INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
We Protect Hoosiers and Our Environment.

Mitchell E. Daniels Jr.
Governor

Thomas W. Easterly
Commissioner

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

TO: Interested Parties / Applicant

DATE: October 6, 2009

RE: Eli Lilly / 157-26577-00006

FROM: Matthew Stuckey, Branch Chief
Permits Branch
Office of Air Quality

Notice of Decision: Approval - Effective Immediately

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 IC 13-15-5-3, this permit is effective immediately, unless a petition for stay of effectiveness is filed and granted according to IC 13-15-6-3, and may be revoked or modified in accordance with the provisions of IC 13-15-7-1.

If you wish to challenge this decision, IC 4-21.5-3 and IC 13-15-6-1 require 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, Suite N 501E, Indianapolis, IN 46204, **within eighteen (18) calendar days of 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.dot12/03/07

IDEM INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
We Protect Hoosiers and Our Environment.

Mitchell E. Daniels, Jr.
Governor

Thomas W. Easterly
Commissioner

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

Ms. Shelly Shope
Eli Lilly and Company - Tippecanoe Laboratories
1650 Lilly Road
Lafayette, IN 47909

October 6, 2009

Re: 157-26577-00006
Significant Source Modification to
Part 70 Renewal No.: T 157-26575-00006

Dear Ms. Shope:

Eli Lilly and Company - Tippecanoe Laboratories was issued a Part 70 Operating Permit on February 27, 2004 for a pharmaceutical manufacturing plant. A letter requesting changes to this permit was received on May 20, 2008. Pursuant to 326 IAC 2-7-10.5 the following emission units are approved for modification at the source:

(a) D.6 Bulk Pharmaceutical Manufacturing (BPM) - Process Operations: The emission units in the BPM production operations can be generally described as process vessels (tanks), crystallizers, filters, centrifuges, dryers, process scrubber systems, and process condenser systems and are referred to as process vents. The detailed equipment list is located in Section D.6 of this permit.

(b) D.7 BPM Support - Solvent Recovery Operations: The BPM solvent recovery emission units can be generally described as columns, stills, evaporators, accumulators, and receivers and are referred to as process vents. The detailed equipment list is located in Section D.7 of this permit.

(c) D.8 BPM Individual Drain Systems (IDSs): The BPM IDSs consist of stationary systems used to convey waste streams to a waste management unit. Segregated stormwater sewer systems, designed and operated for the sole purpose of collecting rainfall-runoff at a facility, and segregated from all other IDSs, are excluded from this definition. The detailed equipment list is located in Section D.8 of this permit.

(d) D.9 BPM Support – Solvent Storage Tank Operations: The BPM solvent storage tanks are defined as any vessel designed to store raw material feedstocks or used solvent to be recovered that contain VOCs and/or VOHAP. Pressure vessels greater than 204.9 kPa without emissions to the atmosphere, vessels attached to motor vehicles, or vessels used to store beverage alcohol are not BPM solvent storage tanks. The detailed equipment list is located in Section D.9 of this permit.

(e) D.10 BPM Support – Waste Storage Tank Operations: The BPM waste storage tanks are defined as any waste management unit designed to contain an accumulation of waste material containing VOCs and/or VOHAP. Pressure vessels greater than 204.9 kPa without emissions to the atmosphere or vessels attached to motor vehicles are not BPM waste storage tanks. The detailed equipment list is located in Section D.10 of this permit.

(f) D.11 BPM Waste Containers: Waste containers are segregated into small and large containers. A small BPM waste container, such as a drum, contains VOC and/or VOHAP with a capacity greater than 26.4 gallons and equal to or less than 110.5 gallons. A large

BPM waste container, such as a melon or a tanker truck, contains VOC and/or VOHAP with a capacity greater than 110.5 gallons. Identification of these types of containers have not been individually listed given they are portable and continually change.

(g) D.12 BPM Control Systems – T49 Liquid Waste Incinerator: The T49 liquid waste incinerator provides treatment of Lilly hazardous and non-hazardous waste to support its operational requirements, including high Btu liquids (primary waste) and low Btu liquids (secondary waste). The T49 incinerator consists of a primary combustion chamber followed by a wet quench system, a condenser/absorber, a particulate matter scrubber, and a stack with continuous emissions monitoring. The detailed equipment list is located in Section D.12 of this permit.

(h) D.13 BPM Control Systems – T149 Rotary Kiln Incinerator: The T149 solids-liquid Rotary Kiln incinerator provides treatment of Lilly hazardous and non-hazardous waste to support its operational requirements, including containerized waste (hazardous and non-hazardous), high Btu liquids (primary waste) and low Btu liquids (secondary waste). The T149 incinerator consists of a rotary kiln and vertical up-fired secondary combustion chamber (SCC), a wet ash handling system, a NO_x abatement system, a wet quench system, a condenser/absorber, a particulate matter scrubber, an induced draft (ID) fan, and a stack with continuous emissions monitoring. The detailed equipment list is located in Section D.13 of this permit.

(i) D.14 BPM Control Systems – RTO Operations: The regenerative thermal oxidizer (RTO) system consists of a closed-vent system that transports fume streams exhausted from the BPM manufacturing and support operations to the RTOs. The RTOs, designed to thermally destruct the VOC and/or VOHAP laden fume streams from the process and support operations, are also equipped with caustic scrubbing systems to control hydrogen halide and halogen emissions. The detailed equipment list is located in Section D.14 of this permit.

(j) D.15 BPM Control Systems – T79 Fume Incinerator System Operations: The T79 fume incinerator system consists of a closed-vent system that transports fume streams exhausted from the BPM manufacturing and support operations to the T79 incinerator. The T79 incinerator, designed to thermally destruct the VOC and/or VOHAP laden fume streams from the process and support operations, are also equipped with caustic scrubbing systems to control hydrogen halide and halogen emissions. The detailed equipment list is located in Section D.15 of this permit.

The following construction conditions are applicable to the proposed project:

1. Effective Date of the Permit
Pursuant to IC 13-15-5-3, this approval becomes effective upon its issuance.

2. All requirements and conditions of this construction approval shall remain in effect unless modified in a manner consistent with procedures established pursuant to 326 IAC 2.

All other conditions of the permit shall remain unchanged and in effect. For your convenience, the entire Part 70 Operating Permit as modified will be provided at issuance.

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 Josiah Balogun, OAQ, 100 North Senate Avenue, MC 61-53, Room 1003, Indianapolis, Indiana, 46204-2251, or call at (800) 451-6027, and ask for Josiah Balogun or extension (4-5257), or dial (317) 234-5257.

Sincerely,

Matt Stuckey, Branch Chief
Permits Branch
Office of Air Quality

Attachments:
Updated Permit
Technical Support Document

JB

cc: File – Tippecanoe County
Tippecanoe County Health Department
U.S. EPA, Region V
Air Compliance Inspector
Compliance Data Section

IDEM
INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
We Protect Hoosiers and Our Environment.

Mitchell E. Daniels Jr.
Governor

Thomas W. Easterly
Commissioner

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

Prevention of Significant Deterioration (PSD) Flexible Permit And Significant Source Modification OFFICE OF AIR QUALITY

Eli Lilly and Company - Tippecanoe Laboratories
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.

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 procedure pursuant to 326 IAC 2-2 and 326 IAC 2-7-10.5, applicable to those conditions.

Significant Source Modification No.: 157-26577-00006	
Issued by: Matthew Stuckey, Branch Chief Permits Branch Office of Air Quality	Issuance Date: October 6, 2009

TABLE OF CONTENTS

SECTION A SOURCE SUMMARY

This permit is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ). The information describing the source contained in conditions A.1 through A.3 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this permit pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

A.1 General Information [326 IAC 2-7-4(c)][326 IAC 2-7-5(15)][326 IAC 2-7-1(22)]

The Permittee owns and operates a stationary pharmaceutical manufacturing plant.

Source Address:	1650 Lilly Road, Lafayette, Indiana 47909
Mailing Address:	1650 Lilly Road, lafayette, IN 47909
General Source Phone Number:	765-477-4300
SIC Code:	2833 and 2879
County Location:	Tippecanoe
Source Location Status:	Attainment for all criteria pollutants
Source Status:	Part 70 Operating Permit Program Major Source, under PSD Rules, PAL for NOx and SO_2 Major Source, Section 112 of the Clean Air Act 1 of 28 Source Categories

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-7-4(c)(3)] [326 IAC 2-7-5(15)]

This stationary source consists of the following emission units and pollution control devices:

(a) D.6 Bulk Pharmaceutical Manufacturing (BPM) - Process Operations: The emission units in the BPM production operations can be generally described as process vessels (tanks), crystallizers, filters, centrifuges, dryers, process scrubber systems, and process condenser systems and are referred to as process vents. The detailed equipment list is located in Section D.6 of this permit.

(b) D.7 BPM Support - Solvent Recovery Operations: The BPM solvent recovery emission units can be generally described as columns, stills, evaporators, accumulators, and receivers and are referred to as process vents. The detailed equipment list is located in Section D.7 of this permit.

(c) D.8 BPM Individual Drain Systems (IDSs): The BPM IDSs consist of stationary systems used to convey waste streams to a waste management unit. Segregated stormwater sewer systems, designed and operated for the sole purpose of collecting rainfall-runoff at a facility, and segregated from all other IDSs, are excluded from this definition. The detailed equipment list is located in Section D.8 of this permit.

(d) D.9 BPM Support – Solvent Storage Tank Operations: The BPM solvent storage tanks are defined as any vessel designed to store raw material feedstocks or used solvent to be recovered that contain VOCs and/or VOHAP. Pressure vessels greater than 204.9 kPa without emissions to the atmosphere, vessels attached to motor vehicles, or vessels used to store beverage alcohol are not BPM solvent storage tanks. The detailed equipment list is located in Section D.9 of this permit.

(e) D.10 BPM Support – Waste Storage Tank Operations: The BPM waste storage tanks are defined as any waste management unit designed to contain an accumulation of waste material containing VOCs and/or VOHAP. Pressure vessels greater than 204.9 kPa without emissions to the atmosphere or vessels attached to motor vehicles are not

BPM waste storage tanks. The detailed equipment list is located in Section D.10 of this permit.

(f) D.11 BPM Waste Containers: Waste containers are segregated into small and large containers. A small BPM waste container, such as a drum, contains VOC and/or VOHAP with a capacity greater than 26.4 gallons and equal to or less than 110.5 gallons. A large BPM waste container, such as a melon or a tanker truck, contains VOC and/or VOHAP with a capacity greater than 110.5 gallons. Identification of these types of containers have not been individually listed given they are portable and continually change.

(g) D.12 BPM Control Systems – T49 Liquid Waste Incinerator: The T49 liquid waste incinerator provides treatment of Lilly hazardous and non-hazardous waste to support its operational requirements, including high Btu liquids (primary waste) and low Btu liquids (secondary waste). The T49 incinerator consists of a primary combustion chamber followed by a wet quench system, a condenser/absorber, a particulate matter scrubber, and a stack with continuous emissions monitoring. The detailed equipment list is located in Section D.12 of this permit.

(h) D.13 BPM Control Systems – T149 Solid-Liquid Waste Incinerator: The T149 solid-liquid waste incinerator provides treatment of Lilly hazardous and non-hazardous waste to support its operational requirements, including containerized waste (hazardous and non-hazardous), high Btu liquids (primary waste) and low Btu liquids (secondary waste). The T149 solid-liquid waste incinerator consists of a rotary kiln and vertical up-fired secondary combustion chamber (SCC), a wet ash handling system, a NO_x abatement system, a wet quench system, a condenser/absorber, a particulate matter scrubber, an induced draft (ID) fan, and a stack with continuous emissions monitoring. The detailed equipment list is located in Section D.13 of this permit.

(i) D.14 BPM Control Systems – RTO Operations: The regenerative thermal oxidizer (RTO) system consists of a closed-vent system that transports fume streams exhausted from the BPM manufacturing and support operations to the RTOs. The RTOs, designed to thermally destruct the VOC and/or VOHAP laden fume streams from the process and support operations, are also equipped with caustic scrubbing systems to control hydrogen halide and halogen emissions. The detailed equipment list is located in Section D.14 of this permit.

(j) D.15 BPM Control Systems – T79 Fume Incinerator System Operations: The T79 fume incinerator system consists of a closed-vent system that transports fume streams exhausted from the BPM manufacturing and support operations to the T79 incinerator. The T79 incinerator, designed to thermally destruct the VOC and/or VOHAP laden fume streams from the process and support operations, are also equipped with caustic scrubbing systems to control hydrogen halide and halogen emissions. The detailed equipment list is located in Section D.15 of this permit.

A.4 Part 70 Permit Applicability [326 IAC 2-7-2]

This stationary source is required to have a Part 70 permit by 326 IAC 2-7-2 (Applicability) because:

(a) It is a major source, as defined in 326 IAC 2-7-1(22);

(b) It is a source in a source category designated by the United States Environmental Protection Agency (U.S. EPA) under 40 CFR 70.3 (Part 70 - Applicability).

SECTION B GENERAL CONDITIONS

B.1 Definitions [326 IAC 2-7-1]

Terms in this permit shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, the applicable definitions found in the statutes or regulations (IC 13-11, 326 IAC 1-2 and 326 IAC 2-7) shall prevail.

B.2 Permit Term [326 IAC 2-7-5(2)][326 IAC 2-1.1-9.5][326 IAC 2-7-4(a)(1)(D)][IC 13-15-3-6(a)]

(a) This permit, T157-26575-00006, is issued for a fixed term of five (5) years from the issuance date of this permit, as determined in accordance with IC 4-21.5-3-5(f) and IC 13-15-5-3. Subsequent revisions, modifications, or amendments of this permit do not affect the expiration date of this permit.

(b) If IDEM, OAQ, upon receiving a timely and complete renewal permit application, fails to issue or deny the permit renewal prior to the expiration date of this permit, this existing permit shall not expire and all terms and conditions shall continue in effect, including any permit shield provided in 326 IAC 2-7-15, until the renewal permit has been issued or denied.

B.3 Enforceability [326 IAC 2-7-7]

Unless otherwise stated, all terms and conditions in this permit, including any provisions designed to limit the source's potential to emit, are enforceable by IDEM, the United States Environmental Protection Agency (U.S. EPA) and by citizens in accordance with the Clean Air Act.

B.4 Termination of Right to Operate [326 IAC 2-7-10][326 IAC 2-7-4(a)]

The Permittee's right to operate this source terminates with the expiration of this permit unless a timely and complete renewal application is submitted at least nine (9) months prior to the date of expiration of the source's existing permit, consistent with 326 IAC 2-7-3 and 326 IAC 2-7-4(a).

B.5 Severability [326 IAC 2-7-5(5)]

The provisions of this permit are severable; a determination that any portion of this permit is invalid shall not affect the validity of the remainder of the permit.

B.6 Property Rights or Exclusive Privilege [326 IAC 2-7-5(6)(D)]

This permit does not convey any property rights of any sort or any exclusive privilege.

B.7 Duty to Provide Information [326 IAC 2-7-5(6)(E)]

(a) The Permittee shall furnish to IDEM, OAQ, within a reasonable time, any information that IDEM, OAQ may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with this permit. The submittal by the Permittee does require the certification by a "responsible official" as defined by 326 IAC 2-7-1(34). Upon request, the Permittee shall also furnish to IDEM, OAQ copies of records required to be kept by this permit.

(b) For information furnished by the Permittee to IDEM, OAQ, the Permittee may include a claim of confidentiality in accordance with 326 IAC 17.1. When furnishing copies of requested records directly to U. S. EPA, the Permittee may assert a claim of confidentiality in accordance with 40 CFR 2, Subpart B.

B.8 Certification [326 IAC 2-7-4(f)][326 IAC 2-7-6(1)][326 IAC 2-7-5(3)(C)]

(a) Where specifically designated by this permit or required by an applicable requirement, any application form, report, or compliance certification submitted shall contain certification by a "responsible official" of truth, accuracy, and completeness. This certification shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

(b) One (1) certification shall be included, using the attached Certification Form, with each submittal requiring certification. One (1) certification may cover multiple forms in one (1) submittal.

(c) A "responsible official" is defined at 326 IAC 2-7-1(34).

B.9 Annual Compliance Certification [326 IAC 2-7-6(5)]

(a) The Permittee shall annually submit a compliance certification report which addresses the status of the source's compliance with the terms and conditions contained in this permit, including emission limitations, standards, or work practices. All certifications shall cover the time period from January 1 to December 31 of the previous year, and shall be submitted no later than July 1 of each year to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

United States Environmental Protection Agency, Region V
Air and Radiation Division, Air Enforcement Branch - Indiana (AE-17J)
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

(b) The annual compliance certification report 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.

(c) The annual compliance certification report shall include the following:

(1) The appropriate identification of each term or condition of this permit that is the basis of the certification;

(2) The compliance status;

(3) Whether compliance was continuous or intermittent;

(4) The methods used for determining the compliance status of the source, currently and over the reporting period consistent with 326 IAC 2-7-5(3); and

(5) Such other facts, as specified in Sections D of this permit, as IDEM, OAQ may require to determine the compliance status of the source.

The submittal by the Permittee does require the certification by a "responsible official" as defined by 326 IAC 2-7-1(34).

B.10 Preventive Maintenance Plan [326 IAC 2-7-5(1),(3) and (13)][326 IAC 2-7-6(1) and (6)][326 IAC 1-6-3]

(a) If required by specific condition(s) in Section D of this permit, the Permittee shall maintain Preventive Maintenance Plans (PMPs) including the following information on each facility:

(1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;

(2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and

(3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

(b) The Permittee shall implement the PMPs, including any required record keeping, as necessary to ensure that failure to implement a PMP does not cause or contribute to an exceedance of any limitation on emissions or potential to emit

(c) A copy of the PMPs shall be submitted to IDEM, OAQ upon request and within a reasonable time, and shall be subject to review and approval by IDEM, OAQ. IDEM, OAQ may require the Permittee to revise its PMPs whenever lack of proper maintenance causes or is the primary contributor to an exceedance of any limitation on emissions or potential to emit. The PMPs do not require the certification by a "responsible official" as defined by 326 IAC 2-7-1(34).

(d) To the extent the Permittee is required by 40 CFR Part 60/63 to have an Operation Maintenance, and Monitoring (OMM) Plan for a unit, such Plan is deemed to satisfy the PMP requirements of 326 IAC 1-6-3 for that unit.

B.11 Emergency Provisions [326 IAC 2-7-16]

(a) An emergency, as defined in 326 IAC 2-7-1(12), is not an affirmative defense for an action brought for noncompliance with a federal or state health-based emission limitation.

(b) An emergency, as defined in 326 IAC 2-7-1(12), constitutes an affirmative defense to an action brought for noncompliance with a technology-based emission limitation if the affirmative defense of an emergency is demonstrated through properly signed, contemporaneous operating logs or other relevant evidence that describe the following:

(1) An emergency occurred and the Permittee can, to the extent possible, identify the causes of the emergency;

(2) The permitted facility was at the time being properly operated;

(3) During the period of an emergency, the Permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards or other requirements in this permit;

(4) For each emergency lasting one (1) hour or more, the Permittee notified IDEM, OAQ, within four (4) daytime business hours after the beginning of the emergency, or after the emergency was discovered or reasonably should have been discovered;

Telephone Number: 1-800-451-6027 (ask for Office of Air Quality, Compliance Section), or
Telephone Number: 317-233-0178 (ask for Compliance Section)
Facsimile Number: 317-233-6865

(5) For each emergency lasting one (1) hour or more, the Permittee submitted the attached Emergency Occurrence Report Form or its equivalent, either by mail or facsimile to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

within two (2) working days of the time when emission limitations were exceeded due to the emergency.

The notice fulfills the requirement of 326 IAC 2-7-5(3)(C)(ii) and must contain the following:

(A) A description of the emergency;

(B) Any steps taken to mitigate the emissions; and

(C) Corrective actions taken.

The notification which shall be submitted by the Permittee does not require the certification by a "responsible official" as defined by 326 IAC 2-7-1(34).

(6) The Permittee immediately took all reasonable steps to correct the emergency.

(c) In any enforcement proceeding, the Permittee seeking to establish the occurrence of an emergency has the burden of proof.

(d) This emergency provision supersedes 326 IAC 1-6 (Malfunctions). This permit condition is in addition to any emergency or upset provision contained in any applicable requirement.

(e) The Permittee seeking to establish the occurrence of an emergency shall make records available upon request to ensure that failure to implement a PMP did not cause or contribute to an exceedance of any limitations on emissions. However, IDEM, OAQ may require that the Preventive Maintenance Plans required under 326 IAC 2-7-4(c)(9) be revised in response to an emergency.

(f) Failure to notify IDEM, OAQ by telephone or facsimile of an emergency lasting more than one (1) hour in accordance with (b)(4) and (5) of this condition shall constitute a violation of 326 IAC 2-7 and any other applicable rules.

(g) If the emergency situation causes a deviation from a technology-based limit, the Permittee may continue to operate the affected emitting facilities during the emergency provided the Permittee immediately takes all reasonable steps to correct the emergency and minimize emissions.

(h) The Permittee shall include all emergencies in the Quarterly Deviation and Compliance Monitoring Report.

B.12 Permit Shield [326 IAC 2-7-15][326 IAC 2-7-20][326 IAC 2-7-12]

(a) Pursuant to 326 IAC 2-7-15, the Permittee has been granted a permit shield. The permit shield provides that compliance with the conditions of this permit shall be deemed compliance with any applicable requirements as of the date of permit issuance, provided that either the applicable requirements are included and specifically identified in this permit or the permit contains an explicit determination or concise summary of a determination that other specifically identified requirements are not applicable. The Indiana statutes from IC 13 and rules from 326 IAC, referenced in conditions in this permit, are those applicable at the time the permit was issued. The issuance or possession of this permit shall not alone constitute a defense against an alleged violation of any law, regulation or standard, except for the requirement to obtain a Part 70 permit under 326 IAC 2-7 or for applicable requirements for which a permit shield has been granted.

This permit shield does not extend to applicable requirements which are promulgated after the date of issuance of this permit unless this permit has been modified to reflect such new requirements.

(b) In addition to the nonapplicability determination set forth in Section D of this permit, the IDEM, OAQ has made the following determination regarding this source.

(1) **40 CFR, Subpart Cb - Emission Guidelines and Compliance Times for Large Municipal Waste Combustors That are Constructed On or Before September 20, 1994:** This rules does not apply because none of the waste incinerators combust municipal waste.

(2) **40 CFR 60, Subpart Ce - Emission Guidelines and Compliance Times for Hospital/Medical/Infectious Waste Incinerators:** This rules does not apply because none of the waste incinerators combust hospital, medical, or infectious waste.

(3) **40 CFR 60, Subpart D – Fossil-fuel fired steam generating units:** This source is not subject to 40 CFR Part 60, Subpart D because none of the boilers at the plant site exceed 250 MMBtu/hr in heat input capacity. [40 CFR 60.40(a)(1)]

(4) **40 CFR 60, Subpart Dc – Standard of Performance for Industrial-Commercial-Institutional steam generating units:** This source is not subject to 40 CFR Part 60, Subpart Dc because none of the boilers with maximum heat input capacities between 10 and 100 MMBtu/hr at plant site were constructed, reconstructed, or modified after June 9, 1989. [40 CFR 60.40c(a)]

(5) **40 CFR 60, Subpart E – Standard of Performance for Incinerators:** This source is not subject to 40 CFR Part 60, Subpart E because none of the incinerators at the plant site exceed a charging rate of 50 metric tons per day. [40 CFR 60.50(a)].

(6) **40 CFR 60, Subparts Ea – Standard of Performance for Municipal Waste Combustors for which Construction Commenced After December 20, 1989 and On or Before September 20, 1994:** This rule does not apply because the waste incinerators have a permit under section 3005 of the Solid Waste Disposal Act. Any combustor required to have a permit under section 3005 of the Solid Waste Disposal Act is not subject to this subpart.

(7) **40 CFR 60, Subparts Eb – Standard of Performance for large Municipal Waste Combustors for which Construction Commenced After December 20, 1994 or for which Modification or reconstruction is Commenced After June 19, 1996:** This rule does not apply because the waste incinerators have a permit under section 3005 of the Solid Waste Disposal Act. Any combustor required to have a permit under section 3005 of the Solid Waste Disposal Act is not subject to this subpart.

(8) **40 CFR 60, Subparts Ec and CCCC – Standard of Performance for Hospital/Medical/Infectious waste incinerators for which Construction is**

Commenced After June 20, 1996 and Standard of Performance for Commercial and Industrial solid waste incineration units for which Construction is Commenced After November 30, 1999 or for which modification or reconstruction is commenced on or after June 1, 2001: This source is not subject to 40 CFR Part 60 Subpart Ec or Subpart CCCC because the combustors at the site are required to have a permit pursuant to Section 3005 of the Solid Waste Disposal Act. [40 CFR 60.50c(d) and 40 CFR 60.2020(g)]

(9) **40 CFR 60, Subparts VV, VVa, III, NNN and RRR – Synthetic organic chemical manufacturing:** This source is not subject to 40 CFR Part 60, Subparts VV, III, NNN, and RRR because the source is not engaged in the manufacture of synthetic organic chemicals as defined by those standards. The source does not produce, as an intermediate, final product, co-product, or by-product, a chemical listed in 40 CFR 60.489 [Subpart VV and Subpart VVa], 40 CFR 60.617 [Subpart III], 40 CFR 60.667 [Subpart NNN], or 40 CFR 60.707 [Subpart RRR].

(10) **40 CFR 60, Subpart K – Storage Vessels for Petroleum Liquids**: This source is not subject to 40 CFR Part 60, Subpart K because none of the storage tanks at the source constructed between June 11, 1973 and May 19, 1978 store petroleum liquids, as defined in 40 CFR 60.111.

(11) **40 CFR 60, Subpart Ka – Storage Vessels for Petroleum Liquids**: This source is not subject to 40 CFR Part 60, Subpart K because none of the storage tanks at the source constructed between May 19, 1978 and July 23, 1984 store petroleum liquids, as defined in 40 CFR 60.111.

(12) **40 CFR 60, Subpart AAAA – Small Municipal Waste Combustion Units**: This source is not subject to 40 CFR Part 60, Subpart AAAA because the incinerators at the source are hazardous waste combustion units that are subject to a permit for under section 3005 of the Solid Waste Disposal Act, as provided in 40 CFR 60.1020(e).

(13) **40 CFR 60, Subpart BBBB – Small Municipal Waste Combustion Units**: This source is not subject to 40 CFR Part 60, Subpart BBBB because the incinerators at the source are hazardous waste combustion units that are subject to a permit for under section 3005 of the Solid Waste Disposal Act, as provided in 40 CFR 60.1555(e).

(14) **40 CFR 60, Subpart CCCC – Commercial and Industrial Solid Waste Incinerators**: This source is not subject to 40 CFR Part 60, Subpart CCCC because the incinerators at the source are hazardous waste combustion units that are subject to requirements under 40 CFR 63, Subpart EEE, as provided in 40 CFR 60.2020(g).

(15) **40 CFR 60, Subpart DDDD – Commercial and Industrial Solid Waste Incinerators**: This source is not subject to 40 CFR Part 60, Subpart DDDD because the incinerators at the source are hazardous waste combustion units that are subject to requirements under 40 CFR 63, Subpart EEE, as provided in 40 CFR 60.2555(g).

(16) **40 CFR 60, Subpart EEEE – Other Solid Waste Incinerators**: This source is not subject to 40 CFR Part 60, Subpart EEEE because the incinerators at the source are hazardous waste combustion units that are subject to requirements under 40 CFR 63, Subpart EEE, as provided in 40 CFR 60.2887(e).

(17) **40 CFR 60, Subpart FFFF – Other Solid Waste Incinerators**: This source is not subject to 40 CFR Part 60, Subpart FFFF because the incinerators at the source are hazardous waste combustion units that are subject to requirements under 40 CFR 63, Subpart EEE, as provided in 40 CFR 60.2993(e).

(18) **40 CFR, Subpart IIII - Stationary Compression Ignition Internal Combustion Engines:** This source is not subject to 40 CFR Part 60, Subpart IIII, because the compression ignition internal combustion engines at the source were manufactured before April 1, 2006 and are not fire pump engines.

(19) **40 CFR, Subpart JJJJ - Stationary Spark Ignition Internal Combustion Engines:** This source is not subject to 40 CFR Part 60, Subpart JJJJ, because the Spark Ignition Internal Combustion Engines at the source were manufactured before July 1, 2007 and are not fire pump engines.

(20) **40 CFR 60, Appendix B, Performance Specification 16 - Predictive Emission Monitoring System:** This rule does not apply because the source does not operate any predictive emission monitoring systems (PEMS).

(21) **Section 111(d) Emission Guidelines:** None of the emission guidelines in 40 CFR Part 60, 40 CFR Part 62, Subpart P, and 326 IAC 11 are applicable to this source because the source does not own or operate an affected facility subject to those requirements. 40 CFR Part 60, Subpart Ce and 326 IAC 11-6, and 40 CFR Part 60, Subpart DDDD and 326 IAC 11-8 are not applicable to this source because combustors at the site are required to have a permit pursuant to Section 3005 of the Solid Waste Disposal Act. [40 CFR 60.32e(d) and 40 CFR 60.2555(g)].

(22) **40 CFR 61, Subpart C – National Emission Standard for Beryllium:** This source is not subject to 40 CFR Part 61, Subpart C and 326 IAC 14-3 because the incinerators at the source do not incinerate beryllium containing waste. [40 CFR 61.30(a) and 40 CFR 61.31(g)]

(23) **40 CFR 61, Subpart E – National Emission Standard for Mercury:** This source is not subject to 40 CFR Part 61, Subpart E and 326 IAC 14-5, which applies to, among other things, incinerators burning wastewater treatment plant sludge because the source does not incinerate wastewater treatment plant sludge in its incinerators.

(24) **40 CFR 61, Subpart FF – National Emission Standard for Benzene Waste Operations:** This source does not handle more than 10 megagrams of benzene waste per year. Therefore, the source is not subject to requirements of 40 CFR Part 61, Subpart FF.

(25) **40 CFR 63, Subpart B Sections 63.50 through 63.56 – Section 112(j)**: This source is not subject to 40 CFR Part 63, Sections 63.50 through 63.56 because there are no affected sources within a source category or subcategory for which USEPA has failed to promulgate emission standards by the section 112(j) deadlines.

(26) **40 CFR 63, Subparts F and G – Synthetic Organic Chemical Manufacturing:** This source is not subject to 40 CFR Part 63, Subparts F and G (326 IAC 20-10) because the source does not manufacture compounds listed in table 1 of Subpart F or use as a reactant compounds listed in table 2 of Subpart F. [40 CFR 63.100(b)]

(27) **40 CFR 63, Subpart O – Ethylene Oxide Sterilizers:** This source is not subject to 40 CFR Part 63, Subpart O and 326 IAC 20-5 because the source does not utilize ethylene oxide in sterilization operations. [40 CFR 63.360]

(28) **40 CFR 63, Subpart Q – Industrial Process Cooling Towers:** This source is not subject to 40 CFR Part 63, Subpart Q and 326 IAC 20-4 because the source does not utilize chromium based water treatment compounds in its cooling towers. [40 CFR 63.400]

(29) **40 CFR 63, Subpart T – Halogenated Solvent Cleaning:** This source is not subject to 40 CFR Part 63, Subpart T and 326 IAC 20-6 because the source does not use halogenated solvents in any solvent cleaning machines. [40 CFR 63.460]

(30) **40 CFR 63, Subpart YY – Generic MACT categories:** This source is not subject to 40 CFR Part 63, Subpart YY and 326 IAC 20-44 because the source is not one of the source categories described in 40 CFR 63.1103. [40 CFR 63.1100]

(31) **40 CFR 63, Subpart MMM – Pesticide Active Ingredient Production:** This source is not subject to 40 CFR Part 63, Subpart MMM and 326 IAC 20-45 because the source does not contain any pesticide active ingredient process units or associated equipment as described in 40 CFR 63.1360. [40 CFR 63.1360]

(32) **40 CFR 63, Subpart EEEE** – **Organic Liquid Distribution:** This source has emission units that are affected sources under 40 CFR Part 63, Subpart EEEE, but the emission units do not exceed the thresholds requiring emission controls. Therefore, the requirements of 40 CFR 63, Subpart EEEE do not apply to the source.

(33) **40 CFR 63, Subpart FFFF** – **Miscellaneous Organic Chemical Production and Processes:** This source is not subject to 40 CFR Part 63, Subpart FFFF because all the affected facilities at the source that would otherwise be subject to Subpart FFFF are subject to 40 CFR 63, Subpart GGG.

(34) **40 CFR, Subpart ZZZZ - Stationary Reciprocating Internal Combustion Engines:** This source is not subject to 40 CFR Part 63, Subpart ZZZZ, because the source only has emergency stationary reciprocating internal combustion engines for which there are no applicable requirements in 40 CFR 63, subpart ZZZZ.

(35) **40 CFR 63, Subpart GGGGG – Site Remediation:** This source is not subject to 40 CFR Part 63, Subpart GGGGG because the site remediation activities at Tippecanoe Laboratories are being performed under a RCRA corrective action program at a treatment, storage and disposal facility.

(36) **326 IAC 4-2 –Incinerators**: This source is not subject to 326 IAC 4-2, Incinerators, because the incinerators at the source are hazardous waste combustion units that are subject to requirements under 40 CFR 63, Subpart EEE, as provided in 326 IAC 4-2-1(b)(2)(F).

(37) **326 IAC 6-5 – Fugitive Particulate Matter Emission Limitations:** This source does not have potential fugitive dust emissions greater than 25 tons per year, and is therefore, not subject to the requirements of this rule.

(38) **326 IAC 8-3 – Organic Solvent Degreasing Operations:** This source does not own or operate degreasing facilities containing organic solvent. Therefore, the requirements of 326 IAC 8-3-3/326 IAC 8-3-6 do not apply.

(39) **326 IAC 8-4 – Petroleum Sources:** This source does not operate any facilities subject to the requirements of 326 IAC 8-4. 326 IAC 8-4-6 is not applicable to this source because the source does not accept deliveries of gasoline by transports, as defined by 326 IAC 1-2-84.

(40) **326 IAC 8-6 – Organic Solvent Emissions Limitations**: The provisions of 326 IAC 8-6 are not applicable to this source because the source is subject to other rules in 326 IAC 8.

(41) **326 IAC 9-1 –Carbon Monoxide Emission Limits**: This source is not subject to 326 IAC 9-1, Carbon Monoxide Emission Limits, because the incinerators at the source are hazardous waste combustion units that are subject to requirements under 40 CFR 63, Subpart EEE, as provided in 326 IAC 9-1-1(b)(5).

(42) **326 IAC 10 – Nitrogen Oxide Rules: This source** does not contain any emission units identified in 326 IAC 10-4. Therefore, the source is not subject to the NOx emission control requirements of that rule.

(43) **326 IAC 11 – Emission Limitations for Specific Types of Operations:** This source does not contain any emission units described in 326 IAC 11. Therefore, the source is not subject to the requirements of those rules.

(44) **326 IAC 15 – Lead Rules:** This source does not contain any emission units described in 326 IAC 15. Therefore, the source is not subject to the requirements of those rules.

(45) **326 IAC 21 – Acid Deposition:** This source does not contain any emission units described in 326 IAC 21. Therefore, the source is not subject to the requirements of those rules.

(c) If, after issuance of this permit, it is determined that the permit is in nonconformance with an applicable requirement that applied to the source on the date of permit issuance, IDEM, OAQ, shall immediately take steps to reopen and revise this permit and issue a compliance order to the Permittee to ensure expeditious compliance with the applicable requirement until the permit is reissued. The permit shield shall continue in effect so long as the Permittee is in compliance with the compliance order.

(d) No permit shield shall apply to any permit term or condition that is determined after issuance of this permit to have been based on erroneous information supplied in the permit application. Erroneous information means information that the Permittee knew to be false, or in the exercise of reasonable care should have been known to be false, at the time the information was submitted.

(e) Nothing in 326 IAC 2-7-15 or in this permit shall alter or affect the following:

(1) The provisions of Section 303 of the Clean Air Act (emergency orders), including the authority of the U.S. EPA under Section 303 of the Clean Air Act;

(2) The liability of the Permittee for any violation of applicable requirements prior to or at the time of this permit's issuance;

(3) The applicable requirements of the acid rain program, consistent with Section 408(a) of the Clean Air Act; and

(4) The ability of U.S. EPA to obtain information from the Permittee under Section 114 of the Clean Air Act.

(f) This permit shield is not applicable to any change made under 326 IAC 2-7-20(b)(2) (Sections 502(b)(10) of the Clean Air Act changes) and 326 IAC 2-7-20(c)(2) (trading based on State Implementation Plan (SIP) provisions).

(g) This permit shield is not applicable to modifications eligible for group processing until after IDEM, OAQ, has issued the modifications. [326 IAC 2-7-12(c)(7)]

(h) This permit shield is not applicable to minor Part 70 permit modifications until after IDEM, OAQ, has issued the modification. [326 IAC 2-7-12(b)(8)]

B.13 Prior Permits Superseded [326 IAC 2-1.1-9.5][326 IAC 2-7-10.5]

(a) All terms and conditions of permits established prior to T157-26575-00006 and issued pursuant to permitting programs approved into the state implementation plan have been either:

(1) incorporated as originally stated,

(2) revised under 326 IAC 2-7-10.5, or

(3) deleted under 326 IAC 2-7-10.5.

(b) Provided that all terms and conditions are accurately reflected in this permit, all previous registrations and permits are superseded by this Part 70 operating permit.

B.14 Deviations from Permit Requirements and Conditions [326 IAC 2-7-5(3)(C)(ii)]

(a) Deviations from any permit requirements (for emergencies see Section B - Emergency Provisions), the probable cause of such deviations, and any response steps or preventive measures taken shall be reported to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

using the attached Quarterly Deviation and Compliance Monitoring Report, or its equivalent. A deviation required to be reported pursuant to an applicable requirement that exists independent of this permit, shall be reported according to the schedule stated in the applicable requirement and does not need to be included in this report.

The Quarterly Deviation and Compliance Monitoring Report does require the certification by a "responsible official" as defined by 326 IAC 2-7-1(34).

(b) A deviation is an exceedance of a permit limitation or a failure to comply with a requirement of the permit.

B.15 Permit Modification, Reopening, Revocation and Reissuance, or Termination
[326 IAC 2-7-5(6)(C)] [326 IAC 2-7-8(a)][326 IAC 2-7-9]

(a) This permit may be modified, reopened, revoked and reissued, or terminated for cause. The filing of a request by the Permittee for a Part 70 Operating Permit modification, revocation and reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any condition of this permit. [326 IAC 2-7-5(6)(C)] The notification by the Permittee does require the certification by a "responsible official" as defined by 326 IAC 2-7-1(34).

(b) This permit shall be reopened and revised under any of the circumstances listed in IC 13-15-7-2 or if IDEM, OAQ determines any of the following:

(1) That this permit contains a material mistake.

(2) That inaccurate statements were made in establishing the emissions standards or other terms or conditions.

(3) That this permit must be revised or revoked to assure compliance with an applicable requirement. [326 IAC 2-7-9(a)(3)]

(c) Proceedings by IDEM, OAQ to reopen and revise this permit shall follow the same procedures as apply to initial permit issuance and shall affect only those parts of this permit for which cause to reopen exists. Such reopening and revision shall be made as expeditiously as practicable. [326 IAC 2-7-9(b)]

(d) The reopening and revision of this permit, under 326 IAC 2-7-9(a), shall not be initiated before notice of such intent is provided to the Permittee by IDEM, OAQ at least thirty (30) days in advance of the date this permit is to be reopened, except that IDEM, OAQ may provide a shorter time period in the case of an emergency. [326 IAC 2-7-9(c)]

B.16 Permit Renewal [326 IAC 2-7-3][326 IAC 2-7-4][326 IAC 2-7-8(e)]

(a) The application for renewal shall be submitted using the application form or forms prescribed by IDEM, OAQ and shall include the information specified in 326 IAC 2-7-4. Such information shall be included in the application for each emission unit at this source, except those emission units included on the trivial or insignificant activities list contained in 326 IAC 2-7-1(21) and 326 IAC 2-7-1(40). The renewal application does require the certification by a "responsible official" as defined by 326 IAC 2-7-1(34).

Request for renewal shall be submitted to:

Indiana Department of Environmental Management
Permits Administration and Support Section (PASS), Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

(b) A timely renewal application is one that is:

(1) Submitted at least nine (9) months prior to the date of the expiration of this permit; and

(2) 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.

(c) If the Permittee submits a timely and complete application for renewal of this permit, the source's failure to have a permit is not a violation of 326 IAC 2-7 until IDEM, OAQ takes final action on the renewal application, except that this protection shall cease to apply if, subsequent to the completeness determination, the Permittee fails to submit by the deadline specified in writing by IDEM, OAQ any additional information identified as being needed to process the application.

B.17 Permit Amendment or Modification [326 IAC 2-7-11][326 IAC 2-7-12] [40 CFR 72]

(a) Permit amendments and modifications are governed by the requirements of 326 IAC 2-7-11 or 326 IAC 2-7-12 whenever the Permittee seeks to amend or modify this permit.

(b) Any application requesting an amendment or modification of this permit shall be submitted to:

Indiana Department of Environmental Management
Permits Administration and Support Section (PASS), Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

Any such application shall be certified by a "responsible official" as defined by 326 IAC 2-7-1(34).

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

(d) No permit amendment or modification is required for the addition, operation or removal of a nonroad engine, as defined in 40 CFR 89.2.

B.18 Permit Revision Under Economic Incentives and Other Programs [326 IAC 2-7-5(8)] [326 IAC 2-7-12(b)(2)]

(a) No Part 70 permit revision shall be required under any approved economic incentives, marketable Part 70 permits, emissions trading, and other similar programs or processes for changes that are provided for in a Part 70 permit.

(b) Notwithstanding 326 IAC 2-7-12(b)(1) and 326 IAC 2-7-12(c)(1), minor Part 70 permit modification procedures may be used for Part 70 modifications involving the use of economic incentives, marketable Part 70 permits, emissions trading, and other similar approaches to the extent that such minor Part 70 permit modification procedures are explicitly provided for in the applicable State Implementation Plan (SIP) or in applicable requirements promulgated or approved by the U.S. EPA.

B.19 Operational Flexibility [326 IAC 2-7-20][326 IAC 2-7-10.5]

(a) The Permittee may make any change or changes at the source that are described in 326 IAC 2-7-20(b),(c), or (e) without a prior permit revision, if each of the following conditions is met:

(1) The changes are not modifications under any provision of Title I of the Clean Air Act;

(2) Any preconstruction approval required by 326 IAC 2-7-10.5 has been obtained;

(3) The changes do not result in emissions which exceed the limitations provided in this permit (whether expressed herein as a rate of emissions or in terms of total emissions);

(4) The Permittee notifies the:

Indiana Department of Environmental Management
Permits Administration and Support Section (PASS), Office of Air Quality 100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

United States Environmental Protection Agency, Region 5
Air and Radiation Division, Regulation Development Branch - Indiana (AR-18J)
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

in advance of the change by written notification at least ten (10) days in advance of the proposed change. The Permittee shall attach every such notice to the Permittee's copy of this permit; and

(5) The Permittee maintains records on-site, on a rolling five (5) year basis, which document all such changes and emission trades that are subject to 326 IAC 2-7-20(b),(c), or (e). The Permittee shall make such records available, upon reasonable request, for public review.

