a double block and bleed system are not required to comply with E.1.1 (d)(5)(A) through (C).
- (6) Valves in gas/vapor and light liquid service shall be operated in accordance with the standard at 63.1255(e). This section provides, generally and in part:
- (A) Valves shall undergo periodic monitoring.
 - (B) Each monitoring period shall be determined by a calculation based on the percentage of leaking valves measured in prior monitoring periods.
 - (C) Valves may be placed into subgroups for periodic monitoring purposes, and may be reassigned among subgroups.
 - (D) After a leaking valve is repaired, it shall be monitored again within 3 months after repair. This monitoring may be considered part of the periodic monitoring, or may, if conducted prior to the periodic monitoring, be considered separately from the periodic monitoring data in determining percent leaking valves for the monitoring period.
- (7) Closed-vent systems and control devices used to comply with LDAR shall be operated in accordance with the standard at 63.1255(b)(4)(ii). Operation of these systems, in conformance with Sections D.9, D.14, or D.15, shall constitute compliance with this requirements;
- (8) Agitators in gas/vapor and light liquid service shall be operated in accordance with the standard at 63.1255(c); This section provides, generally and in part:
- (A) Single seal agitators shall undergo periodic monitoring and visual inspections.
 - (B) Dual mechanical seal agitators shall meet design, operation, inspection, and alarm requirements.
 - (C) Agitators designed without a shaft penetrating the pump housing are not required to be inspected or monitored.
 - (D) Agitators equipped with a closed-vent system limitable of capturing and transporting any leakage from the seals back to the process or to a control device are not required to be inspected or monitored.
- (9) Pumps, valves, connectors, and agitators in heavy liquid service, instrumentation systems, and pressure relief devices in liquid service shall be operated in

accordance with the standard at 63.1255(b)(3), which requires compliance with 63.169. This section provides, generally and in part:

- (A) If a component presents visual, audible, or olfactory evidence of a leak, the leak shall be deemed repaired without monitoring if the component meets any of the following:
 - (i) The visual, audible, or olfactory evidence has been eliminated;
 - (ii) No bubbles are observed at potential leak sites during a leak check using soap solutions; or
 - (iii) The system will hold a test pressure.
 - (B) If there is visual, audible, or olfactory evidence of a leak at one of these components, and the leak is not repaired without monitoring, the component shall be monitored within 5 calendar days to confirm whether a leak is in fact present.
- (10) Connectors in gas/vapor and light liquid service shall be operated in accordance with the standard at 63.1255(b)(4)(iii). This section provides, generally and in part:
- (A) Connectors shall undergo periodic monitoring.
 - (B) Each monitoring period shall be determined by a calculation based on the percentage of leaking connectors measured in prior monitoring periods.
 - (C) Nonrepairable connectors may not be counted in monitoring period calculations. C_{AN} shall be set to zero in the percent leaking connector calculation.
 - (D) Inaccessible, ceramic, or ceramic-lined connectors are not required to be monitored, and are exempt from record keeping and reporting. If they are observed to be leaking, they shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except if delay of repair applies. There is no obligation to make a first attempt at repair within 5 days.
 - (E) Connectors that are not required to be monitored are not included in the calculation of the percentage of leaking connectors.
 - (F) An optional credit may be taken for removed connectors where the weld meets certain testing requirements.
- (e) As an alternative to complying with E.1.1(d), except E.1.1(d)(7), BPM process system components may comply with 63.1255(b)(4)(iv), which incorporates by reference 63.178(b) (Alternative Means of Emission Limitation: Batch Processes) as follows:
- (1) Components shall be pressure tested each time the equipment is reconfigured for production of a different product or intermediate or at least once per calendar year, whichever is more stringent. The pressure testing shall be conducted in accordance with 63.180(f) or (g); and
 - (2) Components must comply with the leak repair requirements before startup of a process as described in 63.178(b)(4).