Such records shall consist of all information required to be submitted to IDEM, OAQ in the notices specified in 326 IAC 2-7-20(b)(1), (c)(1), and (e)(2).

(b) The Permittee may make Section 502(b)(10) of the Clean Air Act changes (this term is defined at 326 IAC 2-7-1(36)) without a permit revision, subject to the constraint of 326 IAC 2-7-20(a). For each such Section 502(b)(10) of the Clean Air Act change, the required written notification shall include the following:

(1) A brief description of the change within the source;

(2) The date on which the change will occur;

(3) Any change in emissions; and

(4) Any permit term or condition that is no longer applicable as a result of the change.

The notification which shall be submitted is not considered an application form, report or compliance certification. Therefore, the notification by the Permittee does not require the certification by a “responsible official” as defined by 326 IAC 2-7-1(34).

(c) Emission Trades [326 IAC 2-7-20(c)]
The Permittee may trade emissions increases and decreases at the source, where the applicable SIP provides for such emission trades without requiring a permit revision, subject to the constraints of Section (a) of this condition and those in 326 IAC 2-7-20(c).

(d) Alternative Operating Scenarios [326 IAC 2-7-20(d)]
The Permittee may make changes at the source within the range of alternative operating scenarios that are described in the terms and conditions of this permit in accordance with 326 IAC 2-7-5(9). No prior notification of IDEM, OAQ, or U.S. EPA is required.

(e) Backup fuel switches specifically addressed in, and limited under, Section D of this permit shall not be considered alternative operating scenarios. Therefore, the notification requirements of part (a) of this condition do not apply.

B.20 Source Modification Requirement [326 IAC 2-7-10.5]

A modification, construction, or reconstruction is governed by the requirements of 326 IAC 2.

B.21 Inspection and Entry [326 IAC 2-7-6][IC 13-14-2-2][IC 13-30-3-1][IC 13-17-3-2]

Upon presentation of proper identification cards, credentials, and other documents as may be required by law, and subject to the Permittee's right under all applicable laws and regulations to assert that the information collected by the agency is confidential and entitled to be treated as such, the Permittee shall allow IDEM, OAQ, U.S. EPA, or an authorized representative to perform the following:

(a) Enter upon the Permittee's premises where a Part 70 source is located, or emissions related activity is conducted, or where records must be kept under the conditions of this permit;

(b) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, have access to and copy any records that must be kept under the conditions of this permit;

(c) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, inspect any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under this permit;

(d) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, sample or monitor substances or parameters for the purpose of assuring compliance with this permit or applicable requirements; and

(e) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, utilize any photographic, recording, testing, monitoring, or other equipment for the purpose of assuring compliance with this permit or applicable requirements.

B.22 Transfer of Ownership or Operational Control [326 IAC 2-7-11]

(a) The Permittee must comply with the requirements of 326 IAC 2-7-11 whenever the Permittee seeks to change the ownership or operational control of the source and no other change in the permit is necessary.

(b) Any application requesting a change in the ownership or operational control of the source shall contain a written agreement containing a specific date for transfer of permit responsibility, coverage and liability between the current and new Permittee. The application shall be submitted to:

Indiana Department of Environmental Management
Permits Administration and Support Section (PASS), Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

The application which shall be submitted by the Permittee does require the certification by a "responsible official" as defined by 326 IAC 2-7-1(34).

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

B.23 Annual Fee Payment [326 IAC 2-7-19] [326 IAC 2-7-5(7)][326 IAC 2-1.1-7]

(a) The Permittee shall pay annual fees to IDEM, OAQ within thirty (30) calendar days of receipt of a billing. Pursuant to 326 IAC 2-7-19(b), if the Permittee does not receive a bill from IDEM, OAQ the applicable fee is due April 1 of each year.

(b) Except as provided in 326 IAC 2-7-19(e), failure to pay may result in administrative enforcement action or revocation of this permit.

(c) The Permittee may call the following telephone numbers: 1-800-451-6027 or 317-233-4230 (ask for OAQ, Billing, Licensing, and Training Section), to determine the appropriate permit fee.

B.24 Advanced Source Modification Approval [326 IAC 2-7-5(16)] [326 IAC 2-7-10.5]

(a) The requirements to obtain a source modification approval under 326 IAC 2-7-10.5 or a permit modification under 326 IAC 2-7-12 are satisfied by this permit for the proposed emission units, control equipment or insignificant activities in Sections A.2 and A.3.

(b) Pursuant to 326 IAC 2-1.1-9 any permit authorizing construction may be revoked if construction of the emission unit has not commenced within eighteen (18) months from the date of issuance of the permit, or if during the construction, work is suspended for a continuous period of one (1) year or more.

B.25 Credible Evidence [326 IAC 2-7-5(3)][326 IAC 2-7-6][62 FR 8314] [326 IAC 1-1-6]

For the purpose of submitting compliance certifications or establishing whether or not the Permittee has violated or is in violation of any condition of this permit, nothing in this permit shall preclude the use, including the exclusive use, of any credible evidence or information relevant to whether the Permittee would have been in compliance with the condition of this permit if the appropriate performance or compliance test or procedure had been performed.

B.26 Term of Conditions [326 IAC 2-1.1-9.5]

Notwithstanding the permit term of a permit to construct, a permit to operate, or a permit modification, any condition established in a permit issued pursuant to a permitting program approved in the state implementation plan shall remain in effect until:

(a) the condition is modified in a subsequent permit action; or

(b) the emission unit to which the condition pertains permanently ceases operation.

SECTION C SOURCE OPERATION CONDITIONS

Entire Source

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

C.1 Particulate Emission Limitations For Processes with Process Weight Rates Less Than One Hundred (100) Pounds per Hour [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2(e)(2), particulate emissions from any process not exempt under 326 IAC 6-3-1(b) or (c) which has a maximum process weight rate less than 100 pounds per hour and the methods in 326 IAC 6-3-2(b) through (d) do not apply shall not exceed 0.551 pounds per hour.

C.2 Opacity [326 IAC 5-1]

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), opacity shall meet the following, unless otherwise stated in this permit:

(a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

(b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

C.3 Open Burning [326 IAC 4-1] [IC 13-17-9]

The Permittee shall not open burn any material except as provided in 326 IAC 4-1-3, 326 IAC 4-1-4 or 326 IAC 4-1-6. The previous sentence notwithstanding, the Permittee may open burn in accordance with an open burning approval issued by the Commissioner under 326 IAC 4-1-4.1.

C.4 Fugitive Dust Emissions [326 IAC 6-4]

The Permittee shall not allow fugitive dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would violate 326 IAC 6-4 (Fugitive Dust Emissions). 326 IAC 6-4-2(4) is not federally enforceable.

C.5 Reserved

C.6 Stack Height [326 IAC 1-7]

The Permittee shall comply with the applicable provisions of 326 IAC 1-7 (Stack Height Provisions), for all exhaust stacks through which a potential (before controls) of twenty-five (25) tons per year or more of particulate matter or sulfur dioxide is emitted. The provisions of 326 IAC 1-7-1(3), 326 IAC 1-7-2, 326 IAC 1-7-3(c) and (d), 326 IAC 1-7-4, and 326 IAC 1-7-5(a), (b), and (d) are not federally enforceable.

C.7 Asbestos Abatement Projects [326 IAC 14-10] [326 IAC 18] [40 CFR 61, Subpart M]

The Permittee shall comply with the applicable requirements of 326 IAC 14-10, 326 IAC 18, and 40 CFR 61.140.

The requirement in 326 IAC 14-10-1(a) that the owner or operator shall use an Indiana Accredited Asbestos Inspector and all the requirements in 326 IAC 18 related to licensing requirements for asbestos inspectors are not federally enforceable.

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

C.8 Performance Testing [326 IAC 3-6]

(a) All testing shall be performed according to the provisions of 326 IAC 3-6 (Source Sampling Procedures), except as provided elsewhere in this permit, utilizing any applicable procedures and analysis methods specified in 40 CFR 51, 40 CFR 60, 40 CFR 61, 40 CFR 63, 40 CFR 75, or other procedures approved by IDEM, OAQ.

A test protocol, except as provided elsewhere in this permit, shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

no later than thirty-five (35) days prior to the intended test date. The protocol submitted by the Permittee does not require certification by a "responsible official" as defined by 326 IAC 2-7-1(34).

(b) The Permittee shall notify IDEM, OAQ of the actual test date at least fourteen (14) days prior to the actual test date. The notification submitted by the Permittee does not require certification by a "responsible official" as defined by 326 IAC 2-7-1(34).

(c) Except as otherwise provided in this permit, pursuant to 326 IAC 3-6-4(b), all test reports must be received by IDEM, OAQ not later than forty-five (45) days after the completion of the testing. An extension may be granted by IDEM, OAQ if the Permittee submits to IDEM, OAQ, a reasonable written explanation not later than five (5) days prior to the end of the initial forty-five (45) day period.

Compliance Requirements 4[326 IAC 2-1.1-11]

C.9 Compliance Requirements [326 IAC 2-1.1-11]

The commissioner may require stack testing, monitoring, or reporting at any time to assure compliance with all applicable requirements by issuing an order under 326 IAC 2-1.1-11. Any monitoring or testing shall be performed in accordance with 326 IAC 3 or other methods approved by the commissioner or the U. S. EPA.

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

C.10 Compliance Monitoring [326 IAC 2-7-5(3)][326 IAC 2-7-6(1)]

(a) This section applies to the operation and maintenance of equipment and devices specified in Section D of this permit to determine or monitor compliance, except that it does not apply to continuous emissions monitoring systems or continuous opacity monitoring systems described in Section D. Section C.11 (Maintenance of Continuous Emission Monitoring Equipment) establishes the general operation and maintenance requirements for continuous emission monitoring systems and continuous opacity monitoring systems.

(b) Unless otherwise specified in this permit, all monitoring and record keeping requirements not already legally required shall be implemented within ninety (90) days of permit issuance. If required by Section D, the Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment. If due to circumstances beyond its control, that equipment cannot be installed and operated within ninety (90) days, the Permittee may extend the compliance schedule related to the equipment for an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

in writing, prior to the end of the initial ninety (90) day compliance schedule, with full justification of the reasons for the inability to meet this date.

The notification which shall be submitted by the Permittee does require the certification by a "responsible official" as defined by 326 IAC 2-7-1(34).

(c) Unless otherwise specified in the approval for the new emission unit(s), compliance monitoring for new emission units or emission units added through a source modification shall be implemented when operation begins.

(d) The Permittee shall keep records of monitoring system operation that include the following:

(1) All maintenance logs, calibration checks, and other required quality assurance activities.

(2) All records of corrective and preventive action.

(3) A log of monitoring system downtime, including the following:

(A) Date of monitoring system downtime.

(B) Time of commencement and completion of each downtime.

(C) Reason for each downtime.

(e) The Permittee shall submit a report of monitoring system downtime as specified in Section D. The report shall include the following:

(1) Date of monitoring system 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 supersedes the monitoring provisions in 40 CFR Part 60 or 40 CFR Part 63.

(g) Instrument Specification;

(1) When required by any condition of this permit, an analog instrument used to measure a parameter related to the operation of an air pollution control device shall have a scale such that the expected maximum reading for the normal range shall be no less than twenty percent (20%) of full scale.

(2) The Permittee may request that the IDEM, OAQ approve the use of an instrument that does not meet the above specifications provided the Permittee can demonstrate that an alternative instrument specification will adequately ensure compliance with permit conditions requiring the measurement of the parameters.

C.11 Maintenance of Continuous Emission Monitoring Equipment [326 IAC 2-7-5(3)(A)(iii)] [326 IAC 2-1.1-11] [326 IAC 3-5]

(a) Unless otherwise specified in this permit, all monitoring and record keeping requirements not already legally required shall be implemented within ninety (90) days of permit issuance. If required by Section D, the Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment. If due to circumstances beyond its control, that equipment cannot be installed and operated within ninety (90) days, the Permittee may extend the compliance schedule related to the equipment for an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, IN 46204-2251

in writing, prior to the end of the initial ninety (90) day compliance schedule, with full justification of the reasons for the inability to meet this date.

The notification, which shall be submitted by the Permittee, does require the certification by a “responsible official” as defined by 326 IAC 2-7-1(34).

(b) The Permittee shall install, calibrate, maintain, and operate all necessary continuous emission monitoring systems (CEMS) and related equipment in accordance with applicable federal regulations and 326 IAC 3-5.

(c) This provision applies only to CEMS operated solely for monitoring compliance with BACT limitations. The CEMS shall be operated at all times as specified in Section D, except during CEMS malfunctions, reasonable periods of necessary CEMS calibration or CEMS maintenance activities. CEMS calibration and maintenance activities shall be properly documented and shall be conducted pursuant to the standard operating procedures under 326 IAC 3-5-4(a).

(d) The Permittee shall keep records in accordance with 326 IAC 3-5-6(b) that includes the following:

(1) All documentation relating to:

(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 supersedes 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). 326 IAC 3-5-5(e)(2) is not federally enforceable.

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.

(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 Part 68]

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

C.14 Response to Abnormal or Out-of-Range Compliance Monitoring Measurements [326 IAC 2-7-5] [326 IAC 2-7-6]

(a) Upon detecting a measurement required by a compliance monitoring condition of this permit that is outside the normal or usual range of values for the monitoring parameter, the Permittee shall restore operation of the emissions unit (including any control device and associated capture system) to its normal or usual manner of operation as expeditiously as practicable in accordance with good air pollution control practices for minimizing emissions.

(b) The response shall include minimizing the period of any startup, shutdown or malfunction and taking any necessary corrective actions to restore normal operation and prevent the likely recurrence of the cause of abnormal or out-of-range monitoring values (other than those caused by excused startup or shutdown conditions). Corrective actions may include, but are not limited to, the following:

(1) initial inspection and evaluation;

(2) recording that operations returned to normal without operator action (such as through response by a computerized distribution control system); or

(3) any necessary follow-up actions to return operation to within the indicator range, designated condition, or below the applicable emission limitation or standard, as applicable.

(c) A determination of whether the Permittee has used acceptable procedures in response to a measurement indicating abnormal or out-of-range monitoring values will be based on information available, which may include, but is not limited to, the following:

(1) monitoring results;

(2) review of operation and maintenance procedures and records; and/or

(3) inspection of the control device, associated capture system, and the process.

(d) Failure to take reasonable response steps shall be considered a deviation from the permit.

(e) The Permittee shall maintain records of corrective actions taken.

C.15 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5][326 IAC 2-7-6]

(a) When the results of a stack test performed in conformance with Section C - Performance Testing, of this permit exceed the level specified in any condition of this permit, the Permittee shall take appropriate response actions. The Permittee shall submit a description of these response actions to IDEM, OAQ, within thirty (30) days of receipt of the test results. The Permittee shall take appropriate action to minimize excess emissions from the affected facility while the response actions are being implemented.

(b) A retest to demonstrate compliance shall be performed within one hundred twenty (120) days of receipt of the original test results. Should the Permittee demonstrate to IDEM, OAQ that retesting in one hundred twenty (120) days is not practicable, IDEM, OAQ may extend the retesting deadline.

(c) IDEM, OAQ reserves the authority to take any actions allowed under law in response to noncompliant stack tests.

The response action documents submitted pursuant to this condition do require the certification by a "responsible official" as defined by 326 IAC 2-7-1(34).

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

C.16 Emission Statement [326 IAC 2-7-5(3)(C)(iii)] [326 IAC 2-7-5(7)] [326 IAC 2-7-19(c)] [326 IAC 2-6]

(a) Pursuant to 326 IAC 2-6-3(a)(1), the Permittee shall submit by July 1 of each year an emission statement covering the previous calendar year. The emission statement shall contain, at a minimum, the information specified in 326 IAC 2-6-4(c) and shall meet the following requirements:

(1) Indicate estimated actual emissions of all pollutants listed in 326 IAC 2-6-4(a);

(2) Indicate estimated actual emissions of regulated pollutants as defined by 326 IAC 2-7-1 (32) (“Regulated pollutant, which is used only for purposes of Section 19 of this rule”) from the source, for purpose of fee assessment.

The statement must be submitted to:

Indiana Department of Environmental Management
Technical Support and Modeling Section, Office of Air Quality
100 North Senate Avenue
MC 61-50 IGCN 1003
Indianapolis, Indiana 46204-2251

The emission statement does require the certification by a “responsible official” as defined by 326 IAC 2-7-1(34).

(b) The emission statement 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.

C.17 General Record Keeping Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-6] [326 IAC 2-2] [326 IAC 2-3]

(a) Records of all required monitoring data, reports and support information required by this permit shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. These records shall be physically present or electronically accessible at the source location for a minimum of three (3) years. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.

(b) Unless otherwise specified in this permit, all record keeping requirements not already legally required shall be implemented within ninety (90) days of permit issuance.

(c) If there is a reasonable possibility that a “project” (as defined in 326 IAC 2-2-1 (qq)) at an existing emissions unit, other than projects at a source with Plant-wide Applicability Limitation (PAL)), which is not part of a “major modification” (as defined in 326 IAC 2-2-1 (ee)) may result in significant emissions increase and the Permittee elects to utilize the “projected actual emissions” (as defined in 326 IAC 2-2-1 (rr)), the Permittee shall comply with following:

(1) construction of the “project” (as defined in 326 IAC 2-2-1 (qq) at an existing emissions unit, document and maintain the following records:

(A) A description of the project.

(B) Identification of any emissions unit whose emissions of a regulated new source review pollutant could be affected by the project.

(C) A description of the applicability test used to determine that the project is not a major modification for any regulated NSR pollutant, including:

(i) Baseline actual emissions;

(ii) Projected actual emissions;

(iii) Amount of emissions excluded under section 326 IAC 2-2-1(rr)(2)(A)(iii); and

(iv) An explanation for why the amount was excluded, and any netting calculations, if applicable.

(2) Monitor the emissions of any regulated NSR pollutant that could increase as a result of the project and that is emitted by any existing emissions unit identified in (1)(B) above; and

(3) Calculate and maintain a record of the annual emissions, in tons per year on a calendar year basis, for a period of five (5) years following resumption of regular operations after the change, or for a period of ten (10) years following resumption of regular operations after the change if the project increases the design capacity of or the potential to emit that regulated NSR pollutant at the emissions unit.

C.18 General Reporting Requirements [326 IAC 2-7-5(3)(C)] [326 IAC 2-1.1-11] [326 IAC 2-2]

(a) The Permittee shall submit the attached Quarterly Deviation and Compliance Monitoring Report or its equivalent. Any deviation from permit requirements, the date(s) of each deviation, the cause of the deviation, and the response steps taken must be reported. This report shall be submitted within thirty (30) days of the end of the reporting period. The Quarterly Deviation and Compliance Monitoring Report shall include the certification by a "responsible official" as defined by 326 IAC 2-7-1(34).

(b) The report required in (a) of this condition and reports required by conditions in Section D of this permit shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

(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 a "responsible official" as defined by 326 IAC 2-7-1(34).

(e) Reporting periods are based on calendar years, unless otherwise specified in this permit. For the purpose of this permit "calendar year" means the twelve (12) month period from January 1 to December 31 inclusive.

(f) If the Permittee is required to comply with the recordkeeping provisions of (d) in Section C - General Record Keeping Requirements for any "project" (as defined in 326 IAC 2-2-1 (qq) and/or 326 IAC 2-3-1 (ll)) at an existing emissions unit, and the project meets the following criteria, then the Permittee shall submit a report to IDEM, OAQ:

(1) The annual emissions, in tons per year, from the project identified in (c)(1) in Section C- General Record Keeping Requirements exceed the baseline actual emissions, as documented and maintained under Section C- General Record Keeping Requirements (c)(1)(C)(i), by a significant amount, as defined in 326 IAC 2-2-1 (xx) and/or 326 IAC 2-3-1 (qq), for that regulated NSR pollutant, and

(2) The emissions differ from the preconstruction projection as documented and maintained under Section C - General Record Keeping Requirements (c)(1)(C)(ii).

(g) The report for project at an existing emissions unit shall be submitted within sixty (60) days after the end of the year and contain the following:

(1) The name, address, and telephone number of the major stationary source.

(2) The annual emissions calculated in accordance with (d)(1) and (2) in Section C - General Record Keeping Requirements.

(3) The emissions calculated under the actual-to-projected actual test stated in 326 IAC 2-2-2(d)(3) and/or 326 IAC 2-3-2(c)(3).

(4) Any other information that the Permittee deems fit to include in this report.

Reports required in this part shall be submitted to:

Indiana Department of Environmental Management
Air Compliance Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

(h) The Permittee shall make the information required to be documented and maintained in accordance with (c) in Section C- General Record Keeping Requirements available for review upon a request for inspection by IDEM, OAQ. The general public may request this information from the IDEM, OAQ under 326 IAC 17.1.

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.

SECTION D.6 BULK PHARMACEUTICAL MANUFACTURING (BPM) PRODUCTION OPERATION CONDITIONS

Emissions Unit Description: [326 IAC 2-7-5(1)]

(a) The emission units listed below are subject to applicable requirements described or referred to in this D section. The emission units in the BPM production operations can be generally described as process vessels (tanks), crystallizers, filters, centrifuges, dryers, process scrubber systems, and process condenser systems and are referred to as process vents under the National Emission Standards of Hazardous Air Pollutants for Pharmaceutical Production Operations (Pharmaceutical MACT) found at 40 CFR Part 63, Subpart GGG.

General activities such as open manway operations, charging a liquid from a drum to a tank, centrifuge emptying operations, drum filling operations, or loading wetcake into driers are also defined as process vents. Individual identification of these activities are not listed in the description tables given they are not stationary or continually change. Each of these activity types will follow the compliance requirements outlined in this permit section.

Ancillary activities, such as heat exchange systems, are not considered process vents and have not been included in the description tables.

Source ID	Equipment Description	Stack/Vent ID	Nominal Capacity	Control Device
Building T27:				
T27-TK30-1	Process Tank	RTO	200 gal	RTO
T27-TK30-2	Process Tank	RTO	200 gal	RTO
T27-TK31-1	Process Tank	RTO	1000 gal	RTO
T27-TK31-2	Process Tank	RTO	1000 gal	RTO
T27-TK31-3	Process Tank	RTO	1000 gal	RTO
T27-TK31-4	Process Tank	RTO	1000 gal	RTO
T27-TK31-5	Process Tank	RTO	1000 gal	RTO
T27-TK32-1	Process Tank	RTO	1000 gal	RTO
T27-TK32-2	Process Tank	RTO	1000 gal	RTO
T27-TK32-3	Process Tank	RTO	1000 gal	RTO
T27-TK32-4	Process Tank	RTO	1000 gal	RTO
T27-TK32-5	Process Tank	RTO	1000 gal	RTO
T27-TK32-7	Process Tank	RTO	350 gal	RTO
T27-TK33-1	Process Tank	RTO	2000 gal	RTO
T27-TK33-2	Process Tank	RTO	2000 gal	RTO
T27-TK33-3	Process Tank	RTO	2000 gal	RTO
T27-TK33-4	Process Tank	RTO	2000 gal	RTO
T27-TK33-5	Process Tank	RTO	500 gal	RTO
T27-TK34-1	Process Tank	RTO	750 gal	RTO
T27-TK34-2	Process Tank	RTO	750 gal	RTO
T27-TK34-4	Process Tank	RTO	750 gal	RTO
T27-TK34-5	Process Tank	RTO	750 gal	RTO
T27-TK34-6	Process Tank	RTO	750 gal	RTO
T27-TK34-7	Process Tank	RTO	1000 gal	RTO

	T27-TK34-8	Process Tank	RTO	350 gal	RTO	
	T27-TK35-1	Process Tank	RTO	2000 gal	RTO	
	T27-TK35-2	Process Tank	RTO	2000 gal	RTO	
	T27-TK35-3	Process Tank	RTO	2000 gal	RTO	
	T27-TK35-4	Process Tank	RTO	2000 gal	RTO	
	T27-TK35-5	Process Tank	RTO	500 gal	RTO	
	T27-TK35-6	Process Tank	RTO	2000 gal	RTO	
	T27-TK36-1	Process Tank	RTO	2000 gal	RTO	
	T27-TK36-2	Process Tank	RTO	1000 gal	RTO	
	T27-TK36-3	Process Tank	RTO	2000 gal	RTO	
	T27-TK36-6	Process Tank	RTO	2000 gal	RTO	
	T27-TK36-7	Process Tank	RTO	500 gal	RTO	
	T27-TK37-2A	Process Tank	RTO	300 gal	RTO	
	T27-TK38-3	Process Tank	RTO	1000 gal	RTO	
	T27-TK40-1	Process Tank	RTO	2000 gal	RTO	
	T27-TK40-2	Process Tank	RTO	2000 gal	RTO	
	T27-TK40-4	Process Tank	RTO	1000 gal	RTO	
	T27-TK40-5	Process Tank	RTO	1500 gal	RTO	
	T27-TK40-6	Process Tank	RTO	2000 gal	RTO	
	T27-TK40-6A	Process Tank	RTO	2000 gal	RTO	
	T27-TK40-7	Process Tank	RTO	2000 gal	RTO	
	T27-TK40-7A	Process Tank	RTO	2000 gal	RTO	
	T27-TK40-8	Process Tank	RTO	2000 gal	RTO	
	T27-TK40-9	Process Tank	RTO	1000 gal	RTO	
	T27-TK40-10	Process Tank	RTO	1000 gal	RTO	
	T27-TK40-11	Process Tank	RTO	1000 gal	RTO	
	T27-TK40-13	Process Tank	RTO	750 gal	RTO	
	T27-TK40-14	Process Tank	RTO	300 gal	RTO	
	T27-TK41-1	Process Tank	RTO	750 gal	RTO	
	T27-TK41-3	Process Tank	RTO	500 gal	RTO	
	T27-TK41-4	Process Tank	RTO	500 gal	RTO	
	T27-TK41-5	Process Tank	RTO	1000 gal	RTO	
	T27-TK42-3	Process Tank	RTO	500 gal	RTO	
	T27-TK42-5	Process Tank	RTO	1000 gal	RTO	
	T27-TK43-1	Process Tank	RTO	750 gal	RTO	
	T27-TK43-2	Process Tank	RTO	500 gal	RTO	
	T27-TK44-1	Process Tank	RTO	2000 gal	RTO	
	T27-TK44-4	Process Tank	RTO	2000 gal	RTO	
	T27-TK45-2	Process Tank	RTO	1000 gal	RTO	
	T27-TK46-1	Process Tank	RTO	1000 gal	RTO	
	T27-TK46-5	Process Tank	RTO	1000 gal	RTO	
	T27-TK47-1	Process Tank	RTO	1000 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-TK50-4	Process Tank	RTO	500 gal	RTO	
	T27-TK372-A	Process Tank	RTO	500 gal	RTO	

T27-CENT19	Centrifuge	RTO	NA	RTO
T27-CENT30	Centrifuge	RTO	NA	RTO
T27-CENT38	Centrifuge	RTO	NA	RTO
Building T28:				
T28-CENT1	Heinkel Centrifuge	T79 or RTO**	NA	T79 or RTO**
T28-CENT2	Heinkel Centrifuge	T79 or RTO**	NA	T79 or RTO**
T28-CENT3	Heinkel Centrifuge	T79 or RTO**	NA	T79 or RTO**
T28-CENT22	Centrifuge	T79 or RTO**	NA	T79 or RTO**
T28-CENT24	Centrifuge	T79 or RTO**	NA	T79 or RTO**
T28-CENT26	Centrifuge	T79 or RTO**	NA	T79 or RTO**
T28-TK28-1	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-1A	Process Tank	T79 or RTO**	300 gal	T79 or RTO**
T28-TK28-2	Process Tank	T79 or RTO**	1000 gal	T79 or RTO**
T28-TK28-3	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-3A	Process Tank	T79 or RTO**	340 gal	T79 or RTO**
T28-TK28-03	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-4	Process Tank	T79 or RTO**	1000 gal	T79 or RTO**
T28-TK28-5	Process Tank	T79 or RTO**	1000 gal	T79 or RTO**
T28-TK28-6	Process Tank	T79 or RTO**	1000 gal	T79 or RTO**
T28-TK28-7	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-8	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-9	Process Tank	T79 or RTO**	1000 gal	T79 or RTO**
T28-TK28-10	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-10A	Process Tank	T79 or RTO**	340 gal	T79 or RTO**
T28-TK28-11	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-12	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-13	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-14	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-15	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-16	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-17	Process Tank	T79 or RTO**	1000 gal	T79 or RTO**
T28-TK28-18	Process Tank	T79 or RTO**	750 gal	T79 or RTO**
T28-TK28-19	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-20	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-21	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-22	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-23	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-24	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-25	Process Tank	T79 or RTO**	1500 gal	T79 or RTO**
T28-TK28-26	Process Tank	T79 or RTO**	1500 gal	T79 or RTO**
T28-TK28-29	Process Tank	T79 or RTO**	1000 gal	T79 or RTO**
T28-TK28-30	Process Tank	T79 or RTO**	500 gal	T79 or RTO**
T28-TK28-31	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-TK28-32	Process Tank	T79 or RTO**	2000 gal	T79 or RTO**
T28-PTK1	Portable Charge Tank	T79 or RTO**	300 gal	T79 or RTO**
T28-PTK2	Portable Charge Tank	T79 or RTO**	300 gal	T79 or RTO**
T28-PTK3	Portable Charge Tank	T79 or RTO**	300 gal	T79 or RTO**

Building T29:				
T29-CENT1401	Heinkel Centrifuge	RTO	140 gal	RTO
T29-CENT2401	Heinkel Centrifuge	RTO	140 gal	RTO
T29-CENT3401	Heinkel Centrifuge	RTO	140 gal	RTO
T29-CD1501	Cone Dryer	RTO	2,640 gal	RTO
T29-FD8501	Filter Dryer	RTO	42 gal	RTO
T29-FD-8503	Filter Dryer	RTO	175 gal	RTO
T29-DRY2502	Filter Dryer	RTO	70 gal	RTO
T29-DRY3501	Cone Dryer	RTO	2,640 gal	RTO
T29-IBC8201	Process Tank	RTO	100 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
T29-IBC8209	Process Tank	RTO	150 gal	RTO
T29-IBC8216	Process Tank	RTO	50 gal	RTO
T29-IBC8217	Process Tank	RTO	50 gal	RTO
T29-IBC8251	Process Tank	RTO	150 gal	RTO
T29-IBC8253	Process Tank	RTO	150 gal	RTO
T29-IBC8254	Process Tank	RTO	150 gal	RTO
T29-IBC8256	Process Tank	RTO	150 gal	RTO
T29-IBC8257	Process Tank	RTO	150 gal	RTO
T29-IBC8259	Process Tank	RTO	150 gal	RTO
T29-IBC8380	Process Tank	RTO	50 gal	RTO
T29-IBC8381	Process Tank	RTO	50 gal	RTO
T29-SFH1121	Process Tank	RTO	NA	RTO
T29-SFH3121	Process Tank	RTO	NA	RTO
T29- REAC1201	Process Tank	RTO	2000 gal	RTO
T29- REAC 1202	Process Tank	RTO	2000 gal	RTO
T29- REAC 1203	Process Tank	RTO	2000 gal	RTO
T29- REAC 1204	Process Tank	RTO	2000 gal	RTO
T29- REAC 1205	Process Tank	RTO	2000 gal	RTO
T29- REAC 2201	Process Tank	RTO	1600 gal	RTO
T29- REAC 2202	Process Tank	RTO	2000 gal	RTO
T29- REAC 2203	Process Tank	RTO	2000 gal	RTO
T29- REAC 2204	Process Tank	RTO	2000 gal	RTO
T29- REAC 2205	Process Tank	RTO	2000 gal	RTO
T29- REAC 3201	Process Tank	RTO	2000 gal	RTO
T29- REAC 3202	Process Tank	RTO	2000 gal	RTO
T29- REAC 3203	Process Tank	RTO	2000 gal	RTO
T29- REAC 3204	Process Tank	RTO	2000 gal	RTO
T29- REAC 3205	Process Tank	RTO	2000 gal	RTO
T29- REAC 4201	Process Tank	RTO	2,000 gal	RTO
T29- REAC 4202	Process Tank	RTO	500 gal	RTO
T29- REAC 4203	Process Tank	RTO	2000 gal	RTO
T29-TK7920	Process Tank	RTO	200 gal	RTO

T29-TK7921	Process Tank	RTO	80 gal	RTO
T29-TK7922	Process Tank	RTO	200 gal	RTO
T29-TK8123	Process Tank	RTO	200 gal	RTO
T29-TK8211	Process Tank	RTO	100 gal	RTO
T29-TK8212	Process Tank	RTO	100 gal	RTO
T29-TK8213	Process Tank	RTO	100 gal	RTO
T29-TK8214	Process Tank	RTO	100 gal	RTO
T29-TK8216	Process Tank	RTO	50 gal	RTO
T29-TK8217	Process Tank	RTO	50 gal	RTO
T29-TK8218	Process Tank	RTO	50 gal	RTO
T29-TK8220	Process Tank	RTO	50 gal	RTO
T29-TK8256	Process Tank	RTO	150 gal	RTO
T29-TK8219	Accumulator Tank	RTO	50 gal	RTO
T29-TK1204A	Accumulator Tank	RTO	50 gal	RTO
T29-TK1401A	Accumulator Tank	RTO	50 gal	RTO
T29-TK2401A	Accumulator Tank	RTO	50 gal	RTO
T29-TK3401	Accumulator Tank	RTO	50 gal	RTO
Building T31:				
T31-CENT	Centrifuge	RTO	13 cf	RTO
T31-FD803	Filter Dryer	RTO	0.6 m^2	RTO
T31-TK601	Process Tank	RTO	500 gal	RTO
T31-TK602	Process Tank	RTO	500 gal	RTO
T31-TK603	Process Tank	RTO	500 gal	RTO
T31-TK604	Process Tank	RTO	500 gal	RTO
T31-TK611	Process Tank	RTO	500 gal	RTO
T31-TK611DT01	Process Tank	RTO	50 gal	RTO
T31-TK612	Process Tank	RTO	500gal	RTO
T31-TK613	Process Tank	RTO	500 gal	RTO
T31-TK614	Process Tank	RTO	500 gal	RTO
T31-TK631	Process Tank	RTO	300 gal	RTO
T31-TK641	Process Tank	RTO	100 gal	RTO
T31-TK643	Process Tank	**	100 gal	T79 or RTO**
Building T31A:				
T31A-CENT985	Centrifuge	RTO	N/A	RTO
T31A-FD861	Filter Dryer	RTO	0.6 m2	RTO
T31A-FD874	Filter Dryer	RTO	0.6 m2	RTO
T31A-TK621	Process Tank	RTO	300 gal	RTO
T31A-TK622	Process Tank	RTO	800 gal	RTO
T31A-TK651	Process Tank	RTO	450 gal	RTO
T31A-TK661	Process Tank	RTO	300 gal	RTO
T31A-TK681	Process Tank	RTO	500 gal	RTO
T31A-TK682	Process Tank	RTO	500 gal	RTO
T31A-TK683	Process Tank	RTO	500 gal	RTO
T31A-TK684	Process Tank	RTO	500 gal	RTO
T31A-TK691	Process Tank	RTO	500 gal	RTO
T31A-TK692	Process Tank	RTO	500 gal	RTO

T31A-TK693	Process Tank	RTO	500 gal	RTO
T31A-TK694	Process Tank	RTO	500 gal	RTO
Building T99:				
T99-ED42	Heinkel Centrifuge	RTO	NA	RTO
T99-PD43	Pan Dryer	RTO	793 gal	RTO
T99-PD44	Pan Dryer	RTO	793 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-D9	Process Tank	RTO	449 gal	RTO
T99-FD-D9*	Filter Dryer	RTO	NA	RTO
T99-TK-D-9D*	Portable Tank	RTO	155 gal	RTO
T99-TK-D41	Process Tank	RTO	300 gal	RTO
T99-TK-D42	Process Tank	RTO	150 gal	RTO
Building T100:				
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-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-TK5A*	Accumulator Tank	RTO	50 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-TK18A*	Distillate Tank	RTO	200 gal	RTO
T100-TK18B*	Charge Tank	RTO	60 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-TK24D*	Distillate Tank	RTO	50 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-PTK1	Portable Cleaning Tank	RTO	150 gal	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
Spare Equipment (not associated with a single building)				
T27-CENT 16	Centrifuge	***	NA	***
T27-CENT 37	Centrifuge	***	NA	***
T27-CENT 40	Centrifuge	***	NA	***
T28-CENT15	Centrifuge	***	NA	***
T31-CENT504	Centrifuge	***	13 gal	***
T31-RVD T47733	Rotary Vacuum Dryer	**	37 gal	***

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

** This equipment is currently not in service; however, this equipment shall be tied into either the RTO control system or the T79 control system upon startup.

*** Spare equipment may be used anywhere on the plant site. If the equipment is used in T27, T28, T31, T31A, T99, or T100, it will be vented to the RTO as required by Section D.6 of the permit. If the equipment is used in the T71 area, it will be vented to the atmosphere as allowed by Section D.16 of the permit.

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

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

D.6.0 VOC, CO and Fluorides PSD BACT Requirements [326 IAC 2-2-3]

(a) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), the Best Available Control Technology (BACT), VOC BACT of 20 parts per million (ppmv) based on a 24 - hour daily average, or 98 % of VOC/VOHAP emissions has been established for the BPM Operation.

(b) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), the Best Available Control Technology (BACT), CO BACT of 78 ppmvdc based on a 24 - hour daily average has been established for the BPM Operation.

(c) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), the Best Available Control Technology (BACT), Fluorides (F-) BACT of NaOH injection to achieve 98% removal of hydrogen halide and halogen emissions, or 20 ppmv of hydrogen halide and halogen emissions over a 24 - hour daily average has been established for the BPM Operation.

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) Except as otherwise provided in Conditions D.6.1(c) and D.6.2, the emission limits and standards applicable for 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 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^{O}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 it's 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)]

The Pharmaceutical MACT requirements for Startup, Shutdown and Malfunction (SSM) [40 CFR 63.1259(a)(3) and 40 CFR 63.1250(g)] shall be used to satisfy the Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)], and PSD BACT requirements [326 IAC 2-2-3].

(a) Pursuant to 40 CFR 63.1259(a)(3)), the Permittee shall develop an SSM Plan to ensure that processes are operated and maintained in a manner to prevent or minimize excess emissions to the extent practical [40 CFR 63.1250(g)]. 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) Reserved

(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.1and 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 Pharmaceutical MACT standards for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.1260(i)] shall be used to satisfy the reporting requirements under the Pharmaceutical MACT standards and PSD BACT requirements [326 IAC 2-2-3].

(1) The Permittee shall report all actions taken during a process SSM event that results in an exceedance of a relevant emission standard when those actions are inconsistent with the procedure 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 a process SSM event that results in an exceedance of a relevant emission standard when those actions taken by the Permittee are inconsistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information:

(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;

(D) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred; and

(E) Actions taken to minimize emissions.

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

D.6.9 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 2-7-10.5), 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 D.7 BPM SUPPORT OPERTIONS - SOLVENT RECOVERY OPERATION CONDITIONS

Emissions Unit Description: [326 IAC 2-7-5(1)]

(a) The emission units listed below are subject to applicable requirements described or referred to in this D section. The BPM solvent recovery emission units can be generally described as columns, stills, evaporators, accumulators, process condensers and receivers and are referred to as process vents under the National Emission Standards of Hazardous Air Pollutants for Pharmaceutical Production Operations (Pharmaceutical MACT) found at 40 CFR 63, Subpart GGG and OSW MACT found at 40 CFR 63, Subpart DD. The solvent recovery columns may also be defined as treatment units under the OSW MACT.

Ancillary activities, such as heat exchange systems, are not considered process vents and have not been included in the description tables.

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
Building T19:				
T19-STL1	Still	T79	1500 gal	T79
T19-STL2	Still	T79	4000 gal	T79
T19-COL3	Column	T79	NA	T79
T19-REC1	Receiver	T79	2000 gal	T79
T19-REC10	Receiver	T79	2000 gal	T79
T19-REC11	Receiver	T79	5300 gal	T79
T19-REC2	Receiver	T79	2000 gal	T79
T19-REC3	Receiver	T79	2000 gal	T79
T19-REC6	Receiver	T79 or RTO*	300 gal	T79 or RTO*
T19-REC7	Receiver	T79 or RTO*	300 gal	T79 or RTO*
T19-REC8	Receiver	T79 or RTO*	750 gal	T79 or RTO*
T19-REC9	Receiver	T79	750 gal	T79
T19-TK-19-29S*	HCl Acid Storage	Atmosphere	6,000 gal	Conservation Vent
T19-TK-19-29N*	HCl Acid Storage	Atmosphere	6,000 gal	Conservation Vent
T19-TK9A3A	Accumulator	T79	100 gal	T79
Building T52:				
T52-REC52-1	Stainless Receiver	T79	2000 gal	T79
T52-REC52-2	Stainless Receiver	T79	2000 gal	T79
T52-ACC9	Accumulator	T79	NA	T79
T52-ACC10	Accumulator	T79	NA	T79
T52-ACC5	Accumulator	T79	NA	T79
T52-ACC6	Accumulator	T79	NA	T79
T52-COL52-8	Wash Column	T79	NA	T79
T52-EVAP10	Evaporator	T79	2000 gal	T79
T52-EVAP5	Evaporator	T79	2000 gal	T79
T52-EVAP6	Evaporator	T79	2000 gal	T79
T52-STPR52-14	Steam Stripper	T79	250 gal	T79
T52-ACC14	Accumulator	T79	NA	T79
T52-TK5K4A*	Sulfuric Acid Storage	Atmosphere	125 gal	None

Building T61:				
T61-COL61-1	Column	T79	NA	T79
T61-TK-1A	Accumulator	T79	100 gal	T79
T61-TK-1B	Accumulator	T79	75 gal	T79
T61-TK-1C	Accumulator	T79	50 gal	T79
T61-COL61-2	Column	T79	NA	T79
T61-TK-2A	Accumulator	T79	100 gal	T79
T61-TK-2B	Accumulator	T79	75 gal	T79
T61-TK-2C	Accumulator	T79	50 gal	T79
T61-COL61-3	Column	T79	NA	T79
T61-TK-3A	Accumulator	T79	100 gal	T79
T61-TK-3B	Accumulator	T79	75 gal	T79
T61-TK-3C	Accumulator	T79	50 gal	T79
T61-REC1	Receiver	T79	5000 gal	T79
T61-REC2	Receiver	T79	5000 gal	T79
T61-REC3	Receiver	T79	5000 gal	T79
T61-REC4	Receiver	T79	5000 gal	T79
T61-REC5	Receiver	T79	5000 gal	T79
T61-REC6	Receiver	T79	5000 gal	T79
T61-REC7	Receiver	T79	5000 gal	T79
T61-REC8	Receiver	T79	5000 gal	T79
Building T127				
T127-TK-46*	50% Caustic Storage	Atmosphere	39,000 gal	Open to Atmosphere
T127-TK-47*	20% Caustic Storage	Atmosphere	39,000 gal	Open to Atmosphere

* This equipment is currently not in service; however, this equipment shall be tied into either the RTO control system or the T79 control system upon startup.