E.1.2 Exceptions to LDAR Standards for BPM Process System Components

- (a) The following facilities are not subject to the LDAR standards under this section of the permit:
- (1) Research and development facilities, activities and equipment (40 CFR 63.1250(d)) not subject to BACT or construction permit requirements;
 - (2) Condition E.1.2(a)(2) was deleted pursuant to Administrative Permit Amendment 157-20003-00006.;
 - (3) Utilities and non-process lines (40 CFR 63.1255(a)(5));
 - (4) Bench scale processes (40 CFR 63.1255(a)(6));
 - (5) Equipment in vacuum service (40 CFR 63.1255(a)(8));
 - (6) Waste components (covered by Section E.2 of this permit).
 - (7) Fermented Products operations;
 - (8) Equipment in VOHAP/VOC service but that is in such service less than 300 hours per calendar year (40 CFR 63.1255(a)(9));
 - (9) Closed loop heat exchange systems (40 CFR 63.1255(a)(5)); and
 - (10) Welded fittings (40 CFR 63.1251).
- (b) Equipment that is designated as unsafe to monitor, unsafe to inspect, difficult to monitor, difficult to inspect, or inaccessible shall comply with 63.1255(f). This section provides, generally, that accessible equipment shall be monitored according to a written plan that provides for monitoring as often as practicable, considering safety concerns, but not more often than otherwise applicable. Inaccessible equipment is not required to be routinely monitored at any time, although any observed leaks must be repaired within 15 days.

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

E.1.3 Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)]

- (a) Records shall be kept in accordance with 63.1255(g), including but not limited to:
- (1) Identification of components that are subject to the rule with information indicating their method of compliance, with justifications as appropriate, except that inaccessible, ceramic, or ceramic-lined connectors subject to 40 CFR 63.1255(f)(4) need not be identified;
 - (2) Schedule for monitoring connectors and valves and the percent connectors and valves found leaking;
 - (3) Design criteria and any changes to these criteria for each dual mechanical seal system;
 - (4) List of equipment designated as unsafe to monitor/inspect or difficult to monitor/inspect and a copy of the plan for monitoring or inspecting such equipment;

- (5) Equipment complying via the provisions of 40 CFR 63.178(c);
 - (6) List of equipment added since the last monitoring period, and
 - (7) If monitoring frequencies are adjusted for time in use, records demonstrating the proportion of the time the equipment is in VOC/VOHAP use during the calendar year;
 - (8) Records of visual inspections;
 - (9) Records of leaks detected, repair information, and delays of repair;
 - (10) Records of pressure tests, the test pressure, and the pressure drop observed during the test;
 - (11) Records of compressor and relief device compliance tests;
 - (12) Records for closed-vent systems and control devices subject to E.1.1(d)(7);
 - (13) For components in heavy liquid service, records demonstrating that they are in heavy liquid service;
 - (14) Identification of components exempt because they are in VOHAP/VOC service for less than 300 hours per year; and
 - (15) Records of alternative means of compliance determination.
- (b) Condition E.1.3(b) was deleted pursuant to Administrative Permit Amendment 157-20003-00006.
- (c) Reporting requirements shall be conducted in accordance with 63.1255(h), including:
- (1) LDAR Periodic Reports shall cover the monitoring periods from January 1 to June 30, and July 1 to December 31, respectively. Reports shall be submitted 30 days following the 6-month monitoring period. The report shall include any revisions to the information reported earlier if the method of compliance has changed since the last report. The report shall also contain the following information:
 - (A) For equipment not complying via the alternative standard, the Permittee shall report the following information for pumps, valves, agitators, and connectors subject to periodic LDAR monitoring:
 - (i) Number of leaks detected and percent leakers;
 - (ii) Number of leaks not repaired within the required timeframe;
 - (iii) An explanation of any delay of repairs;
 - (iv) Notice of a change to monthly monitoring for either pumps or valves, if applicable; and
 - (v) Notification of a change in connector monitoring alternatives, if applicable.

- (B) Results of all monitoring required for applicable compressors, pressure relief devices in gas/vapor service, and closed-vent systems;
 - (i) Number of leaks not repaired within the required timeframe; and
 - (ii) An explanation of any delay of repairs.
- (C) For equipment complying via the alternative standard at 1255(b)(4)(iv), the Permittee shall report the following information for each product process equipment train:
 - (i) Number of pressure tests conducted;
 - (ii) Number of instances where the equipment failed either a retest or 2 consecutive pressure tests;
 - (iii) Facts that explain any delay of repairs; and
 - (iv) Results of all monitoring to determine compliance for closed-vent systems used to comply with this section of the permit.