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

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

D.7.0 VOC PSD BACT Requirements [326 IAC 2-2-3]

Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), the Best Available Control Technology (BACT), VOC BACT of 98% control of VOC emissions has been established for the BPM Support.

D.7.1 Standards for BPM Support Process Vents [40 CFR 63.1254, CFR 63.690, 326 IAC 2-2-3, and 326 IAC 8-5-3]

The following streamlined standards for the BPM solvent recovery operations satisfy the Pharmaceutical MACT Standards for process vents [40 CFR 63.1254], OSWRO MACT Standards for process vents [40 CFR 63.690], PSD BACT requirements [326 IAC 2-2-3] and RACT requirements for synthesized pharmaceutical manufacturing operations [326 IAC 8-5-3]:

(a) Except as otherwise provided in Condition D.7.1(c), the emission limits and standards for each operating BPM process vent containing undiluted and uncontrolled process vent streams equal to or greater than 50 ppmv VOHAP and/or 50 ppmv VOC are described in SECTION D.14 for emission units controlled by the RTO control system and described in SECTION D.15 for emission units controlled by the T79 fume incinerator control system.

(b) The Permittee shall cover all in-process tanks associated with the BPM solvent recovery operations, 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 Support 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 Support 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^{O}C.

D.7.2 Treatment Unit Requirements [326 IAC 2-2-3 and 40 CFR 63.684]

When a solvent recovery column is used as the final treatment step to treat off-site waste containing VOHAP or VOC equal to or greater than 500 ppmw, the Permittee shall reduce the VOHAP and VOC concentrations of the off-site material to a level that is less than 500 ppmw to satisfy the requirements of 326 IAC 2-2-3 and 40 CFR 63.684(b).

D.7.3 Leak Detection and Repair (LDAR) for Fugitive Emissions [326 IAC 2-2-3 and 40 CFR 63.1255]

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

D.7.4 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 exchangers [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 - 211.67(b)(3).

D.7.5 Startup, Shutdown and Malfunction Requirements [326 IAC 2-2-3, 40 CFR 63.1259(a)(3), and 40 CFR 63.697(b)(3)]

The Pharmaceutical MACT [40 CFR 63.1259(a)(3)] and Offsite Waste MACT requirements [40 CFR 63.697(b)(3)] for Startup, Shutdown and Malfunction (SSM) shall be used to satisfy 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 2-2-3].

(a) Pursuant to 40 CFR 63.1259(a)(3) and 40 CFR 63.697(b)(3), the Permittee shall develop an SSM Plan to ensure that processes are operated and maintained in a manner to prevent or minimize excess emissions to the extent practical [40 CFR 63.1250(g)]. 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, and associated closed-vent systems, 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.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.

(2) LDAR Records - The record keeping requirements for the LDAR standards are described in Sections E.1 and E.2 of this permit.

(3) Process Records – The Permittee shall maintain the following records when using the process vent standard described in Condition D.7.1(c):

(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.

(4) Solvent Recovery Records – The Permittee shall track how the solvent recovery columns are being utilized in an operating scenario maintained in the On-Site Implementation Log. If a solvent recovery column is used as a treatment column for offsite waste, then the Permittee shall maintain the following records:

(A) Initial and annual demonstration records;

(B) Records of all required CMS data;

(C) Records of each CMS calibration checks;

(D) Maintenance records for each CMS; and

(E) Occurrence/duration records of each CMS malfunction.

(5) 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).

(6) 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.

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

(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.

(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 Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)] and Offsite Waste MACT standards [40 CFR 63.697(b)(3)] for Startup, Shutdown and Malfunction (SSM) shall be used to satisfy the reporting requirements under the Pharmaceutical MACT standards, Offsite Waste MACT standards, and PSD BACT requirements [326 IAC 2-2-3].

(1) The Permittee shall report all actions taken during a process SSM event that results in an exceedance of a relevant emission standard when those actions are inconsistent with the procedure 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 a process SSM event that results in an exceedance of a relevant emission standard when those actions taken by the Permittee are inconsistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information:

(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;

(D) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred; and

(E) Actions taken to minimize emissions.

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 2-7-10.5), 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 D.8 BPM SUPPORT OPERATIONS - INDIVIDUAL DRAIN SYSTEM OPERATION CONDITIONS

Emissions Unit Description: BPM SUPPORT OPERATIONS – INDIVIDUAL DRAIN SYSTEM CONDITIONS

The emission units listed below are subject to applicable requirements described or referred to in this D section. These sumps are defined as individual drain systems under the National Emission Standards of Hazardous Air Pollutants for Pharmaceutical Production Operations (Pharmaceutical MACT) found at 40 CFR 63, Subpart GGG or under the National Emission Standards of Hazardous Air Pollutants from Off-site Waste and Recovery Operations (OSWRO MACT) found at 40 CFR 63, Subpart DD.

Unit ID	Unit Description	Stack/Vent	Nominal Capacity	Control Device
Building T27:				
T27-Sump*	Sump Tank/Lift Station	RTO	2,000 gal	RTO
Building T28:				
T28-Sump*	Sump	T79 or RTO**	1,300 gal	T79 or RTO**
Building T31:				
T31-Sump*	Sump	RTO	5,900 gal	RTO
Building T31A:				
T31A-Sump*	Sump	RTO	300 gal	RTO
Building T19:				
T19-1-Sump*	Sump	None	NA	None
Building T148:				
T148-TK782*	IDS	None	100 gal	None

* Emission units marked with an asterisk are insignificant activities as defined by 326 IAC 2-7-1(21)(A)-(C).
** This equipment is currently not in service; however, this equipment shall be tied into either the RTO control system or the T79 control system upon startup.

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

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

D.8.1 BPM Individual Drain System (IDS) Standards [40 CFR 63.1256(e), 40 CFR 63.689(b), and 326 IAC 2-2-3]

The following streamlined standards for BPM IDSs satisfy the requirements of the Pharmaceutical MACT Standards for individual drain systems [40 CFR 63.1256(e)], OSWRO MACT Standards for transfer systems [40 CFR 63.689(b)], and PSD BACT requirements [326 IAC 2-2-3]:

(a) Definition Standards:

(1) A BPM IDS is defined as any stationary system used to convey waste streams containing HAP or VOC to a waste management unit. A segregated stormwater sewer system, which is a drain and collection system designed and operated for the sole purpose of collecting rainfall-runoff at a facility, and which is segregated from all other individual drain systems, is excluded from this definition. An IDS that is used for the sole purpose of collecting wastewater from drips, spills and leaks, or water from safety showers, condensation and fire deluge systems, is

excluded from this definition. For purposes of inspections in Section D.8.1(c), a BPM IDS includes any fixed roof, cover, and/or enclosure, and closed vent system section from the IDS to the inlet of the production building roof fan exhausting to the control device or to the IDS conservation vent.

(b) Operational Standards:

(1) The Permittee shall cover the openings of each operating BPM IDS containing waste equal to or greater than 500 parts per million by weight (ppmw) HAP and/or 500 ppmw VOC at all times during use except when it is necessary to use the opening for sampling or removal of material, or for equipment inspection, maintenance, or repair; and

(2) Except as otherwise provided in this Condition, the emission limits and standards for each operating BPM IDS containing waste equal to or greater than 500 ppmw HAP and/or 500 ppmw VOC are described in SECTION D.14 for emission units controlled by the RTO control system and described in SECTION D.15 for emission units controlled by the T79 fume incinerator control system; or

(3) For each BPM IDS equipped with a water seal, the Permittee is not subject to the requirements in (1) and (2) of this section, but instead shall ensure that the water seal is maintained on a semiannual basis. For example, a flow-monitoring device indicating positive flow from a main to a branch water line supplying a trap or water being continuously dripped into the trap by a hose could be used to verify flow of water to the trap. Visual observation is also an acceptable alternative.

(c) Inspection Standards:

(1) For each BPM IDS containing waste equal to or greater than 500 ppmw HAP and/or 500 ppmw VOC, the Permittee shall perform the following visual inspections and, when necessary, comply with the following repair requirements:

(A) Initial and semiannual visual inspections of each BPM IDS for improper work practices such as leaving open any access hatch or other opening when such hatch or opening is not in use for sampling or removal, or for equipment inspection, maintenance, or repair.

(B) Initial and semiannual visual inspections of each BPM IDS for control equipment failures such as a cracked or broken joint, lid, cover, or door.

(C) Initiate repair of any leak no later than 5 calendar days after identification, and complete repair within 15 days after identification, except for the following allowances for delay of repair:

(i) Repair is technically infeasible without a shutdown;

(ii) Emissions resulting from immediate repair would be greater than the emissions likely to result from delay of repair. In such cases, repair shall occur by the end of the next shutdown;

(iii) Equipment is emptied or is no longer used to treat waste equal to or greater than 500 ppmw HAP and/or VOC; or

(iv) Unavailability of parts beyond the control of the Permittee.

(2) For each BPM IDS containing waste equal to or greater than 500 ppmw HAP and/or 500 ppmw VOC and not operated under negative pressure, the Permittee shall perform the following additional inspections and, when necessary, comply with the following repair requirements:

(A) Initial one-time Method 21 inspection on the cover of each BPM IDS. For new equipment, this inspection shall be performed within 150 days upon startup of the new equipment.

(B) Semiannual visual inspections for visible, audible, or olfactory indications of leaks.

(C) Initiate repair of any leak no later than 5 calendar days after identification, and complete repair within 15 days after identification, except for the following situations:

(i) Delay of repair is allowed if the repair is technically infeasible without a shutdown; or

(ii) Delay of repair is allowed if the emissions resulting from immediate repair would be greater than the emissions likely to result from delay of repair.

(3) For each BPM IDS equipped with a water seal, the Permittee is not subject to the requirements in (1) and (2) of this section, but instead shall ensure that the water seal is maintained on a semiannual basis. For example, a flow-monitoring device indicating positive flow from a main to a branch water line supplying a trap or water being continuously dripped into the trap by a hose could be used to verify flow of water to the trap. Visual observation is also an acceptable alternative.

(4) BPM IDSs containing waste equal to or greater than 500 ppmw HAP and/or 500 ppmw VOC that are unsafe or difficult to inspect are not subject to the requirements of D.8.1 (b)(2) and D.8.1(c).

D.8.2 Startup, Shutdown and Malfunction Requirements [40 CFR 63.1259(a)(3), 40 CFR 63.697(b)(3), and 326 IAC 2-2-3]

The Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)] and Offsite Waste MACT standards [40 CFR 63.697(b)(3)] for Startup, Shutdown and Malfunction (SSM) shall be used to satisfy 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 2-2-3].

(a) Pursuant to 40 CFR 63.1259(a)(3) and 40 CFR 63.697(b)(3), the Permittee shall develop an SSM Plan to ensure that processes are operated and maintained in a manner to prevent or minimize excess emissions to the extent practical [40 CFR 63.1250(g)].

(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.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.

(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 wit the procedures in the SSM Plan.

(D) 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 Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)] and Offsite Waste MACT standards [40 CFR 63.697(b)(3)] for Startup, Shutdown and Malfunction (SSM) shall be used to satisfy the reporting requirements under the Pharmaceutical MACT standards, Offsite Waste MACT standards, and PSD BACT requirements [326 IAC 2-2-3].

(1) The Permittee shall report all actions taken during a process SSM event that results in an exceedance of a relevant emission standard when those actions are inconsistent with the procedure 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 a process SSM event that results in an exceedance of a relevant emission standard when those actions taken by the Permittee are inconsistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information:

(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;

(D) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred; and

(E) Actions taken to minimize emissions.

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), 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.

Non-Applicability of Requirements

D.8.7 Non-Applicability Determinations [326 IAC 8-5-3]

The control requirements of the Synthesized Pharmaceutical RACT rules (326 IAC 8-5-3) do not apply to the individual drain systems identified above in the Facility Description section because the potential to emit VOC emissions from each facility is less than the rule applicability threshold level of 6.8 kilograms per day (15 pounds per day).

SECTION D.9 BPM SUPPORT OPERATIONS – SOLVENT STORAGE TANK OPERATION CONDITIONS

Emissions Unit Description:

Emission Unit ID	Emission Unit Description**	Stack/Vent	Nominal Capacity	Control Device
Building T143 – Tank Module:				
T143-TK01	Solvent Tank	T79	38,245 gal	T79
T143-TK03	Solvent Tank	T79	38,245 gal	T79
T143-TK05	Solvent Tank	T79	38,245 gal	T79
T143-TK07	Solvent Tank	T79	38,245 gal	T79
T143-TK09	Solvent Tank	T79	38,245 gal	T79
T143-TK11	Solvent Tank	T79	38,245 gal	T79
T143-TK12	Solvent Tank	T79	18,500 gal	T79
T143-TK13	Solvent Tank	T79	18,500 gal	T79
T143-TK14	Solvent Tank	T79	18,500 gal	T79
T143-TK17	Solvent Tank	T79	18,500 gal	T79
T143-TK18	Solvent Tank	T79	18,500 gal	T79
T143-TK19	Solvent Tank	T79	18,500 gal	T79
T143-TK20	Solvent Tank	T79	18,500 gal	T79
T143-TK21	Solvent Tank	T79	18,500 gal	T79
T143-TK22	Solvent Tank	T79	18,500 gal	T79
T143-TK23	Solvent Tank	T79	18,500 gal	T79
T143-TK24	Solvent Tank	T79	18,500 gal	T79
Building T145 – Tank Module:				
T145-TK25	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*
T145-TK26	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*
T145-TK27	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*
T145-TK28	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*
T145-TK29	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*
T145-TK30	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*
T145-TK31	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*
T145-TK32	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*
T145-TK33	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*
T145-TK34	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*
T145-TK35	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*
T145-TK36	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*
T145-TK37	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*
T145-TK38	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*
T145-TK39	Solvent Tank	T79 or RTO*	18,900 gal	T79 or RTO*

T145-TK40	Solvent Tank	T79	18,900 gal	T79
T145-TK41	Solvent Tank	T79	18,900 gal	T79
T145-TK42	Solvent Tank	T79	18,900 gal	T79
T145-TK43	Solvent Tank	T79	18,900 gal	T79
T145-TK44	Solvent Tank	T79	18,900 gal	T79
T145-TK45	Solvent Tank	T79	18,900 gal	T79
T145-TK46	Solvent Tank	T79	18,900 gal	T79
T145-TK47	Solvent Tank	T79	18,900 gal	T79
T145-TK48	Solvent Tank	T79	18,900 gal	T79
T145-TK49	Solvent Tank	T79	18,900 gal	T79
T145-TK50	Solvent Tank	T79	10,000 gal	T79
T145-TK51	Solvent Tank	T79	10,000 gal	T79
T145-TK52	Solvent Tank	T79	10,000 gal	T79
T145-TK53	Solvent Tank	T79	10,000 gal	T79
T145-TK54	Solvent Tank	T79	10,000 gal	T79
T145-TK55	Solvent Tank	T79	10,000 gal	T79
T145-TK56	Solvent Tank	T79	10,000 gal	T79
T145-TK57	Solvent Tank	T79	10,000 gal	T79
T145-TK58	Solvent Tank	T79	10,000 gal	T79
T145-TK59	Solvent Tank	T79	10,000 gal	T79
Building T146 – Tank Module:				
T146-TK01	Solvent Tank	RTO	19,000 gal	RTO
T146-TK02	Solvent Tank	RTO	19,000 gal	RTO
T146-TK03	Solvent Tank	RTO	19,000 gal	RTO
T146-TK04	Solvent Tank	RTO	19,000 gal	RTO
T146-TK05	Solvent Tank	RTO	19,000 gal	RTO
T146-TK06	Solvent Tank	RTO	19,000 gal	RTO
T146-TK07	Solvent Tank	RTO	19,000 gal	RTO
T146-TK08	Solvent Tank	RTO	19,000 gal	RTO
T146-TK09	Solvent Tank	RTO	19,000 gal	RTO
T146-TK10	Solvent Tank	RTO	19,000 gal	RTO
T146-TK13	Solvent Tank	RTO	19,000 gal	RTO
T146-TK14	Solvent Tank	RTO	19,000 gal	RTO
T146-TK15	Solvent Tank	RTO	19,000 gal	RTO
T146-TK16	Solvent Tank	RTO	19,000 gal	RTO
T146-TK17	Solvent Tank	RTO	19,000 gal	RTO
T146-TK18	Solvent Tank	RTO	19,000 gal	RTO
T146-TK19	Solvent Tank	RTO	19,000 gal	RTO
T146-TK22	Solvent Tank	RTO	19,000 gal	RTO

* This equipment is currently not in service; however, this equipment shall be tied into either the RTO control system or the T79 control system upon startup.

** This equipment may store solvent or waste.

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

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

D.9.1 Standards for BPM Solvent Storage Tanks [40 CFR 63.1253(c)(1)(i), 40 CFR 60.112b and 60.113b, 326 IAC 8-5-3, and 326 IAC 2-2]

The following streamlined standards for the BPM solvent storage tanks satisfy the requirements of the Pharmaceutical MACT Standards for storage tanks [40 CFR 63.1253(c)(1)(i)], Volatile Organic Liquid Storage Vessel Standards [40 CFR 60.112b and 60.113b], PSD BACT requirements [326 IAC 2-2-3] and RACT requirements for synthesized pharmaceutical manufacturing operations [326 IAC 8-5-3]:

(a) Definition Standards:

(1) A BPM solvent storage tank is defined as any vessel designed to store raw material feedstocks or used solvent to be recovered that contain VOCs and/or VOHAP. Pressure vessels greater than 204.9 kPa without emissions to the atmosphere, vessels attached to motor vehicles, or vessels used to store beverage alcohol are not BPM solvent storage tanks. For purposes of inspections in Section D.9.1(c), a BPM solvent storage tank includes any fixed roof, cover, and/or enclosure, and closed vent system section from the BPM solvent storage tank to the inlet of the production building roof fan exhausting to the control device or to the BPM solvent storage tank conservation vent.

(b) Operational Standards:

(1) Except as otherwise provided in this Condition and in Condition D.9.2, the emission limits and standards for each operating BPM solvent storage tank are described in Section D.14 for equipment controlled by the RTO control system and described in Section D.15 for equipment controlled by the T79 fume incinerator control system.

(2) Solvent storage tanks shall be of fixed-roof design.

(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 Section E.1 of this permit.

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

The Pharmaceutical MACT standards for Startup, Shutdown and Malfunction (SSM) [40 CFR 63.1259(a)(3) and 40 CFR 63.1250(g)] shall be used to satisfy the Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)], and PSD BACT requirements [326 IAC 2-2-3].

(a) Pursuant to 40 CFR 63.1259(a)(3), the Permittee shall develop an SSM Plan to ensure that processes are operated and maintained in a manner to prevent or minimize excess emissions to the extent practical [40 CFR 63.1250(g)].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:

(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 affected 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 solvent 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 is 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.1 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 each BPM solvent storage tank.

(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) Periodic Reporting Requirements

(1) The following streamlined quarterly reporting requirements shall satisfy 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 Pharmaceutical MACT standards for Startup, Shutdown and Malfunction (SSM) [40 CFR 63.1250(i)] shall be used to satisfy the reporting requirements under the Pharmaceutical MACT standards and PSD BACT requirements [326 IAC 2-2-3].

(1) The Permittee shall report all actions taken during a process SSM event that results in an exceedance of a relevant emission standard when those actions are

inconsistent with the procedure 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 a process SSM event that results in an exceedance of a relevant emission standard when those actions taken by the Permittee are inconsistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information:

(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;

(D) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred; and

(E) Actions taken to minimize emissions.

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

D.9.8 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.

(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 and 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.

Alternative Operating Scenario [326 IAC 2-7-20(d)]

D.9.9 Alternative Operating Scenario

(a) For tanks listed in D section, the Permittee shall comply with one of the following alternative operating scenarios:

(1) The Permittee shall follow the conditions of this D section when the tank is storing solvent;

(2) The Permittee shall follow the conditions of D.10 when the tank is storing waste.

(b) The Permittee shall keep log of the scenario under which the tank is operating according to 326 IAC 2-7-5(9)(A). A summary of these records shall be included in the annual compliance certification.

SECTION D.10 BPM SUPPORT OPERATIONS - WASTE TANK OPERATION CONDITIONS

Emissions Unit Description: [326 IAC 2-7-5(1)]

Emission Unit ID	Emission Unit Description ***	Stack/Vent	Nominal Capacity	Control Device
Building T27:				
T27-TK53-10*	Waste Tank	RTO	500 gal	RTO
Building T28:				
T28-TK-28HW*	Waste Tank	T79 or RTO**	250 gal	T79 or RTO**
Building T29:				
T29-TK7902*	Waste Tank	RTO	1000 gal	RTO
Building T31:				
T31-TK609*	Waste Tank	RTO	100 gal	RTO
T31-TK669*	Waste Tank	RTO	100 gal	RTO
Building T31A:				
T31A-TK451K*	Waste Tank	RTO	100 gal	RTO
T31A-TK688*	Waste Tank	RTO	125 gal	RTO
Building T69:				
T69-TK1*	Waste Tank	None	106 gal	None
Building T99:				
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-TK9DB*	Waste Tank	RTO	10 gal	RTO
T99-TK-D45A*	Waste Tank	RTO	100 gal	RTO
Building T100:				
T100-TK-10A*	Waste Tank	RTO	200 gal	RTO
T100-TK-48*	Waste Tank	RTO	3300 gal	RTO
Building T79:				
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
Building T102-RTOs				
T102-TK102*	90 day RCRA Tank	RTO	700 gal	RTO
Tank Module Building T140:				
T140-TK3122	Waste Tank	T79	38,425 gal	T79
T140-TK3123	Waste Tank	T79	38,425 gal	T79
T140-TK3124	Waste Tank	T79	38,425 gal	T79
T140-TK3125	Waste Tank	T79	38,425 gal	T79
T140-TK3126	Waste Tank	T79	38,425 gal	T79
T140-TK3227*	Waste Tank	T79 -324 stream	18,130 gal	T79
T140-TK3228*	Waste Tank	T79 - 324 stream	18,130 gal	T79

T140-TK3229*	Waste Tank	T79 - 324 stream	500 gal	T79
Tank Module Building T142:				
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
T142-TK56*	Knock Out Pot	T79	32 gal	T79
Tank Module Building T143:				
T143-TK02*	Waste Tank	T79 - 325 stream	19,500 gal	T79
T143-TK06*	Waste Tank	T79 - 325 stream	19,500 gal	T79
T143-TK10*	Waste Tank	T79 - 325 stream	19,500 gal	T79
T143-TK15*	Waste Tank	T79 - 325 stream	18,500 gal	T79
T143-TK16	Waste Tank	T79	18,500 gal	T79
T143-TK56*	Knock Out Pot	T79	45 gal	T79
Tank Module Building T145:				
T145-TK76*	Knock Out Pot	T79	45 gal	T79 Incinerator
T145-TK77*	Knock Out Pot	T79 or RTO**	45 gal	T79 or RTO**
Tank Module Building T146:				
T146-TK23	Waste Tank	RTO	19,000 gal	RTO
T146-TK24	Waste Tank	RTO	19,000 gal	RTO
T146-TK11*	Waste Tank	RTO	19,000 gal	RTO
T146-TK20*	Waste Tank	RTO	19,000 gal	RTO
T146-TK21*	Waste Tank	RTO	19,000 gal	RTO
T146-TK12	Waste Tank	RTO	19,000 gal	RTO
T146-TK56*	Knock Out Pot	RTO	45 gal	RTO
T48 Tank Farm:				
T48-TK3207*	Waste Tank	T79 - 324 stream	102,759 gal	T79
T48-TK3208*	Waste Tank	T79 - 324 stream	102,759 gal	T79
T48-TK3209*	Waste Tank	T79 - 324 stream	102,759 gal	T79

T48-TK3211*	Waste Tank	T79 - 324 stream	260,650 gal	T79
T48-TK3212*	Waste Tank	T79 - 324 stream	260,650 gal	T79

* Emission units marked with an asterisk are insignificant activities as defined by 326 IAC 2-7-1(21)(A)-(C).
** This equipment is currently not in service; however, this equipment shall be tied into either the RTO control system or the T79 control system upon startup.
*** This equipment may store solvent or waste.

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

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

D.10.1 Standards for BPM Waste Storage Tanks [40 CFR 63.1256(b), 40 CFR 63.685, 40 CFR 60.110b, 326 IAC 2-2-3, and 326 IAC 8-5-3]

The following streamlined standards for BPM waste storage tanks satisfy the requirements of the Pharmaceutical MACT Standards for wastewater tanks [40 CFR 63.1256(b)], Volatile Organic Liquid Storage Vessel Standards [40 CFR 60.110b], OSWRO MACT Standards for waste tanks [40 CFR 63.685], PSD BACT requirements [326 IAC 2-2-3], and RACT requirements for synthesized pharmaceutical manufacturing operations [326 IAC 8-5-3]:

(a) Definition Standards:

(1) A BPM waste storage tank is defined as any waste management unit that is designed to contain an accumulation of waste material containing VOCs and/or VOHAP. Pressure vessels greater than 204.9 kPa without emissions to the atmosphere or vessels attached to motor vehicles are not BPM waste storage tanks. For purposes of inspections in Section D.10.1(c), BPM waste storage tank includes any fixed roof, cover, and/or enclosure, and closed vent system section from the BPM waste storage tank to the inlet of the production building roof fan exhausting to the control device or to the BPM waste storage tank conservation vent.

(b) Operational Standards:

(1) Except as otherwise provided in this Condition and in Condition D.10.2, the emission limits and standards for each operating BPM waste storage tank are described in Section D.14 for equipment controlled by the RTO control system and described in Section D.15 for equipment controlled by the T79 fume incinerator control system.

(2) BPM waste storage tanks shall be of fixed-roof design.

(c) Inspection Standards:

(1) The Permittee shall conduct one-time Method 21 inspections on each new fixed roof BPM waste 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 the fixed roof and all openings of each BPM waste storage tank for visible, audible, or olfactory indications of leaks.

(3) The Permittee shall initiate repair of any leak on a BPM waste storage tank no

later than 5 calendar days after identification, and complete the repair within 15 days after identification, unless:

(A) The repair is technically infeasible without a shutdown of an operation or process; or

(B) 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.10.2 Exceptions to Standards for BPM Waste Storage Tanks [40 CFR 63.1256(b), 40 CFR 63, 40 CFR 60.110b, 326 IAC 8-5-3, 326 IAC 2-7-24, and 326 IAC 2-2-3]

(a) Pursuant to 326 IAC 2-2 and 40 CFR 63.1256(b)(10), the BPM waste storage tanks are not subject to the standards established in Condition D.10.1 (b) during periods of planned routine maintenance on the control device, as long as the control device's planned routine maintenance activities do not exceed 240 hours per 365 day period. The tanks shall not be loaded during periods of planned routine maintenance on the control device.

(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), and 326 IAC 2-2-3]

The Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)] and Offsite Waste MACT standards [40 CFR 63.697(b)(3)] for Startup, Shutdown and Malfunction (SSM) shall be used to satisfy 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 2-2-3].

(a) Pursuant to 40 CFR 63.1259(a)(3) and 40 CFR 63.697(b)(3), the Permittee shall develop an SSM Plan to ensure that processes are operated and maintained in a manner to prevent or minimize excess emissions to the extent practical [40 CFR 63.1250(g)]. 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.

D.10.6 Monitoring Requirements

The monitoring requirements for the RTO control system and T79 fume incinerator control system 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, 326 IAC 2-2, 40 CFR 60.7, 40 CFR 60 Subpart Kb, 40 CFR 63 Subpart DD, and 40 CFR 63 Subpart GGG]

D.10.7 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 used to control emissions from these emission units 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 waste storage tanks unsafe to inspect, including a plan for when these tanks will be inspected;

(B) Identification and explanation of all BPM waste storage tanks difficult to inspect, including a plan for when these tanks will be inspected;

(C) Visual inspection log of BPM waste 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 waste storage tank, including the date of inspection and a statement that no leaks were detected, if applicable;

(E) Information on each BPM waste storage tank 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) 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 wit 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 Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)] and Offsite Waste MACT standards [40 CFR 63.697(b)(3)] for Startup, Shutdown and Malfunction (SSM) shall be used to satisfy the reporting requirements under the Pharmaceutical MACT standards, Offsite Waste MACT standards, and PSD BACT requirements [326 IAC 2-2-3].

(1) The Permittee shall report all actions taken during a process SSM event that results in an exceedance of a relevant emission standard when those actions are inconsistent with the procedure 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 a process SSM event that results in an exceedance of a relevant emission standard when those actions taken by the Permittee are inconsistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information:

(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;

(D) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred; and

(E) Actions taken to minimize emissions.

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.

(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.

Alternative Operating Scenario [326 IAC 2-7-20(d)]

D.10.9 Alternative Operating Scenario

(a) For tanks listed in D section, the Permittee shall comply with one of the following alternative operating scenarios:

(1) The Permittee shall follow the conditions of this D.9 when the tank is storing solvent;

(2) The Permittee shall follow the conditions of D section when the tank is storing waste.

(b) The Permittee shall keep log of the scenario under which the tank is operating according to 326 IAC 2-7-5(9)(A). A summary of these records shall be included in the annual compliance certification.

SECTION D.11 BPM SUPPORT OPERATIONS - WASTE CONTAINER OPERATION CONDITIONS

Emissions Unit Description [326 IAC 2-7-5(15)]:

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
SMALL BPM WASTE CONTAINERS:*				
A small BPM waste container, such as a drum, is defined as containing VOC/VOHAP and having a capacity greater than 0.1 cubic meters (26.4 gallons) and equal to or less than 0.42 cubic meters (110.5 gallons). Identification of these types of containers have not been individually listed given they are portable and continually change. Each onsite wastewater container and offsite waste container with this description type will follow the compliance requirements outlined in this section.				
LARGE BPM WASTE CONTAINERS:*				
A large BPM waste container, such as tanker or melon, is defined as containing VOC/VOHAP and having a capacity greater than 0.42 cubic meters (110.5 gallons). Identification of these types of containers have not been individually listed given they are portable and continually change. Each container with this description type will follow the compliance requirements outlined in this section.				

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

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

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

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

The following streamlined standards for small BPM waste containers satisfy the requirements of the Pharmaceutical MACT Standards for wastewater containers [40 CFR 63.1256(d)], OSWRO MACT Standards for waste containers [40 CFR 63.688], and PSD BACT requirements [326 IAC 2-2-3]:

(a) Definition Standards:

(1) A small 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 0.1 cubic meters (26.4 gallons) and less than or equal to 0.42 cubic meters (110.5 gallons).

(b) Operational Standards:

(1) The cover and all openings on each BPM waste container shall be maintained in the closed position, except when adding material, removing material, accessing material for non-transfer-related routine activities, openings caused from a pressure relief device, or opening of a safety device.

(2) Each BPM waste container containing VOC/VOHAP shall meet existing Department of Transportation (DOT) specifications and testing requirements under 49 CFR 178.

(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.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.

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

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.

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

D.11.4 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 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 D.12 T49 LIQUID WASTE INCINERATOR, INCLUDING ASSOCIATED AIR POLLUTION CONTROL EQUIPMENT AND CONTINUOUS MONITORING SYSTEMS OPERATION CONDITIONS

Emissions Unit Description [326 IAC 2-7-5(15):

Emission Unit Description	Building	Stack/Vent	Nominal Capacity	Control Device
T49 Liquid Waste Incinerator	T49	T49 Stack	75 MMBtu/hr	Condenser/Absorber; Hydro-SonicTM Scrubber

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

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

D.12.0 VOC, CO and Fluoride PSD BACT Requirements [326 IAC 2-2-3]

(a) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), the Best Available Control Technology (BACT), VOC BACT for the T49 is good combustion practices and compliance with the 100 ppmvdc CO limit.

The IDEM agrees that the VOC BACT for both the T49 liquid waste incinerator is a good combustion practice and compliance with CO limit.

(b) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), the Best Available Control Technology (BACT), CO BACT for the T49 is good combustion practices to control CO emissions to 100 ppmvdc based on a 1-hour block period.

The CO BACT for the T49 incinerator is proper combustion to limit CO emissions to no more than 100 ppmvdc, based on a 1-hour average. This is equivalent to the CO MACT limit contained in 40 CFR Part 63, Subpart EEE.

(c) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), the Best Available Control Technology (BACT), Fluorides (F-) BACT of NaOH injection to achieve 98% removal of hydrogen Chloride (HCl).

The fluorides BACT for the T49 incinerator is caustic scrubbing with NaOH to achieve 98% removal efficiency of HCl. This 98% removal efficiency corresponds to an outlet concentration of 77 ppmvdc, which is equivalent to the MACT HCl and Cl2 limit for existing sources contained in 40 CFR Part 63, Subpart EEE. IDEM, OAQ believes that this level of control is as stringent as or more stringent than any limit contained in applicable rules or permits for comparable emission units.

D.12.1 General Applicability Requirements with Emission Standards [326 IAC 2-2-3 and 40 CFR 63, Subparts DD and EEE]

(a) Pursuant to the Hazardous Waste Combustor (HWC) MACT Standards [40 CFR 63.1206(b)(1)(i)] and the PSD BACT requirements [326 IAC 2-2-3], the emission standards and operating requirements shall apply as specified in Conditions D.12.2, D.12.3, D.12.4, D.12.5, D.12.6, and D.12.7 except during periods of startup, shutdown, and malfunction.

(b) Pursuant to the Off-Site Waste and Recovery Operations MACT Standards [40 CFR 63.684(b)(5)(i)], the T49 liquid waste incinerator shall have a permit issued under 40 CFR 270 whenever off-site waste material is treated and destroyed in the T49 liquid waste incinerator. The incinerator shall operate in accordance with the HWC MACT standards under 40 CFR 63, Subpart EEE.

(c) Pursuant to the HWC MACT standards [40 CFR 63.1206(b)(5)(ii) and (iii)] and the PSD requirements [326 IAC 2-2-3], the Permittee may make a change in the design, operation, or maintenance practices documented in the comprehensive performance test plan (CPT plan), Documentation of Compliance (DOC), Notification of Compliance (NOC), or startup, shutdown, and malfunction plan (SSM plan), as long as the Permittee complies with the following requirements:

(1) If it is determined that the change may adversely affect compliance with any emission standard, the Permittee shall comply with the requirements specified in 40 CFR 63.1206(b)(5)(i) prior to implementing the change(s).

(2) If it is determined that the change will not adversely affect compliance with the emission standards of this condition, the Permittee may implement the change(s) but must revise as necessary the performance test plan, DOC, NOC, and SSM plan, to reflect the change(s).

D.12.2 Particulate Matter Emission Standards [40 CFR 63.1219 and 326 IAC 4-2]

In order to satisfy the HWC MACT standards [40 CFR 63.1219(a)(7)], the particulate matter (PM) emissions from the T49 liquid waste incinerator stack exhaust shall not exceed 0.013 gr/dscf (30 mg/dscm) corrected to 7 percent oxygen.

D.12.3 Sulfur Dioxide (SO_2) Emission Standards [326 IAC 2-2-3]

In order to satisfy the PSD BACT requirements [326 IAC 2-2-3], the T49 liquid waste incinerator shall be equipped with a caustic scrubber system to control SO_2 emissions. The SO_2 emissions from the incinerator stack exhaust shall not exceed 500 ppmv dry corrected to 7% oxygen, averaged over a 24-hour daily period when burning waste streams. This facility is not subject to emission limitations and standards in 326 IAC 7 because the incinerator does not have the capability to burn fuel oil.

D.12.4 Oxides of Nitrogen (NOx) Emission Standards [326 IAC 2-2-3]

In order to satisfy the PSD BACT requirements [326 IAC 2-2-3], the T49 liquid waste incinerator shall implement good combustion practices to control NO_x emissions. The NOx emissions from the incinerator stack exhaust shall not exceed 975 ppmv dry corrected to 7% oxygen, expressed as NO_2, averaged over a 24-hour daily period when burning waste streams.

D.12.5 Hazardous Air Pollutant (HAP) and Fluoride Emission Standards [40 CFR 63.1203 and 326 IAC 2-2-3]

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

(a) Mercury – Pursuant to the HWC MACT standards [40 CFR 63.1219(a)(2)], the mercury emissions from the T49 liquid waste incinerator stack exhaust shall not exceed 130 ug/dscm, corrected to 7% oxygen on a 12-hour rolling average basis, from block hourly averages.

(b) Lead and Cadmium – In order to satisfy the HWC MACT standards [40 CFR 63.1219(a)(3)], the total semi-volatile metals (lead and cadmium) emissions from the T49 liquid waste incinerator stack exhaust shall not exceed 230 ug/dscm, corrected to 7% oxygen on a 12-hour rolling average basis, from block hourly averages.

(c) Arsenic, Beryllium, and Chromium – In order to satisfy the HWC MACT standards [40 CFR 63.1219(a)(4)], the total low volatile metals (arsenic, beryllium, and chromium) emissions from the T49 liquid waste incinerator stack exhaust shall not exceed 92 ug/dscm, corrected to 7 percent oxygen on a 12-hour rolling average basis, from block hourly averages.

(d) Hydrochloric Acid/Chlorine Gas (HCl/Cl_2) and Fluorides – In order to satisfy the HWC MACT standards [40 CFR 63.1219(a)(6)], the HCl/Cl_2 emissions from the T49 liquid waste incinerator stack exhaust shall not exceed 32 ppmv dry corrected to 7% oxygen, expressed as HCl equivalent. In order to satisfy the PSD BACT requirements for fluorides [326 IAC 2-2-3], the T49 liquid waste incinerator control system shall achieve an HCl control efficiency of 98 percent or greater.

(e) Dioxin/Furans – In order to satisfy HWC MACT standards [40 CFR 63.1219(a)(1)(ii)], the dioxin/furan emissions from the T49 liquid waste incinerator stack exhaust shall not exceed 0.40 ng TEQ/dscm, corrected to 7 percent oxygen.

(f) Principle Organic Hazardous Constituents (POHCs) – In order to satisfy the HWC MACT standards [40 CFR 63.1219(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 T49 liquid waste incinerator.

(g) Operating Parameter Limits – In order to comply with the NESHAP from Hazardous Waste Combustors (HWC) emission limits in this condition, the operating parameters of the T49 Incinerator, as established during the performance tests done on August 10 through 12, 2004, and associated emission control equipment shall not exceed limits described below as maximum limits or fail to achieve limits described as minimum limits.

Operating Parameter	Limit	Units	Averaging Period	Demonstrates Compliance for:
Minimum Atomizing Air Media Pressure	60	psig	1-HR RA	D.12.5(f)
Maximum Primary Waste Feed Viscosity	460	centipoise	NA	D.12.5(f)
Maximum Secondary Waste Feed Viscosity	460	centipoise	NA	D.12.5(f)
Maximum Primary Waste Feed Rate	7,117	lbs/hr	1-HR RA	D.12.5(e) D.12.5(f)
Maximum Secondary Waste Feed Rate	18,326	lbs/hr	1-HR RA	D.12.5(e) D.12.5(f)
Minimum Combustion Temperature	1,850	^{o}F	1-HR RA	D.12.5(e) D.12.5(f)
Maximum Combustion Air Flow Rate	15,022	acfm	1-HR RA	D.12.2 D.12.5(a) D.12.5(b) D.12.5(c) D.12.5(d) D.12.5(e) D.12.5(f)

Operating Parameter	Limit	Units	Averaging Period	Demonstrates Compliance for:
Maximum Mercury Feed Rate	0.0042	lbs/hr	12-hr RA	D.12.5(a)
Maximum Semi-Volatile Metals (SVM) Feed Rate	0.21	lbs/hr	12-hr RA	D.12.5(b)
Maximum Low-Volatile Metals (LVM) Feed Rate	0.30	lbs/hr	12-hr RA	D.12.5(c)
Maximum Ash Feed Rate	1,710	lbs/hr	12-hr RA	D.12.2
Maximum Total Chlorine Feed Rate	3,690	lbs/hr	12-hr RA	D.12.5(d)
Minimum Condenser/Absorber Flow Rate	600	gpm	1-HR RA	D.12.5(a) D.12.5(b) D.12.5(c) D.12.5(d)
Minimum Differential Pressure across Condenser/Absorber	0.5	in.w.c	1-HR RA	D.12.5(a) D.12.5(b) D.12.5(c) D.12.5(d)
Minimum Hydro-Sonic Scrubber Flow Rate	290	gpm	1-HR RA	D.12.2 D.12.5(a) D.12.5(b) D.12.5(c) D.12.5(d)
Minimum Hydro-Sonic Equivalent Differential Pressure	75	in.w.c	1-HR RA	D.12.2 D.12.5(a) D.12.5(b) D.12.5(c) D.12.5(d)
Minimum Condenser/Absorber pH	4.9	S.U.	1-HR RA	D.12.5(d)
Maximum Condenser/Absorber % Solids	3.5	%TDS	12-hr RA	D.12.2 D.12.5(a) D.12.5(b) D.12.5(c)

D.12.6 Carbon Monoxide (CO) Emission Standards [326 IAC 2-2-3, 326 IAC 9-1, and 40 CFR 63.1219]

In order to satisfy the HWC MACT standards [40 CFR 63.1219(b)(5)(i)] and the PSD BACT requirements [326 IAC 2-2-3], the CO emissions from the T49 liquid waste incinerator stack exhaust shall not exceed 100 ppmv dry corrected to 7% oxygen, rolled on an hourly basis, at all times the incinerator is operating except during periods of startup, shutdown, and malfunction.

D.12.7 Hydrocarbon (HC) and Volatile Organic Compound (VOC) Emission Standards [326 IAC 2-2-3 and 40 CFR 63.1203]

(a) In order to satisfy the HWC MACT standards [40 CFR 63.1219(a)(5)(i) and the PSD BACT requirements [326 IAC 2-2-3], the highest hourly rolling average hydrocarbon emissions achieved, as monitored with a CEMS during an acceptable DRE test, shall not exceed 10 ppmv dry corrected to 7% oxygen or 99.99 percent, reported as propane.

(b) During the DRE test for hydrocarbons, the CO emissions shall not exceed an hourly rolling average of 100 ppmv dry corrected to 7% oxygen (monitored with continuous emissions monitoring system).

D.12.8 Automatic Waste Feed Cutoff System Requirements [40 CFR 63.1206]

In order to satisfy the HWC MACT standards [40 CFR 63.1206], the Permittee shall operate the T49 liquid waste incinerator with a functioning Automatic Waste Feed Cutoff (AWFCO) system that meets the requirements of 40 CFR 63.1206(c)(3).

(a) Except as allowed under (c) of this condition, the AWFCO system shall be operated such that it immediately and automatically cuts off the hazardous waste feed when any of the following occur at any time:

(1) An operating parameter is exceeded;

(2) An emission standard monitored by the CO CEMS is exceeded;

(3) A span value of any CMS, except a CEMS, is met or exceeded;

(4) Upon malfunction of a CMS (excluding the NOx and SO_2 CEMS) monitoring an operating parameter limit or emission level; or

(5) When any component of the automatic waste feed cutoff system fails.

(b) During all AWFCO events, the Permittee shall continue to:

(1) Duct combustion gases to the air pollution control system while hazardous waste remains in the combustion chamber; and

(2) Monitor the applicable combustor operating parameters and emission levels.