Modifications and Construction Requirements [326 IAC 2-7-10.5, 326 IAC 2-7-12, 326 IAC 2-2]

E.1.4 Modifications and Construction: Advance Approval of Permit Conditions

- (a) The Permittee may modify any existing components listed in this section of the permit without obtaining a source modification approval (otherwise required by 326 IAC 2-7-10.5), a Title V permit modification (otherwise required by 326 IAC 2-7-12), or a Prevention of Significant Deterioration permit (otherwise required by 326 IAC 2-2), provided the modified emission units are subject to the same applicable requirements listed in this D section, and the Permittee shall comply with the Change Management and Flexible Permit provisions in Section F.1 of this permit.
- (b) The Permittee may construct and install new emission units of the types described in this D section without obtaining a source modification approval (otherwise required by 326 IAC 2-7-10.5), a Title V permit modification (otherwise required by 326 IAC 2-7-12), or a Prevention of Significant Deterioration permit (otherwise required by 326 IAC 2-2), provided the new emission units are subject to the same applicable requirements listed in this D section, and the Permittee shall comply with the Change Management and Flexible Permit provisions in Section F.1 of this permit.

SECTION E.2 LEAK DETECTION AND REPAIR (LDAR) CONDITIONS FOR BPM WASTE SYSTEM COMPONENTS

Facility Description [326 IAC 2-7-5(15)]

The following facility description of LDAR components subject to this permit section is descriptive information and does not constitute enforceable conditions:

- (a) LDAR applies to BPM waste system components consisting of pumps, compressors, pressure relief devices, sampling connection systems, open-ended valves and lines, valves, connectors, control devices, and closed-vent systems used to comply with this LDAR program, intended to operate in volatile organic hazardous air pollutant and/or volatile organic compound (VOHAP/VOC) service for 300 hours or more during the calendar year. In VOHAP/VOC service means that a piece or equipment either contains or contacts a fluid (liquid or gas) that is at least 10 percent by weight of total VOHAP/VOC.
- (b) LDAR BPM waste system components are located from the point of generation (POG) or point of determination (POD), as applicable, to the last component prior to entering the hazardous waste combustor or being loaded onto tankers for transport offsite. The closed-vent systems not used to control emissions from LDAR components are not subject to the conditions of this section, but instead are subject to the conditions in Sections D.10, D.14, and D.15.

Emission Limitations and Standards [326 IAC 2-7-5(1)]

E.2.1 LDAR Standards for BPM Waste System Components [40 CFR 63.691, 326 IAC 8-5-3(b)(6), 326 IAC 2-2, CP157-4148 (Revised by this permit)]

Except as provided in Condition E.2, the following LDAR standards satisfy the requirements of the Volatile Organic Liquid Storage Vessel Standards [40 CFR 60.110b], Offsite Waste and Recovery Operations (OSWRO) MACT Standards [40 CFR 63.691], Best Available Control Technology (BACT) requirements [326 IAC 2-2-3], Reasonably Available Control Technology (RACT) LDAR requirements for synthesized pharmaceutical manufacturing operations [326 IAC 8-5-3(b)(6)], and construction permit [CP157-4148] requirements for LDAR components associated with the research and development operations in Building T71:

- (a) The Permittee shall implement the LDAR program under 40 CFR 61 Subpart V for all BPM waste system component types listed in item (a) of the facility description section from the point of determination (POD) or at the exit of the pharmaceutical manufacturing process unit (PMPU) to the last piece of regulated equipment prior to entering the hazardous waste combustor or loaded onto tankers for transport offsite.
- (b) Existing BPM waste system components in VOC/VOHAP service are covered under 40 CFR 264 and 265, Subpart BB. Data taken for purposes of Subpart BB shall satisfy the data requirements for entry into the alternate standard at 40 61.243-3. Monitoring periods are calendar periods as defined at 40 CFR 61 Subpart V and 40 CFR 264 and 265, Subpart BB.
- (c) Each new or changed BPM waste system component in VOC/VOHAP service identified during the course of each monitoring period shall be incorporated into the existing component list as necessary within 90 days, or by the next LDAR Periodic Report, following the end of the monitoring period for the type of component monitored, whichever is later.
- (d) The following BPM waste system components in VOHAP/VOC service shall comply with design standards, shall be operated in accordance with work practice standards, or shall

undergo periodic LDAR monitoring in accordance with the provisions cited below. Periodic LDAR monitoring shall be performed in accordance with 40 CFR 60, Appendix A, Method 21. The regulatory language cited by reference in this section appears in full in Appendix A.

- (1) Pumps shall be operated in accordance with the standard at 61.242-2. This section provides, generally and in part:
 - (A) Single seal pumps shall undergo periodic monitoring and visual inspections.
 - (B) Dual mechanical seal pumps shall meet design, operation, inspection, and alarm requirements.
 - (C) Pumps designed without a shaft penetrating the pump housing shall be monitored initially and annually, but are not subject to other inspections.
 - (D) Pumps equipped with a closed-vent system limitable of capturing and transporting any leakage from the seals back to the process or to a control device are not required to be inspected or monitored.
 - (E) Pumps designated as unsafe-to-monitor shall be monitored according to a written plan by which they are monitored as frequently as possible during safe-to-monitor times, but not more frequently than otherwise applicable.
- (2) Compressors shall be operated in accordance with the standard at 61.242-3. This section provides, generally and in part:
 - (A) Compressors with barrier fluid seal systems shall meet design, operation, inspection, and alarm requirements.
 - (B) Compressors equipped with a closed-vent system to capture and transport leakage from the compressor drive shaft seal back to a process or a fuel gas system or to a control device are not required to be inspected or monitored.
 - (C) Compressors designated to operate with an instrument reading of less than 500 ppmv above background shall be monitored initially and annually.
- (3) Pressure relief devices in gas/vapor service shall be operated in accordance with the standard at 61.242-4. This section provides, generally and in part:
 - (A) Except during pressure releases, pressure relief devices shall be operated with an instrument reading of less than 500 ppmv above background.
 - (B) After each pressure release, the device shall be returned to a monitored condition of less than 500 ppmv above background within 5 calendar days after the release, except if delay of repair applies.
 - (C) A rupture disk is satisfies conditions E.2.1 (d)(3)(A) and (B) without monitoring if it is replaced within 5 calendar days after each pressure release, except if delay of repair applies.

- (D) Any pressure relief device satisfies conditions E.2.1 (d)(3)(A) and (B) without monitoring if it is routed to a process or fuel gas system or equipped with a closed-vent system limitable of capturing and transporting leakage from the pressure relief device to a control device.
- (4) Sampling Connection Systems shall be operated in accordance with the standard at 61.242-5. This section provides, generally and in part:
- (A) Gases displaced during filling of a sample container are not required to be captured or collected.
 - (B) Each sampling connection system shall be equipped with a closed-purge, closed-loop or closed-vent system, which shall:
 - (i) Return the purged process fluid directly to the process line;
 - (ii) Collect and recycle the purged process fluid;
 - (iii) Be designed and operated to capture and transport the purged process fluid to a control device;
 - (iv) Collect, store, and transport the purged process fluid to a SOCMH/HON waste management unit (40 CFR Part 63, Subpart G) operated according to the provisions which apply to Group 1 wastewater streams, or to a treatment, storage, or disposal facility subject to regulation under 40 CFR Part 262, 264, 265 or 266 (a RCRA unit), or, if the purged fluids are not hazardous waste, to a facility with an appropriate State permit to manage municipal or industrial solid waste; or
 - (v) In-situ sampling systems, and sampling systems without purges, have no other obligations under this section.
- (5) Open-ended valves or lines shall be operated in accordance with the standard at 61.242-6. This section provides, generally and in part:
- (A) Each open-ended valve and line shall be equipped with a limit, blind flange, plug or second valve, which shall seal the open end at all times except when operations require fluid flow through the open-ended valve or line, or during maintenance or repair.
 - (B) If a second valve is used, the valve on the process fluid end shall be closed before the other valve is closed.
 - (C) If a double block and bleed arrangement is used, the bleed valve may remain open during operations requiring venting the line between the block valves, but shall be closed otherwise in accordance with E.2.1 (d)(5)(B).
 - (D) Open-ended valves and lines in an emergency shutdown system which are designed to open automatically in the event of a process upset are not required to comply with E.2.1 (d)(5)(A) through (C).
 - (E) Open-ended valves or lines containing materials, which would autocatalytically polymerize are not required to comply with E.2.1 (d)(5)(A) through (C).