(c) The Permittee may ramp down the hazardous waste feed rate of pumpable hazardous waste over a period not to exceed one (1) minute during an AWFCO event in accordance with the procedures in the O&M plan, providing the automatic waste feed cutoff is not triggered by an exceedance of any of the following operating limits:

(1) Minimum combustion chamber temperature,

(2) Maximum hazardous waste feed rate, or

(3) Any hazardous waste combustor firing system operating limits.

The procedures for AWFCO events specified in the O& M plan must include a statement that the ramp down must begin immediately upon initiation of automatic waste feed cutoff and must prescribe a bona fide ramping down.

(d) After an AWFCO event, the Permittee shall not restart the hazardous waste feed until the operating parameters and emission levels are within their respective limits.

(e) If after any AWFCO event, there is an exceedance of an emission standard or operating requirement, irrespective of whether the exceedance occurred while hazardous waste remained in the combustion chamber, the Permittee shall:

(1) Investigate the cause of the AWFCO,

(2) Take appropriate corrective measures to minimize future AWFCOs, and

(3) Record the findings and corrective measures in the operating record.

D.12.9 Leak Detection and Repair (LDAR) Program [326 IAC 2-2-3, 40 CFR 63, Subpart DD, 40 CFR 61, Subpart V]

The LDAR standards that apply to components associated with the waste transfer/feed systems connected to the T49 liquid waste incinerator are described in Section E.2 of this permit.

D.12.10 Inspection Requirements [40 CFR 63.1206(c)]

(a) In order to satisfy the HWC MACT standards [40 CFR 63.1206(c)(5)], the Permittee shall conduct daily visual inspections of the T49 liquid waste incinerator to ensure the combustion zone is sealed.

(b) In order to satisfy the HWC MACT standards [40 CFR 63.1206(c)(3)(vii)], the Permittee shall test the AWFCO system and associated alarms at least once per week to verify operability, unless the operating record documents that the weekly inspections unduly restrict or upset operations and that less frequent inspection will be adequate. At a minimum, the Permittee shall conduct operability testing monthly.

D.12.11 Training and Certification Requirements [40 CFR 63.1206(c)(6)]

(a) Pursuant to the HWC MACT standards [40 CFR 63.1206(c)(6)], the Permittee shall establish a Training and Certification Program for all categories of personnel whose activities may reasonably be expected to directly affect emissions of HAPs from all operations associated with the T49 liquid waste incinerator.

Said programs shall be of a technical level commensurate with the person’s duties as specified in the training manual. All operating training and certification programs shall be recorded in the operating record.

(b) A certified control room operator shall be on duty at the site at all times the T49 liquid waste incinerator is in operation and the T49 liquid waste incinerator, including associated air pollution control equipment and continuous monitoring systems, shall be operated and maintained at all times by persons who are trained and certified according to the Training and Certification Program.

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), to ensure that the T49 liquid waste incinerator, including associated air emission control equipment and CEMS and CMS, is operated and maintained 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) Comprehensive Performance Test

(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 12 months after the HWC MACT compliance date unless an exemption is granted pursuant to 40 CFR 63.1207(e)(3).

(3) The Permittee shall submit a notification of intention to conduct the comprehensive performance test at least 60 calendar days before the test is scheduled to begin.

(4) The comprehensive performance tests shall be conducted under operating conditions representative of the extreme range of normal conditions as specified in 40 CFR 63.1207(g) and 63.7(e)(1) for the worst case mode associated with each applicable pollutant limit or emission standard.

(5) The operating parameters defined in Condition D.12.15 shall be monitored during the performance test to establish the parametric limits.

(6) All required comprehensive performance testing shall be completed within 60 days after the date of commencement of the tests pursuant to 40 CFR 63.1207(d)(3).

(7) The Permittee may use previous emissions test data in lieu of the initial comprehensive performance tests as allowed under 40 CFR 63.1207(c)(2).

(8) Pursuant to 40 CFR 63.7(h)(2), individual performance tests may be waived upon written application to the Administrator if, in the Administrator's judgment, the source is meeting the relevant standard(s) on a continuous basis, or the source is being operated under an extension of compliance, or the owner or operator has requested an extension of compliance and the Administrator is still considering the request.

(9) Pursuant to 40 CFR 63.1207(j), the Permittee shall:

(A) Postmark a Notification of Compliance (NOC) documenting compliance or noncompliance with the emission standards and continuous monitoring system requirements and identify operating parameter limits under 40 CFR 63.1209 within 90 days of completion of the comprehensive performance test; and

(B) Comply with all operating requirements specified in the NOC in lieu of the limits specified in the Documentation of Compliance required under 40 CFR 63.1211(c) upon postmark of the NOC.

These submittal requirements satisfy the reporting requirements of 326 IAC 3-6 as allowed under extension provisions of 326 IAC 3-6-4(b).

(b) Confirmatory Performance Tests

(1) The Permittee shall submit a notification of intention to conduct a confirmatory performance test and CMS performance evaluation and a site-specific test plan and CMS performance evaluation test plan at least 60 days before the performance test and performance evaluation are scheduled to begin.

(2) The confirmatory performance tests shall be conducted under operating conditions representative of the range of normal conditions as specified in 40 CFR 63.1207(g)(2) and 63.7(e)(1) for the parameters specified in 40 CFR 63.1207(g)(2) associated with the dioxin/furan emission standard unless the Administrator approves an alternative range under 40 CFR 63.1207(g)(v).

(3) The operating parameters defined in Condition D.12.15 shall be monitored during the performance test.

(4) All required comprehensive performance testing shall be completed within 60 days after the date of commencement of the tests pursuant to 40 CFR 63.1207(d)(3).

(5) Pursuant to 40 CFR 63.7(h)(2), individual performance tests may be waived upon written application to the Administrator if, in the Administrator's judgment, the source is meeting the relevant standard(s) on a continuous basis, or the source is being operated under an extension of compliance, or the owner or operator has requested an extension of compliance and the Administrator is still considering the request.

(6) Pursuant to 40 CFR 63.1207(j), the Permittee shall postmark a Notification of Compliance (NOC) documenting compliance or noncompliance with the applicable dioxin/furan emission standard within 90 days of completion of the comprehensive performance test
This submittal requirement satisfies the reporting requirements of 326 IAC 3-6 as allowed under extension provisions of 326 IAC 3-6-4(b).

(c) Subsequent Performance Tests

The Permittee shall conduct subsequent Comprehensive Performance Tests and Confirmatory Performance Tests at the frequencies specified in 40 CFR 63.1207(d).

(d) Pursuant to 326 IAC 3-6-4(b), 40 CFR 63.1207(i)(1) and 40 CFR 63.1207(i)(2), the Permittee shall submit the performance test reports within 90 days following the test.

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 O_2 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 O_2 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 monitor means a device which continuously samples the regulated parameter without interruption, evaluates the detector response at least once every 15 seconds and computes and records the average at least every 60 seconds, except during allowable periods of calibration and other exceptions identified in applicable requirements, plans and/or procedures. One-minute average means the average of detector responses calculated at least every 60 seconds from response obtained at least every 15 seconds.

(b) SO_2 and NOx CEMS Operation Requirements – The following requirements shall apply when the T49 Incinerator is burning waste

(1) The Permittee shall install and operate the SO_2 and NOx 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 monitor means a device which continuously samples the regulated parameter without interruption, evaluates the detector response at least once every 15 seconds and computes and records the average at least every 60 seconds, except during allowable periods of calibration and other exceptions identified in applicable requirements, plans and/or procedures. One-minute average means the average of detector responses calculated at least every 60 seconds from response obtained at least every 15 seconds.

(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 SO_2 or NOx CEMS malfunction:

(A) When the SO_2 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 NOx 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 NOx 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 NOx 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 CMS to monitor the Operating Parameter Limits (OPLs) listed in D.12.5(g) 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 parameters listed in D.12.5(g) shall be monitored at all times the T49 incinerator is in operation.

(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 the requirements of (a) and (c) of this condition.

D.12.16 Minimum Data Requirements – SO_2 and NOx Compliance [326 IAC 2-1.1-11]

The following defines when CEMS data must be supplemented with data required by condition D.12.14 (b)(3), D.12.17 (a)(12), and D.12.18 (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 % 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.

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 4 0 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 NOx and SO_2 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 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 1,650 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 HWC MACT standards [40 CFR 63.1211] for Startup, Shutdown and Malfunction (SSM) shall be used to satisfy the reporting requirements under the HWC MACT standards and PSD BACT requirements [326 IAC 2-2-3].

(A) The Permittee shall report all actions taken during a T49 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 that results in an exceedance of a relevant emission standard when those actions taken by the Permittee are inconsistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information:

(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;

(iv) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred; and

(v) Action taken to minimize emissions.

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

D.12.19 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 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 D.13 T149 SOLID-LIQUID WASTE INCINERATOR, INCLUDING ASSOCIATED AIR POLLUTION CONTROL EQUIPMENT AND CONTINUOUS MONITORING SYSTEMS OPERATION CONDITIONS

Emissions Unit Description [326 IAC 2-7-5(15)]:

Emission Unit Description	Building	Stack/Vent	Nominal Capacity	Control Device
T149 solid-liquid waste incinerator with Secondary Combustion Chamber (Natural Gas for Startup, Fuel Oil for Deslagging Operations)	T149	T149 Stack	50 MMBtu/hr	SNCR; Condenser/Absorber; Hydro-SonicTM Scrubber

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

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

D.13.0 VOC, CO and Fluoride PSD BACT Requirements [326 IAC 2-2-3]

(a) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), the Best Available Control Technology (BACT), VOC BACT for the T149 is good combustion practices and compliance with the 100 ppmvdc CO limit.

The VOC BACT for both the T49 (liquid waste incinerator) and T149 (solid-liquid waste incinerator) may be established as 10 ppm (or 100 ppm CO surrogate), which is equivalent to the MACT THC limits contained in 40 CFR Part 63, Subpart EEE.

(b) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), the Best Available Control Technology (BACT), CO BACT for the T149 is good combustion practices to control CO emissions to 100 ppmvdc based on a 1-hour block period.

The CO BACT for the T149 incinerator is proper combustion to limit CO emissions to no more than 100 ppmvdc, based on a 1-hour average. This is equivalent to the CO MACT limit contained in 40 CFR Part 63, Subpart EEE.

(c) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), the Best Available Control Technology (BACT), Fluorides (F-) BACT of NaOH injection to achieve 98% removal of hydrogen Chloride (HCl).

The fluorides BACT for the T149 incinerator is caustic scrubbing with NaOH to achieve 98% removal efficiency of HCl. This 98% removal efficiency corresponds to an outlet concentration of 77 ppmvdc, which is equivalent to the MACT HCl and Cl2 limit for existing sources contained in 40 CFR Part 63, Subpart EEE. IDEM, OAQ believes that this level of control is as stringent as or more stringent than any limit contained in applicable rules or permits for comparable emission units.

D.13.1 General Applicability Requirements with Emission Standards [326 IAC 2-2-3 and 40 CFR 63, Subparts DD and EEE]

(a) Pursuant to the Hazardous Waste Combustor (HWC) MACT Standards [40 CFR 63.1206(b)(1)(i)] and the PSD BACT requirements [326 IAC 2-2-3], the emission standards and operating requirements shall apply as specified in Conditions D.13.2, D.13.3, D.13.4, D.13.5, D.13.6, and D.13.7 except during periods of startup, shutdown, and malfunction.

(b) Pursuant to the Off-Site Waste and Recovery Operations MACT Standards [40 CFR 63.684(b)(5)(i)], the T149 solid-liquid waste incinerator shall have a permit issued under 40 CFR 270 whenever off-site waste material is treated and destroyed in the T149 solid-liquid waste incinerator. The incinerator shall operate in accordance with the HWC MACT standards under 40 CFR 63, Subpart EEE.

(c) Pursuant to the HWC MACT standards [40 CFR 63.1206(b)(5)(ii) and (iii)] and the PSD BACT requirements [326 IAC 2-2-3], the Permittee may make a change in the design, operation, or maintenance practices documented in the comprehensive performance test plan (CPT plan), Documentation of Compliance (DOC), Notification of Compliance (NOC), or startup, shutdown, and malfunction plan (SSM plan), as long as the Permittee complies with the following requirements:

(1) If it is determined that the change may adversely affect compliance with any emission standard, the Permittee shall comply with the requirements specified in 40 CFR 63.1206(b)(5)(i) prior to implementing the change(s).

(2) If it is determined that the change will not adversely affect compliance with the emission standards of this condition, the Permittee may implement the change(s) but must revise as necessary the performance test plan, Documentation of Compliance, Notification of Compliance, and startup, shutdown, and malfunction plan, to reflect the change(s).

D.13.2 Particulate Matter Emission Standards [40 CFR 63.1219]

In order to satisfy the HWC MACT standards [40 CFR 63.1219(a)(7)], the particulate matter (PM) emissions from the T149 solid-liquid waste incinerator stack exhaust shall not exceed 0.013 gr/dscf (30 mg/dscm), corrected to 7 percent oxygen.

D.13.3 Sulfur Dioxide (SO_2) Emission Standards [326 IAC 2-2-3 and 326 IAC 7-1.1-2]

(a) In order to satisfy the PSD BACT requirements [326 IAC 2-2-3], the T149 solid-liquid waste incinerator shall be equipped with a caustic scrubber system to control SO_2 emissions. The SO_2 emissions from the incinerator stack exhaust shall not exceed 400 ppmv dry corrected to 7% oxygen, averaged over a 24-hour daily period when burning waste streams.

(b) In order to satisfy the State SO_2 rules [326 IAC 7-1.1-2], the SO_2 emissions from the combustion of fuel oil during the deslagging process in the T149 solid-liquid waste incinerator shall not exceed 0.5 pounds per million British thermal units (lbs/MMBtu).

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

In order to satisfy the PSD BACT requirements [326 IAC 2-2-3], the T149 solid-liquid waste incinerator shall be equipped with selective non-catalytic reduction (SNCR) equipment to control NO_x emissions. The NOx emissions from the incinerator stack exhaust shall not exceed 170 ppmv dry corrected to 7% oxygen, expressed as NO_2, averaged over a 24-hour daily period when burning waste streams.

D.13.5 Hazardous Air Pollutant (HAP) Emission Standards [40 CFR 63.1219, US EPA approved Alternative Monitoring Petition initially approved January 27, 2006]

Except for periods of startup, shutdown and malfunctions, the following emission standards shall apply at all times the T149 solid-liquid waste incinerator is operating:

(a) Mercury – Pursuant to the HWC MACT standards [40 CFR 63.1219(a)(2)], the mercury emissions from the T149 solid-liquid waste incinerator stack exhaust shall not exceed 130 ug/dscm, corrected to 7% oxygen on a 12-hour rolling average basis, from block hourly averages.

(b) Lead and Cadmium – Pursuant to the HWC MACT standards [40 CFR 63.1219(a)(3)], the total semi-volatile metals (lead and cadmium) emissions from the T149 solid-liquid waste incinerator stack exhaust shall not exceed 230 ug/dscm, corrected to 7 percent oxygen on a 12-hour rolling average basis, from block hourly averages.

(c) Arsenic, Beryllium, and Chromium – Pursuant to the HWC MACT standards [40 CFR 63.1219(a)(4)], the total low volatile metals (arsenic, beryllium, and chromium) emissions from the T149 solid-liquid waste incinerator stack exhaust shall not exceed 92 ug/dscm, corrected to 7 percent oxygen on a 12-hour rolling average basis, from block hourly averages.

(d) Hydrochloric Acid/Chlorine Gas (HCl/Cl_2) and Fluorides - In order to satisfy the HWC MACT standards [40 CFR 63.1219(a)(6)], the HCl/Cl_2 emissions from the T149 solid-liquid waste incinerator stack exhaust shall not exceed 32 ppmvdc, expressed as HCl equivalent on a 12-hour rolling average basis, from block hourly averages. In order to satisfy the PSD BACT requirements for fluorides [326 IAC 2-2-3], the T149 solid-liquid waste incinerator control system shall achieve an HCl control efficiency of 98 percent or greater.

(e) Dioxin/Furans – Pursuant to HWC MACT standards [40 CFR 63.1219(a)(1)], the dioxin/furan emissions from the T149 solid-liquid waste incinerator stack exhaust shall not exceed 0.40 ng TEQ/dscm, corrected to 7 percent oxygen.

(f) Principle Organic Hazardous Constituents (POHCs) – Pursuant to the HWC MACT standards [40 CFR 63.1219(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 solid-liquid waste incinerator.

(g) Operating Parameter Limits – In order to comply with the NESHAP from Hazardous Waste Combustors (HWC) emission limits in this condition, the operating parameters of the T149 solid-liquid waste Incinerator, as established during the performance tests done on September 20 through 22, 2005, and associated emission control equipment shall not exceed limits described below as maximum limits or fail to achieve limits described as minimum limits.

The limits below are applicable when monitoring is required by D.13.15(a).

Operating Parameter Limit	Averaging Period	Operating Limit	Units
Maximum Primary Waste Feed to Primary Combustion Chamber	1-hr RA[1]	1,501	lbs/hr
Maximum Secondary Waste Feed to Primary Combustion Chamber	1-hr RA[1]	4,655	lbs/hr
Maximum Solid Feed Rate	1-hr RA[1]	5,529	lbs/hr
Minimum Primary Combustion Chamber Temperature	1-hr RA[1]	1,598	^oF
Maximum Primary Waste Feed to Secondary Combustion Chamber	1-hr RA[1]	1,801	lbs/hr
Maximum Secondary Waste Feed to Secondary Combustion Chamber	1-hr RA[1]	1,440	lbs/hr
Minimum Secondary Combustion Chamber Temperature	1-hr RA[1]	1,809	^oF
Maximum Stack Gas Flow Rate	1-hr RA[1]	18,812	dscfm
Maximum Waste Feed Viscosity	Monthly Analysis	460	Centi-poise
Minimum Waste Atomizing Pressure	1-hr RA[1]	75	psig
Maximum Mercury Feed Rate in all Feed Streams	12-hr RA	0.0038	lbs/hr
Maximum SVM Feed Rate in all Feed Streams	12-hr RA	3.2	lbs/hr
Maximum LVM Feed Rate in all Feed Streams	12-hr RA	460	lbs/hr
Maximum LVM Feed Rate in all Pumpable Feed Streams	12-hr RA	4.7	lbs/hr
Maximum ash feed rate in all feed streams	12-hr RA	4,168	lbs/hr
Maximum Total Chlorine feed rate in all feed streams	12-hr RA	1,977	lbs/hr
Minimum Condenser/Absorber pressure drop	1-hr RA	1	in w.c.
Minimum Condenser/Absorber liquid feed pressure	1-hr RA	5	psig
Minimum Condenser/Absorber scrubber water pH	1-hr RA	2.5	pH
Minimum Condenser/Absorber scrubber liquid flow rate	1-hr RA	980	gpm
Minimum Hydro-Sonic Scrubber Equivalent Pressure Drop	1-hr RA	53	in w.c.
Maximum Hydro-Sonic Scrubber conductivity	12-hr RA	2.3	% solids
Minimum Hydro-Sonic Scrubber Liquid Feed Rate	1-hr RA	286	gpm
Minimum Hydro-Sonic Scrubber water pH	1-hr RA	2.5	pH

1. CMS shall be operated as described in D.13.15.

D.13.6 Carbon Monoxide (CO) Emission Standards [326 IAC 2-2-3, 326 IAC 9-1, and 40 CFR 63.1219]

In order to satisfy the HWC MACT standards [40 CFR 63.1219(a)(5)(i)] and the PSD BACT requirements [326 IAC 2-2-3], the CO emissions from the T149 solid-liquid waste 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 hourly rolling basis, at all times the incinerator is operating except during startup, shutdown and malfunctions.

D.13.7 Hydrocarbon (HC) and Volatile Organic Compound (VOC) Emission Standards [326 IAC 2-2-3 and 40 CFR 63.1219]

(a) In order to satisfy the HWC MACT standards [40 CFR 63.1219(a)(5)(i)] and the PSD BACT requirements [326 IAC 2-2-3], the highest hourly rolling average hydrocarbon emissions achieved, as monitored with a CEMS during an acceptable DRE test, shall not exceed 10 ppmv dry corrected to 7% oxygen or 99.99 percent, reported as propane.

(b) During the DRE test for hydrocarbons, the CO emissions shall not exceed an hourly rolling average of 100 ppmv dry corrected to 7% oxygen (monitored with continuous emissions monitoring system).

D.13.8 Automatic Waste Feed Cutoff System Requirements [40 CFR 63.1206]

In order to satisfy the HWC MACT standards, the Permittee shall operate the T149 solid-liquid waste incinerator with a functioning Automatic Waste Feed Cutoff (AWFCO) system that meets the requirements of 40 CFR 63.1206(c)(3).

(a) Except as allowed under (c) of this condition, the AWFCO system shall be operated such that it immediately and automatically cuts off the hazardous waste feed when any of the following occur at any time:

(1) An operating parameter is exceeded;

(2) An emission standard monitored by the CO CEMS is exceeded;

(3) A span value of any CMS, except a CEMS, is met or exceeded;

(4) Upon malfunction of a CMS (excluding the NOx and SO_2 CEMS) monitoring an operating parameter limit or emission level; or

(5) When any component of the automatic waste feed cutoff system fails.

(b) During all AWFCO events, the Permittee shall continue to:

(1) Duct combustion gases to the air pollution control system while hazardous waste remains in the combustion chamber; and

(2) Monitor the applicable combustor operating parameters and emission levels.

(c) The Permittee may ramp down the hazardous waste feedrate of pumpable hazardous waste over a period not to exceed one (1) minute during an AWFCO event in accordance with the procedures in the O&M plan, providing the automatic waste feed cutoff is not triggered by an exceedance of any of the following operating limits:

(1) Minimum combustion chamber temperature,

(2) Maximum hazardous waste feed rate, or

(3) Any hazardous waste combustor firing system operating limits.

The procedures for AWFCO events specified in the O& M plan must include a statement that the ramp down must begin immediately upon initiation of automatic waste feed cutoff and must prescribe a bona fide ramping down.

(d) After an AWFCO event, the Permittee shall not restart the hazardous waste feed until the operating parameters and emission levels are within their respective limits.

(e) If after any AWFCO event, there is an exceedance of an emission standard or operating requirement, irrespective of whether the exceedance occurred while hazardous waste remained in the combustion chamber, the Permittee shall:

(1) Investigate the cause of the AWFCO,

(2) Take appropriate corrective measures to minimize future AWFCOs, and

(3) Record the findings and corrective measures in the operating record.

D.13.9 Leak Detection and Repair (LDAR) Program [326 IAC 2-2-3, 40 CFR 63, Subpart DD, 40 CFR 61, Subpart V]

The LDAR standards that apply to components associated with the waste transfer/feed systems connected to the T149 solid-liquid waste incinerator are described in Section E.2 of this permit.

D.13.10 Inspection Requirements [and 40 CFR 63.1206(c)]

(a) In order to satisfy the HWC MACT standards [40 CFR 63.1206(c)(5)], the Permittee shall conduct daily visual inspections of the T149 solid-liquid waste incinerator to ensure the combustion zone is sealed.

(b) In order to satisfy the HWC MACT standards [40 CFR 63.1206(c)(3)(vii)], the Permittee shall test the AWFCO system and associated alarms at least once per week to verify operability, unless the operating record documents that the weekly inspections unduly restrict or upset operations and that less frequent inspection will be adequate. At a minimum, the Permittee shall conduct operability testing monthly.

D.13.11 Training and Certification Requirements [40 CFR 63.1206(c)(6)]

(a) Pursuant to the HWC MACT standards [40 CFR 63.1206(c)(6)], the Permittee shall establish a Training and Certification Program for all categories of personnel whose activities may reasonably be expected to directly affect emissions of HAPs from all operations associated with the T149 solid-liquid waste incinerator.

Said programs shall be of a technical level commensurate with the person's duties as specified in the training manual. All operating training and certification programs shall be recorded in the operating record.

(b) A certified control room operator shall be on duty at the site at all times the T149 solid-liquid waste incinerator is in operation and the T149 solid-liquid waste incinerator, including associated air pollution control equipment and continuous monitoring systems, shall be operated and maintained at all times by persons who are trained and certified according to the Training and Certification Program.

D.13.12 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 – The SSM Plan shall be developed and implemented in accordance with 40 CFR 63.1206(c)(2), to ensure that the T149 solid-liquid waste incinerator, including associated air emission control equipment and CEMS and CMS, is operated and maintained 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 T149 solid-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) Emergency Safety Vent (ESV) Operating Plan – The ESV Operating Plan shall be developed and implemented in accordance with 40 CFR 63.1206(c)(4). The emission standards and operating plans apply even if hazardous waste is in the combustion chamber.

(d) 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.13.15.

(e) Continuous Emissions Monitoring System (CEMS) Standard Operating Procedures (SOP) – The Permittee shall prepare and implement an 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.13.13 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) Comprehensive Performance Tests:

(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 12 months after the HWC MACT compliance date unless an exemption is granted pursuant to 40 CFR 63.1207(e)(3).

(3) The Permittee shall submit a notification of intention to conduct the comprehensive performance test at least 60 calendar days before the test is scheduled to begin.

(4) The comprehensive performance tests shall be conducted under operating conditions representative of the extreme range of normal conditions as specified in 40 CFR 63.1207(g) and 63.7(e)(1) for the worst case mode associated with each applicable pollutant limit or emission standard.

(5) The operating parameters defined in Condition D.12.15 shall be monitored during the performance test to establish the parametric limits.

(6) All required comprehensive performance testing shall be completed within 60 days after the date of commencement of the tests pursuant to 40 CFR 63.1207(d)(3).

(7) The Permittee may use previous emissions test data in lieu of the initial comprehensive performance tests as allowed under 40 CFR 63.1207(c)(2).

(8) Pursuant to 40 CFR 63.7(h)(2), individual performance tests may be waived upon written application to the Administrator if, in the Administrator's judgment, the source is meeting the relevant standard(s) on a continuous basis, or the source is being operated under an extension of compliance, or the owner or operator has requested an extension of compliance and the Administrator is still considering the request.

(9) Pursuant to 40 CFR 63.1207(j), the Permittee shall:

(A) Postmark a Notification of Compliance (NOC) documenting compliance or noncompliance with the emission standards and continuous monitoring system requirements and identify operating parameter limits under 40 CFR 63.1209 within 90 days of completion of the comprehensive performance test; and

(B) Comply with all operating requirements specified in the NOC in lieu of the limits specified in the Documentation of Compliance required under 40 CFR 63.1211(c) upon postmark of the NOC.

These submittal requirements satisfy the reporting requirements of 326 IAC 3-6 as allowed under extension provisions of 326 IAC 3-6-4(b).

(b) Confirmatory Performance Tests

(1) The Permittee shall submit a notification of intention to conduct a confirmatory performance test and CMS performance evaluation and a site-specific test plan and CMS performance evaluation test plan at least 60 days before the performance test and performance evaluation are scheduled to begin.

(2) The confirmatory performance tests shall be conducted under operating conditions representative of the range of normal conditions as specified in 40 CFR 63.1207(g)(2) and 63.7(e)(1) for the parameters specified in 40 CFR 63.1207(g)(2) associated with the dioxin/furan emission standard unless the Administrator approves an alternative range under 40 CFR 63.1207(g)(v).

(3) The operating parameters defined in Condition D.12.15 shall be monitored during the performance test.

(4) All required comprehensive performance testing shall be completed within 60 days after the date of commencement of the tests pursuant to 40 CFR 63.1207(d)(3).

(5) Pursuant to 40 CFR 63.7(h)(2), individual performance tests may be waived upon written application to the Administrator if, in the Administrator's judgment, the source is meeting the relevant standard(s) on a continuous basis, or the source is being operated under an extension of compliance, or the owner or operator has requested an extension of compliance and the Administrator is still considering the request.

(6) Pursuant to 40 CFR 63.1207(j), the Permittee shall postmark a Notification of Compliance (NOC) documenting compliance or noncompliance with the applicable dioxin/furan emission standard within 90 days of completion of the comprehensive performance test

This submittal requirement satisfies the reporting requirements of 326 IAC 3-6 as allowed under extension provisions of 326 IAC 3-6-4(b).

(c) Subsequent Performance Tests

The Permittee shall conduct subsequent Comprehensive Performance Tests and Confirmatory Performance Tests at the frequencies specified in 40 CFR 63.1207(d).

(d) Pursuant to 326 IAC 3-6-4(b) and 40 CFR 63.1207(i)(2), the Permittee shall submit the performance test reports within 90 days following the test.

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, Alternative Monitoring Petition initially approved January 27, 2006]

(a) CO and O_2 CEMS Operation Requirements – The following requirements shall be applied at all times the T149 solid-liquid waste 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 O_2 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), the applicable performance specification requirements of 40 CFR 60, Appendix B, and the Alternative Monitoring Petition ("AMP") initially approved on January 27, 2006 and all subsequent revisions to the AMP.

(2) The CEMS shall be installed and operational upon certification of the DOC for the HWC MACT.

(3) Continuous monitor means a device which continuously samples the regulated parameter without interruption, evaluates the detector response at least once every 15 seconds and computes and records the average at least every 60 seconds, except during allowable periods of calibration and other exceptions identified in applicable requirements, plans and/or procedures. One-minute average means the average of detector responses calculated at least every 60 seconds from response obtained at least every 15 seconds.

(b) SO_2 and NOx CEMS Operation Requirements – The following requirements shall apply when the T149 solid-liquid waste incinerator is burning waste:

(1) The Permittee shall install and operate the SO_2 and NOx CEMS in accordance with the QA/QC criteria set forth in 40 CFR 60, Appendix B, 40 CFR 60, Appendix F, Procedure 1, and the AMP approved on January 27, 2006.

(2) Continuous monitor means a device which continuously samples the regulated parameter without interruption, evaluates the detector response at least once every 15 seconds and computes and records the average at least every 60 seconds, except during allowable periods of calibration and other exceptions identified in applicable requirements, plans and/or procedures. One-minute average means the average of detector responses calculated at least every 60 seconds from response obtained at least every 15 seconds.

(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 SO_2 or NOx CEMS malfunction:

(A) When the SO_2 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 NOx 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 NOx 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 NOx BACT limit.

(c) Particulate Matter [PM] CEMS Alternative Operating Scenario Requirements –
This permit provides the Permittee with the following Alternative Operating Scenario for purposes of satisfying the monitoring requirements of 40 CFR 63.1209. The Permittee shall operate the PM CEMS at all times the T149 solid-liquid waste incinerator is in operation, except as provided in paragraphs (3) or (4) below.

(1) The Permittee shall install and operate the PM CEMS in accordance with the QA/QC criteria set forth the AMP approved on January 27, 2006, and all subsequent revisions to the AMP.

(2) Continuous operation is defined as the collection of at least one measurement for each successive 15-minute period. In order to calculate a valid one-hour block average, valid results must be available for at least three of the four 15-minute cycles in each hour.

(3) During periods when the PM CEMS is malfunctioning or inoperative, the Permittee may use data from the Multi-Metal CEMS, as provided in the AMP approved January 27, 2006.

(4) In lieu of operating the PM CEMS, the Permittee may satisfy the monitoring requirements of 40 CFR 63.1209 through operation of the Continuous Monitoring System requirements described in Section D.13.15(a).

(d) Multi-Metals [MMX] CEMS Alternative Operating Scenario Requirements –
This permit provides the Permittee with the following Alternative Operating Scenario for purposes of satisfying the monitoring requirements of 40 CFR 63.1209. The Permittee shall operate the MMX CEMS at all times the T149 solid-liquid waste incinerator is in operation, except as provided in paragraphs (3) or (4) below.

(1) The Permittee shall install and operate the MMX CEMS in accordance with the QA/QC criteria set forth the AMP approved on January 27, 2006, and all subsequent revisions to the AMP.

(2) Continuous operation is defined as the collection of at least one measurement for each successive 15-minute period. In order to calculate a valid one-hour block average, valid results must be available for at least three of the four 15-minute cycles in each hour.

(3) During periods when the MMX CEMS is malfunctioning or inoperative, the Permittee may use data from the PM CEMS, as provided in the AMP approved

on January 27, 2006 and all subsequent revisions to the AMP.

(4) In lieu of operating the MMX CEMS, the Permittee may satisfy the monitoring requirements of 40 CFR 63.1209 through operation of the Continuous Monitoring System requirements described in Section D.13.15(a).

(e) Hydrogen Chloride [HCl] CEMS Alternative Operating Scenario Requirements – This permit provides the Permittee with the following Alternative Operating Scenario for purposes of satisfying the monitoring requirements of 40 CFR 63.1209. The Permittee shall operate the HCl CEMS at all times the T149 solid-liquid waste incinerator is in operation, except as provided in paragraphs (3) or (4) below.

(1) The Permittee shall install and operate the HCl CEMS in accordance with the QA/QC criteria set forth the AMP approved on January 27, 2006, and all subsequent revisions to the AMP.

(2) Continuous operation is defined as the collection of at least one measurement for each successive 15-minute period.

(3) In lieu of operating the HCl CEMS, the Permittee may satisfy the monitoring requirements of 40 CFR 63.1209 through operation of the following Continuous Monitoring System requirements described in Section D.13.15(a).

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 solid-liquid waste 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 solid-liquid waste incinerator is in operation. The Permittee shall operate the CMS as provided in the table below. The CEMS mode is when the HCl CEMS, and either the PM and/or the Metal CEMS are in operation in accordance with Condition D.13.14. If the Permittee is not operating in CEMS mode, then the CMS in the Parametric Mode must be monitored.

Operating Parameter	Monitor when in CMS Parametric Mode	Monitor when in CEMS Mode	Averaging Period	Units	Parameter for
Maximum Primary Waste Feed to Primary Combustion Chamber	X	X	1-hr RA	lbs/hr	D.13.5(e) D.13.5(f)
Maximum Secondary Waste Feed to Primary Combustion Chamber	X	X	1-hr RA	lbs/hr	D.13.5(e) D.13.5(f)
Maximum Solid Feed Rate	X	X	1-hr RA	lbs/hr	D.13.5(e) D.13.5(f)
Minimum Primary Combustion Chamber Temperature	X	X	1-hr RA	^{o}F	D.13.5(e) D.13.5(f)

Operating Parameter	Monitor when in CMS Parametric Mode	Monitor when in CEMS Mode	Averaging Period	Units	Parameter for
Maximum Primary Waste Feed to Secondary Combustion Chamber	X	X	1-hr RA	lbs/hr	D.13.5(e) D.13.5(f)
Maximum Secondary Waste Feed to Secondary Combustion Chamber	X	X	1-hr RA	lbs/hr	D.13.5(e) D.13.5(f)
Minimum Secondary Combustion Chamber Temperature	X	X	1-hr RA	^oF	D.13.5(e) D.13.5(f)
Maximum Stack Gas Flow Rate	X	X	1-hr RA	dscfm	D.13.2(a) D.13.5(a) D.13.5(b) D.13.5(c) D.13.5(d) D.13.5(e) D.13.5(f)
Maximum waste feed viscosity	X	X	Monthly Analysis	Centi-poise	D.13.5(f)
Minimum Waste Atomizing Pressure	X	X	1-hr RA	psig	D.13.5(f)
Maximum Particulate Matter (PM) limit		X	6-hr RA	mg/dscm	D.13.2
Maximum HCl/Cl_2 emissions		X	12-hr RA	ppmv	D.13.5(d)
Maximum Mercury Emissions		X	12-hr RA	ug/dscm	D.13.5(a)
Maximum SVM emissions		X	12-hr RA	ug/dscm	D.13.5(b)
Maximum LVM Emissions		X	12-hr RA	ug/dscm	D.13.5(c)
Maximum mercury feed rate in all feed streams	X		12-hr RA	lbs/hr	D.13.5(a)
Maximum SVM feed rate in all feed streams	X		12-hr RA	lbs/hr	D.13.5(b)
Maximum LVM feed rate in all feed streams	X		12-hr RA	lbs/hr	D.13.5(c)
Maximum LVM feed rate in all pumpable feed streams	X		12-hr RA	lbs/hr	D.13.5(c)
Maximum ash feed rate in all feed streams	X		12-hr RA	lbs/hr	D.13.2

Operating Parameter	Monitor when in CMS Parametric Mode	Monitor when in CEMS Mode	Averaging Period	Units	Parameter for
Maximum Total Chlorine feed rate in all feed streams	X		12-hr RA	lbs/hr	D.13.5(d)
Minimum Condenser/Absorber pressure drop	X		1-hr RA	in w.c.	D.13.5(a) D.13.5(b) D.13.5(c) D.13.5(d)
Minimum Condenser/Absorber liquid feed pressure	X		1-hr RA	psig	D.13.5(a) D.13.5(b) D.13.5(c) D.13.5(d)
Minimum Condenser/Absorber scrubber water pH	X		1-hr RA	pH	D.13.5(d)
Minimum Condenser/Absorber scrubber liquid flow rate	X		1-hr RA	gpm	D.13.5(a) D.13.5(b) D.13.5(c) D.13.5(d)
Minimum Hydro-Sonic Scrubber Equivalent Pressure Drop	X		1-hr RA	in w.c.	D.13.2 D.13.5(a) D.13.5(b) D.13.5(c) D.13.5(d)
Maximum Hydro-Sonic Scrubber conductivity	X		12-hr RA	% solids	D.13.2 D.13.5 (a) D.13.5(b) D.13.5(c)
Minimum Hydro-Sonic Scrubber Liquid Feed Rate	X		1-hr RA	gpm	D.13.2 D.13.5(a) D.13.5(b) D.13.5(c) D.13.5(d)
Minimum Hydro-Sonic Scrubber water pH	X		1-hr RA	pH	D.13.5(d)

(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 SO_2 [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 – SO_2 and NOx 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.

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 solid-liquid waste 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).

(14) The time periods in which the Permittee is operating in CEMS mode as the primary monitoring scenario or the CMS systems described in D.13.15 as the primary monitoring scenario.

(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 solid-liquid waste 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 T149 solid-liquid 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

(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 NOx and SO_2 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 HWC MACT standards [40 CFR 63.1211] for Startup, Shutdown and Malfunction (SSM) shall be used to satisfy the reporting requirements under the HWC MACT standards and PSD BACT requirements [326 IAC 2-2-3].

(A) The Permittee shall report all actions taken during T149 solid-liquid waste 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 that results in an exceedance of a relevant emission standard when those actions taken by the Permittee are inconsistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information:

(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;

(iv) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred; and

(v) Action taken to minimize emissions.

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

D.13.20 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 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 D.14 BPM CONTROL SYSTEMS – RTO OPERATIONS CONDITIONS

Emissions Unit Description [326 IAC 2-7-5(15)]:

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

Emission Unit Description	Building	Stack/Vent	Nominal Capacity	Control Device
Regenerative Thermal Oxidizer 1 (RTO1)	RTO1	RTO1 Stack	36 MMBtu/hr	Caustic Scrubber System
Regenerative Thermal Oxidizer 2 (RTO2)	RTO2	RTO2 Stack	36 MMBtu/hr	Caustic Scrubber System

The RTO control system consists of two Regenerative Thermal Oxidizers, identified as RTO1 and RTO2, each equipped with caustic scrubbing systems and each exhausting to individual stacks.

The closed vent system (CVS) associated with the RTO control system begins at the production building process, storage, and waste tank vent lines and ends at the entrance of the RTO control system. The positive pressure portions of the CVS are at the outlet of the production building roof fans exhausting to the RTO fume transports system, and up to the inlet side of the tank conservation vents of the tank modules exhausting to the RTO fume transport system.

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

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

D.14.0 Requirement to Control Emissions [40 CFR 60 Subpart Kb, 40 CFR 63 Subpart GGG, 40 CFR 63 Subpart DD, 326 IAC 2-2-3, and 326 IAC 8-5-3]

Except for equipment excluded from emission control requirements and except as otherwise provided by statute or rule, or in this permit, the fumes from all emission units which reference this section shall be continuously routed to the RTO control system while emission units vented to the control equipment are in operation. Except as otherwise provided by statute or rule, or in this permit, the RTO control system shall be operated at all times that the emission units vented to the control equipment are in operation.

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)]

(a) RTO Control Device Standards – The RTO control device standards shall apply at all times the unit is burning waste fume streams, except as provided in Condition D.14.2 (a):

(1) Carbon Monoxide (CO) – In order to satisfy PSD BACT requirements [326 IAC 2-2-3], CO emissions at the outlet of the RTO system shall not exceed a 24-hour daily average of 73 parts per million by volume (ppmv).

(2) Oxides of Nitrogen (NOx) – In order to satisfy PSD BACT requirements [326 IAC

2-2-3], NOx emissions at the outlet of the RTO system shall not exceed a 24-hour daily average of 91 ppmv.

(3) Sulfur Dioxide (SO_2) – In order to satisfy PSD BACT requirements [326 IAC 2-2-3], SO_2 emissions, as measured at the outlet of the RTO system, shall not exceed a 24-hour daily average of 100 ppmv.

(4) Volatile Organic Compounds (VOC)/Volatile Organic Hazardous Air Pollutant (VOHAP) – 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 one of the following streamlined VOC/VOHAP emission standards:

(A) Concentration Emission Standard:

(i) The VOC/VOHAP emissions shall not exceed 20 ppmv over a 24-hour daily average at the outlet of the RTO system, measured via a TOC CEMS;

(ii) The RTO combustion chamber temperature shall not be less than 1500F over a 24-hour daily average; and

(iii) The RTO combustion chamber residence time shall not be less than 0.75 seconds over a 24-hour daily average, which is equivalent to a maximum 24-hour daily average stack exhaust air flow rate of 3340 standard cubic feet per second; or

(B) Control Efficiency Emission Standard:

(i) The VOC/VOHAP emissions shall be reduced by a control efficiency of 98% or more at the outlet of the RTO system;

(ii) The RTO combustion chamber temperature shall not be less than 1500F over a 24-hour daily average; and

(iii) The solvent concentration going to the RTO, measured as a percent of the lower explosive limit (LEL), shall not exceed a 24-hour daily average established from a compliant stack test.

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

(5) Hydrogen Halide/Halogen and Fluorides – 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 one of the following hydrogen halide and halogen emission standards:

(A) Concentration Emission Standard:

(i) The hydrogen halide and halogen emissions, which includes hydrogen fluoride emissions, shall not exceed 20 ppmv over a 24-hour daily average at the outlet of the RTO system, measured via a HCl CEMS; or

(B) Control Efficiency Emission Standard:

(i) The hydrogen halide and halogen emissions, which include hydrogen fluoride emissions, shall be reduced by a control efficiency of 98% or more at the outlet of the RTO system;

(ii) The 24-hour daily average scrubber liquid pH of the caustic scrubbing system shall not be less than the value established from a compliant stack test;

(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:

(A) Install and monitor the position of the closed vent system bypass valve at least once every 15 minutes, where the closed position means there is no bypass flow; or

(B) Secure the bypass line valve in the closed position with a car seal or lock and key type configuration. Monthly visual inspections of seal or locking device shall be performed to ensure the seal is not broken or the valve is in the closed position and the vent stream is not diverted through the bypass line.

D.14.2 Exceptions to RTO Control System Standards [40 CFR 63.1250(g), 40 CFR 63.681, 63.685(g), 63.693(b) and 326 IAC 2-2-3]

(a) Exceptions to RTO Control Device Operational Standards – The following streamlined standards satisfy the Pharmaceutical MACT standards [40 CFR 63.1250(g)], Offsite Waste MACT standards [40 CFR 63.681, 63.685(g) and 63.693(b)], and PSD BACT requirements [326 IAC 2-2-3]:

(1) The Permittee may open a safety device and bypass the RTO system at any time conditions require it to do so to avoid unsafe conditions.

(2) The provisions of Conditions D.14.1 (a) shall not apply during periods of startup, shutdown or malfunction that preclude the Permittee from complying with Condition D.14.1 (a).

(b) Exceptions to RTO Closed Vent System Inspection Standards – The following streamlined standards satisfy the Pharmaceutical MACT standards [40 CFR 63.1258(h)(6) and (7)], and PSD BACT requirements [326 IAC 2-2-3]:

(1) The Permittee is not required to inspect if unsafe or difficult to inspect.

D.14.3 Startup, Shutdown, and Malfunction Requirements for RTO Control System [40 CFR 63.1259(a)(3), 40 CFR 63.697(b)(3), and 326 IAC 2-2-3]

The Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)] and Offsite Waste MACT standards [40 CFR 63.697(b)(3)] for Startup, Shutdown and Malfunction (SSM) Plans shall be used to satisfy 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 2-2-3].

(a) Pursuant to 40 CFR 63.1259(a)(3) and 40 CFR 63.697(b)(3), the Permittee shall develop an SSM Plan to ensure that processes are operated and maintained in a manner to prevent or minimize excess emissions to the extent practical [40 CFR 63.1250(g)].The SSM Plan shall contain the following information:

(1) Detailed plans and/or procedures for operating and maintaining the RTO system, including associated CEMS and CMS equipment, during periods of startup, shutdown, and malfunction; and

(2) Corrective action program for malfunctioning air pollution control, CEMS, and CMS equipment.

Compliance Determination Requirements

D.14.4 Requirement to Control Emissions [40 CFR 60 Subpart Kb, 40 CFR 63 Subpart GGG, 40 CFR 63 Subpart DD, 326 IAC 2-2-3, and 326 IAC 8-5-3]

Except for equipment excluded from emission control requirements and except as otherwise provided by statute or rule, or in this permit, the RTO control system shall be operated at all times that the emission units vented to the control equipment are in operation.

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

D.14.5 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 SO_2 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, NOx, and SO_2 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 SO_2 or NOx CEMS malfunction:

(A) When the SO_2 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 NOx 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 NOx 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 NOx 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* ("AMP") submitted to EPA OAQPS on August 15, 2003, and all subsequent revisions to the AMP, 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.14.6 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) 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)(5)(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 of 15 days if a reasonable explanation is provided within 40 days following the test.

(b) Subsequent Comprehensive Performance Test Requirements:

If the Permittee is complying with the control efficiency emission standards for VOC/VOHAP and Hydrogen Halide/Halogens, the performance tests shall be repeated at least once every fifth year from the date of the most recent valid compliance demonstration.

D.14.7 Parametric Continuous Monitoring System (CMS) Requirements [40 CFR 63.8(c), 40 CFR 60.113b(c), 40 CFR 63.1257(b), 63.1258(a) and (b), and 63.1260(e), 40 CFR 63.693(b), 326 IAC 2-1.1-11, 326 IAC 2-7-24, and 326 IAC 3-5-5(d)]

(a) VOC/VOHAP CMS Operation Requirements - The following streamlined requirements shall apply only when burning waste fume streams to satisfy the Pharmaceutical MACT standards [40 CFR 63.1258(a) and (b)], Offsite Waste MACT standards [40 CFR 63.693(b)], Volatile Organic Liquid Storage Vessel requirements [40 CFR 60.113b(c)], PSD BACT requirements [326 IAC 2-1.1-11], and continuous monitoring requirements for flow rate [326 IAC 3-5-5(d)]:

(1) RTO Combustion Chamber Temperature – The Permittee shall install and operate the RTO combustion chamber temperature CMS in accordance with 40 CFR 63.8(c).

(2) Lower Explosive Level (LEL) Concentration – When applying the VOC/VOHAP control efficiency standard, the Permittee shall install and operate the LEL CMS in accordance with 40 CFR 63.8(c).

(3) Flow Rate Monitor – When applying the VOC/VOHAP concentration emission standard, the Permittee shall install and operate airflow rate CMS at the stack exhaust in accordance with 326 IAC 3-5-5(d).

(4) Continuous operation is defined as the collection of at least one measurement for each successive 15-minute period.

(b) Hydrogen Halide/Halogen and Fluorides CMS Requirements – When applying the control efficiency standard requirements shall apply only when burning waste fume streams:

(1) The Permittee shall install and operate the following CMSs in accordance with 40 CFR 63.8(c):

(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.14.8 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.14.9 Minimum Data Requirements – SO_2, CO, and NOx Compliance [326 IAC 2-1.1-11]

The following defines when CEMS data must be supplemented with data required by conditions D.14. 5 (a)(3), D.14.10 (a)(1)(L), and D.14.10 (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.14.10 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;

(B) Monthly visual inspection records of bypass line valves and the occurrence of all periods the valve position has changed, if complying via this method;

(C) Record each CVS component that is unsafe to inspect, and a plan for inspecting the component as frequently as practicable during safe-to-inspect times;

(D) Record each CVS component that is difficult to inspect and a written plan for inspecting the component at least once every five years;

(E) Record the following information if no leaks are detected during applicable Method 21 inspections and CVS annual visual inspections:

(i) Date each inspection was performed; and

(ii) Statement for each inspection that no leaks were detected.

(F) For each part of the CVS not operated under negative pressure, record the following information for all leaks detected during the initial Method 21 inspection:

(i) Identification of leaking equipment;

(ii) Instrument ID and operator name or initials;

(iii) Date the leak was detected and date of first attempt to repair leak;

(iv) Maximum instrument reading after leak from initial Method 21 is successfully repaired or declared non-repairable; and

(v) 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.

(G) Record the following information for all leaks detected from the CVS annual visual inspection:

(i) Identification of leaking equipment;

(ii) Date leak was detected and first attempt to repair leak; and

(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 Reports

(1) The following streamlined reporting requirements satisfy the Pharmaceutical MACT requirements [40 CFR 63.1260(g)] and the Offsite Waste MACT standards [40 CFR 63.697], Volatile Organic Liquid Storage Vessel requirements [40 CFR 60.115b], PSD BACT requirements [326 IAC 2-2-3], and the 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, percentage of excursions 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 have been inoperative, out of control, repaired or adjusted;

(E) For CVS bypass lines with flow indicator, report all periods when vent stream is diverted from control device through bypass line when on waste;

(F) For CVS 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; and

(H) SSM summary reports for the RTO control system, including associated CEMS and CMS equipment.

(2) In addition to the requirements described in D.14. (b)(1) of this condition, the Permittee shall report the following information for the SO_2, CO, and NOx CEMS to satisfy the PSD BACT requirements [326 IAC 2-1.1-11]:

(A) A list of days when condition D.14.8 requires that CEMS data must be supplemented:

(B) A detailed report for each day when condition D.14.8 requires that CEMS data must be supplemented that provides:

(i) the information required by Condition D.14.4 (a)(3), and

(ii) an analysis of whether that information indicates continuous compliance with the limits established in Condition D.14.1 and if the NOx CEMS malfunctions for greater than six continuous hours, an assessment of NOx emissions, using process knowledge, whether the quantity of nitrogen fed into the RTO 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 NOx BACT limit.

(c) Immediate Reporting Requirements

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

(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 that results in an exceedance of a relevant emission standard when those actions taken by the Permittee are inconsistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information:

(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;

(D) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred; and

(E) Action taken to minimize emissions.

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

D.14.11 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 CONDITIONS

Emissions Unit Description [326 IAC 2-7-5(15)]:

(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	1,500 cfm	T79
T79-COL305	Air Stripper Column	T79	1,500 cfm	T79
T79-TK320	Condensate Collection Tank	T79-321 Fume Stream	200 gal	T79
T79-TK315	Caustic Supply Tank	Atmosphere	750 gal	N/A

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 production building process, storage, and waste tank vent lines and ends at the entrance of the T79 control system. The positive pressure portions of the CVS are after the steam jet prior to the T79 thermal oxidizer. In addition, the following fume streams have positive pressure portions as noted:

324 Fume Stream: The T140 tank system is positive up to the flow valve for the building, and the Secondary Tank Farm is positive up to the common flow valve.
325 Fume Stream: Waste tank vent lines prior to each tank's conservation vent.

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

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

D.15.0 Requirement to Control Emissions [40 CFR 60 Subpart Kb, 40 CFR 63 Subpart GGG, 40 CFR 63 Subpart DD, 326 IAC 2-2-3, and 326 IAC 8-5-3]

Except for equipment excluded from emission control requirements and except as otherwise provided by statute or rule, or in this permit, the fumes from all emission units which reference this section shall be continuously routed to the T79 control system while emission units vented to the control equipment are in operation. Except as otherwise provided by statute or rule, or in this permit, the T79 control system shall be operated at all times that the emission units vented to the control equipment are in operation.

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:

(A) The HCl/Cl_2 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 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.

(2) The Permittee shall monitor each bypass line on the T79 CVS 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:

(A) Install and monitor the position of the T79 CVS bypass valve at least once every 15 minutes, where the closed position means there is no bypass flow; or

(B) Secure the bypass line valve in the closed position with a car seal or lock and key type configuration. Monthly visual inspections of seal or locking device shall be performed to ensure the seal is not broken or the valve is in the closed position and the vent stream is not diverted through the bypass line.

D.15.2 Exceptions to T79 Control System Standards [40 CFR 63.1250(g), 40 CFR 63.681, 63.685(g), 63.693(b) and 326 IAC 2-2-3]

(a) Exceptions to T79 Control Device Operational Standards – The following streamlined standards satisfy the Pharmaceutical MACT standards [40 CFR 63.1250(g)], Offsite Waste MACT standards [40 CFR 63.681, 63.685(g) and 63.693(b)], and PSD BACT requirements [326 IAC 2-2-3]:

(1) The Permittee may open a safety device and bypass the T79 system at any time conditions require it to do so to avoid unsafe conditions.

(2) The provisions of Conditions D.15.1 (a) shall not apply during periods of startup, shutdown or malfunction that preclude the Permittee from complying with Condition D.15.1 (a).

(b) Exceptions to T79 CVS Inspection Standards – The following streamlined standards satisfy the Pharmaceutical MACT standards [40 CFR 63.1258(h)(6) and (7)], and PSD BACT requirements [326 IAC 2-2-3]:

(1) The Permittee is not required to inspect if unsafe or difficult to inspect.

D.15.3 Startup, Shutdown, and Malfunction Requirements for T79 Control System [40 CFR 63.1259(a)(3), 40 CFR 63.697(b)(3) and 326 IAC 2-2-3]

(a) The Pharmaceutical MACT standards [40 CFR 63.1259(a)(3)] and Offsite Waste MACT standards [40 CFR 63.697(b)(3)] for Startup, Shutdown and Malfunction (SSM) Plans shall be used to satisfy 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 2-2-3].

(b) Pursuant to 40 CFR 63.1259(a)(3) and 40 CFR 63.697(b)(3), the Permittee shall develop an SSM Plan to ensure that processes are operated and maintained in a manner to prevent or minimize excess emissions to the extent practical [40 CFR 63.1250(g)]. The SSM Plan shall contain the following information:

(1) Detailed procedures for operating and maintaining the T79 system, including associated CEMS and CMS equipment, during periods of startup, shutdown, and malfunction; and

(2) Corrective action program for malfunctioning air pollution control equipment.

Compliance Determination Requirements

D.15.4 Requirement to Control Emissions [40 CFR 60 Subpart Kb, 40 CFR 63 Subpart GGG, 40 CFR 63 Subpart DD, 326 IAC 2-2-3, and 326 IAC 8-5-3]

Except for equipment excluded from emission control requirements and except as otherwise provided by statute or rule or in this permit, the T79 control system shall be operated at all times that the emission units vented to the control equipment are in operation.

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

D.15.5 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), and 326 IAC 2-1.1-11]

(a) Reserved

(b) Comprehensive Performance Test Requirements:

If at any time the Permittee changes the design, operation and maintenance features of the T79 Fume Incinerator System in a manner that could reasonably be expected to affect its ability to meet the VOC/VOHAP control efficiency, then the Permittee shall conduct a performance test to demonstrate compliance with the VOC/VOHAP control efficiency requirements. If at any time the Permittee changes the design, operation and maintenance features of the T79 Fume Incinerator System in a manner that could reasonably be expected to affect its ability to meet the Hydrogen Halide/Halogens control efficiency, then the Permittee shall conduct a performance test to demonstrate compliance with the Halide/Halogen control efficiency requirements.

D.15.6 Parametric Continuous Monitoring System (CMS) Requirements [40 CFR 63.8(c), 40 CFR 60.113b(c), 40 CFR 63.1257(b), 63.1258(a) and (b), and 63.1260(e), 40 CFR 63.693(b), 326 IAC 2-1.1-11, and 326 IAC 3-5-5(d)]

(a) VOC/VOHAP CMS Requirements - The following streamlined requirements apply only when burning waste fume streams to satisfy the Pharmaceutical MACT standards [40 CFR 63.1258(a) and (b)], Offsite Waste MACT standards [40 CFR 63.684(e)(1)], Volatile Organic Liquid Storage Vessel requirements [40 CFR 60.113b(c)], and PSD BACT requirements [326 IAC 2-1.1-11]:

(1) T79 Combustion Chamber Temperature – The Permittee shall install and operate the T79 combustion chamber temperature CMS in accordance with 40 CFR 63.8(c).

(2) Continuous operation is defined as the collection of at least one measurement for each successive 15-minute period.

(b) Hydrogen Halide/Halogen and Fluorides CMS Requirements – The following requirements apply only when burning waste fume streams to satisfy the Pharmaceutical MACT standards for hydrogen halides and halogens [40 CFR 63.1257(b), 63.1258(b), and 63.1260(e)] and the PSD BACT requirements for fluorides [326 IAC 2-1.1-11]:

(1) The Permittee shall install and operate the following CMSs in accordance with 40 CFR 63.8(c):

(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 Quality Control Program – The Permittee shall prepare and implement a quality control program for the CMS units in accordance with 40 CFR 63.8(d).

D.15.7 Excursions [40 CFR 63.1258(b)(6)]

(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 Condition D.15.5:

(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.15.8 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], 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) 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;

(B) Monthly visual inspection records of bypass line valves and the occurrence of all periods the valve position has changed, if complying via this method;

(C) For each portion of the CVS not operated under negative pressure, record each component that is unsafe to inspect, and a plan for inspecting the component as frequently as practicable during safe-to-inspect times;

(D) For each portion of the CVS not operated under negative pressure, record each component that is difficult to inspect and a written plan for inspecting the component at least once every five years;

(E) For each part of the CVS not operated under negative pressure, record the following information if no leaks are detected during the initial Method 21 inspection or annual visual inspections:

(i) Date each inspection was performed; and

(ii) Statement for each inspection that no leaks were detected.

(F) For each part of the CVS not operated under negative pressure, record the following information for all leaks detected during the initial Method 21 inspection:

(i) Identification of leaking equipment;

(ii) Instrument ID and operator name or initials;

(iii) Date the leak was detected and date of first attempt to repair leak;

(iv) Maximum instrument reading after leak from initial Method 21 is successfully repaired or declared non-repairable; and

(v) 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.

(G) For each part of the CVS not operated under negative pressure, record the following information for all leaks detected from the annual visual inspection:

(i) Identification of leaking equipment;

(ii) Date leak was detected and first attempt to repair leak; and

(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)] 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 2-2-3], 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 have 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

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

(1) The Permittee shall report all actions taken during a T79 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 that results in an exceedance of a relevant emission standard when those actions taken by the Permittee are inconsistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information:

(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;

(D) Report any excess emissions and/or parameter monitoring exceedances are believed to have occurred; and

(E) Actions taken to minimize emissions.

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

D.15.9 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 2-7-10.5), 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 F.1 CHANGE MANAGEMENT AND FLEXIBLE PERMIT OPERATION CONDITIONS

Emissions Unit Description:

(a) The areas of the plant site listed below are subject to the change management and flexible permit conditions described in this F section. These conditions apply to all emission units listed in the specific sections of the permit listed below and emission units added to the site pursuant to the provisions of this section:

(1) D.6 BPM - Process Operations [referred to as "BPM"]
(2) D.7 BPM Support – Solvent Recovery Operations
(3) D.8 BPM Support – Individual Drain Systems
(4) D.9 BPM Support – Solvent Storage Tank Operations
(5) D.10 BPM Support – Waste Storage Tank Operations
(6) D.11 BPM Support – Waste Containers
(7) D.12 BPM Control Systems – T49 Liquid Waste Incinerator
(8) D.13 BPM Control Systems – T149 Solid-Liquid Waste Incinerator
(9) D.14 BPM Control Systems – RTO Operations
(10) D.15 BPM Control Systems – T79 Fume Incinerator Operations

(b) The following operation is not subject to the change management provisions of this section except for the VOC emission limit requirements in Sections F.1.1(e) and F.1.7(c):

(1) D.18 BPM Support – Chemical Wastewater Treatment Plant

(c) The operations in the areas listed below are not subject to the change management and flexible permit conditions in this G section:

(1) D.1 Utilities
(2) D.2 Utilities Support
(3) D.3 – D.5 Fermented Products
(4) D.16 Research and Development Operations
(5) D.19 BPM Transfer Activities
(6) Insignificant Activities described in Section A and outside the BPM production and support operations

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

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

F.1.1 Emission limits [326 IAC 2-2]

(a) Carbon monoxide (CO) emissions from the facilities operating under the flexible permit conditions shall not exceed 150 tons per 12-month period, rolled on a calendar month basis. Carbon monoxide emissions from the T79 fume incinerators shall not exceed 30 tons per 12-month period, rolled on a calendar month basis.

(b) Fluoride (F) emissions from the facilities operating under the flexible permit conditions shall not exceed 6 tons per 12-month period, rolled on a calendar month basis. Fluoride emissions from the T79 fume incinerators shall not exceed 2 tons per 12-month period, rolled on a calendar month basis.

(c) Nitrogen oxides (NOx) 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. 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 (SO_2) 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 solid-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 solid-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 solid-liquid waste incinerator, and measure the combustion and atomized air flow rate into the T49 liquid waste incinerator.

(3) **Mass emission calculation**: The Permittee shall calculate CO emissions, in tons, each calendar month by using the CEMS data and flow rate data.

(4) **Minimum data collection requirements:**

(A) For the RTOs, the Permittee shall monitor and record CO concentrations as required in Section D.14.

(B) For the T49 liquid waste incinerator, the Permittee shall monitor and record CO concentrations as required in Section D.12.

(C) For the T149 solid-liquid waste incinerator, the Permittee shall monitor and record CO concentrations as required in Section D.13.

(5) **Data substitution:**

(A) During periods of CEMS calibration, the Permittee shall substitute, in one-minute increments, the last valid one-minute CO concentration measurement obtained prior to the calibration in lieu of actual readings from the CO CEMS for the RTO and T149 CEMS, and the last valid one-minute CO emission rate measurement obtained prior to the calibration in lieu of actual readings from the CO CEMS for the T49 CEMS.

(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 CO data collection, the Permittee shall substitute the following data in lieu of actual readings from the CO CEMS:

(i) When combusting only natural gas, the following CO mass emission rates shall be substituted:

(1) RTO CO mass emission rate = 0.05 lb/min
(2) T49 CO mass emission rate = 0.10 lb/min
(3) T149 CO mass emission rate = 0.07 lb/min

(ii) When incinerating a waste stream, the following CO concentrations shall be substituted:

(1) RTO CO concentration = 73 ppmv
(2) T49 CO concentration = 100 ppmv
(3) T149 CO concentration = 100 ppmv

(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 CO mass emission rates shall be substituted:

(1) RTO CO mass emission rate = 0.05 lb/min
(2) T49 CO mass emission rate = 0.10 lb/min
(3) T149 CO mass emission rate = 0.07 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

(6) **Emissions during RTO bypass periods**: When determining compliance with the CO emission limit, the Permittee shall include any known CO emissions from BPM production buildings not emitted through the RTO due to diversions at 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.

(b) The following requirements apply to the T79 fume incinerators (309 and 310):

(1) **Natural gas usage**: The Permittee shall determine the amount of natural gas burned by the T79 fume incinerators each calendar month.

(2) **Emission calculation**: The Permittee shall calculate CO emissions, in tons, each calendar month by multiplying the monthly natural gas usage, in mmscf, by an emission factor of 84 lbs/mmscf and converting the resulting emissions to tons.

(3) **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 valid data, the Permittee shall substitute a natural gas consumption rate for each incinerator of 0.0075 mmscf/hour [based on the nominal heat input rate of 7.626 MMBtu/hr per incinerator].

F.1.4 Fluorides emission limit determination

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

(a) The following requirements apply to the RTOs and the T79 fume incinerators:

(1) **Uncontrolled hydrogen fluoride emissions**: The Permittee shall determine the mass of fluorine atoms emitted to the RTOs and T79 fume incinerators [as components of fluorinated solvents] by BPM and BPM Support operations, by using engineering calculation methods based on ideal gas law equations, stoichiometry and mass balance. All fluorine atoms shall be considered emitted as hydrogen fluoride (HF) after combustion in the RTOs or the T79 fume incinerators.

(2) **HF control efficiency:** The Permittee shall base fluoride emissions on an RTO and T79 scrubber control efficiency of 98% or a control efficiency determined from an approved stack test. 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%).

(3) **Emission calculation**: The Permittee shall calculate fluoride emissions, in tons, for each calendar month by multiplying the amount of HF created by combustion of the fluorine atoms in the RTOs and T79 fume incinerators by the respective HF control efficiency.

(4) **Emissions during RTO bypass periods**: When determining compliance with the fluoride emission limit, the Permittee shall include any known fluoride emissions from BPM production buildings not emitted through the RTO due to diversions at the fume transport system. The Permittee may use engineering calculation methods based on ideal gas law equations, stoichiometry, and mass balance, to estimate these emissions.

(b) The following requirements apply to the T49 liquid waste incinerator and the T149 solid-liquid waste incinerator:

(1) **Uncontrolled hydrogen fluoride emissions**: When burning liquid wastes, the Permittee shall determine the mass of fluorine atoms burned in the incinerators by sampling the liquid waste and analyzing the sample for fluorine content, no less frequently than once per quarter. All fluorine atoms shall be considered emitted as hydrogen fluoride (HF). When burning solid wastes in the T149 solid-liquid waste incinerator, the Permittee shall determine monthly HF emissions by multiplying an emission factor of 0.149 pounds/ton solid waste burned by the monthly solid waste throughput.

(2) **HF control efficiency:** The Permittee shall base fluoride emissions on an incinerator scrubber control efficiency of 98.0% or a control efficiency determined from an approved stack test. 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%).

(3) **Emission calculation**: The Permittee shall calculate fluoride emissions, in tons, for each calendar month by multiplying the amount of uncontrolled HF emissions by the HF control efficiency.

F.1.5 Nitrogen oxides (NO_X) 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 solid-liquid waste incinerator:

(1) **NOx measurement**: The Permittee shall measure NOx concentration in the exhaust of with a NOx continuous emission monitoring system (CEMS) in accordance with 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 solid-liquid waste incinerator, and measure the combustion and atomized air flow rate into the T49 liquid waste incinerator with a system.

(3) **Emission calculation**: The Permittee shall calculate NOx emissions, in tons, each calendar month by using the CEMS data and flow rate data.

(4) **Data substitution:**

(A) During periods of CEMS calibration, the Permittee shall substitute, in one-minute increments, the last valid one-minute NOx concentration measurement obtained prior to the calibration in lieu of actual readings from the NOx CEMS for the RTO and T149 CEMS, and the last valid one-minute NOx emission rate measurement obtained prior to the calibration in lieu of actual readings from the NOx CEMS for the T49 CEMS.

(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 solid-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.

(b) The following requirements apply to the T79 Fume Incinerators:

(1) **NOx 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 NOx emissions from natural gas combustion, in tons, each calendar month by multiplying the monthly natural gas usage by an emission factor of 50 lbs/mmscf and converting the resulting emissions to tons.

(2) **NOx emission calculation for combustion of nitrogen-containing solvents**: The Permittee shall determine the mass of nitrogen atoms emitted to the T79 fume incinerators [as components of solvents containing nitrogen] by the BPM Support operations by using engineering calculations based on ideal gas law equations, stoichiometry, or mass balance. Six (6%) of the nitrogen atoms shall be considered emitted as nitrogen oxides after combustion in the T79 fume incinerators.

(3) **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 valid data, the Permittee shall determine NOx 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.1.6 Sulfur dioxide (SO_2) emission limit determination

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

(a) The following requirements apply to RTOs, the T49 liquid waste incinerator, and the T149 solid-liquid waste incinerator:

(1) **SO_2 measurement**: The Permittee shall measure SO_2 concentration in the exhaust of RTO, and incinerators with a SO_2 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 the T149 solid-liquid waste incinerator, and measure the combustion and atomized air flow rate into the T49 liquid waste incinerator.

(3) **Emission calculation**: The Permittee shall calculate SO_2 emissions, in tons, each calendar month by using the CEMS data and flow rate data.

(4) **Data substitution:**

(A) During periods of CEMS calibration, the Permittee shall substitute, in one-minute increments, the last valid one-minute SO_2 concentration measurement obtained prior to the calibration in lieu of actual readings from the SO_2 CEMS for the RTO and T149 CEMS, and the last valid one-minute SO_2 emission rate measurement obtained prior to the calibration in lieu of actual readings from the SO_2 CEMS for the T49 CEMS.

(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 SO_2 data collection, the Permittee shall substitute the following data in lieu of actual readings from the SO_2 CEMS:

(i) When combusting only natural gas, the following SO_2 mass emission rates shall be substituted:

(1) RTO SO_2 mass emission rate = 0.0004 lb/min
(2) T49 SO_2 mass emission rate = 0.0007 lb/min
(3) T149 SO_2 mass emission rate = 0.0005 lb/min

(ii) When incinerating a waste stream, the following SO_2 concentrations shall be substituted:

(1) RTO SO_2 concentration = 100 ppmv
(2) T49 SO_2 Concentration = 500 ppmv
(3) T149 SO_2 concentration = 400 ppmv

(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 SO_2 mass emission rates shall be substituted:

(1) RTO SO_2 mass emission rate = 0.0004 lb/min
(2) T49 SO_2 mass emission rate = 0.0007 lb/min
(3) T149 SO_2 mass emission rate = 0.0005 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 SO_2 concentrations as required in Section D.14.
(B) For the T49 liquid waste incinerator, the Permittee shall monitor and record SO_2 concentrations as required in Condition D.12.
(C) For the T149 solid-liquid waste incinerator, the Permittee shall monitor and record SO_2 concentrations as required in Condition D.13.

(6) **Emissions during RTO bypass periods:** When determining compliance with the SO_2 emission limit, the Permittee shall include any known SO_2 emissions from BPM production buildings and 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.

(b) The following requirements apply to the T79 fume incinerators:

(1) **SO_2 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 SO_2 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 SO_2 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 SO_2 as a result of combustion in the T79 fume incinerators.

(3) **SO_2 control efficiency:** The Permittee shall base SO_2 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 SO_2 emissions, in tons, each calendar month by multiplying the amount of SO_2 created by combustion of the sulfur atoms in the T79 fume incinerators by the scrubber SO_2 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 SO_2 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 solid-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 solid-liquid waste incinerator, the Permittee shall use 10 ppmdvc 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.

(2) **Flow rate measurement:** The Permittee shall measure the actual exhaust gas flow rate from the RTOs and the T149 solid-liquid waste incinerator, and

measure the combustion and atomized air flow rate into the T49 liquid waste incinerator.

(3) **Emission calculation**: The Permittee shall calculate VOC emissions, in tons, each calendar month by using the TOC CEMS concentration data, measured as methane (MW = 16), and exhaust gas flow rate data.

(4) **Data substitution:**

(A) During periods of CEMS calibration, the Permittee shall substitute, in one-minute increments, the last valid one-minute TOC/CO concentration measurement obtained prior to the calibration in lieu of actual readings from the TOC/CO CEMS.

(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 TOC/CO data collection, the Permittee shall substitute the following data in lieu of actual readings from the TOC/CO CEMS:

(i) When combusting only natural gas, the following VOC mass emission rates shall be substituted:

(1) RTO VOC mass emission rate = 0.003 lb/min
(2) T49 VOC mass emission rate = 0.007 lb/min
(3) T149 VOC mass emission rate = 0.004 lb/min

(ii) When incinerating a waste stream, the following TOC concentrations shall be substituted:

(1) RTO TOC concentration = 20 ppmv methane
(2) T49 TOC concentration = 10 ppmv methane
(3) T149 TOC concentration = 10 ppmv methane

(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 VOC mass emission rates shall be substituted:

(1) RTO VOC mass emission rate = 0.003 lb/min
(2) T49 VOC mass emission rate = 0.007 lb/min
(3) T149 VOC mass emission rate = 0.004 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 VOC concentrations as required in condition D.14.

(B) For the T49 liquid waste incinerator, the Permittee shall monitor and record VOC concentrations as required in condition D.12.

(C) For the T149 solid-liquid waste incinerator, the Permittee shall monitor and record VOC concentrations as required in D.13.

(6) **Emissions during RTO bypass periods:** The Permittee shall include any known VOC emissions from BPM production buildings 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.

(b) The following requirements apply to the RTOs when compliance is based on the 98% control efficiency standard and the T79 fume incinerators:

(1) **VOC emission calculation for natural gas usage:** The Permittee shall determine the amount of natural gas burned by the RTOs and the T79 fume incinerators each calendar month. The Permittee shall calculate VOC emissions from natural gas combustion, in tons, each calendar month by multiplying the monthly natural gas usage by an emission factor of 5.5 lbs/mmscf and converting the resulting emissions to tons.

(2) **VOC emission calculation from BPM production operations and BPM support operations exhausting to the RTOs and the T79 fume incinerator system:** The Permittee shall estimate the uncontrolled VOC emissions from the BPM production operations and the BPM support operations exhausting to the RTOs and the T79 fume incinerator system by using engineering calculation methods based on ideal gas law equations, stoichiometry, or mass balance. The Permittee shall base VOC emissions on an RTO and T79 fume incinerator control efficiency of 98%. If the compliance monitoring data is not available or indicates the RTO or T79 fume incinerator is not achieving this control efficiency, the Permittee shall use a control efficiency of zero percent (0%).

(3) **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 RTOs or T79 fume incinerator system are not collecting valid data, the Permittee may assume that natural gas is consumed at a rate of 0.0075 mmscf/hour [based on the nominal heat input rate of 7.626 MMBtu/hr per incinerator].

(c) Fugitive VOC emissions from BPM and BPM Support Operations, *including the Chemical Wastewater Treatment Plant*: The Permittee shall determine monthly fugitive VOC emissions using the following calculation methods:

(1) **Emission factors:** The Permittee shall develop emission factors to calculate monthly fugitive VOC emissions. The emission factors shall be developed according to the following methods.

(A) For each VOC compound that the Permittee reports release of in the annual SARA Title III TRI report ("reportable SARA VOCs"), the Permittee shall develop a compound-specific emission factor, expressed in pounds of emissions per 100 pounds of solvent usage. Reportable SARA VOC emission factors shall be derived from mass-balance data used to submit SARA reports. Each compound-specific fugitive emission factor for reportable SARA VOCs shall be updated and applied to monthly fugitive emission calculations beginning July 1 of each year.

(B) For VOC compounds not reported under SARA Title III, the Permittee shall use a generic fugitive emission factor, expressed in pounds of emissions per 100 pounds of solvent usage. The generic fugitive emission factor shall be equal to the highest representative emission factor developed in (A) above for a reportable SARA VOC used as a raw material in production processes. In the alternative, the Permittee may develop and apply a compound-specific emission factor for a compound not reported under SARA Title III. The generic fugitive emission factor and any compound-specific fugitive emission factor shall be updated and applied to monthly fugitive emission calculations beginning July 1 of each year.

(2) **Emission calculation method:** For VOCs with a compound-specific emission factor described in (1), the Permittee shall calculate monthly fugitive VOC emissions by multiplying the compound-specific emission factor by the corresponding compound-specific monthly solvent usage. For VOCs without a compound-specific emission factor, the Permittee shall calculate monthly fugitive VOC emissions by multiplying the generic emission factor described in (1)(B) by the monthly solvent usage of those compounds.

Record keeping and reporting [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

F.1.8 Records and reporting emission limits [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

(a) The Permittee shall record and maintain records of all information including all measurements and calculations described in Sections F.1.3 through F.1.7.

(b) The Permittee shall submit a quarterly report of actual emissions of CO, fluorides, NOx, SO_2, and VOC, as determined in accordance with Sections F.1.4 through F.1.8, to the address listed in Section C – General Reporting Requirements, within thirty (30) days after the end of the calendar quarter being reported. This report requires the certification by a “responsible official” as defined by 326 IAC 2-7-1(34).

F.1.9 Change management evaluation process

For purposes of the requirements of the Pharmaceutical MACT standards [40 CFR 63, Subpart GGG], the Permittee shall employ a change management evaluation process to determine whether changes will affect compliance. This change evaluation process shall include the following elements:

(a) New processes, process changes, and physical changes to process equipment that increase hazardous air pollutant emissions from process vents, wastewater streams, and storage tanks will be considered “new process operating scenarios”. Changes which affect fugitive emissions equipment components will not be considered new operating scenarios and will be managed per the relevant provisions of the leak detection and repair program, which includes provisions addressing the addition of, and changes to, components.

(b) Each new process operating scenario [as defined in F.1.10 (a)] will be reviewed to determine whether the change will affect compliance with the emission standards under the Pharmaceutical MACT requirements. Compliance with the following standards will be evaluated: process vent standards [40 CFR 63.1254]; storage tank standards [40 CFR 63.1253]; and wastewater streams [40 CFR 63.1256].

(c) Documentation of the evaluation of each new process operating scenario will contain the following information:

(1) For new or changed process vents, a statement regarding the method for complying with 40 CFR 63.1254. The statement shall include an analysis that shows whether the new or changed process vents fit within an existing compliance demonstration, or whether another demonstration must be conducted.

(2) For new or changed storage tanks, a statement regarding the method for complying with 40 CFR 63.1253. The statement shall include an analysis that shows whether the new or changed storage tank fits within an existing compliance demonstration, or whether another demonstration must be conducted.

(3) For new or changed wastewater streams, a statement regarding the method for complying with 40 CFR 63.1256. The statement shall include an analysis that shows whether the new or changed wastewater stream fits within an existing compliance demonstration, or whether another demonstration must be conducted.

(d) If a new process-operating scenario will trigger applicable requirements not described in this permit or compliance with applicable requirements will be demonstrated by methodologies not described in this permit, this permit must be revised pursuant to 326 IAC 2-7-12.

F.1.10 Records and reporting of site modifications [326 IAC 2-7-5(16)] [326 IAC 2-7-20(a)] [40 CFR 63.1259] [40 CFR 63.1260]

(a) Changes made pursuant to advance approval provisions:

The Permittee shall record and maintain records of all modifications that would have otherwise required a revision to this permit pursuant to 326 IAC 2-7-12 or a source modification approval if the provisions of 326 IAC 2-7-10.5 were applicable.

(b) Pharmaceutical MACT operating scenarios:

(1) Pursuant to 40 CFR 63.1259(c), for all equipment subject to the pharmaceutical MACT requirements, the Permittee shall develop a record describing operating scenarios that may occur in the BPM operations and BPM Support operations.

(2) Pursuant to 40 CFR 63.1259(f)(4), for all equipment subject to the pharmaceutical MACT requirements, the Permittee shall list all known operating scenarios that may occur in the BPM operations and BPM Support operations in the notification of compliance status report.

(3) Pursuant to 40 CFR 63.1259(b)(8), for all equipment subject to the pharmaceutical MACT requirements, the Permittee shall maintain a log that records, which operating scenarios have been, put into effect in the BPM operations and BPM Support operations.

F.1.11 Notifications for site modifications [326 IAC 2-1.1-12(e)-(f)]

(a) The Permittee shall submit a notification for any modification that would have otherwise required a source modification approval if the provisions of 326 IAC 2-7-10.5 were applicable, to the address listed in Section C – General Reporting Requirements, at least ten (10) days before implementing the modification.

(b) The notification shall include the following information:

(1) the company name and address and source and permit identification numbers;

(2) a description of the physical or operational change, including an estimate of the potential to emit of the emissions associated with the change;

(3) an identification of the emission unit or units being changed on the layout diagram of the source;

(4) the schedule for constructing each physical change and implementing each operational change;

(5) identification of any applicable requirements that are applicable to the physical or operational change and include any monitoring, record keeping, or reporting requirements to assure compliance with the applicable requirements;

(6) a statement for all regulated pollutants, except the pollutant for which the emissions limit has been established, that demonstrates that the physical or operational change will not trigger any federal or state permitting requirement for any regulated pollutant; and

(7) a statement that the physical or operational change will not result in emissions greater than the emissions limit.

(c) This notification does not require the certification by a “responsible official” as defined by 326 IAC 2-7-1(34).

F.1.12 Inclusion of site modifications in Pharmaceutical MACT Periodic Report

(a) Pursuant to 40 CFR 63.1260(g)(2)(vii), the Permittee shall include in the Periodic Report information for each new operating scenario operated since the time period covered by the last periodic report. These reports shall be submitted as required in Conditions D.14.10 or D.15.8 – Reporting Requirements.

(b) Pursuant to 40 CFR 63.1260(h)(1), whenever a new process is introduced, or a change in any of the information submitted in the Notification of Compliance Status Report, the Permittee shall submit the following information with the next Periodic report as required in Conditions D.14.9 or D.15.8 – Reporting Requirements:

(1) A brief description of the process change;

(2) A description of any modifications to standard procedures or quality assurance procedures;

(3) Revisions to any of the information reported in the original Notification of Compliance Status Report under paragraph (f) of this section; and

(4) Information required by the Notification of Compliance Status Report under

paragraph (f) of this section for changes involving the addition of processes or equipment.

(c) Pursuant to 40 CFR 63.1260(h)(2), the Permittee must submit a report 60 days before the scheduled implementation date of either of the following:

(1) Any change in the activity covered by the Precompliance report.

(2) A change in the status of a control device from small to large.

F.1.13 Reports of changes affected by Hazardous Waste Combustor MACT

(a) Pursuant to 40 CFR 63.1206(b)(5)(iii), a change is defined as any change in design, operation or maintenance practices that were documented in the comprehensive performance test plan, Notification of Compliance, or startup, shutdown, and malfunction plan.

(b) For changes that may adversely affect compliance which are not monitored with a CEMS, the Permittee shall:

(1) Notify the Administrator at least 60 days prior to the change, unless circumstances are documented that dictate that such prior notice is not reasonably feasible.

(2) Conduct a comprehensive performance test under the requirements of 40 CFR 63.1207(f)(1) and (g)(1) to document compliance with the affected emission standard(s) and establish operating parameter limits as required under 40 CFR 63.1209, and submit the Administrator a Notification of Compliance under 40 CFR 63.1207(j) and 40 CFR 63.1210(d); and

(3) Not burn hazardous waste for more than a total of 720 hours after such change is made and prior to submitting the notification of compliance unless the Administrator provides a written approval to burn hazardous waste in the interim.

(c) For changes that will not affect compliance, the Permittee shall document the change in the operating record upon making such change. The Permittee shall revise as necessary the performance test plan, Documentation of Compliance, Notification of Compliance, and startup, shutdown and malfunction plan to reflect these changes.

Other flexible permit requirements

F.1.14 Valid period for Best Available Control Technology [326 IAC 2-2-3(4)]

The modifications that occur under this permit qualify as a single, ongoing phase of construction and modification to Tippecanoe Laboratories. The BACT requirements established in Sections D.6 through D.15 shall remain valid over the entire period of this permit. If the time between consecutive modifications exceeds 18 months, the Permittee shall demonstrate that the initial BACT determination incorporated into the permit is still valid or propose new BACT requirements. Upon expiration of this permit, Major New Source Review requirements (Prevention of Significant Deterioration and Nonattainment NSR) shall apply.

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.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
PART 70 OPERATING PERMIT
CERTIFICATION

Source Name: Eli Lilly and Company - Tippecanoe Laboratories
Source Address: 1650 Lilly Road, Lafayette, Indiana 47909
Mailing Address: 1650 Lilly Road, lafayette, IN 47909
Part 70 Permit No.: T157-26575-00006

This certification shall be included when submitting monitoring, testing reports/results or other documents as required by this permit.

Please check what document is being certified:

☐ Annual Compliance Certification Letter

☐ Test Result (specify)

☐ Report (specify)

☐ Notification (specify)

☐ Affidavit (specify)

☐ Other (specify)

I certify that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.
Signature:
Printed Name:
Title/Position:
Phone:
Date:

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY

COMPLIANCE AND ENFORCEMENT BRANCH
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251
Phone: 317-233-0178
Fax: 317-233-6865

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, IN 47909
Part 70 Permit No.: T157-26575-00006

This form consists of 2 pages **Page 1 of 2**

☐ This is an emergency as defined in 326 IAC 2-7-1(12) • The Permittee must notify the Office of Air Quality (OAQ), within four (**4**) business hours (1-800-451-6027 or 317-233-0178, ask for Compliance Section); and • The Permittee must submit notice in writing or by facsimile within two (**2**) working days (Facsimile Number: 317-233-6865), and follow the other requirements of 326 IAC 2-7-16.

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

Facility/Equipment/Operation:
Control Equipment:
Permit Condition or Operation Limitation in Permit:
Description of the Emergency:
Describe the cause of the Emergency:

If any of the following are not applicable, mark N/A **Page 2 of 2**

Date/Time Emergency started:
Date/Time Emergency was corrected:
Was the facility being properly operated at the time of the emergency? Y N
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.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION
PART 70 OPERATING PERMIT
QUARTERLY DEVIATION AND COMPLIANCE MONITORING REPORT

Source Name:	Eli Lilly and Company - Tippecanoe Laboratories
Source Address:	1650 Lilly Road, Lafayette, Indiana 47909
Mailing Address:	1650 Lilly Road, lafayette, IN 47909
Part 70 Permit No.:	T157-26575-00006

Months: ______ to _ Year: ________

Page 1 of 2

This report shall be submitted quarterly based on a calendar year. Any deviation from the requirements, the date(s) of each deviation, the probable cause of the deviation, and the response steps taken must be reported. A deviation required to be reported pursuant to an applicable requirement that exists independent of the permit, shall be reported according to the schedule stated in the applicable requirement and does not need to be included in this report. Additional pages may be attached if necessary. If no deviations occurred, please specify in the box marked "No deviations occurred this reporting period".	
☐ NO DEVIATIONS OCCURRED THIS REPORTING PERIOD.	
☐ THE FOLLOWING DEVIATIONS OCCURRED THIS REPORTING PERIOD	
Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	
Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	

Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	
Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	
Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	

Form Completed by:______________________________

Title / Position: _________________________________

Date:____

Phone: _______________________________________

Attach a signed certification to complete this report.