- (F) Open-ended valves or lines containing materials which could cause a serious safety hazard if capped or equipped with a double block and bleed system are not required to comply with E.2.1 (d)(5)(A) through (C).
- (6) Valves shall be operated in accordance with the standard at 61.242-7. This section provides, generally and in part:
- (A) Each valve shall be monitored monthly, except as provided below.
 - (B) Any valve may be monitored quarterly, in the first month of the quarter, if it has completed two successive months without a leak, as long as it does not leak.
 - (C) Each leaking valve shall be monitored monthly after it is repaired until it has completed two successive months without a leak.
 - (D) Valves designed for no detectable emissions, which have no external actuating mechanism in contact with process fluid, are required only to be monitored initially and annually.
 - (E) Valves designated as unsafe-to-monitor are required to be monitored only according to a written plan, which provides for their monitoring during safe-to-monitor times.
 - (F) Valves designated as difficult-to-monitor are required to be monitored only according to a written plan that provides for their monitoring at least once per year.
- (7) Pressure relief devices in liquid service and connectors shall be operated in accordance with the standard at 61.242-8 This section provides, generally and in part:
- (A) If a component presents visual, audible, or olfactory evidence of a leak, the leak shall be deemed repaired without monitoring if the visual, audible, or olfactory evidence has been eliminated.
 - (B) If there is visual, audible, or olfactory evidence of a leak at one of these components, and the leak is not repaired without monitoring, the component shall be monitored within 5 calendar days to confirm whether a leak is in fact present.
- (8) Closed-vent systems and control devices used to comply with Section E.2 of this permit shall be operated in accordance with the standard at 61.242-11, as may be applicable. Operation of these systems in conformance with Sections D.9, D.14 or D.15 shall constitute compliance with these requirements.
- (9) As an alternative to complying with E.2.1 (d)(6), above, valves may comply with the alternative standards for valves-allowable percentage of valves leaking under 61.243-1. This section provides, generally and in part:
- (A) Upon 90 days' advance notice to the Administrator, the designated process unit shall have no more than 2.0 percent leaking valves.
 - (B) All valves in the designated process unit shall be monitored initially upon designation, and annually thereafter, and

- (6) Records of compliance tests on equipment (compressors, pumps, or valves) designated for no detectable emissions and for pressure relief devices in gas/vapor service;
 - (7) Records for closed-vent systems and control devices, subject to E.2.1 (d)(8);
 - (8) Records of information supporting designation that components are not in VOHAP/VOC service or are in vacuum service;
 - (9) Identification of components exempt because they are in VOC/VOHAP service for less than 300 hours per year;
 - (10) Records of alternative means of compliance determination; and
 - (11) Records may be kept in one or more recordkeeping systems, providing each record is identified by process unit.
- (b) Condition E.2.3(b) was deleted pursuant to Administrative Permit Amendment 157-20003-00006.
- (c) Reporting requirements shall be conducted in accordance with 61.247, including:
- (1) LDAR Periodic Reports shall cover the periods from January 1 to June 30, and July 1 to December 31, respectively. Reports shall be submitted 30 days following the 6-month period. The report shall include any revisions to the information reported earlier if the method of compliance has changed since the last report. The report shall also contain the following information, divided and identified by process unit:
 - (A) For each month during the period covered by the report, the number of leaks detected for valves, pumps, and compressors and the number not repaired within 15 days, with the facts that explain any delay of repairs, and, where appropriate, why a process unit shutdown was technically infeasible;
 - (B) The results of all performance tests and monitoring to determine compliance with the alternative standards for valves at 40 CFR 61.243-1 and 61.243-2;
 - (C) Results of all monitoring and performance tests required to determine compliance with no detectable emissions; and
 - (D) The dates of process unit shutdowns which occurred during the reporting period.

basis. Nitrogen oxide emissions from the T79 fume incinerators shall not exceed 30 tons per 12-month period, rolled on a calendar month basis.

- (d) Sulfur dioxide (SO₂) emissions from the facilities operating under the flexible permit conditions shall not exceed 300 tons per 12-month period, rolled on a calendar month basis. Sulfur dioxide emissions from the T79 fume incinerators shall not exceed 5 tons per 12-month period, rolled on a calendar month basis.
- (e) Volatile organic compounds (VOC) emissions from the facilities operating under the flexible permit conditions shall not exceed 300 tons per 12-month period, rolled on a calendar month basis.

F.1.2 Site modifications and advance approval of modifications [326 IAC 2-7-5(9)] [326 IAC 2-7-5(16)]

The Permittee may make modifications described in subsection (a) below to the operations in Sections D.6 through D.15 of this permit. If actual emissions do not exceed the limits in section F.1.1, and the Permittee complies with the other provisions of this section, then the Permittee is not required to obtain a source modification approval (otherwise required by 326 IAC 2-7-10.5), a Title V permit modification (otherwise required by 326 IAC 2-7-12), or a Prevention of Significant Deterioration permit (otherwise required by 326 IAC 2-2).

(a) Permitted modifications

The Permittee may implement changes, including but not limited to, the following modifications without triggering the administrative review processes described above:

(1) BPM Process Operations:

- (A) A change in bulk pharmaceutical products or intermediate products manufactured;
- (B) A change in raw materials stored and utilized;
- (C) A change in the method of operation to a process or existing equipment;
- (D) Piping changes, including but not limited to, process piping, waste piping and fume transport piping;
- (E) A physical change to existing equipment;
- (F) Reconstruction or replacement of existing equipment, including but not limited to, process tanks, crystallizers, distillation operations, filters, centrifuges, and dryers;
- (G) Installation of new equipment, including but not limited to, process tanks, crystallizers, distillation operations, filters, centrifuges, and dryers;
- (H) Reconstruction or replacement of existing production buildings; and

(2) BPM Support Operations:

- (A) A change in solvent material recovered;
- (B) A change in raw materials stored and utilized;
- (C) A change in the method of operation to a process or existing equipment;
- (D) Piping changes, including but not limited to, process piping, waste piping and fume transport piping;
- (E) A physical change to existing equipment;
- (F) Reconstruction or replacement of existing equipment, including but not limited to, process tanks, receivers, stills, storage tanks, and container transfer operations;
- (G) Installation of new equipment, including but not limited to, process tanks, receivers, stills, storage tanks, and container transfer operations;

- (H) Reconstruction or replacement of existing solvent recovery operations, storage tanks, storage tank modules, and distillation operations; and
- (3) T49 liquid waste incinerator and T149 solids-liquid waste incinerator:
 - (A) A change in waste materials disposed in the incinerators;
 - (B) A change in the use of portable containers, including but not limited to, drums, melons, and tank trailers;
 - (C) A change in the method of operation that does not affect compliance with 40 CFR 63, Subpart EEE;
 - (D) Piping changes;
 - (E) A physical change that does not affect compliance with 40 CFR 63, Subpart EEE;
 - (F) Reconstruction or replacement of incinerator components and support equipment, including but not limited to, cooling towers and waste container management; and
 - (G) Installation of new incinerator equipment components, support equipment or emission control equipment.
- (b) Advance approval and applicable requirements

In addition to the emission limits identified in Condition F.1.1 of this permit, the emission limits and standards, compliance demonstration requirements, compliance monitoring requirements, record keeping requirements, reporting requirements, and other permit conditions applicable to the type of equipment or operation being modified, replaced, reconstructed or installed are described in Sections D.6 through D.15 of this permit. Each modification will be subject to the relevant provisions of those permit conditions. If a modification would cause an applicable requirement that is not described in this permit to apply, the Permittee must obtain a source modification approval if otherwise required by 326 IAC 2-7-10.5 and a Title V permit modification pursuant to 326 IAC 2-7-12.