Indiana Department of Environmental Management
Office of Air Quality

Technical Support Document (TSD) for a Significant Source Modification

Source Background and Description

Source Name:	**Eli Lilly and Company - Tippecanoe Laboratories**
Source Location:	**1650 Lilly Road, Lafayette, IN 47909**
County:	**Tippecanoe**
SIC Code:	**2833 and 2834**
Significant Source Modification No.:	**157-26577-00006**
Permit Renewal No.:	**157-26575-00006**
Permit Reviewer:	**Josiah Balogun**

The Office of Air Quality (OAQ) has reviewed the operating permit renewal application from Eli Lilly and Company - Tippecanoe Laboratories relating to the operation of a pharmaceutical manufacturing plant.

History

On May 20, 2008, Eli Lilly and Company - Tippecanoe Laboratories submitted an application to the OAQ requesting to renew its operating permit. Eli Lilly and Company - Tippecanoe Laboratories was issued a Part 70 Operating Permit on February 27, 2004.

The Office of Air Quality (OAQ) has reviewed a Part 70 permit application and Prevention of Significant Deterioration (PSD) permit application from Eli Lilly and Company – Tippecanoe Laboratories. The PSD permit application is for the construction, modification, and operation of bulk pharmaceutical manufacturing operations and associated support facilities. The Part 70 permit application addresses the bulk pharmaceutical manufacturing operations (BPM), support operations for BPM (BPM supports) such as solvent storage, solvent recovery and waste treatment and incineration of liquid and solid wastes (T49 incineration and T149 Solid-liquid waste incineration).

Permitted Emission Units and Pollution Control Equipment

The source consists of the following operating areas that are made up of various types of emission units and pollution control devices. These operating areas correspond to the various “D” sections of the Part 70 permit and are described in more detail in Appendix A of this TSD. Appendix A of this TSD also includes a detailed description of the Leak Detection and Repair (LDAR) program that applies to the emission units and control equipment. The LDAR program requirements correspond to the “E” sections of the Part 70 permit.

(a) Utility operations – The utilities operations consist of three coal-fired boilers that can be co-fired with natural gas and equipped with an ash handling system and supported by a coal pile and coal conveyor system, and two natural gas boilers with fuel oil backup supplied by one fuel oil tank. The boilers provide steam to process operations in bulk pharmaceutical manufacturing and fermented products.

(b) Utility support operations – The utility support operations consist of a lime system for the potable water system (T9/T23), glycol tanks for heating and cooling of BPM tanks, and chillers, generators and compressors.

(c) Fermented products fermentation operations – The fermentation processes include the dry material storage area (T46), the raw material prep area (T1), the fermentation production areas (T2, T2A, T2C) and product storage area (T63).

(d) Fermented products purification operations – The whole broth from fermentation are continuously fed to the purification operations consisting of extraction and elution equipment located in buildings T3. Products are stored in Building T39. Solvents used in the purification processes are stored in tank module T147 and recovered in the T4 solvent recovery operation.

(e) Fermented products support operations – The support operations for the Fermented Products (FP) area consists of the FP wastewater treatment plant and FP wastewater sludge storage operations.

(f) Bulk pharmaceutical manufacturing (BPM) process operations – The bulk pharmaceutical manufacturing component of Tippecanoe Labs includes Buildings T27, T28, T29, T31/31A, T99, and T100. Pharmaceutical products are manufactured by chemical synthesis in bulk scale in all of these buildings. Typical production equipment includes process vessels (tanks), centrifuges and dryers. Depending on the process, production facilities may also utilize process condensers and/or process scrubbers. The exhaust streams from the process equipment are vented to the RTO system for control of emissions.

(g) BPM storage tanks – Solvents used as raw material in BPM, used solvents to be recovered in solvent recovery, and waste solvents generated in BPM are stored in several storage tank modules. The modules are identified as T140, T142, T143, T145 and T146. Some waste solvents are stored in waste tanks within the BPM operating buildings. The exhaust streams from the storage tanks are vented to either the T79 fume incinerators or RTOs for control of VOC and VOHAP emissions.

(h) Waste containers – Waste containers from the BPM operations or waste containers from other Lilly facilities consist of any portable container with a capacity greater than or equal to 0.1 cubic meters (26.4 gallons) used to convey, store, treat, or dispose of affected waste streams or residuals. Waste containers are located in the BPM process operation buildings as well as the T148 container storage building.

(i) BPM individual drain system – The individual drain systems are stationary systems, such as sumps, process drains and lift stations, used to convey affected wastewater streams or residuals to a waste management unit in the BPM operating areas. The exhaust streams from the BPM individual drain systems are vented to the RTO system for control of VOC and VOHAP emissions.

(j) BPM solvent recovery - Solvent Recovery occurs in buildings T19, T52, T61 and T127. This department recovers used solvent collected from the BPM production buildings for recycling and reuse. The types of equipment used to recover solvents consist of distillation columns, evaporators, steam strippers, wash columns, and receivers (tanks).

(k) Waste incinerators – Liquid solvent waste generated on site and at other Lilly sites is burned in the T49 Trane incinerator, which is capable of burning liquid waste, or the T149 solid - liquid waste incinerator which is capable of burning both liquid and solid wastes generated on site and at other Lilly sites.

(l) BPM Regenerative Thermal Oxidizers (RTO) – Emissions from the BPM process operations and some of the BPM storage tanks are routed to a common regenerative thermal oxidizer (RTO) system. The site has two co-located RTOs that typically operate at alternative times. The RTOs are equipped with caustic scrubbing systems to remove acid gases. The RTOs reduce CO, VOC, and organic HAP emissions, while the scrubbers remove acid gases such as SO2, hydrogen chloride (HCl) and hydrogen fluoride (HF).

(m) BPM T79 fume incinerator – Emissions from the BPM solvent recovery operations and some of the BPM storage tanks are routed to the T79 fume incinerator system. The site maintains two identical T79 fume incinerators that typically operate at alternate times. The T79 incinerators are equipped with caustic scrubbing systems to remove acid gases.

(n) Research and development – The research and development operations at the plant site are located in building T71. The research and development operations consist of process tanks, charge tanks, and dryers. There are no controls on these operations.

(o) BPM wastewater treatment plant – Wastewater generated by BPM production may be voluntarily pretreated by the T79 wastewater treatment system before it is transferred to the BPM wastewater treatment plant. The T79 wastewater treatment system consists of equalization tanks, a neutralization tank, and air stripper columns. The exhaust stream from the equalization tanks and air stripper columns is vented to the T79 fume incinerators for control of VOC and VOHAP emissions.

(p) BPM fugitive emissions – BPM equipment 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 may generate fugitive emissions. These fugitive emissions are minimized through the use of a Leak Detection And Repair (LDAR) program.

(q) The source also consists of two (2) natural gas-fired or fuel oil boilers, identified as No. 6 and No.7, constructed in 2007, with a maximum heat input capacity of 156.1 million British thermal units per hour, each, with emissions uncontrolled and exhausting to stack S-T26-BLR006 and S-T26-BLR007, respectively.

New Emission Units and Pollution Control Equipment Receiving Advanced Source Modification Approval

Tippecanoe Laboratories has proposed to modify the Bulk Pharmaceutical Manufacturing operations and supporting areas through a series of product and process changes, equipment changes, equipment replacement, and new equipment. The actual nature of these changes is not specifically defined, but fall into the categories of changes described in Appendix B. The applicable requirements for these changes, including Best Available Control Technology, have been defined in the permit and will apply through the advance approval procedures described in 326 IAC 2-7-6(16).

Emission Units and Pollution Control Equipment Constructed and/or Operated without a Permit

There are no unpermitted emission units operating at this source during this review process.

Emission Units and Pollution Control Equipment Removed From the Source

Emission units removed from the source or permit are stated as follows:

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
Building T2 - Fermentation Production Area:					
TK013	Bump Tank	S-T2-FERM	5,000	liters	None
Building T1 –Raw Material Prep Area:					
DISP001	Automated Dispensing Station	PV-T1-T44984	N/A	liters	Dust Collector T44984**
TK125	Make Up Tank	PV-T1-T67489	24,600	liters	Rotoclone 67489**
TK126	Make Up Tank	PV-T1-T67492	24,600	liters	Rotoclone 67492**
Building T1 – Liquid Storage Area:					
TK245	Liquid Storage Tank	N/A	100,000	liters	None
TK246	Liquid Storage Tank	N/A	100,000	liters	None
TK247	Liquid Storage Tank	N/A	100,000	liters	None
TK248	Liquid Storage Tank	N/A	30400	liters	None
Building T1 – Filter Room:					
TK813	Lime Tank	PV-T1-316488	8600	liters	Rotoclone 316488**
TK814	Filter Room Tank (Tank 8.5)	PV-T1-316488	9600	liters	None
Building T3 - Purification Production Area:					
T3-TK47718*	Azo Receiver Tank	Vent	1000	gallons	None
T3-TK56*	Vent Condensed Tank	Vent	30	gallons	None
T3-CENT004*	Stacked Plate Centrifuge	Vent	20	gallons	None
T3-TK378-1T*	Process Tank	Vent	500	gallons	None
T3-TK397-1T*	Spent Aqueous Tank	Vent	2,000	gallons	None
Building T40 - Purification Production Area:					
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
Building T4 – Solvent Recovery:					
T4-TK001*	Process Tank	Vent	1985	gallon	None

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
Outside Storage Tanks:					
TK420-1T*	Hydrochloric Acid Tank	Scrubber Vent	12,000	gallons	Acid Scrubber**
Fermented Products Wastewater Sludge Management Operations:					
T42-B	Sludge Centrifuge*	T174	150	gal/min	-
Building T27:					
T27-TK32-6	Process Tank	RTO	1000 gal	-	RTO
T27-TK33-6	Process Tank	RTO	1000 gal	-	RTO
T27-TK35-10B	Process Tank	RTO	1000 gal	-	RTO
T27-TK40-31	Process Tank	RTO	500 gal	-	RTO
T27-TK41-6	Process Tank	RTO	300 gal	-	RTO
T27-TK45-3	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-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-CENT9	Centrifuge	RTO	NA	-	RTO
T27-DT46-1	Process Tank	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

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
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
Building T28:					
T28-CENT3	Centrifuge	RTO	NA	-	RTO
T28-TK28-27	Process Tank	RTO	140 gal	-	RTO
T28-SCR1	Process Scrubber	T79 or RTO**	NA	-	T79 or RTO**
T28-SCR2	Process Scrubber	T79 or RTO**	NA	-	T79 or RTO**
T28-SCR3	Process Scrubber	T79 or RTO**	NA	-	T79 or RTO**
T28-SCR4	Process Scrubber	T79 or RTO**	NA	-	T79 or RTO**
T28-SCR6	Process Scrubber	T79 or RTO**	NA	-	T79 or RTO**
T28-SCRTK1	Scrubber Tank	T79 or RTO**	NA	-	T79 or RTO**
T28-SCRTK2	Scrubber Tank	T79 or RTO**	NA	-	T79 or RTO**
T28-SCRTK4	Scrubber Tank	T79 or RTO**	NA	-	T79 or 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
Building T29:					
T29-DRY2402	Filter Dryer	RTO	863 gal	-	RTO
T29-TK8501	Process Tank	RTO	0.75 sf	-	RTO
T29-HE1201	Process Condenser	RTO	NA	-	RTO
T29-HE1202	Process Condenser	RTO	NA	-	RTO
T29-HE1203	Process Condenser	RTO	NA	-	RTO

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
T29-HE1204	Process Condenser	RTO	NA	-	RTO
T29-HE1205	Process Condenser	RTO	NA	-	RTO
T29-HE2201	Process Condenser	RTO	NA	-	RTO
T29-HE2202	Process Condenser	RTO	NA	-	RTO
T29-HE2203	Process Condenser	RTO	NA	-	RTO
T29-HE2204	Process Condenser	RTO	NA	-	RTO
T29-HE2205	Process Condenser	RTO	NA	-	RTO
T29-HE3201	Process Condenser	RTO	NA	-	RTO
T29-HE3202	Process Condenser	RTO	NA	-	RTO
T29-HE3203	Process Condenser	RTO	NA	-	RTO
T29-HE3203	Process Condenser	RTO	NA	-	RTO
T29-HE3204	Process Condenser	RTO	NA	-	RTO
T29-HE3205	Process Condenser	RTO	NA	-	RTO
T29-HE4201	Process Condenser	RTO	NA	-	RTO
T29-HE4203	Process Condenser	RTO	NA	-	RTO
T29-TK4201A	Accumulator Tank	RTO	70 gal	-	RTO
T29-SCR1601	Process Scrubber	RTO	NA	-	RTO
T29-SCR2601	Process Scrubber	RTO	NA	-	RTO
T29-SCR3601	Process Scrubber	RTO	NA	-	RTO
Building T31:					
T31-HE501	Process Condenser	RTO	NA	-	RTO
T31-HE503	Process Condenser	RTO	NA	-	RTO
T31-HE511	Process Condenser	RTO	NA	-	RTO
T31-HE512	Process Condenser	RTO	NA	-	RTO
T31-HE531	Process Condenser	RTO	NA	-	RTO
T31-HE541	Process Condenser	RTO	NA	-	RTO
T31-SCR-OZ	Process Condenser (Ozone)	RTO	NA	-	RTO
T31-SCR721	Process Condenser	RTO	200 gal	-	RTO
Building T31A:					
T31A-RVD881	Dryer	RTO	100cf	-	RTO
T31A-RVD891	Dryer	RTO	100cf	-	RTO
T31A-DT683	Drowning Tank 001	RTO	NA	-	RTO
T31A-TK623	Process Tank	RTO	400 gal	-	RTO
T31A-TK624	Process Tank	RTO	300 gal	-	RTO
T31A-TK625	Process Tank	RTO	300 gal	-	RTO
T31A-TK626	Process Tank	RTO	500 gal	-	RTO
T31A-TK861K	Process Tank	RTO	50 gal	-	RTO
T31A-HE481	Process Condenser	RTO	NA	-	RTO
T31A-HE482	Process Condenser	RTO	NA	-	RTO
T31A-HE491	Process Condenser	RTO	NA	-	RTO
T31A-HE492	Process Condenser	RTO	NA	-	RTO
T31A-HE521	Process Condenser	RTO	NA	-	RTO

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
T31A-HE551	Process Condenser	RTO	NA	-	RTO
T31A-HE561	Process Condenser	RTO	NA	-	RTO
T31A-HE581	Process Condenser	RTO	NA	-	RTO
T31A-HE583	Process Condenser	RTO	NA	-	RTO
T31A-HE591	Process Condenser	RTO	NA	-	RTO
T31A-HE593	Process Condenser	RTO	NA	-	RTO
T31A-HE781	Process Condenser	RTO	NA	-	RTO
T31A-HE791	Process Condenser	RTO	NA	-	RTO
T31A-SCR261	Process Scrubber	RTO	NA	-	RTO
T31A-SCR262	Process Scrubber	RTO	NA	-	RTO
T31A-SCR781	Process Scrubber	RTO	200 gal	-	RTO
T31A-SCR791	Process Scrubber	RTO	500 gal	-	RTO
T31A-SCRTK781	Process Scrubber Tank	RTO	300 gal	-	RTO
T31A-SCRTK791	Process Scrubber Tank	RTO	300 gal	-	RTO
Building T99:					
T99-D-9B	Condensate Tank	RTO	10 gal	-	RTO
T99-HE43	Process Condenser	RTO	NA	-	RTO
T99-HE44	Process Condenser	RTO	NA	-	RTO
Building T100:					
T100-TK1C	Process Tank	RTO	NAl	-	RTO
T100-HE1	Process Condenser	RTO	NA	-	RTO
T100-HE1C	Process Condenser	RTO	NA	-	-
T100-HE2	Process Condenser	RTO	NA	-	RTO
T100-HE4	Process Condenser	RTO	NA	-	RTO
T100-HE6	Process Condenser	RTO	NA	-	RTO
T100-HE7	Process Condenser	RTO	NA	-	RTO
T100-HE8	Process Condenser	RTO	NA	-	RTO
T100-HE11	Process Condenser	RTO	NA	-	RTO
T100-HE12	Process Condenser	RTO	NA	-	RTO
T100-HE13	Process Condenser	RTO	NA	-	RTO
T100-HE14	Process Condenser	RTO	NA	-	RTO
T100-HE14B	Process Condenser	RTO	NA	-	RTO
T100-HE16	Process Condenser	RTO	NA	-	RTO
T100-HE21A	Process Condenser	RTO	NA	-	RTO
T100-HE21B	Process Condenser	RTO	NA	-	RTO
T100-HE26	Process Condenser	RTO	NA	-	RTO

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
T100-HE28	Process Condenser	RTO	NA	-	RTO
T100-HE31	Process Condenser	RTO	NA	-	RTO
T100-SCR80	Process Scrubber	RTO	NA	-	RTO
T100-SCR81	Process Scrubber	RTO	NA	-	RTO
T100-SCR82	Process Scrubber	RTO	NA	-	RTO
T100-SCR83	Process Scrubber	RTO	NA	-	RTO
T100-SCR84	Process Scrubber	RTO	NA	-	RTO
T100-SCR85	Process Scrubber	RTO	NA	-	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
Building T52:					
T52-REC52-11	Receiver	T79 or RTO*	4000 gal	-	T79 or RTO*
T52-REC52-12	Receiver	T79 or RTO*	4000 gal	-	T79 or RTO*
T52-REC52-13	Receiver	T79 or RTO*	4000 gal	-	T79 or RTO*
Building T64:					
T64-TK2	Phenol Storage Tank	RTO	10,000 gal	-	RTO

Insignificant Activities

Most insignificant activities are noted in the specific sections of the TSD relating to an individual operating area. The source also consists of the following insignificant activities, as defined in 326 IAC 2-7-1(21), not otherwise listed in specific sections of this TSD:

(a) Natural gas-fired combustion sources with heat input equal to or less than ten (10) million Btu per hour;

(b) Propane or liquefied petroleum gas, or butane-fired combustion sources with heat input equal to or less than six (6) million (6,000,000) Btu per hour;

(c) Equipment powered by internal combustion engines of capacity equal to or less than 500,000 Btu/hour, except where total capacity of equipment operated by one stationary source exceeds 2,000,000 Btu/hour;

(d) A gasoline fuel transfer and dispensing operation handling less than or equal to 1,300 gallons per day, such as filling of tanks, locomotives, automobiles, having a storage capacity less than or equal to 10,500 gallons;

(e) A petroleum fuel, other than gasoline, dispensing facility, having a storage capacity of less than or equal to 10,500 gallons, and dispensing less than or equal to 230,000 gallons per month;

(f) VOC/HAP storage tanks with capacity less than or equal to 1,000 gallons and annual throughputs less than 12,000 gallons;

(g) VOC/HAP storage vessels storing lubricating oils, hydraulic oils, machining oils, and machining fluids;

(h) Refractory storage not requiring air pollution control equipment;

(i) Machining where an aqueous cutting coolant continuously floods the machining interface;

(j) Degreasing operations that do not exceed 145 gallons per 12 months; except if subject to 326 IAC 20-6;

(k) Cleaners and solvents with a combined use less than or equal to 145 gallons per 12 months characterized having a vapor pressure equal to or less than 2 kPa, 15 mm Hg, or 0.3 psi measured at 38C (100F); or having a vapor pressure equal to or less than 0.7 kPa, 5 mmHg, or 0.1 psi measured at 20C (68F);

(l) Closed loop heating and cooling systems;

(m) Structural and bridge fabrication activities including cutting 200,000 linear feet or less of one inch plate or equivalent, or using 80 tons or less of welding consumables;

(n) Activities associated with the treatment of wastewater streams with an oil and grease content less than or equal to 1% by volume;

(o) Activities associated with the transportation and treatment of sanitary sewage, provided discharge to the treatment plant is under the control of the owner/operator, that is, an on-site sewage treatment facility;

(p) Any operation using aqueous solutions containing less than 1% by weight of VOCs excluding HAPs;

(q) Noncontact cooling tower systems with forced and induced draft cooling tower system not regulated under a NESHAP;

(r) Replacement or repair of electrostatic precipitators, bags in baghouses and filters in other air filtration equipment;

(s) Heat exchanger cleaning and repair;

(t) Process vessel degassing and cleaning to prepare for internal repairs;

(u) Stockpiled soils from soil remediation activities that are covered and waiting transport for disposal;

(v) Paved and unpaved roads and parking lots with public access;

(w) Covered conveyors for coal or coke conveying of less than or equal to 360 tons per day;

(x) Coal bunker and coal scale exhausts and associated dust collector vents;

(y) Asbestos abatement projects regulated by 326 IAC 14-10;

(z) Purging of gas lines and vessels that is related to routine maintenance and repair of buildings, structures, or vehicles at the source where air emissions from those activities would not be associated with any production process;

(aa) Equipment used to collect any material that might be released during a malfunction, process upset, or spill cleanup including catch tanks, temporary liquid separators, tanks and fluid handling equipment;

(bb) Blowdown from sight glasses; boilers; compressors; pumps; and cooling towers;

(cc) On-site fire and emergency response training approved by the department;

(dd) Emergency generators including gasoline generators not exceeding 110 horsepower, diesel generators not exceeding 1600 horsepower; and natural gas turbines or reciprocating engines not exceeding 16,000 horsepower;

(ee) Stationary fire pumps;

(ff) Grinding and machining operations controlled with fabric filters, scrubbers, mist collectors, wet collectors and electrostatic precipitators with a design grain loading of less than or equal to 0.03 grains per actual cubic foot and a gas flow rate less than or equal to 4000 actual cubic feet per minute, including the following: deburring; buffing; polishing; abrasive blasting; pneumatic conveying; and woodworking operations;

(gg) Purge double block and bleed valves;

(hh) Filter or coalescer media changeout;

(ii) Vents from ash transport systems not operated at positive pressure;

(jj) A laboratory as defined in 326 IAC 2-7-1(21)(D);

(kk) Research and development activities defined in 326 IAC 2-7-1(21)(E), including the T71 Development Engineering Facility;

(ll) Farm operations; and

(mm) Activities with emissions equal to or less than thresholds listed in 326 IAC 2-7-1(21)(A)-(C) including:

(1) Portable Cleaning and Collection Tanks;
(2) T4 Sulfuric Acid Tank;
(3) T47 Trash Transfer;
(4) Sump Tanks;
(5) T116 Hydrogen Chloride Storage Tank;
(6) T14 Ranney Well;
(7) T99 Ethylene Glycol Expansion Tank System;
(8) T100 MACE tanks/system
(9) T100 Unit 1 Drumming Operations;
(10) T99/T100 Solids Particle Sizing Equipment (mills and delumpers); and
(11) Fermentation and Purification Activities.

Existing Approvals

Since the issuance of the Part 70 Operating Permit 157-6879-00006 on February 27, 2004, the source has constructed or has been operating under the following approvals as well:

(a) Significant Source Modification T157-20160-00006, issued on December 30, 2004;

(b) Significant Permit Modification T157-20216-00006, issued on January 19, 2005;

(c) Administrative Amendment T157-20003-00006, issued on April 1, 2005;

(d) Administrative Amendment T157-21143-00006, issued on May 11, 2005;

(e) Significant Permit Modification T157-20732-00006, issued on August 15, 2005;

(f) SPM - PAL T157-21811-00006, issued on May 9, 2006;

(g) Significant Source Modification T157-21809-00006, issued on June 7, 2006;

(h) Significant Permit Modification T157-22717-00006, issued on March 20, 2007;

(i) Minor Source Modification T157-24812-00006, issued on July 9, 2007;

(j) Significant Source Modification T157-24400-00006, issued on September 28, 2007;

(k) Significant Permit Modification T157-24771-00006, issued on October 22, 2007; and

(l) Administrative Amendment T157-25261-00006, issued on November 15, 2007;

All terms and conditions of previous permits issued pursuant to permitting programs approved into the state implementation plan have been either incorporated as originally stated, revised, or deleted by this permit. All previous registrations and permits are superseded by this permit.

Enforcement Issue

There are no enforcement actions pending.

Emission Calculations

The calculations submitted by the applicant have been verified and found to be accurate and correct. These calculations methodologies can be found in the documentation accompanying the original part 70 permit application for the source.

County Attainment Status

The source is located in Tippecanoe County

Pollutant	Designation
SO_2	Better than national standards.
CO	Unclassifiable or attainment effective November 15, 1990.
O_3	Unclassifiable or attainment effective June 15, 2004, for the 8-hour ozone standard.[1]
$PM_{2.5}$	Unclassifiable or attainment effective April 5, 2005.
PM_{10}	Unclassifiable effective November 15, 1990.
NO_2	Cannot be classified or better than national standards.
Pb	Not designated.
[1]Unclassifiable or attainment effective October 18, 2000, for the 1-hour ozone standard which was revoked effective June 15, 2005. Unclassifiable or attainment effective April 5, 2005, for PM2.5.	

(a) Ozone Standards

(1) Volatile organic compounds (VOC) and Nitrogen Oxides (NOx) are regulated under the Clean Air Act (CAA) for the purposes of attaining and maintaining the National Ambient Air Quality Standards (NAAQS) for ozone. Therefore, VOC and NOx emissions are considered when evaluating the rule applicability relating to ozone. Tippecanoe County has been designated as attainment or unclassifiable for ozone. Therefore, VOC and NOx emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

(b) PM2.5
Tippecanoe County has been classified as attainment for PM2.5. On May 8, 2008 U.S. EPA promulgated the requirements for Prevention of Significant Deterioration (PSD) for PM2.5 emissions, and the effective date of these rules was July 15th, 2008. Indiana has three years from the publication of these rules to revise its PSD rules, 326 IAC 2-2, to include those requirements. The May 8, 2008 rule revisions require IDEM to regulate PM10 emissions as a surrogate for PM2.5 emissions until 326 IAC 2-2 is revised.

(c) Other Criteria Pollutants
Tippecanoe County has been classified as attainment or unclassifiable in Indiana for all criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

(d) Fugitive Emissions
Since this type of operation is in one of the twenty-eight (28) listed source categories under 326 IAC 2-2 or 326 IAC 2-3, fugitive emissions are counted toward the determination of PSD and Emission Offset applicability.

Unrestricted Potential Emissions

This table reflects the unrestricted potential emissions of the source.

Pollutant	tons/year
PM	> 100
PM_{10}	> 100
$PM_{2.5}$	> 100
SO_2	> 100
VOC	> 100
CO	> 100
NO_x	> 100

HAPs	tons/year
Single HAP	> 10
Total HAPs	> 25

(a) The potential to emit (as defined in 326 IAC 2-7-1(29)) of PM10, SO2, VOC, CO and NOx are equal to or greater than 100 tons per year. Therefore, the source is subject to the provisions of 326 IAC 2-7.

(b) The potential to emit (as defined in 326 IAC 2-7-1(29)) of any single HAP is equal to or greater than ten (10) tons per year and/or the potential to emit (as defined in 326 IAC 2-7-1(29)) of a combination of HAPs is equal to or greater than twenty-five (25) tons per year. Therefore, the source is subject to the provisions of 326 IAC 2-7.

Part 70 Permit Conditions

This source is subject to the requirements of 326 IAC 2-7, pursuant to which the source has to meet the following:

(a) Emission limitations and standards, including those operational requirements and limitations that assure compliance with all applicable requirements at the time of issuance of Part 70 permits.

(b) Monitoring and related record keeping requirements which assume that all reasonable information is provided to evaluate continuous compliance with the applicable requirements.

Permit Level determination - Part 70

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as “the maximum capacity of a stationary source or emission unit to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U. S. EPA, IDEM, or the appropriate local air pollution control agency.”

The modification consists of Prevention of Significant Deterioration [PSD] / Flexible Permit for carbon monoxide (CO), volatile organic compounds (VOC) and fluorides (F-). Therefore, this source modification shall be processed as PSD/Significant Source Modification pursuant to 326 IAC 2-7-10.5(f)(1). Additionally, the modification will be incorporated into the Part 70 Operating Permit through the Renewal Permit.

Potential to Emit After Issuance

The table below summarizes the potential to emit, reflecting all limits, of the emission units. Any control equipment is considered federally enforceable only after issuance of this Part 70 permit renewal, and only to the extent that the effect of the control equipment is made practically enforceable in the permit.

Process/ Emission Unit	PM (tons/yr)	PM_{10} (tons/yr)	$PM_{2.5}$ (tons/yr)	SO_2 (tons/yr)	VOC (tons/yr)	CO (tons/yr)	NO_X (tons/yr)	HAP (tons/yr)
BPM Operations	> 100	> 100	> 100	> 100	> 100	> 100	> 100	- Single HAP > 10 Total HAPs > 25
BPM Support	> 100	> 100	> 100	> 100	> 100	> 100	> 100	
T49 Liquid Waste Incineration	> 100	> 100	> 100	> 100	> 100	> 100	> 100	
T149 Solid-Liquid Waste Incinerator	> 100	> 100	> 100	> 100	> 100	> 100	> 100	
PAL Limit	-	-	-	2059.7	-	-	648	
Source-wide	> 100	> 100	> 100	> 100	> 100	> 100	> 100	
Total Emissions	> 100	> 100	> 100	> 100	> 100	> 100	> 100	Single HAP > 10 Total HAPs > 25

This existing stationary source is major for PSD because the emissions of at least one regulated pollutant are greater than one hundred (>100) tons per year, and it is one of the twenty-eight (28) listed source categories.

Federal Rule Applicability

326 IAC 2-2.4 and 40 CFR 51.166

(a) This rule establishes actual plantwide applicability limitations (PAL) for nitrogen oxides and sulfur dioxide. A source that is subject to P.L. 231-2003, Section 6 shall comply with the requirements of 326 IAC 2-2.6. Eli Lilly and Company does not belong to one of the SIC codes listed in the 326 IAC 2-2.6 (Federal Requirements for Sources Subject to PL 231-2003, Endangered Industries), therefore, Eli Lilly and Company is not subject to 326 IAC 2-2.6.

(b) If Lilly maintains its total source-wide nitrogen oxides and sulfur dioxide emissions below the PAL levels, meets the requirements in this rule, and complies with the PAL permit, then any physical change in or change in the method of operation of the source:

(1) is not a major modification for the PAL permit;

(2) does not have to be approved through 326 IAC 2-2; and

(3) is not subject to 2-2-8(a)(3).

(c) Except as provided under subsection (b)(3), Lilly shall continue to comply with all applicable federal or state requirements, emissions limitations, and work practice requirements that were established prior to the effective date of the PAL.

Federal Rule Applicability – New Source Performance Standards (NSPS)
[40 CFR Part 60 and 326 IAC 12]

(a) **NSPS applicable to source:**

(1) **Subpart Kb – Solvent Storage Tanks:** This source is subject to 40 CFR Part 60, Subpart Kb, which applies to solvent storage tanks. The specific applicability of this NSPS and the requirements incorporated into this permit are discussed in the relevant portions of this TSD.

(2) **Subpart Db – Industrial-Commercial-Institutional steam generating units:** 326 IAC 12 and 40 CFR 60, Subpart Db-Standard of Performance for Small Industrial-Commercial Institutional Steam Generating Unit.

The boilers, identified as No. 6 and No.7, completed in 2007, with a heat input capacity of 156.1 million British thermal units per hour, each, with emissions uncontrolled and exhausting to stacks S-T26-BLR006 and S-T26-BLR007, respectively, are subject to the requirements of the New Source Performance Standard, 40 CFR 60, Subpart Db, Standard of Performance for Small Industrial-Commercial Institutional Steam Generating Unit, because the boilers were constructed after June 19, 1984, which is the applicability date for this rule and each boiler has a heat input capacity of greater 100 million British thermal units per hour.

The boilers, identified as No.6 and No.7 are subject to the following sections of 40 CFR Part 60, Subpart Db.

(1) 40 CFR 60.40b
(2) 40 CFR 60.41b
(3) 40 CFR 60.42b
(4) 40 CFR 60.43b
(5) 40 CFR 60.44b
(6) 40 CFR 60.45b
(7) 40 CFR 60.46b
(8) 40 CFR 60.47b
(9) 40 CFR 60.48b; and
(10) 40 CFR 60.49b

The provisions of 40 CFR 63 Subpart A – General Provisions, which are incorporated as 326 IAC 12-1, apply to the facility described in this section except when otherwise specified in 40 CFR 60 Subpart Db.

(b) **NSPS not applicable to source:** IDEM has determined that the following NSPS are not applicable to this source:

(1) **40 CFR 60, Subpart D – Standard of Performance for Fossil-fuel fired steam generator for which Construction Commenced After August 17, 1971:** This source is not subject to 40 CFR Part 60, Subpart D because none of the boilers at the plant site exceed 250 MMBtu/hr in heat input capacity. [40 CFR 60.40(a)(1)]

(2) **40 CFR 60, Subpart Dc – Standard of Performance for Industrial-Commercial-Institutional steam generating units:** This source is not subject to 40 CFR Part 60, Subpart Dc because none of the boilers with maximum heat input capacities between 10 and 100 MMBtu/hr at plant site were constructed, reconstructed, or modified after June 9, 1989. [40 CFR 60.40c(a)]

(3) **40 CFR 60, Subpart E – Standard of Performance for Incinerators:** This source is not subject to 40 CFR Part 60, Subpart E because none of the incinerators at the plant site exceed a charging rate of 50 metric tons per day. [40 CFR 60.50(a)]

(4) **40 CFR 60, Subparts Ec and CCCC – Standard of Performance for Hospital/Medical/Infectious waste incinerators for which Construction is Commenced After June 20, 1996 and Standard of Performance for Commercial and Industrial solid waste incineration units for which Construction is Commenced After November 30, 1999 or for which modification or reconstruction is commenced on or after June 1, 2001:** This source is not subject to 40 CFR Part 60 Subpart Ec or Subpart CCCC because the combustors at the site are required to have a permit pursuant to Section 3005 of the Solid Waste Disposal Act. [40 CFR 60.50c(d) and 40 CFR 60.2020(g)]

(5) **40 CFR 60, Subparts VV, VVa, III, NNN and RRR – Synthetic organic chemical manufacturing:** This source is not subject to 40 CFR Part 60, Subparts VV, III, NNN, and RRR because the source is not engaged in the manufacture of synthetic organic chemicals as defined by those standards. The source does not produce, as an intermediate, final product, co-product, or by-product, a chemical listed in 40 CFR 60.489 [Subpart VV and Subpart VVa], 40 CFR 60.617 [Subpart III], 40 CFR 60.667 [Subpart NNN], or 40 CFR 60.707 [Subpart RRR].

(6) **40 CFR 60, Subpart K – Storage Vessels for Petroleum Liquids**: This source is not subject to 40 CFR Part 60, Subpart K because none of the storage tanks at the source constructed between June 11, 1973 and May 19, 1978 store petroleum liquids, as defined in 40 CFR 60.111.

(7) **40 CFR 60, Subpart Ka – Storage Vessels for Petroleum Liquids**: This source is not subject to 40 CFR Part 60, Subpart Ka because none of the storage tanks at the source constructed between May 19, 1978 and July 23, 1984 store petroleum liquids, as defined in 40 CFR 60.111.

(8) **40 CFR 60, Subpart AAAA – Small Municipal Waste Combustion Units**: This source is not subject to 40 CFR Part 60, Subpart AAAA because the incinerators at the source are hazardous waste combustion units that are subject to a permit for under section 3005 of the Solid Waste Disposal Act, as provided in 40 CFR 60.1020(e).

(9) **40 CFR 60, Subpart BBBB – Small Municipal Waste Combustion Units**: This source is not subject to 40 CFR Part 60, Subpart BBBB because the incinerators at the source are hazardous waste combustion units that are subject to a permit for under section 3005 of the Solid Waste Disposal Act, as provided in 40 CFR 60.1555(e).

(10) **40 CFR 60, Subpart CCCC – Commercial and Industrial Solid Waste Incinerators**: This source is not subject to 40 CFR Part 60, Subpart CCCC because the incinerators at the source are hazardous waste combustion units

that are subject to requirements under 40 CFR 63, Subpart EEE, as provided in 40 CFR 60.2020(g).

(11) **40 CFR 60, Subpart DDDD – Commercial and Industrial Solid Waste Incinerators**: This source is not subject to 40 CFR Part 60, Subpart DDDD because the incinerators at the source are hazardous waste combustion units that are subject to requirements under 40 CFR 63, Subpart EEE, as provided in 40 CFR 60.2555(g).

(12) **40 CFR 60, Subpart EEEE – Other Solid Waste Incinerators**: This source is not subject to 40 CFR Part 60, Subpart EEEE because the incinerators at the source are hazardous waste combustion units that are subject to requirements under 40 CFR 63, Subpart EEE, as provided in 40 CFR 60.2887(e).

(13) **40 CFR 60, Subpart FFFF – Other Solid Waste Incinerators**: This source is not subject to 40 CFR Part 60, Subpart FFFF because the incinerators at the source are hazardous waste combustion units that are subject to requirements under 40 CFR 63, Subpart EEE, as provided in 40 CFR 60.2993(e).

(14) **40 CFR 60, Subpart IIII - Stationary Compression Ignition Internal Combustion Engines**: This source is not subject to 40 CFR Part 60, Subpart IIII, because the compression ignition internal combustion engines at the source were manufactured before April 1, 2006 and are not fire pump engines.

(15) **40 CFR 60, Subpart JJJJ - Stationary Spark Ignition Internal Combustion Engines**: This source is not subject to 40 CFR Part 60, Subpart JJJJ, because the stationary spark ignition internal combustion engines at the source were manufactured before July 1, 2007.

(16) **All other NSPS:** This source is not subject to other NSPS requirements not listed here because the source does not own or operate the affected facilities subject to those NSPS.

Federal Rule Applicability – Section 111(d) Emission Guidelines
[40 CFR Part 60 and 326 IAC 11]

(a) **Emissions guidelines not applicable to source:** IDEM has determined that the none of the emission guidelines in 40 CFR Part 60, 40 CFR Part 62, Subpart P, and 326 IAC 11 are applicable to this source because the source does not own or operate an affected facility subject to those requirements. 40 CFR Part 60, Subpart Ce and 326 IAC 11-6, and 40 CFR Part 60, Subpart DDDD and 326 IAC 11-8 are not applicable to this source because combustors at the site are required to have a permit pursuant to Section 3005 of the Solid Waste Disposal Act. [40 CFR 60.32e(d) and 40 CFR 60.2555(g)]

Federal Rule Applicability – National Emission Standards for Hazardous Air Pollutants (NESHAPs)
[40 CFR Part 61 and 326 IAC 14]

(a) **Part 61 NESHAPs applicable to source:**

(1) **Subpart A – General Provisions:** The provisions of 40 CFR 61 Subpart A - General Provisions, apply to the facilities described in items (2) through (5) below, except when otherwise specified in the relevant Subpart.

(2) **40 CFR 61, Subpart M – National Emission Standard for Asbestos:** This source is subject to 40 CFR Part 61, Subpart M and 326 IAC 14-10, which applies to, among other things, demolition and renovation operations and asbestos containing materials.

The requirements of this NESHAP are reflected in Condition C.7 of this permit.

(3) **40 CFR 61, Subpart V - National Emission Standard for Equipment Leaks (Fugitive Emissions Sources):** This source has elected to comply with the Off-Site Waste and Recovery NESHAPs [40 CFR 63, Subpart DD] in part by following the requirements of 40 CFR Part 61, Subpart V and 326 IAC 14-8. This NESHAP establishes standards for controlling fugitive emissions from equipment leaks. The specific applicability of this NESHAP and the requirements incorporated into this permit are discussed in Section E.2 of this TSD.

(a) **Part 61 NESHAPs not applicable to source:** IDEM has determined that the following NESHAPs are not applicable to this source:

(1) **40 CFR 61, Subpart C – National Emission Standard for Beryllium:** This source is not subject to 40 CFR Part 61, Subpart C and 326 IAC 14-3 because the incinerators at the source do not incinerate beryllium containing waste. [40 CFR 61.30(a) and 40 CFR 61.31(g)]

(2) **40 CFR 61, Subpart E – National Emission Standard for Mercury:** This source is not subject to 40 CFR Part 61, Subpart E and 326 IAC 14-5, which applies to, among other things, incinerators burning wastewater treatment plant sludge because the source does not incinerate wastewater treatment plant sludge in its incinerators.

(3) **40 CFR 61, Subpart FF – National Emission Standard for Benzene Waste Operations:** This source does not handle more than 10 megagrams of benzene waste per year. The source is subject to 40 CFR Part 61, Subpart FF, but Subpart FF does not impose any requirements to sources that handle less than 10 megragrams of benzene waste per year.

(4) **Other Part 61 NESHAP:** This source is not subject to other Part 61 NESHAP requirements not listed here because the source does not own or operate the affected facilities subject to those NESHAPs.

Federal Rule Applicability – National Emission Standards for Hazardous Air Pollutants (NESHAPs) [40 CFR Part 63 and 326 IAC 20]

(a) **Part 63 NESHAPs applicable to source:**

(1) **Subpart A – General Provisions:** The provisions of 40 CFR 63, Subpart A apply to the facilities described in items (2) through (5) below, except when otherwise specified in the relevant Subpart.

(2) **Subpart I – Equipment Leaks:** This source is subject to 40 CFR Part 63, Subpart I and 326 IAC 20-12, which applies to pharmaceutical production processes using carbon tetrachloride or methylene chloride. The source may comply with this NESHAP by complying with equipment leak standards in 40 CFR Part 63 Subpart H (Equipment Leaks) or 40 CFR Part 63 Subpart GGG (Pharmaceutical Production MACT). The source has elected to comply with Subpart I by following the requirements of Subpart GGG and streamlined permit conditions reflecting the most stringent of applicable equipment leak standards. The details of these requirements are discussed in Section E.1 (LDAR) of this TSD.

(3) **Subpart DD – Off-site Waste and Recovery Operations:** This source is subject to 40 CFR 63, Subpart DD and 326 IAC 20-23 which applies to facilities treating and recovering wastes originating from other sites. This NESHAP establishes standards for controlling point source and fugitive emissions. The specific applicability of this NESHAP and the requirements incorporated into this permit are discussed in Sections D.7 (Solvent Recovery), D.10 (Waste Tanks), and D.11 (Waste Containers) of this TSD.

(4) **Subparts OO, PP, QQ, RR, SS, TT, UU, VV, WW:** To the extent that these general MACT requirements apply, the source shall demonstrate compliance with these generic standards through compliance with the requirements established in the Pharma MACT, HWC MACT, or OSWRO MACT, as applicable. Specific applicability of 40 CFR Part 63 Subparts OO [Level 1 Tanks], PP [Containers], QQ [Surface Impoundments], RR [Individual Drain Systems], SS [Closed vent systems and control devices], TT [Equipment leaks – Level 1], UU [Equipment leaks – Level 2], VV [Separators], and WW [Storage Tanks – Level 2] (326 IAC 20-35 through 20-43) are discussed in Sections D.8 (Individual Drain Systems), D.9 (Solvent Storage Tanks), D.10 (Waste Tanks), D.11 (Waste Containers), D.14 (RTO Control System and associated Closed Vent System), D.15 (T79 Fume Incinerator and associated Closed Vent System), and E.1 (LDAR) of this TSD.