Testing and Monitoring Requirements [326 IAC 2-7-6(1) (6)] [326 IAC 2-7-5(1)]

F.1.3 Carbon monoxide (CO) emission limit determination

The Permittee shall determine actual annual emissions by employing the following techniques:

- (a) The following requirements apply to the RTOs, the T49 liquid waste incinerator, and the T149 solids-liquid waste incinerator:
 - (1) **CO measurement:** The Permittee shall measure CO concentration in the exhaust of with a CO continuous emission monitoring system (CEMS) that meets the requirements of 40 CFR Part 60, Appendix B and 326 IAC 3.
 - (2) **Flow rate measurement:** The Permittee shall measure the actual exhaust gas flow rate from the RTOs and T149 solids-liquid waste incinerator, and measure the combustion and atomized air flow rate into the T49 liquid waste incinerator.

- (B) During periods of flow meter calibration, the Permittee shall substitute, in one-minute increments, the last valid one-minute exhaust gas flow rate measurement obtained prior to the calibration in lieu of actual readings from the flow meter.
- (C) During periods of CEMS maintenance, malfunction, repair, or other periods of invalid NOx data collection, the Permittee shall substitute the following data in lieu of actual readings from the NOx CEMS:
 - (i) When combusting only natural gas, the following NOx mass emission rates shall be substituted:
 - (1) RTO NOx mass emission rate = 0.03 lb/min
 - (2) T49 NOx mass emission rate = 0.12 lb/min
 - (3) T149 NOx mass emission rate = 0.08 lb/min
 - (ii) When incinerating a waste stream, the following NOx concentrations shall be substituted:
 - (1) RTO NOx concentration = 91 ppmv
 - (2) T49 NOx concentration = 975 ppmvdc
 - (3) T149 NOx concentration = 170 ppmvdc
- (D) During periods of flow meter maintenance, malfunction, repair, or other periods of invalid exhaust gas flow rate data collection, the Permittee shall substitute the following data in lieu of actual readings from the flow meter:
 - (i) When combusting only natural gas, the following NOx mass emission rates shall be substituted:
 - (1) RTO NOx mass emission rate = 0.03 lb/min
 - (2) T49 NOx mass emission rate = 0.12 lb/min
 - (3) T149 NOx mass emission rate = 0.08 lb/min
 - (ii) When incinerating a waste stream, the following exhaust gas flow rates shall be substituted:
 - (1) RTO exhaust gas flow rate = 93,000 scfm
 - (2) T49 exhaust gas flow rate = 17,735 dscfm
 - (3) T149 exhaust gas flow rate = 14,340 dscfm
- (5) **Minimum** data collection requirements:
 - (A) For the RTOs, the Permittee shall monitor and record NOx concentrations as required in Section D.14.
 - (B) For the T49 liquid waste incinerator, the Permittee shall monitor and record NOx concentrations as required in Condition D.12.
 - (C) For the T149 solids-liquid waste incinerator, the Permittee shall monitor and record NOx concentrations as required in Section D.13.
- (6) **Emissions during RTO bypass periods:** When determining compliance with the NOx emission limit, the Permittee shall include any known NOx emissions from BPM production buildings or storage tank modules not emitted through the RTO due to diversions in the fume transport system. The Permittee may use **engineering** calculation methods based on ideal gas law equations, stoichiometry, or mass balance to estimate these emissions.

- (1) **SO₂ emission calculation for natural gas usage:** The Permittee shall determine the amount of natural gas burned by the T79 fume incinerators each calendar month. The Permittee shall calculate SO₂ emissions from natural gas combustion, in tons, each calendar month by multiplying the monthly natural gas usage by an emission factor of 0.6 lbs/mmscf and converting the resulting emissions to tons.
- (2) **Uncontrolled SO₂ emission calculation for combustion of sulfur-containing solvents:** The Permittee shall determine the mass of sulfur atoms emitted to the T79 fume incinerators [as components of solvents containing sulfur] by the BPM Support operations by using engineering calculation methods based on ideal gas law equations, stoichiometry, or mass balance. All of the sulfur atoms shall be considered converted to SO₂ as a result of combustion in the T79 fume incinerators.
- (3) **SO₂ control efficiency:** The Permittee shall base SO₂ emissions on T79 scrubber control efficiency of 95%. If the compliance monitoring data is not **available** or indicates the scrubbers are not achieving this control efficiency, the Permittee shall use a control efficiency of zero percent (0%).
- (4) **Emission calculation:** The Permittee shall calculate SO₂ emissions, in tons, each calendar month by multiplying the amount of SO₂ created by combustion of the sulfur atoms in the T79 fume incinerators by the scrubber SO₂ control efficiency.
- (5) **Data substitution:** During periods of time when the Permittee is unable to determine natural gas usage because of auditing, calibration, maintenance, **malfunction**, repair, or other periods when the natural gas meters for the T79 fume incinerators are not collecting data properly, the Permittee shall determine SO₂ emissions based on a natural gas consumption rate of 0.0075 mmscf/hour [based on the nominal heat input rate of 7.626 MMBtu/hr per incinerator].

F.1.7 Volatile organic compound (VOC) emission limit determination

The Permittee shall determine actual annual emissions by employing the following techniques:

- (a) The following requirements apply to the RTOs when compliance is based on the 20 ppmv alternative standard, the T49 liquid waste incinerator, and the T149 solids-liquid waste incinerator:
 - (1) **VOC measurement:**
 - (A) For the RTO operations, the Permittee shall directly measure TOC concentration, as methane, in the exhaust gas using a TOC continuous emission monitoring system (CEMS) that meets the requirements of 40 CFR Part 63. The Permittee shall assume VOC, a subset of total organic compounds (TOC), is equal to TOC.
 - (B) For the T49 liquid waste incinerator and the T149 solids-liquid waste incinerator, the Permittee shall use 10 ppmvdc methane or shall use the highest hourly rolling average HC level achieved during the DRE test runs as the TOC concentration in the exhaust gas, as long as the CO concentration, as measured by the CO CEMS, is less than 100 ppmvdc, averaged over a rolling hourly period. VOC, a subset of total organic compounds (TOC), shall be equal to TOC.

F.1.15 Emission increases from increased utilization of ancillary equipment [326 IAC 2-2] (Deleted)

Condition F.1.15 was deleted pursuant to Administrative Permit Amendment 157-20003-00006.

F.1.16 NSPS and NESHAP pre-construction notification and reviews

The provisions of this permit do not relieve the Permittee of the notification and pre-construction approval requirements found in 40 CFR 60.7, 40 CFR 61.07, 40 CFR 61.08, and 40 CFR 63.5. If the Permittee constructs, reconstructs, or modifies an affected facility in a manner that requires notification or pre-construction approval under 40 CFR 60.7, 40 CFR 61.07, 40 CFR 61.08, or 40 CFR 63.5, the Permittee shall comply with those requirements.

F.1.17 Pollution Prevention Program

The Permittee shall implement a pollution prevention program as described below:

- (a) The Permittee shall develop a pollution prevention strategy that describes the site's involvement and efforts to reduce the use of raw materials and reduce waste and emissions generation. The plan shall be available to IDEM upon request.
- (b) The Permittee shall communicate its pollution prevention strategy to the public by conducting public outreach meetings.

Tippecanoe Laboratories will submit an annual report to IDEM describing specific pollution prevention efforts that took place during the calendar year. The report shall include an estimate of the air emission, wastewater, and waste reductions prevented or achieved by pollution prevention activities.

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If any of the following are not applicable, mark N/A

Date/Time Emergency started:
Date/Time Emergency was corrected:
Was the facility being properly operated at the time of the emergency? Y N Describe:
Type of Pollutants Emitted: TSP, PM-10, SO ₂ , VOC, NO _x , CO, Pb, other:
Estimated amount of pollutant(s) emitted during emergency:
Describe the steps taken to mitigate the problem:
Describe the corrective actions/response steps taken:
Describe the measures taken to minimize emissions:
If applicable, describe the reasons why continued operation of the facilities are necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw materials of substantial economic value:

Form Completed by: _____

Title / Position: _____

Date: _____

Phone: _____

A certification is not required for this report.