(5) **Subpart EEE – Hazardous Waste Combustors:** This source is subject to 40 CFR Part 63, Subpart EEE and 326 IAC 20-28, which applies to hazardous waste incinerators, among other things. This NESHAP establishes emission limitations and work practices for controlling point source emissions. The specific applicability of this NESHAP and the requirements incorporated into this permit are discussed in Sections D.12 (T49 Liquid Incinerator) and D.13 (T149 Solid-Liquid Waste Incinerator) of this TSD.

(6) **Subpart GGG – Pharmaceuticals Production:** This source is subject to 40 CFR Part 63, Subpart GGG, which applies to pharmaceutical manufacturing facilities. This NESHAP establishes emission limitations and work practice standards for controlling point source and fugitive emissions. The specific applicability of the various aspects of this NESHAP and the requirements incorporated into this permit are discussed in Sections D.6 (BPM Operations), D.7 (BPM Solvent Recovery Operations), D.8 (BPM Wastewater and BPM Individual Drain System Operations), D.9 (BPM Solvent Storage Tanks), D.10 (Waste Tanks), and D.11 (BPM Waste Containers) of this TSD.

(a) **Part 63 NESHAPs not applicable to source:** IDEM has determined that the following NESHAPs are not applicable to this source:

(1) **Subpart B – Case-by-case MACT determination:** This source is not subject to 40 CFR Part 63, Sections 63.50, through 63.56 because there are no affected sources within a source category or subcategory for which USEPA has failed to promulgate emission standards by the section 112(j) deadlines.

(2) **40 CFR 63, Subparts F and G – Synthetic Organic Chemical Manufacturing:** This source is not subject to 40 CFR Part 63, Subparts F and G (326 IAC 20-10) because the source does not manufacture compounds listed in table 1 of Subpart F or use as a reactant compounds listed in table 2 of Subpart F. [40 CFR 63.100(b)]

(3) **40 CFR 63, Subpart O – Ethylene Oxide Sterilizers:** This source is not subject to 40 CFR Part 63, Subpart O and 326 IAC 20-5 because the source does not utilize ethylene oxide in sterilization operations. [40 CFR 63.360]

(3) **40 CFR 63, Subpart Q – Industrial Process Cooling Towers:** This source is not subject to 40 CFR Part 63, Subpart Q and 326 IAC 20-4 because the source does not utilize chromium based water treatment compounds in its cooling towers. [40 CFR 63.400]

(4) **40 CFR 63, Subpart T – Halogenated Solvent Cleaning:** This source is not subject to 40 CFR Part 63, Subpart T and 326 IAC 20-6 because the source does not use halogenated solvents in any solvent cleaning machines. [40 CFR 63.460]

(5) **40 CFR 63, Subpart YY – Generic MACT categories:** This source is not subject to 40 CFR Part 63, Subpart YY and 326 IAC 20-44 because the source is not one of the source categories described in 40 CFR 63.1103. [40 CFR 63.1100]

(6) **40 CFR 63, Subpart MMM – Pesticide Active Ingredient Production:** This source is not subject to 40 CFR Part 63, Subpart MMM and 326 IAC 20-45 because the source does not contain any pesticide active ingredient process units or associated equipment as described in 40 CFR 63.1360. [40 CFR 63.1360]

(7) **40 CFR 63, Subpart EEEE** – **Organic Liquid Distribution:** This source has emission units that are affected sources under 40 CFR Part 63, Subpart EEEE, but the emission units do not exceed the thresholds requiring emission controls. Therefore, the requirements of 40 CFR 63, Subpart EEEE do not apply to the source.

(8) **40 CFR 63, Subpart FFFF** – **Miscellaneous Organic Chemical Production and Processes:** This source is not subject to 40 CFR Part 63, Subpart FFFF because all the affected facilities at the source that would otherwise be subject to Subpart FFFF are subject to 40 CFR 63, Subpart GGG.

(10) **40 CFR 63, Subpart ZZZZ - Stationary Reciprocating Internal Combustion Engines:** This source is not subject to 40 CFR Part 63, Subpart ZZZZ because the source only has emergency stationary reciprocating internal combustion engines for which there are no applicable requirements in 40 CFR 63, Subpart ZZZZ.

(9) **40 CFR 63, Subpart GGGGG – Site Remediation:** This source is not subject to 40 CFR Part 63, Subpart GGGGG because the site remediation activities at Tippecanoe Laboratories are being performed under a RCRA corrective action program at a treatment, storage and disposal facility.

(10) **Other Part 63 NESHAPs:** This source is not subject to other NESHAP requirements not listed here because the source does not own or operate the affected facilities subject to those NESHAPs.

Federal Rule Applicability – Other Provisions

(a) **Part 64 – Compliance Assurance Monitoring:** The provisions of 40 CFR Part 64 applicable to this source has been added to the Part 70 permit

(b) **Part 68 – Chemical Accident Prevention:** The provisions of 40 CFR Part 68 and 326 IAC 20-2 are applicable to this source because the source may have more than a threshold quantity of a substance regulated by Part 68. The source is required to prepare a Risk Management Plan meeting the requirements of Part 68. The source submitted its most recent plan on November 11, 2005.

(c) **Part 70 – Operating Permits:** This source is a major source, as defined by 40 CFR 70.2 and 326 IAC 2-7-1, and is subject to the Part 70 operating permits program. This permit serves as the Part 70 operation permit for the source.

(d) **Parts 72-78 – Acid Rain Program Provisions:** This source is not an affected source subject to the Acid Rain Program Provisions found in 40 CFR Parts 72-78 and 326 IAC 21.

(e) **Part 82 – Protection of Stratospheric Ozone:** This source conducts maintenance of appliances containing ozone depleting substances, and therefore is subject to the recycling and emission reduction requirements of 40 CFR Part 82, Subpart F. Condition C.18 of this permit describes the requirements of these provisions.

(f) **Other Clean Air Act Regulations:** This source is not subject to other Clean Air Act requirements not listed in this permit because the source does not own or operate the affected facilities subject to those requirements nor does it conduct the activities subject to those requirements.

State Rule Applicability - Entire Source

326 IAC 2-2-3 (PSD BACT: Control Technology Review Requirements)
Pursuant to PSD/Operating Permit 157-26575-00006 and 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD)), the following are determined as Best Available Control Technologies (BACTs) for BPM Operations, BPM Support Operations, T49 Liquid Waste Incinerator and T149 Solid-Liquid Waste Incinerator Operations:

BPM Operations.

(1) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed VOC BACT of 20 parts per million (ppmv) based on a 24 - hour daily average, or 98 % of VOC/VOHAP emissions for the BPM Operation. The BACT determination is based on the following facts and findings:

(A) BPM Operations

(a) The emission rates represent the most stringent applicable regulatory requirement;

(b) With the exception of the Pfizer facility in Holland, Michigan, the most stringent listing in the RBLC is consistent with the proposed BACT limit proposed by the source.

(c) The installation of an afterburner is considered economically infeasible. In order for Lilly to meet a control efficiency comparable to that required for Pfizer in Holland, Michigan, an afterburner would have to be installed after the RTO control system. The cost effectiveness to add an afterburner to the existing RTO control system is $735,000 per ton of additional VOC removed using accepted cost equations contained in the EPA document Control Technologies for Hazardous Air Pollutants (EPA/625/6-91/014).

(B) Fugitive Emissions

IDEM, OAQ has approved the proposed LDAR program to satisfy the fugitive VOC BACT in the BPM process operations area based on the following facts and findings:

(a) The proposed LDAR program is consistent with the most stringent regulatory standards. These standards are described in detail in Appendix A – Section E (LDAR Program) of the TSD; and

(b) There were no control requirements listed in the RBLC database that addressed fugitive emissions.

(2) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed CO BACT of 73 ppmvdc based on a 24 - hour daily average. The BACT determination is based on the following facts and findings:

(A) It is not practical to compute CO emissions from BPM on the basis of a concentration of 73 ppmv and an exhaust flow rate of 120,000 scfm for the entire year. The exhaust flow rate from BPM is expected to typically be 60,000 scfm, and the CO emission rate is expected to be less than 4 ppmv on a daily average basis.

(B) Because average CO emissions are less than 4 ppmv on a daily average, the quantity of CO which would be controlled in reducing peak hourly emissions from 73 ppmv to 10 ppmv is very small, while the cost to control these emissions would be significant (both in regards to the capital cost to treat an air stream of up to 120,000 acfm and the operating costs for supplemental fuel).

(C) In addition to the fact that little CO would actually be controlled, significant additional NOx emissions would be expected from the combustion control system that would be necessary to achieve the lower CO emissions.

(3) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed Fluorides (F-) BACT of NaOH injection to achieve 98% removal of hydrogen halide and halogen emissions, or 20 ppmv of hydrogen halide and halogen emissions over a 24-hour daily average. The BACT determination is based on the following facts and findings:

(A) There are no applicable regulations or RBLC entries limiting fluoride emissions from this type of operation.

(B) This level of control is as stringent as the Pharmaceutical MACT limit for hydrogen chloride.

BPM Support.

Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed VOC BACT of 98% control of VOC emissions for the BPM Support. The BACT determination is based on the following facts and findings.

(a) The most stringent VOC emission limitation applicable to this emission unit is the MACT standard for pharmaceutical operations. This rule requires organic HAP emissions to be controlled by 93% to 98% or to 20 ppm. For the BPM support operations, the MACT rule requires 95% control of point source organic HAP emissions. This rule also contains requirements for leak detection and repair programs for components in organic HAP service. There are no emission limits for similar sources that would create any more stringent emission limits for pharmaceutical operations.

(b) In order for Lilly to meet a control efficiency comparable to that required for Pfizer in Holland, Michigan, an afterburner would have to be installed after the T79 fume incinerator. The cost effectiveness to add an afterburner to the existing T79 control system is $735,000 per ton of additional VOC removed using accepted cost equations contained in the EPA document Control Technologies for Hazardous Air Pollutants (EPA/625/6-91/014). Therefore, it is not economically feasible to install afterburner after the existing T79 fume incineration system.

(c) With the exception of the Pfizer facility in Holland, Michigan, the most stringent listing in the RBLC is consistent with the proposed BACT limit proposed by the source.

Fugitive Emissions

IDEM, OAQ has approved the proposed LDAR program to satisfy the fugitive VOC BACT in the BPM process operations area. This conclusion is based on the following facts and findings:

(1) The proposed LDAR program is consistent with the most stringent regulatory standards. These standards are described in detail in Appendix A – Section E (LDAR Program) of the TSD; and

(2) There were no control requirements listed in the RBLC database.

T49 Liquid Waste Incineration.

(1) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed VOC BACT for the T49 is good combustion practices and compliance with the 100 ppmvdc CO limit.

The IDEM agrees that the VOC BACT for both the T49 liquid waste incinerator is a good combustion practice and compliance with CO limit.

(2) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed CO BACT for the T49 is good combustion practices to control CO emissions to 100 ppmvdc based on a 1-hour block period. The BACT determination is based on the following facts and findings:

The CO BACT for the T49 incinerator is proper combustion to limit CO emissions to no more than 100 ppmvdc, based on a 1-hour average. This is equivalent to the CO MACT limit contained in 40 CFR Part 63, Subpart EEE.

IDEM, OAQ believes that the hospital/medical/infectious waste incineration limit is not appropriate for hazardous waste incineration units for the following reasons:

(a) Incinerators of the type regulated under Subpart Ec are typically much smaller than units such as T49; and

(b) The waste stream for these units of the type regulated under Subpart Ec is generally more uniform than that encountered in T49.

(3) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed Fluorides (F-) BACT of NaOH injection to achieve 98% removal of hydrogen chloride (HCl).

The fluorides BACT for the T49 incinerator is caustic scrubbing with NaOH to achieve 98% removal efficiency of HCl. This 98% removal efficiency corresponds to an outlet concentration of 77 ppmvdc. IDEM, OAQ believes that this level of control is as stringent as or more stringent than any limit contained in applicable rules or permits for comparable emission units.

T149 Solid-Liquid Waste Incinerator.

(1) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed VOC BACT for the T149 is good combustion practices and compliance with the 10 ppmvdc.

The IDEM agrees that the VOC BACT for T149 Solid-Liquid Waste incinerator may be established as 10 ppm (or 100 ppm CO surrogate), which is equivalent to the MACT THC limits contained in 40 CFR Part 63, Subpart EEE.

(2) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed CO BACT for the T149 is good combustion practices to control CO emissions to 100 ppmvdc based on a 1-hour block period.. The BACT determination is based on the following facts and findings:

The CO BACT for the T149 Solid-Liquid Waste incinerator is proper combustion to limit CO emissions to no more than 100 ppmvdc, based on a 1-hour average. This is equivalent to the CO MACT limit contained in 40 CFR Part 63, Subpart EEE.

IDEM, OAQ believes that the hospital/medical/infectious waste incineration limit is not appropriate for hazardous waste incineration units for the following reasons:

(a) Incinerators of the type regulated under Subpart Ec are typically much smaller than units such as T149; and

(b) The waste stream for these units of the type regulated under Subpart Ec is generally more uniform than that encountered in T149.

(3) Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed Fluorides (F-) BACT of NaOH injection to achieve 98% removal of hydrogen Chloride (HCl).

The fluorides BACT for the T149 Solid-Liquid Waste incinerator is caustic scrubbing with NaOH to achieve 98% removal efficiency of HCl. This 98% removal efficiency corresponds to an outlet concentration of 77 ppmvdc. IDEM, OAQ believes that this level of control is as stringent as or more stringent than any limit contained in applicable rules or permits for comparable emission units.

326 IAC 2 (Permit Review Rules): This source is subject to the permit review rules in 326 IAC 2 as described below.

(1) **326 IAC 2-1.1 – General Provisions:** Except where other rules in 326 IAC 2 require otherwise, the provisions of 326 IAC 2-1.1apply to the entire source.

(2) **326 IAC 2-2 – Prevention of Significant Deterioration [PSD]:** This source is a major stationary source, as defined in 326 IAC 2-2-1, and is therefore subject to PSD requirements when major modifications occur at the source. This permit serves as a PSD permit for the modifications that will occur in Bulk Pharmaceutical Manufacturing [BPM] operations, BPM support operations, and the waste incinerators during the term of this permit.

The following aspects of the PSD permitting program were reviewed and evaluated and determined to satisfy the PSD permitting requirements:

- Best Available Control Technology [326 IAC 2-2-3];
- Air Quality Analysis [326 IAC 2-2-4(a) and 326 IAC 2-2-5],
- Evaluation of PSD increment consumption [326 IAC 2-2-6]; and
- Additional impacts analysis [326 IAC 2-2-7].

The detailed analyses of the Air Quality Modeling and BACT review results can be found in Appendix C and Appendix D of this TSD, respectively.

(3) **326 IAC 2-3 – Emission Offset:** This source is located in an area designated as attainment or unclassifiable for all criteria pollutants. Therefore, the requirements of 326 IAC 2-3 do not apply to this source.

(4) **326 IAC 2-4.1 – Major Sources of Hazardous Air Pollutants [HAPs]:** This source is a major source of hazardous air pollutants. If the source proposes to construct or reconstruct a major source of HAPs, as defined in 40 CFR 63.41, and that major source is not excluded pursuant to 326 IAC 2-4.1(b), then the source must comply with the requirements of 326 IAC 2-4.1-1(c) and (d) for case-by-case Maximum Achievable Control Technology determinations. The source does not anticipate constructing or reconstructing a major source of HAPs that will be subject to these requirements.

(5) **326 IAC 2-5.1 – Construction of New Sources:** This source is an existing source, and therefore cannot be considered to construct a "new source" as defined by 326 IAC 2-1.1-1(10). Therefore, 326 IAC 2-5.1 does not apply to this source.

(6) **326 IAC 2-7 – Part 70 Operating Permit Program:** This source is a major source, as defined by 326 IAC 2-7-1, and is therefore, subject to the requirements of 326 IAC 2-7.

(7) **326 IAC 2-13 – Interim operating permit revision approvals:** This source is eligible to seek interim operating permit revision approvals for minor modifications that may occur at the source.

(8) **Other permit review rules:** This source is an existing source operating under a Part 70 permit, and therefore, is not subject to the requirements of 326 IAC 2-5.5 [Registrations], 326 IAC 2-6.1 [Minor Source Operating Permit Program], 326 IAC 2-8 [Federally Enforceable State Operating Permit Program], 326 IAC 2-9 [Source Specific Operating Agreement Program], 326 IAC 2-10 [Permit by Rule], 326 IAC 2-11 [Permit by Rule for Specific Source Categories], 326 IAC 2-12

[General Permits], and 326 IAC 2-14 [Portable Sources].

326 IAC 2-6 (Emission Reporting)
This source is subject to 326 IAC 2-6 (Emission Reporting) because it is required to have an operating permit under 326 IAC 2-7, Part 70 program. Pursuant to this rule, the Permittee shall submit an emission statement certified pursuant to the requirements of 326 IAC 2-6. In accordance with the compliance schedule specified in 326 IAC 2-6-3, an emission statement must be submitted annually by July 1 of each year. The emission statement shall contain, at a minimum, the information specified in 326 IAC 2-6-4.

326 IAC 5-1 (Opacity Limitations)
Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Exemptions), opacity shall meet the following, unless otherwise stated in the permit:

(a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

(b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

326 IAC 3 (Monitoring requirements):
This source includes facilities subject to the continuous monitoring, source sampling and fuel sampling provisions of 326 IAC 3. The specific monitoring, source sampling, and fuel sampling requirements applicable to the source are described in specific sections of this permit.

326 IAC 4 (Burning regulations):
This source is subject to two aspects of 326 IAC 4. The open burning limitations and standards in 326 IAC 4-1 are applicable to the entire source. These limitations are described in Condition C.3 of the permit.

326 IAC 4-2 establishes particulate matter limitations and other standards for incinerators. This rule applies to incinerators burning solid or liquid wastes. It does not apply to incinerators used to reduce emissions from process operations. Therefore, this rule is not applicable to the Regenerative Thermal Oxidizers or T79 Fume Incinerators.

Because the T49 Liquid Waste Incinerator and the T149 Solid-Liquid Waste Incinerator are subject to the requirements of 40 CFR Part 63, Subpart EEE [Hazardous Waste Combustor MACT], these incinerators are not subject to the requirements of 326 IAC 4-2.

326 IAC 6 (Particulate Rules)

326 IAC 6-1 – Nonattainment Area Limitations: This source is located in an attainment area for particulate matter. Therefore, 326 IAC 6-1 does not apply to any facilities at this source.

326 IAC 6-2 – Particulate Emission Limitations for Sources of Indirect Heating: This source includes boilers that are subject to the requirements of this rule. The specific limitations and other requirements applicable to these facilities are described in Sections D.1 and D.20 (Utilities Operations) of this TSD.

326 IAC 6-3 – Process Operations: This rule establishes particulate matter limits for manufacturing processes that emit particulate matter. This source includes several facilities subject to the requirements of this rule. The permit includes specific conditions, including expression of the particulate matter emission limitations, incorporating this requirement for manufacturing processes and emission units in various locations of the plant site. As a result, this requirement will be described in multiple locations in the permit. In addition, this permit includes a general condition [Condition C.1], that generally describes the emission limitation for all other manufacturing processes subject to 326 IAC 6-3 which are not described in detail in D sections of the permit. Administrative, maintenance, research and development, and other support activities conducted at the source that are not manufacturing are not subject to this rule.

326 IAC 6-4 – Fugitive Dust Emissions: This source is subject to the fugitive dust limitations in 326 IAC 6-4. The source may not allow fugitive emissions to cross the property boundaries of the site, including easements and rights-of-way, in a manner that violates this rule. Condition C.4 of this permit describes the requirements of this rule in greater detail.

326 IAC 6-5 – Fugitive Particulate Matter Emission Limitations: This source does not have potential fugitive dust emissions greater than 25 tons per year, and is therefore, not subject to the requirements of this rule.

326 IAC 7 (Sulfur dioxide rules): This source includes boilers that are subject to the requirements of 326 IAC 7. The specific limitations and other requirements applicable to these facilities are described in Section D.1 (Utilities Operations) of this TSD. No other emission units are subject to the requirements of this rule.

326 IAC 8 (Volatile Organic Compound Rules): This source is subject to the VOC control rules in 326 IAC 8 as described below.

326 IAC 8-1 – General Provisions: Because this source operates facilities subject to rules in 326 IAC 8, the General Provisions in 326 IAC 8-1apply to the source. Where a specific provision of 326 IAC 8-1 is applicable to facilities at this source, those provisions will be contained in a specific section of the permit and described in the appropriate section of the TSD. Sections 326 IAC 8-1-7, 8-1-10, 8-1-11, and 8-1-12 are not applicable to this source.

326 IAC 8-3 – Organic Solvent Degreasing Operations: This source does not own or operate open top degreasing facilities containing organic solvent. Therefore, the requirements of 326 IAC 8-3-3/326 IAC 8-3-6 do not apply.

326 IAC 8-4 – Petroleum Sources: This source does not operate any facilities subject to the requirements of 326 IAC 8-4. 326 IAC 8-4-6 is not applicable to this source because the source does not accept deliveries of gasoline by transports, as defined by 326 IAC 1-2-84.

326 IAC 8-5-3 – Synthesized Pharmaceutical Manufacturing Operations: This source includes various operations subject to the requirements of 326 IAC 8-5-3. This rule establishes emission limitations and work practices for production and support equipment engaged in manufacturing pharmaceuticals by chemical synthesis. The permit includes specific conditions incorporating these requirements. The Permittee has requested that most of the requirements of this rule be "streamlined" into permit conditions incorporating the requirements of the Pharmaceutical Production MACT [40 CFR Part 63, Subpart GGG] and the BACT emission limitations and standards established as part of the BACT PSD review described in Appendix C this TSD. The specific requirements of this rule, and the streamlining of its requirements into other permit conditions are described in Appendix A of this TSD.

326 IAC 8-6 – Organic Solvent Emissions Limitations:
The provisions of 326 IAC 8-6 are not applicable to this source because the source is subject to other rules in 326 IAC 8.

Other rules in 326 IAC 8:
This source is not subject to other requirements in 326 IAC 8 not listed here because the source does not own or operate the affected facilities subject to those rules.

326 IAC 9 (Carbon Monoxide Rules): Because the T49 Liquid Waste Incinerator and T149 Solid-Liquid Waste Incinerator are subject to the requirements of 40 CFR 63, Subpart EEE [Hazardous Waste Combustor MACT], these incinerators are not subject to the requirements of 326 IAC 9-1.

326 IAC 10 (Nitrogen Oxide Rules):
This source does not contain any emission units identified in 326 IAC 10-4. Therefore, the source is not subject to the NOx emission control requirements of that rule.

326 IAC 11 (Emission Limitations for Specific Types of Operations):
This source does not contain any emission units described in 326 IAC 11. Therefore, the source is not subject to the requirements of those rules.

326 IAC 12 (New Source Performance Standards):
The applicability of the New Source Performance Standards, as embodied in Indiana air quality regulations, is described in greater detail in the section of this TSD addressing the federal NSPS program.

326 IAC 14 (Emission Standards for Hazardous Air Pollutants):
The applicability of these Emission Standards for Hazardous Air Pollutants, as embodied in Indiana air quality regulations, is described in greater detail in the section of this TSD addressing the federal Part 61 NESHAPs program.

326 IAC 15 (Lead Rules):
This source does not contain any emission units described in 326 IAC 15. Therefore, the source is not subject to the requirements of those rules.

326 IAC 20 (Hazardous Air Pollutants):
The applicability of Part 63 National Emission Standards for Hazardous Air Pollutants, as embodied in 326 IAC 20, is described in greater detail in the section of this TSD addressing the federal Part 63 NESHAPs program.

326 IAC 21 (Acid Deposition):
This source does not contain any emission units described in 326 IAC 21. Therefore, the source is not subject to the requirements of those rules.

326 IAC 2-2-4 (Air Quality Analysis Requirements)
Section (4)(a) of this rule, requires that the PSD application shall contain an analysis of ambient air quality in the area that the major stationary source would affect for pollutants that are emitted at major levels or significant amount. Eli Lilly and Company - Tippecanoe Laboratories, Inc. has submitted an air quality analysis, which has been evaluated by the Technical Support and Modeling Section.

326 IAC 2-2-5 (Air Quality Impact Requirements)
326 IAC 2-2-5(e)(1) of this rule, requires that the air quality impact analysis required by this section shall be conducted in accordance with the following provisions:

(1) Any estimates of ambient air concentrations used in the demonstration processes required by this section shall be based upon the applicable air quality models, data bases, and other requirements specified in 40 CFR Part 51, Appendix W (Requirements for Preparation, Adoption, and Submittal of Implementation Plans, Guideline on Air Quality Models).

(2) Where an air quality impact model specified in the guidelines cited in subdivision (1) is inappropriate, a model may be modified or another model substituted provided that all applicable guidelines are satisfied.

(3) Modifications or substitution of any model may only be done in accordance with guideline documents and with written approval from U.S. EPA and shall be subject to public comment procedures set forth in 326 IAC 2-1.1-6.

Economic Growth

The purpose of the growth analysis is to quantify project associated growth and estimate the air quality impacts from this growth either quantitatively or qualitatively.

No new construction is part of this application. No commercial growth is anticipated to occur. Since the area is predominately rural, it is not expected that growth impacts will cause a violation of the NAAQS.

Soils and Vegetation Analysis

A list of soil types present in the general area was determined. Soil types include the following: Loamy Glacial Till, Moderate Thick Loess over Loamy Glacial Till and Thin Loess over Loamy Glacial Till.

Due to the agricultural nature of the land, crops in the Tippecanoe County area consist mainly of corn, sorghum, wheat, soybeans, and oats (2002 Agricultural Census for Tippecanoe County). The maximum modeled concentrations for Eli Lilly are well below the threshold limits necessary to have adverse impacts on the surrounding vegetation such as autumn bent, nimblewill, barnyard grass, bishopscap and horsetail, and milkweed (Flora of Indiana – Charles Deam). Livestock in Tippecanoe County consist mainly of hogs, cattle, and sheep (2002 Agricultural Census for Tippecanoe County) and will not be adversely impacted from the facility. Trees in the area are mainly hardwoods. These are hardy trees and no significant adverse impacts are expected due to modeled concentrations.

Federal and State Endangered Species Analysis

Federal and state endangered or threatened species are listed by the U.S. Fish and Wildlife Service; Division of Endangered Species for Indiana and includes 5 amphibians, 27 birds, 10 fishes, 7 mammals, 15 mollusks, and 15 reptiles. Of the federal and state endangered species on the list, 2 reptiles, 12 mollusks, 11 birds, and 2 mammals have habitat within Tippecanoe County. The mollusks, fish, amphibians and certain species of birds and mammals are found along rivers and lakes while the other species of birds and mammals are found in forested areas. The facility is not expected to have any additional adverse effects on the habitats of the species than what has already occurred from the industrial, farming, and residential activities in the area.

Federal and state endangered or threatened plants are listed by the U.S. Fish and Wildlife Service, Division of Endangered Species for Indiana. They list 13 state endangered species of plants. At this time no federally endangered plant species are found in Tippecanoe County. The endangered plants do not thrive in industrialized and residential areas. The facility is not expected to adversely affect any plant on the endangered species list.

326 IAC 2-2-7 (Additional Analysis, Requirements)
326 IAC 2-2-7(a) requires an analysis of the impairment to visibility, soils and vegetation. An analysis of the air quality impact projected for the area as a result of general commercial, residential, industrial, and other growth associated with the source.

The results of the additional impact analysis conclude the operation of the facility will have no significant impact on economic growth, soils or vegetation in the immediate vicinity or on any Class I area. CO is not a pollutant that affects visibility. The visibility analysis was not necessary for this application.

326 IAC 2-2-10 (Source Information)
The Permittee has submitted all information necessary to perform analysis or make the determination required under this rule.

326 IAC 2-2-12 (Permit Rescission)
The permit issued under this rule shall remain in effect unless and until it is rescinded, modified, revoked, or it expires in accordance with 326 IAC 2-1.1.-9.5 or section 8 of this rule.

326 IAC 22 (Emission Standards for Hazardous Air Pollutants):
The applicability of Part 82 Stratospheric Ozone Protection program, as embodied in 326 IAC 22, is described in greater detail in the section of this TSD addressing the Part 82 program.

326 IAC 2-2.4-7 (Contents of the PAL permit)
This permit contains a PAL and it meets the requirements of 326 IAC 2-2.4.

Reporting

Because of the streamlined permitting requirements, submittal of reports as prescribed by this permit satisfies the various requirements to submit reports under individual regulations.

Recommendation

The staff recommends to the Commissioner that the Part 70 Operating Permit Renewal approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An application for the purposes of this review was received on May 28, 2008.

Conclusion

The operation of this pharmaceutical manufacturing plant shall be subject to the conditions of the attached Part 70 Operating Permit Renewal No.T157-26575-00006.

Appendix A

Indiana Department of Environmental Management

Office of Air Quality

Technical Support Document (TSD) for a Part 70 Operating Permit Renewal

Section D.1 - Section D.5

D.1: Utilities Operations

Background and Description

The utilities operations consist of three coal-fired boilers (with natural gas co-firing capabilities) equipped with an ash handling system and supported by a coal pile and coal conveyor system, and two natural gas boilers with fuel oil backup supplied by one fuel oil tank. The boilers provide steam to process operations in bulk pharmaceutical manufacturing and fermented products.

Types of Emission Units and Pollution Control Equipment

(a) Boilers

The site operates three coal-fired boilers (with natural gas co-firing capabilities) each rated at 92 MMBtu per hour (Boilers 1, 2 and 3) constructed in 1953 and controlled by multiclones. The site also operates two natural gas/fuel oil boilers rated at 142 MMBtu per hour (Boiler 4) and 97 MMBtu per hour (Boiler 5) which were constructed in 1973 and 1982, respectively.

(b) Ash Handling System

The ash handling system transfers the ash generated by the three coal-fired boilers to a two-stage centrifugal separator and baghouse system to control particulate emissions.

(c) Out Coal Pile/Coal Conveyor System

The coal pile is located outside. Coal is transferred to a covered coal conveyor system that feeds the coal-fired boilers.

(d) Fuel Oil Storage Tank

The fuel oil tank is a vertical, fixed roof type with a storage capacity of 250,000 gallons. The maximum annual fuel oil throughput is 30,000 gal/yr. This tank was modified in January 1989 to store fuel oil as a backup fuel source for the two natural gas-fired boilers.

Insignificant Activities

(a) Out Coal Pile/Coal Conveyor System

The coal conveying system is defined as an insignificant activity pursuant to 326 IAC 2-7-1(21)(G)(xiv)(AA) (Covered coal conveyors transferring $\leq$ 360 tons per day) because the system is covered and the boilers do not have the capability of burning 360 tons per day.

(b) Fuel Oil Storage Tank

The fuel oil tank is considered an insignificant activity because the uncontrolled potential emissions are less than the applicability thresholds stated in 326 IAC 2-7-1(21)(A).

Existing Approvals

With respect to the utilities operations, the source has been operating under the following previous approvals.

Description	Permit #	Date
Operating Permits		
Title V Permit	T157-6879-00006	Issued February 27, 2004

Federal Rule Applicability

There are no federal rules that apply to these utilities operations. The following non-applicability determinations are included for clarification purposes.

(a) Boilers

40 CFR 60, Subpart D (New Source Performance Standard (NSPS) for Fossil-Fuel Fired Steam Generating Units) – This source is not subject to 40 CFR Part 60, Subpart D because none of the boilers at the plant site exceed 250 MMBtu/hour in heat input capacity [40 CFR 60.40(a)(1)].

40 CFR 60, Subpart Db (NSPS for Industrial Steam Generating Units) – This standard applies to units constructed, reconstructed, or modified after June 19, 1984 with the capability of combusting more than 100 MMBtu per hour heat input. All of the boilers described in this subsection were constructed prior to the rule applicability date, and therefore are not subject to this rule.

40 CFR 60, Subpart Dc (NSPS for Small Industrial Steam Generating Units) – This standard applies to units constructed after June 9, 1989 having a maximum heat input capacity of 100 MMBtu per hour. All of the boilers with maximum heat inputs between 10 and 100 MMBtu/hour were constructed prior to the rule applicability date, and therefore are not subject to this rule.

(b) Fuel Oil Storage Tank

40 CFR 60, Subpart Kb (NSPS for Volatile Organic Liquid Storage Vessels – Pursuant to 40 CFR 60.110b(c), the fuel oil storage tank, constructed in 1973, is not subject to the control requirements of this subpart because the true vapor pressure of fuel oil is less than 3.5 kPa.

State Rule Applicability

(a) Boilers

326 IAC 6-2-3 (Particulate Rules for Indirect Heating) – This rule applies to both the coal-fired boilers and natural gas-fired boilers.

The particulate emissions from each coal-fired boiler (Boilers 1, 2, and 3) shall not exceed 0.56 pounds per million British thermal units (MMBtu) heat input.

The particulate emissions from Boiler 4 shall not exceed 0.39 pounds per MMBtu heat input and Boiler 5 shall not exceed 0.31 pounds per MMBtu heat input.

326 IAC 5-1 (Opacity Limitations) – The opacity from the coal-fired boilers shall not exceed an average of 40% in any one 6-minute averaging period or 60% for more than a cumulative total of 15 minutes in a 6-hour period. These boilers are allowed temporary alternative opacity limits for startup/shut down of a boiler and when removing ashes or blowing tubes in a boiler pursuant to 326 IAC 5-1-3(a) and (b).

326 IAC 7-1.1-2 (Sulfur Dioxide Emission Limitations) – This rule limits the SO_2 emissions from boilers.

The SO2 emissions from each of the coal-fired boilers (Boilers 1, 2 and 3) shall be limited to 6.0 pounds per MMBtu heat input.

The SO2 emissions from Boilers 4 and 5 shall be limited to 0.5 pounds per MMBtu heat input, when burning No. 2 fuel oil.

326 IAC 3-7-2(b) (Coal Sampling and Analysis Procedures) – Because the SO2 emissions from the coal-fired boilers (Boilers 1, 2, and 3) are related to the sulfur content in the coal, the Permittee is required to sample and analyze the coal in accordance with the sampling and analysis procedure outlined in 326 IAC 3-7-5. This rule is used to demonstrate compliance with the SO2 limit under 326 IAC 7-1.1-2.

326 IAC 3-7-4 (Fuel Oil Sampling and Analysis Procedures) – Before fuel oil can be burned in Boilers 4 and 5, the fuel oil analysis of the sulfur content must be compliant with the SO2 limitations established in 326 IAC 7-1.1-2.

(b) Ash Handling System

326 IAC 6-3-2 (Process Weight Rate) –The following equation from 326 IAC 6-3-2 was used to determine the allowable particulate emission rate from the ash handling system:

$E = 4.10P^{0.67}$

where
E = allowable rate of emission in pounds/hour;
P = process weight rate in tons per hour
= 7906 tons ash/yr x 1yr/8760 hrs
= 0.903 tons ash/hr

$E = 4.10\ (0.903)^{0.67}$
E = 3.83 lbs/hr X 8760hr/yr X 1 ton/2000 lbs/hr
E = 16.8 tons/yr

The ash from the boilers is pneumatically conveyed through a two-stage centrifugal separator to a storage silo via a steam jet exhauster. The two-stage centrifugal separator is integral to the process as it serves to separate the air from the bottom ash. According to IDEM guidance, the potential uncontrolled particulate emissions in the air stream of the ash handling system are determined after the separator because it is integral to the process. A baghouse is located after the separator for particulate control. The ash handling system is in compliance with this rule as demonstrated by the following particulate (PM) emission calculations because the maximum controlled emissions are less than the allowable emissions:

Ash Separator Efficiency, % = 94+%

Baghouse Efficiency, % = 99.9%

Max Uncontrolled Ash (PM), tons/yr = [7950 tons ash/yr x <u>(100% ash - 94% eff)] / 100% ash</u>
= 477 tons PM/yr

Max Controlled PM, tons/yr = Max Uncontrolled PM Emissions x Baghouse Efficiency
= 477 tons uncontrolled particulate/yr x (100% - 99.9%)/ 100%
= 0.477 tons particulate/yr

(c) Out Coal Pile/Coal Conveyor System

<u>326 IAC 6-5 (Fugitive Particulate Matter Emission Limits)</u> –The requirements of 326 IAC 6-5 do not apply to the out coal pile and coal conveyor system because it was constructed prior to the rule applicability date of December 13, 1985.

(d) Fuel Oil Storage Tank

<u>326 IAC 8-9 (Volatile Organic Liquid Storage Vessels)</u> – The fuel oil tank is not subject to the requirements of this rule because the site is located in Tippecanoe County. According to 326 IAC 8-9-1(a), this rule only applies to tanks located in Clark, Floyd, Lake or Porter County.

Compliance Requirements

(a) Boilers

The following compliance activities are required for the boilers:

1. Coal sampling and analysis shall be performed according to the Permittee's Coal Sampling and Assay Plan, submitted pursuant to 326 IAC 3-7-5(a), to demonstrate compliance with SO2 limitations under 326 IAC 7-1.1-2.

2. Particulate stack tests for the coal fired boilers (Boilers 1, 2, and 3) shall be performed every third calendar year from the calendar year of the most recently completed compliance stack test to demonstrate compliance with the particulate standards under 326 IAC 6-2-3. This three-year cycle is based on an agreement between Lilly and IDEM, established in 1988.

3. Analysis of the fuel oil must show compliance with the SO2 limits established under 326 IAC 7-1.1-2 before the fuel oil can be burned in Boilers 4 and 5.

4. Preventive maintenance plan required for boilers and multiclones.

(b) Fuel Oil Storage Tank

According to NSPS Subpart Kb, the fuel oil storage tank is not subject to any control or compliance requirements.

(c) Alternative Operating Scenario

The Permittee may elect to perform the tests in D.1.6(a) (compliance stack testing) while burning a mixture of natural gas and coal (co-fire). The Permittee shall inform IDEM in writing whenever the co-fire operating scenario is used, in which case, a gas flow meter and stream flow rate meter shall be installed and operated. The 24-hour daily average gas ratio shall be greater than or equal to the value determined in the most recent performance test.

If the Permittee has conducted a performance test under co-fired conditions to establish a minimum gas ratio, but subsequently wants to operate a boiler without natural gas co-fired or at a gas ratio that is lower than the ratio established at the performance test, then the Permittee must demonstrate that particulate matter emissions are less than the emission limits in D.1.1(a) pursuant to a performance test as described in D.1.6(a) under the desired operating conditions. The Permittee may not begin to operate under the new conditions until the performance test results are submitted to IDEM, OAQ.

(d) Compliance Assurance Monitoring (CAM)

The following CAM activities are required for the boilers and ash handling system.

(1) A continuous monitoring system shall be calibrated, maintained, and operated for measuring opacity from the coal-fired boilers (BLR001, BLR002, and BLR003). The opacity continuous monitoring system is not required when the coal-fired boilers are burning only natural gas.

(2) The boiler continuous monitoring system shall following quality assurance and quality control (QA/QC) practices:

(A) For calibration drift (CD) assessment, the COMS shall be checked at least once daily. The CD shall be quantified and recorded at zero (0) (or low level) and upscale level opacity. The COMS shall be adjusted whenever the CD exceeds the specification as described in 40 CFR Part 60, Appendix B, Performance Specification 1 (PS-1), and the COMS shall be declared out of control when the CD exceeds twice the specification of PS-1. Corrective actions, followed by a validating CD assessment, are required when the COMS is out of control;

(B) For fault indicators assessment, the fault lamp indicators, data acquisition system error messages, and other system self-diagnostic indicators shall be checked at least daily. Appropriate corrective actions shall be taken when the COMS is operating outside the preset limits;

(C) A performance audit shall be performed, at a minimum, on a calendar quarter basis. The performance audit shall include checks for stack exit correlation error, zero and upscale responses, zero compensation, optical alignment, optical surface dust accumulation, and calibration error. The performance audit criteria described in 326 IAC 3-5-5(c)(4)(A) shall be used to determine if the COMS audit results are acceptable.

(3) The ash handling system (CONASH) baghouse shall be inspected and maintained with a daily visual inspection shall be performed to check for the operation and to detect any bypass of the baghouse to the atmosphere, and an annual visual inspection and maintenance check shall be performed to internally inspect the baghouse and determine whether bag replacement is required. Bag

(4) If the COMS does not collect valid opacity data, as described in Condition D.1.20(a)(2) for four consecutive hours, the Permittee shall conduct a visible emissions notation once per day during daylight operation.

D.2: Utilities Support Operations

Background and Description

The utility support facilities include the lime system for the potable water system (T9/T23), glycol tanks for heating and cooling of BPM tanks and chillers, generators and compressors. The following report has been generated for each of these facilities making up the utility support section of the Title V permit to document technical information used to prepare the Title V permit conditions and demonstrate compliance with the TV requirements.

(a) Lime System for the T9/T23 Potable Water Process Systems

Lime is used to treat (soften) the potable water used on the site. The lime system serves two potable water process systems (T9 and T23), but only one of the water systems can operate at a time. Lime is transferred to the lime storage silo with an integrated bin vent, via lime bags. Particulate matter is the only type of emission generated from this process. The lime from the lime storage silo is injected to the potable water for treatment via a pneumatic system. There are no emissions generated from the injection process because the lime is injected directly into the water.

(b) Glycol System

The glycol system is used for more efficient heating and cooling of process tanks and chillers in bulk pharmaceutical manufacturing (BPM).

(c) Generators/Compressors

There are various generators and compressors on site that are dedicated to different purposes. Some generators are used intermittently to supply power during periods of peak electrical consumption or to power the site's fire pumps; while other generators are dedicated to emergency situations only. The compressors may be used to clean/blow the lines in the fermentation area to prevent/remove clogs or may be used for maintenance activities like breaking up concrete.

Types of Emission Units and Pollution Control Equipment

The following emission units are associated with the utility support operations:

Emission Unit ID	Emission Unit Description	Control Device
Building T5:		
T5	Diesel Generator	None
Building T6:		
T121	Diesel Generator	None
Portable Units:		
T62*	Diesel Generator	None
T135*	Diesel Generator	None
T78*	Diesel Compressor	None
T89-1*	Diesel Compressor	None
Building T97/T98:		
T97/T98*	Glycol System	None
Building T9/T23:		
T9/T23*	Lime Storage Silo	None
Building T70		

Emission Unit ID	Emission Unit Description	Control Device
Gen-7001*	Diesel Generator	None

* Emission units marked with a single asterisk are insignificant activities as defined in 326 IAC 2-7-1(21).

Insignificant Activities

(a) Lime System for the T9/T23 Potable Water Process Systems

The lime system is an insignificant activity because the potential uncontrolled particulate emissions are below the particulate threshold levels (5 lbs/hr, 25 lbs/day, and 5 tons/yr) that define the facility as an insignificant activity pursuant to 326 IAC 2-7-1(21)(A) through (C).

(b) Glycol System

The glycol tanks are considered insignificant activities pursuant to 326 IAC 2-7-1(21)(vi)(FF) (Closed loop heating and cooling systems).

(c) Generators/Compressors

Generators T5, T135 and T62 are operated only in emergency situations, and therefore classified as insignificant activities under 326 IAC 2-7-1(21)(G)(xxii)(BB) (Emergency generators).

Federal Rule Applicability

There are no federal rules that apply to the utility support operations.

State Rule Applicability

(a) Lime System for the T9/T23 Potable Water Process Systems

326 IAC 6-3-2 (Process Weight Rate) - The recently revised process weight rate rule clarifies that the rule does not apply to processes that have the potential to emit less than 0.551 pounds per hour of particulate matter before controls. The lime system is not subject to the requirements of 326 IAC 6-3 because potential uncontrolled emissions from the system is less than 0.551 pounds PM per hour.

(b) Glycol System

There are no state rules that apply to the glycol system.

(c) Generators/Compressors

The requirements for the generators/compressors are reflected in the Plantwide Applicability Limitations (PAL) Permit.

Compliance Requirements

(a) Lime System for the T9/T23 Potable Water Process Systems

Because this facility is an insignificant activity, and it is not subject to any applicable federal or state air pollution control requirements, no compliance monitoring is required.

(b) Glycol System

The glycol system is not subject to any compliance requirements because it is not subject to any state or federal rules or other limits or standards required by a federally enforceable permit.

(c) Generators/Compressors

The generators/compressors are not subject to any compliance requirements because these emission units are not subject to any state or federal rules.

D.3: Fermented Products – Fermentation Operations

Background and Description

The fermentation processes include the dry material storage area (T46), the raw material prep area (T1), the fermentation production areas (T2, T2A, T2C) and product storage area (T63). The equipment associated with the finishing area (T1) has been permanently taken out of service; therefore, this equipment has not been included in the Title V permit. PM/PM10 and VOC are the only emissions generated in the fermentation area. The following summary has been prepared for each of these areas making up the fermentation section of the Title V permit to document technical information used to prepare the Title V permit conditions and to demonstrate compliance with the Title V requirements.

Types of Emission Units and Pollution Control Equipment

(a) Dry Material Bulk Storage Area (T46)

The bulk storage area consists of 12 bins equipped with voluntary pulsed jet bag filters. Dry raw material such as corn gluten, soybean meal and calcium carbonate are used in fermentation as nutrient media for the microorganisms. The bulk storage area is used for high-volume dry raw materials. These materials are pneumatically transferred from rail cars or tank trucks to the storage bins. Particulate is the only pollutant emitted from the bulk storage area.

(b) Bulk Liquid Storage Area (T1)

The liquid storage area is made up of liquid storage tanks that store raw materials such as lard and vegetable oil, liquid waste from the fermentation operations, and whole broth from the fermentation operations. The emissions from these operations are insignificant and were not calculated. There are no dry materials added to these tanks and the tanks are not agitated. The storage tanks are not subject to any applicable rules or compliance monitoring requirements. This equipment is being included in the description section of the Title V permit for clarification purposes only.

(c) Raw Material Prep Area (T1)

The raw material prep area consists of a dispensing station of raw materials, mixing tanks, make-up tanks and slurry tanks. Raw material such as corn gluten, soybean meal and calcium carbonate are used in fermentation as nutrient media for the microorganisms. Particulate is the only pollutant emitted from the raw material prep area.

(d) Fermentation Production Areas (T2, T2A, T2C)

The fermentation production areas consist of bump tanks and fermentation tanks. The fermentation process begins in the culture laboratory. In the laboratory, a shake flask containing sterile media is inoculated under sterile conditions using a preserved culture. The shake flask is grown for several days and then several shake flasks are used to inoculate a bump tank. The bump tank will be grown for several days and is used to inoculate a fermentor. During the process, air is sparged into the fermentors and bump tanks for agitation and to provide oxygen for the microorganisms. Both particulate and VOC emissions may be emitted from the fermentation production areas.

(e) Product Storage Area (T63)

The T63 product storage area consists of two tanks that hold the whole broth product from fermentation prior to purification. The fermentation process is a batch operation and the purification process is a continuous operation. The whole broth product from fermentation is emptied into one of these tanks and then continuously fed to the purification equipment as capacity allows. There are de minimis emissions from the product storage area.

Insignificant Activities

Each emission unit associated with the fermentation operations is considered insignificant because the potential uncontrolled particulate emissions are below the particulate threshold levels (5 lbs/hr, 25 lbs/day, and 5 tons/yr) as defined in 326 IAC 2-7-1(21)(B) and the potential uncontrolled VOC emissions are below the VOC threshold levels (3 pounds per hour or 15 pounds per day) as defined in 326 IAC 2-7-1(21)(A)(iv).

Federal Rule Applicability

There are no federal rules that apply to the fermentation operations:

40 CFR 63 Subpart GGG (Pharmaceutical MACT Standard) – This rule does not apply to the emission units associated with the fermentation operations 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).

State Rule Applicability

(a) Dry Material Bulk Storage Area (T46)

326 IAC 6-3-2 (Process Weight Rate) - The process weight rate rule states that the rule does not apply to processes that have the potential to emit less than 0.551 pounds per hour of particulate matter before controls. The storage bins are not subject to the requirements of 326 IAC 6-3 because potential uncontrolled emissions from each bin is less than 0.551 pounds PM per hour.

(b) Bulk Liquid Storage Area (T1)

There are no state rules that apply to the bulk liquid storage tanks located in the fermentation operations.

(c) Raw Material Prep Area (T1)

326 IAC 6-3-2 (Process Weight Rate) - The process weight rate rule states that the rule does not apply to processes that have the potential to emit less than 0.551 pounds per

hour of particulate matter before controls. The tanks in the raw material prep area are not subject to the requirements of 326 IAC 6-3 because potential uncontrolled emissions from each bin is less than 0.551 pounds PM per hour.

The mixers and conveyor for the mixers are subject to the requirements of this rule. These emission units were considered to be a single process for purposes of calculating the allowable particulate emissions pursuant to 326 IAC 6-3. The maximum throughput rate for the process (maximum material throughput = 1762 lbs/hr) was used to calculate the allowable emission rate:

$$\begin{aligned} \text{Allowable PM, tons/yr} &= 4.10 \times (\text{Process Wt, tons/hr})^{0.67} \\ &= 4.10 \times (0.88 \text{ tons/hr})^{0.67} \\ &= 3.77 \text{ lbs PM/hr} \end{aligned}$$

Because the combined potential uncontrolled particulate emissions from one mixer (conveyor system can only fill one mixer at a time) and the conveyor (2.91 lb/hr) are less than the allowable emissions (3.77 lb/hr), the equipment is in compliance with this rule and no control device is required.

(d) Fermentation Production Areas (T2, T2A, T2C)

326 IAC 6-3-2 (Process Weight Rate) - The process weight rule (326 IAC 6-3) for particulate matter applies to the equipment associated with the fermentation production areas because the potential emissions are greater than 0.551 pounds per hour and are not an exempt category. The process weight rate rule requires that allowable emissions be calculated by "process". The allowable emissions as defined in the existing construction permits are based on equipment constructed at the same time. In reviewing the Title V permit application, it was decided that related equipment be grouped as a process. The bump tanks in each building feed into any of the fermentation tanks located in the same building.

Therefore, the production equipment in each building was defined as a process. The calculation methodologies are provided in the Title V permit application. According to these calculations, the uncontrolled emissions for each fermentation production process are less than the respective allowable particulate emissions. Therefore, the process equipment is in compliance with this rule and no control devices are required.

326 IAC 8-5-3 (Synthetic Pharmaceutical RACT Rule) – The emission units associated with fermentation do not manufacture pharmaceutical products by chemical synthesis. Therefore, the emission units associated with fermentation are not subject to the requirements of 326 IAC 8-5-3 (VOC Emission Limitations for Synthesized Pharmaceutical Manufacturing Operations).

326 IAC 8-1-6 (State VOC BACT Rule) – The emission units associated with fermentation 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.4: Fermented Products – Purification Operations

Background and Description

The whole broth products from fermentation are stored in Building T63 and then continuously fed to the purification equipment as capacity allows. The purification department consists of extraction and elution processes (T3), solvent recovery (T4), raw and recovered material storage (T147), and product storage (T39). PM/PM10 and VOC are generally the only emissions generated in the purification area. One dryer emits HAPs. The following summary has been prepared for each of these areas making up the purification section of the Title V permit to document technical information used to prepare the Title V permit conditions and to demonstrate compliance with the Title V permit requirements.

Types of Emission Units and Pollution Control Equipment

(a) Purification Production Area (T3)

The purification production areas isolate and purify fermentation products through extraction and elution processes. The extraction and elution equipment are closed systems and therefore generate de minimis VOC emissions. VOC emissions occur from the displacement of air at initial start up and from sweeping the equipment with nitrogen to maintain an inert atmosphere. Emissions from tanks that collect enriched solvent occur as they are filled. The particulate emissions are at de minimis levels.

The filters and cryogenic condenser associated with the rotary vacuum dryer (T3-RVD40) are voluntary controls because the potential uncontrolled emissions are less than applicable limitations.

(b) Solvent Recovery Area (T4)

Solvents used in the purification processes are recovered for reuse in the solvent recovery area. Equipment in this area includes four atmospheric pressure distillation systems, two flash evaporators and two distillation columns. Each of the columns, flash evaporators and distillation systems are equipped with process condensers followed by process vent condensers to collect the recovered material. There are also two storage tanks (one hydrochloric acid tank and one sulfuric acid tank) located outside to the northeast of Building T4. These tanks were constructed in 1953 and vent to a voluntary caustic scrubber.

The scrubber used to control VOC emissions from the two outside storage tanks (T420-1T, T434-1T) is a voluntary control because the potential uncontrolled emissions are less than the applicable limitations.

The condensers and vent condensers associated with the columns, evaporator, and distillation systems associated with the solvent recovery processes are considered process condensers, not control devices. Therefore, the condensers are considered integral to the process.

(c) Product Storage Area (T39)

Once the antibiotic material is purified, the product may be loaded into tanker trucks or temporarily stored in the product storage area (T39). The product storage area consists of six storage tanks.

(d) Storage Tank Module (T147)

This storage tank module stores new and recovered solvent material used in the purification process, as well as waste material generated from the purification process.

The vent condensers associated with the storage tanks in the T147 tank module are not required controls because the potential uncontrolled emissions are less than the applicable limitations.

Insignificant Activities

(a) T3 Purification Production Area

With the exception of one evaporator, T3-EVAP305, the emission units associated with the T3 purification production area are considered "insignificant activities" because the potential emissions are less than the threshold values defined in 326 IAC 2-7-1(21).

(b) T4 Solvent Recovery Area

With the exception of one distilling column, T4-COL001, the emission units associated with the T4 solvent recovery area are considered "insignificant activities" because the potential emissions are less than the threshold values defined in 326 IAC 2-7-1(21).

(c) Product Storage Area (T39)

All or the emission units in the T39 product storage area are considered "insignificant activities" because the potential emissions are less than the threshold values defined in 326 IAC 2-7-1(21).

Federal Rule Applicability

(a) Building T3

NSPS 40 CFR 60, Subpart Kb – Volatile Organic Liquid Storage Vessels
The T3 tanks are not subject to Subpart Kb because they were all installed prior to the July 23, 1984 rule applicability date, and the tanks have not been modified since that date. Regardless, these tanks are process tanks and do not meet the definition of a storage vessel.

NESHAP 40 CFR 63, Subpart GGG – Pharmaceutical MACT
With the exception of the rotary vacuum dryer, the emission units associated with the T3 purification process are not subject to Subpart GGG because these emission units do not generate, produce or use HAP emissions in excess of 50 ppmv pursuant to 40 CFR 63.1251 (Process Vent Definition).

The rotary vacuum dryer is subject to the requirements of Subpart GGG because the HAP emissions from the drying operations may be greater than the process vent HAP emission threshold level of 50 ppmv as defined in 40 CFR 63.1251.

Lilly shall accept a process-based annual mass limit of 900 kilograms (kg) per 365-day period on the rotary vacuum dryer to comply with the process vent standard under 40 CFR 63.1254(a)(2)(i). The emission limit has been incorporated into the Title V permit.

(b) Solvent Recovery Area (T4)

40 CFR 60, Subpart Kb – Volatile Organic Liquid Storage Vessels
The two acid tanks are not subject to Subpart Kb because these tanks were installed prior to the July 23, 1984 applicability date and have not been modified since that date.

40 CFR 63, Subpart GGG – Pharmaceutical MACT
Building T4 is not subject to Subpart GGG because there are no HAPs emitted or used in the purification process.

(c) Product Storage Area (T39)

40 CFR 60, Subpart Kb – Volatile Organic Liquid Storage Vessels
The T39 storage tanks are not subject to Subpart Kb because these tanks were installed prior to the July 23, 1984 applicability date, and have not been modified after the applicability date.

40 CFR 63, Subpart GGG – Pharmaceutical MACT
The T39 storage tanks are not subject to Subpart GGG 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).

(e) Storage Tank Module (T147)

40 CFR 60, Subpart Kb – Volatile Organic Liquid Storage Vessels
The storage tanks (T147-001 – T147-012) associated with the T147 tank module are not subject to Subpart Kb, because the individual tank capacities are less than 75 cubic meters.

NSPS 40 CFR 60, Subpart VV – Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry – The storage tanks in the T147 tank module are not subject to this rule. Although the site is a synthetic organic chemical manufacturing facility and the T147 tanks were constructed after the applicability date, the tanks do not contain chemicals referenced in the rule. Therefore, this rule does not apply to the T147 tank module.

This determination is based on the decision to dedicate the T147 tank module to provide service to only the fermented products manufacturing area. Because the fermented products manufacturing area does not use chemicals referenced in the rule, this rule does not apply.

The existing permit requirement in CP 157-3319 relating to the T147 tank module and 326 IAC 8-5-3 has not been incorporated into the Title V permit.

40 CFR 63, Subpart GGG – Pharmaceutical MACT
The storage tanks associated with the T147 tank module are not subject to Subpart GGG because these tanks do not store HAP compounds pursuant to 40 CFR 63.1251 (Storage Tank Definition).

State Rule Applicability

(a) Building T3

326 IAC 8-1-6 – VOC BACT Rule
The T3 purification process equipment is not subject to 326 IAC 8-1-6 because either the equipment was installed before January 1, 1980 or VOC emissions from the equipment are less than 25 tons per year.

326 IAC 8-5-3 – Synthesized Pharmaceutical Manufacturing Operations – With the exception of the rotary vacuum dryer, the fermentation and purification operations do not manufacture pharmaceutical products by chemical synthesis. Therefore, this equipment is not subject to this requirement.

The rotary vacuum dryer has the capability to dry pharmaceutical intermediates/products produced by chemical synthesis. However, when the dryer processes chemically synthesized products, the potential to emit VOC is less than 15 lb/day. Therefore, the control requirements of Rule 8-5-3 does not apply to the rotary vacuum dryer, even when processing chemically synthesized products.

326 IAC 8-6-1 – Organic Solvent Rule
The T3 purification process equipment is not subject to the requirements of 326 IAC 8-6-1 because the equipment was installed prior to October 7, 1974 or after January 1, 1980, or the equipment does not have potential VOC emissions greater than 100 tons per year.

(b) Solvent Recovery Area (T4)

326 IAC 8-1-6 – VOC BACT Rule
The emission units associated with the T4 solvent recovery operations are not subject to 326 IAC 8-1-6 because the equipment was installed before January 1, 1980 or VOC emissions are less than 25 tons per year.

326 IAC 8-5-3 – Synthesized Pharmaceutical Manufacturing Operations
The fermentation and purification operations do not manufacture pharmaceutical products by chemical synthesis. Therefore, this equipment is not subject to this requirement.

326 IAC 8-6-1 – Organic Solvent Rule
The T4 solvent recovery equipment is not subject to the requirements of 326 IAC 8-6-1 because the equipment was installed prior to October 7, 1974 or after January 1, 1980.

(c) Product Storage Area (T39)

326 IAC 8-1-6 – VOC BACT Rule
The T39 storage tanks are not subject to 326 IAC 8-1-6 because the equipment was installed before the January 1, 1980 applicability date.

326 IAC 8-5-3 – Synthesized Pharmaceutical Manufacturing Operations
The fermentation and purification operations do not manufacture pharmaceutical products by chemical synthesis. Therefore, this equipment is not subject to this requirement.

326 IAC 8-6-1 – Organic Solvent Rule
The T39 storage tanks are not subject to the requirements of 326 IAC 8-6-1 because tanks T39-021, T39-022, T39-023 were installed prior to the October 7, 1974 applicability date and because the potential VOC emissions from tanks T39-030, T39-031, T39-036, installed between October 7, 1974 and January 1, 1980, are less than 100 tons per year.

(d) Storage Tank Module (T147)

326 IAC 8-1-6 – VOC BACT Rule
The storage tanks associated with the T147 tank module are not subject to 326 IAC 8-1-6 because the potential VOC emissions from the tanks are less than 25 tons per year.

This determination is based on the potential emission calculations using the worst-case solvent (amyl acetate) used in the purification operations since this tank module is dedicated to the fermented products manufacturing area.

326 IAC 8-6-1 – Organic Solvent Rule
The storage tanks associated with the T147 tank module are not subject to the requirements of 326 IAC 8-6-1 because the tanks were installed after January 1, 1980.

326 IAC 8-5-3 – Synthesized Pharmaceutical Manufacturing Operations – The T147 tank module only serves the fermented products manufacturing area. Products manufactured in the fermented products area are based on fermentation principles, not by chemical synthesis. Therefore, the storage tanks associated with T147 tank module are not subject to this requirement.

Construction Permit 157-3319 states that the T147 tank module is subject to this rule. Because the T147 tank module only serves the fermented products area that manufactures dedicated products using non-chemical synthesis techniques, the requirements of 326 IAC 8-5-3 do not apply. The existing permit terms in CP 157-3319 related to 326 IAC 8-5-3 and the T147 tank module have not been incorporated into the Title V permit.

326 IAC 2-2 – Prevention of Significant Deterioration – CP 157-3319 established VOC emission limits on tank modules T143, T145, T146, and T147 to avoid the requirements of PSD. This permit requires the use of VOC controls to satisfy emission netting done in the permit. Tank modules T143, T145, and T146 are associated with the BPM operations, while tank module T147 is dedicated to fermented products operations.

As part of the Title V permitting process, the tank modules associated with BPM operations (T143, T145, T146) have been evaluated under the PSD program. Therefore, the VOC emission limits established in CP 157-3319 for these tank modules no longer apply. These tank modules were evaluated under the PSD program because they are part of the flexible permit strategy for the BPM operations.

Because the fermented products (fermentation and purification) operations manufacture dedicated products which do not require many physical changes or changes in the method of operation, this flexibility is not necessary. Using solvents associated with the fermented products operations, the potential uncontrolled VOC emission calculations for the T147 tank module are below the PSD significant threshold levels. Therefore, the emission limit required by CP 157-3319 has not been included in the Title V permit. Any change to the T147 tank module would require a permit assessment before such change could be made.

Compliance Requirements

The emission units associated with the purification operations are not subject to any compliance requirements beyond record keeping requirements.

D.5: Fermented Products – Support Operations

Background and Description

The support operations for the Fermented Products (FP) area consists of the FP wastewater treatment plant and FP wastewater sludge storage operations. The pollutants of concern are VOCs, hydrogen sulfide, total reduced sulfur compounds, reduced sulfur compounds, SO2, CO, NOx and particulates. The following summary has been prepared for each of these areas making up the FP Support Operations section of the Title V permit to document technical information used to prepare the Title V permit conditions and to demonstrate compliance with the Title V permit requirements.

Types of Emission Units and Pollution Control Equipment

(a) Fermented Products Wastewater Treatment Plant

The wastewater from the fermentation and purification manufacturing areas is collected in an equalization system. The wastewater is then treated in the biological treatment facilities consisting of aeration tanks, clarifiers, and nitrification/denitrification tanks. A majority of the emissions associated with the wastewater treatment plant are exhausted to a voluntary thermal research foul air incinerator (T174) for odor control.

(b) Fermented Products Wastewater Sludge Management

Upon the completion of wastewater treatment, sludge is removed from the clarifiers and a portion is wasted from the system. This sludge is centrifuged to increase the solids content and then stored in four bio-solids storage tanks. Emissions from the bio-solids storage tanks are controlled by the iron sponge reactor. Emissions may also be voluntarily controlled by the thermal research foul air incinerator (T174) for odor control.

Insignificant Activities

(a) Fermented Products Wastewater Treatment Plant

With the exception of tanks TK101 through TK104 and TK120, the emission units associated with the fermented products wastewater treatment plant are “insignificant activities” as defined in 326 IAC 2-7-1(21). TK101 through TK104 and TK120 are not insignificant activities because each tank has potential total reduced sulfur emissions greater than 5 tons per year.

Federal Rule Applicability

(a) Fermented Products Wastewater Treatment Plant

40 CFR 60, Subpart Kb – Volatile Organic Liquid Storage Vessels
The tank emission units associated with the fermented products wastewater treatment plant are not subject to Subpart Kb because they were all installed prior to the July 23, 1984 rule applicability date and the tanks have not been modified since the applicability date.

40 CFR 63, Subpart GGG – Pharmaceutical MACT
The emission units associated with the FP support operations are not subject to 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).

(b) Fermented Products Wastewater Sludge Management

40 CFR 60, Subpart Kb – Volatile Organic Liquid Storage Vessels
The bio-solids storage tanks are subject to Subpart Kb because they were installed after July 23, 1984 and have individual capacities greater than 19,812 gallons. Because these storage tanks have volumes greater than 39,889 gallons, but contain a material with a vapor pressure of less than 3.5 kPa (the bio-solids have a vapor pressure of 2.34 kPa at 20^0C), the Permittee is only required to maintain records of the storage tank capacities and dimensions for the life of the source.

40 CFR 63, Subpart GGG – Pharmaceutical MACT
The emission units associated with the FP support operations are not subject to Subpart GGG 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).

State Rule Applicability

(a) Fermented Products Wastewater Treatment Plant

326 IAC 2-2 – Prevention of Significant Deterioration (PSD)
The requirements of PSD for hydrogen sulfide and total reduced sulfur compounds do not apply to tanks 101, 102, 103, and 104 because these tanks were installed in 1960, prior to the PSD regulations. Hydrogen sulfide and total reduced sulfur emissions are less than 10 tons per year for all other equipment installations after 1977.

326 IAC 4-2 – Incinerators
The thermal research foul air incinerator (T174) is not subject to the requirements of 326 IAC 4-2 because it does not incinerate solid or liquid waste.

Operation Permit 79-04-90-0386 allowed for the operation of four incinerators. The permit conditions broadly required that all of the incinerators comply with the particulate matter emission standards in 326 IAC 4-2. Because the voluntary foul air incinerator is only used to control odor and not used to burn solid or liquid wastes, it is not subject to the requirements of 326 IAC 4-2.

326 IAC 8-1-6 – VOC BACT Rule
The FP wastewater treatment plant is not subject to the state BACT requirements under 326 IAC 8-1-6 because the equipment was installed prior to the 1980 rule applicability date or because the VOC emissions associated with each emission unit or emission project are less than 25 tons per year.

326 IAC 8-5-3 – Synthesized Pharmaceutical Manufacturing Operations
The fermentation and purification operations do not manufacture pharmaceutical products by chemical synthesis. Therefore, this equipment is not subject to this requirement.

(b) Fermented Products Wastewater Sludge Management

326 IAC 2-2 – Prevention of Significant Deterioration (PSD)
The requirements of PSD for hydrogen sulfide, total reduced sulfur, and reduced sulfur compounds do not apply to bio-solids storage tanks because CP 157-4363, Amendment 157-8953 and minor source Modification 157-24812-00006 establish enforceable emission limits and control requirements.

The PSD significant threshold levels for each pollutant (hydrogen sulfide, total reduced sulfur and reduced sulfur) is 10 tons per year, while the emission limitation in the existing construction permits and amendment is 4 tons per year. The outlet concentration limit has been revised in the Title V permit as follows to reflect an emission limit that shall equal or exceed 10 tons TRS per year:

Max Gas Flow Rate	=	800 acfm
TRS Emission Limit	<	10 tpy, 2.28 lb/hr
Conversion Factor	=	28.3 liters/cf
Conversion Factor	=	454 grams/lb
Conversion Factor	=	10^6 ug/g
Max Outlet TRS Conc	<	(hourly emission rate) / (gas flow rate)

$< (2.28 \text{ lb/hr} \times 454\times10^6 \text{ ug/lb}) / (800 \text{ acfm} \times 28.3 \text{ l/cf} \times 60 \text{ min/hr})$

< 762 ug/l

The hydrogen sulfide and reduced sulfur compounds are a subset of total reduced sulfur. Therefore, compliance with the TRS emission limit will satisfy compliance with the hydrogen sulfide and reduced sulfur compound emission limits.

The control requirements established in the existing permit and amendment have also been revised in the Title V permit to eliminate redundancy and unnecessary monitoring tasks. Because the air flowrate and pressure drop across the iron sponge reactor are both used to demonstrate that the bio-solids tanks are exhausting to the iron sponge and that the iron sponge is operating properly, only one of these monitoring parameters is necessary. The Title V permit only requires that the pressure drop be measured once per day.

326 IAC 8-1-6 – VOC BACT Rule
The storage tanks are not subject to the state BACT requirements under 326 IAC 8-1-6 because the potential VOC emissions are less than the applicability threshold level of 25 tons per year.

326 IAC 8-5-3 – Synthesized Pharmaceutical Manufacturing Operations
The fermentation and purification operations do not manufacture pharmaceutical products by chemical synthesis. Therefore, the fermented products support equipment is not subject to this requirement.

Compliance Requirements

(a) Wastewater Sludge Management Operations

The following compliance activities are required for the iron sponge reactor associated with the wastewater sludge management operations:

1. The TRS outlet concentration of the iron sponge shall be measured and analyzed once per calendar week.

2. The pressure drop across the iron sponge reactor shall be monitored once per day. The reading should be within a pressure drop range of 0.2 – 2.0 inches water column.

Appendix A

Indiana Department of Environmental Management
Office of Air Quality

Section D.6 - Section D 11

D.6: BPM Operations

Background and Description

The bulk pharmaceutical manufacturing (BPM) component of Tippecanoe Labs currently consists of Buildings T27, T28, T29, T31, T31A, T99, and T100. Pharmaceutical products are manufactured in bulk scale in all of these buildings using batch type processing operations. Historically Buildings T31 and 31A have been referred to as the "pilot plant". While generally the equipment in T31/31A is used for scale-up development of new pharmaceutical products and production of clinical trial materials, manufacturing of product material for sale can occur in these buildings. Therefore, Buildings T31/31A have been included in the rule applicability determination.

Types of Emission Units and Pollution Control Equipment

A wide variety of process equipment, also referred to as process vents, can be used in a number of different manufacturing operations including distillations, heating, cooling, chemical reactions, filtration, cetrifugation, and drying. The centrifuges are used to separate solids and mother liquor for both intermediate and final separations. The dryers are used to remove any residual solvent from the centrifuged wet cake. The following types of process vents, controlled by two Regenerative Thermal Oxidizers equipped with caustic scrubbing systems (RTO system), are used in the bulk pharmaceutical manufacturing operations:

Process Tanks
While these tanks are only used in the production of bulk pharmaceutical drugs, the type of products manufactured will vary with market demand. The process used to model the emissions from process tanks is a worst-case process designed to give a maximum emissions estimate for any process that may be run in the equipment. Some of the tanks in the manufacturing areas are not as versatile as the general process tanks because they do not have jackets. Jackets supply heating/cooling media (i.e. MACE, ethyene glycol, syltherm) that is needed to perform heating/cooling process activities. Process tanks without jackets include charge tanks (used to prepare solutions that will be transferred to a general process tank for further processing) and accumulator tanks (used to collect condensate from condensers on stills and dryers). Depending on process chemistry, process scrubbers and process condensers may be required in the manufacture of certain products. The process scrubber systems and condenser operations are an integral part of the process tanks.

Centrifuges
There are two types of centrifuges, basket and Heinkel centrifuges. The centrifuges separate solids and mother liquor for both intermediate and final separations. Centrifugation can be broken down into steps that include loading the slurry, spin cycles to separate the liquid from the solid wash cycles to clean impurities from crystals, and unloading the crystals.

Dryers
There are various types of dryers used in bulk pharmaceutical manufacturing. Rotary vacuum dryers (RVDs) are most common, but filter/dryers, pan dryers, vacuum shelf dryers, and fluid bed dryers are also used. The dryers in T31/T31A are portable and may be moved between the two buildings.

General Activities
General activities such as open manway operations, charging a liquid from a drum to a tank, centrifuge emptying operations, drum filling operations, or loading wetcake into driers are also defined as process

vents. Individual identification of these activities are not listed in the description tables given they are not stationary or continually change.

Insignificant Activities

The general activities associated with the production operations, such as open manway operations, charging a liquid from a drum to a tank, centrifuge emptying operations, drum filling operations, or loading wetcake into driers, are considered insignificant activities pursuant to 326 IAC 2-7-1(21)(E).

Federal and State Rule Applicability Streamlining Proposal

The equipment and process vents that comprise BPM are subject to several similar and overlapping emission limitations and other requirements. In such situations, Indiana's Title V program rules provide a means to streamline the multiple requirements into a comprehensive, but simplified set of requirements. Lilly has proposed to streamline the requirements of 326 IAC 8-5-3 [the Indiana RACT rule for synthesized pharmaceutical manufacturing operations] and the SOCMI HON Subpart I LDAR [40 CFR Part 63, Subpart I] into more stringent applicable requirements found in the Pharmaceutical MACT rules and the flexible PSD permit requirements that will be established in the Title V permit. To the extent possible, the flexible permit requirements will mirror the Pharmaceutical MACT requirements, thereby establishing the Pharmaceutical MACT requirements as the default most stringent requirements of the applicable rules. IDEM has reviewed the streamlining proposal and has determined it meets the requirements of 326 IAC 2-7-24.

Applicability

The following streamlining table is applicable only to the Bulk Pharmaceutical Production (BPM) buildings at Tippecanoe Laboratories, including the production buildings identified as T27, T28, T29, T31/T31A, T99 and T100. It does not apply to BPM support operations such as waste management, solvent recovery and storage tanks. The types of emitting equipment found in the BPM buildings includes process tanks, reactors, distillation units, crystallizers, filters, centrifuges, and dryers. Fugitive emissions may be emitted from components such as piping connectors, pumps, valves and agitators.

Overview of applicable requirements

The equipment in these buildings is currently subject to three air pollution control requirements dealing with volatile organic compound emissions (VOC) and volatile hazardous air pollutant emissions (VOHAP): 326 IAC 8-5-3 [an Indiana RACT rule applicable to synthesized pharmaceutical manufacturing facilities], 40 CFR 63 Subpart I [a fugitive emissions control rule applicable to, among other things, pharmaceutical manufacturing facilities using methylene chloride or carbon tetrachloride], and 40 CFR 63, Subpart GGG [Pharmaceutical Production MACT]. The equipment in these production buildings will be subject to the "process vent" standards in 40 CFR 63.1254 and the fugitive emission control program in 40 CFR 63.1255. Upon issuance of this permit, the Permittee will also be subject to BACT and flexible permit requirements established in this permit. The BACT limits are materially consistent with the MACT requirements.

Comparison of applicable requirements

326 IAC 2-7-24(b) requires any Permittee that seeks to streamline multiple applicable requirements to present a side-by-side comparison of the requirements and the proposed streamlining. The attached table presents a comparison of 326 IAC 8-5-3, 40 CFR Part 63 Subpart GGG and the proposed flexible permit requirements. Generally, Subpart GGG is the most stringent and extensive requirement and forms the basis of the streamlined requirement.

The fugitive emission control program in 40 CFR 63, Subpart I is not included in the attached table because streamlining of that provision is very simple. 40 CFR 63.1250(h)(4) [part of the pharmaceutical production MACT] provides that a source may comply with Subpart I by complying with the fugitive emissions control program in the pharmaceutical MACT rules. Therefore, no additional comparison is needed

BPM production Operations: Streamlining Table.

Affected Units: Unit operations in pharmaceutical production buildings	Current applicable requirements			Streamlined applicable requirement
	326 IAC 8-5-3 (Synthetic Pharmaceutical RACT)	40 CFR Part 63, Subpart GGG, (Pharmaceutical MACT)	326 IAC 2-2-3 (PSD BACT)	
Applicability				
	VOC emissions > 15 lb/day and constructed after 1/1/80 [326 IAC 8-5-3(a)]	Process vents with ≥ 50 ppm HAP [40 CFR 63.1251]	Process vents > 15 lbs/day VOC or ≥ 50 ppm VOC	Process vents ≥ 50 ppm HAP and /or ≥ 50 ppm VOC or Process vents > 15 lbs/day VOC
Emission limits, control requirements, performance requirements, and work practices				
TOC Point Source Emission Limits and Standards	This rule requires that TOC BPM operation emissions above the applicability threshold be routed to a control device. The details are described in the RTO control device section.	This rule requires that TOC BPM operation emissions above the applicability threshold be routed to a control device. The details are described in the RTO control device section.	The PSD BACT requirement and streamlined requirement requires BPM operation emissions greater than the applicability threshold be routed to the RTO control system via a closed vent system. The control device standards and limits are addressed in the RTO section of this TSD.	
TOC Point Source Emission Limits and Standards not requiring control device	No control required if below the applicability threshold levels described above	Mass Limitations: Uncontrolled process vents within a single process < 900 kg HAP (TOC +HX) *AND* Combined Uncontrolled Processes < 1800 kg HAP [63.1254(a)(3)]	Mass Limitations: Uncontrolled process vents within a single process < 900 kg HAP (TOC + HX) AND Combined Uncontrolled Processes < 1800 kg HAP	
Hydrogen Halide (HX) Point Source Emission Limits and Standards	N/A	This rule requires that BPM operation emissions above the applicability threshold be routed to a control device. The details are described in the RTO control device section.	The PSD BACT requirement and streamlined requirement requires BPM operation emissions greater than the applicability threshold be routed to the RTO control system via a closed vent system. The control device standards and limits are addressed in the RTO section of this TSD.	
Hydrogen Halide (HX) Point Source Emission Limits and Standards not requiring control device	None specified	Uncontrolled process vents within a single process < 900 kg HAP (TOC +HX) *AND* Combined Uncontrolled Processes < 1800 kg HAP [63.1254(a)(3)]	Uncontrolled process vents within a single process < 900 kg HAP (TOC +HX) *AND* Combined Uncontrolled Processes < 1800 kg HAP (TOC + HX)	
Heat Exchange System Requirement	No comparable provisions	Inspect physical integrity of heat exchange system that uses water to cool process equipment/materials in accordance with current good manufacturing	Inspect physical integrity of heat exchange systems that use water to cool process equipment/materials in accordance with current good manufacturing practice.	

Affected Units: Unit operations in pharmaceutical production buildings	Current applicable requirements			Streamlined applicable requirement
	326 IAC 8-5-3 (Synthetic Pharmaceutical RACT)	40 CFR Part 63, Subpart GGG, (Pharmaceutical MACT)	326 IAC 2-2-3 (PSD BACT)	
		practice.		
Work Practice Standards	Enclose centrifuges, rotary vacuum filters and other filters with exposed surfaces [326 IAC 8-5-3(b)(4)] AND Keep covers in place for inprocess tanks [326 IAC 8-5-3(b)(5)]	No comparable provision	Enclose centrifuges, rotary vacuum filters and other filters with exposed surfaces AND Keep covers in place for inprocess tanks	
TOC Fugitive Emission Standards	These emission standards are addressed in the LDAR section of this TSD.			
Compliance demonstration methods				
TOC and HX Continuous emissions monitoring (CEMS) requirements	These compliance standards for the control devices are addressed in the RTO section of the TSD			
TOC and HX Continuous Monitoring System (CMS) Requirements	These compliance standards for the control devices are addressed in the RTO section of the TSD			
TOC and HX Stack Testing Requirements	These compliance standards for the control devices are addressed in the RTO section of the TSD			
Record keeping and reporting				
Record keeping	None	Records of mass limits [1259(b)(5(ii)] Records of compliance with control device standards [63.1259] are addressed in RTO section AND Records of HAP LDAR standards are addressed in LDAR section	Records necessary to demonstrate compliance with short term BACT limits (e.g., MACT monitoring data) and emission caps are addressed in the RTO section and Change Management section, respectively AND Records of LDAR standards are addressed in LDAR section	Records of mass limits Records of compliance with control device standards are addressed in RTO section of this TSD AND Records of LDAR standards are addressed in LDAR section of this TSD
Reporting	None	Reporting requirements for control device standards are addressed in RTO section Reporting requirements for LDAR standards are addressed in LDAR		

Affected Units: Unit operations in pharmaceutical production buildings	Current applicable requirements			Streamlined applicable requirement
	326 IAC 8-5-3 (Synthetic Pharmaceutical RACT)	40 CFR Part 63, Subpart GGG, (Pharmaceutical MACT)	326 IAC 2-2-3 (PSD BACT)	
		section		

Other Federal Requirements

There are no other federal requirements that apply specifically to the BPM operating areas.

Other State Requirements

There are no other state requirements that apply specifically to the BPM operating areas.

Testing and Compliance Requirements

The compliance determination and compliance monitoring requirements for the BPM process vents are described in the streamlining proposal above.

D.7: BPM Solvent Recovery Operations

Background and Description

The solvent recovery operations at Tippecanoe Labs currently consist of Buildings T19, T52, T61 and T127. Spent solvent from both onsite pharmaceutical operations and offsite pharmaceutical operations at other Lilly facilities are recovered in these buildings.

Types of Emission Units and Pollution Control Equipment

Equipment used in the solvent recovery operations is also referred to as process vents. Typical solvent recovery equipment includes distillation equipment, evaporators, steam strippers, wash columns, and receivers. Emissions associated with the distillation columns, evaporators, steam strippers, and wash columns occur during the initial start up. Once the inerts initially present in the equipment are purged from the system and the equipment is operating at steady state, no emissions occur. Emissions from the receivers occur as they are filled. The solvent recovery equipment currently in operation is controlled by the T79 fume incinerator system followed by a caustic scrubbing system. Solvent recovery equipment currently not in operation shall be connected to either the RTO system or T79 fume incinerator system prior to operation.

Insignificant Activities

None of the BPM solvent recovery equipment is considered an insignificant activity pursuant to 326 IAC 2-7-1(21)(E).

Federal and State Rule Applicability Streamlining Proposal

The process vents that comprise the BPM solvent recovery operations are potentially subject to several similar and overlapping emission limitations and other requirements. In such situations, Indiana's Title V program rules provide a means to streamline the multiple requirements into a comprehensive, but simplified set of requirements. Lilly has proposed to streamline the requirements of 326 IAC 8-5-3 [the Indiana RACT rule for synthesized pharmaceutical manufacturing operations] and the requirements of 40 CFR 63.690 [Offsite waste and Recovery Operations Standards for process vents] into more stringent applicable requirements found at 40 CFR 63.1254 [Pharmaceutical MACT Standards for process vents]. To the extent possible, the flexible PSD permit requirements will mirror the Pharmaceutical MACT requirements, thereby establishing the Pharmaceutical MACT requirements as the default most stringent requirements of the applicable rules. IDEM has reviewed the streamlining proposal and has determined it meets the requirements of 326 IAC 2-7-24.

Applicability
The following streamlining table is applicable only to the BPM solvent recovery buildings (T19, T52, and T62) at Tippecanoe Laboratories. Fugitive emissions emitted from components such as piping connectors, pumps, valves and agitators are addressed in the LDAR section of this TSD.

Overview of applicable requirements
The equipment in these buildings is potentially subject to three air pollution control requirements dealing with volatile organic compound emissions (VOC) and volatile hazardous air pollutant emissions (VOHAP): 326 IAC 8-5-3 [an Indiana RACT rule applicable to synthesized pharmaceutical manufacturing facilities], 40 CFR 63 Subpart DD [Offsite Waste and Recovery Operations MACT], and 40 CFR 63, Subpart GGG [Pharmaceutical Production MACT]. The equipment in these production buildings will be subject to the "process vent" standards in 40 CFR 63.1254 and the fugitive emission control program in 40 CFR 63.1255. Upon issuance of this permit, the Permittee will also be subject to BACT and flexible permit requirements established in this permit. The BACT limits are materially consistent with the MACT requirements.

Comparison of applicable requirements
326 IAC 2-7-24(b) requires any Permittee that seeks to streamline multiple applicable requirements to present a side-by-side comparison of the requirements and the proposed streamlining. The attached table presents a comparison of 326 IAC 8-5-3, 40 CFR 63 Subpart DD, 40 CFR 63 Subpart GGG and the proposed flexible permit requirements. Generally, Subpart GGG is the most stringent and extensive requirement and forms the basis of the streamlined requirement.

BPM Solvent Recovery Operations: Streamlining Table

Affected Units: Solvents recovery operations	Current applicable requirements				Streamlined applicable requirement
	326 IAC 8-5-3 (Synthetic Pharma. RACT)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma. MACT)	326 IAC 2-2-3 (PSD BACT)	
Applicability					
	VOC emissions > 15 lb/day and constructed after 1/1/80 [8-5-3(a)]	Any new/existing/ modified process vent containing offsite waste with a VOHAP content of ≥ 500 ppmw [63.680(b)(1) and 63.683(b)(1)(iii)]	Process vents ≥ 50 ppmv HAP [63.1251]	Process vents ≥ 50 ppmv VOC OR Process vents > 15 lb/day VOC	Process vents ≥ 50 ppmv HAP and/or ≥ 50 ppmv VOC OR Process vents > 15 lb/day VOC
Emission limits, control requirements, performance requirements, and work practices					
TOC Point Source Emission Limits and Standards	These control device standards and limits are addressed in either the T79 section or RTO section of the TSD				
TOC Point Source Emission Limits and Standards not requiring control device	See applicability threshold levels above	See applicability threshold levels above	Mass Limitations: Uncontrolled process vents in a single process < 900 kg HAP (TOC + HX) AND combined uncontrolled processes <1800kg [63.1254(a)(2)]	Mass Limitations: Uncontrolled process vents within a single process < 900 kg HAP (TOC + HX) AND Combined Uncontrolled Processes < 1800 kg HAP	
Hydrogen Halides (HX) Point source emission limits and standards	These control device standards and limits are addressed in either the T79 section or RTO section of the TSD				

Affected Units: Solvents recovery operations	Current applicable requirements				Streamlined applicable requirement
	326 IAC 8-5-3 (Synthetic Pharma. RACT)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma. MACT)	326 IAC 2-2-3 (PSD BACT)	
Hydrogen Halides (HX) Point source emission limits and standards requiring no control device	N/A	None specified	Mass Limitations: Uncontrolled process vents in a single process < 900 kg HAP (TOC + HX) AND combined uncontrolled processes < 1800 kg HAP [63.1254(a)(2)]		Mass Limitations: Uncontrolled process vents within a single process < 900 kg HAP (TOC + HX) AND Combined Uncontrolled Processes < 1800 kg HAP
Heat Exchange System Requirement	No comparable provisions	No comparable provisions	Inspect physical integrity of heat exchange system that uses water to cool process equipment/materials in accordance with current good manufacturing practice.		Inspect physical integrity of heat exchange systems that use water to cool process equipment/materials in accordance with current good manufacturing practice.
TOC fugitive emissions	Fugitive TOC emissions are addressed in the LDAR section of this TSD				
Compliance demonstration methods					
TOC and HX CEMS requirements	These compliance standards for control devices are addressed in either the T79 section or RTO section of the TSD				
TOC and HX CMS requirements	These compliance standards for control devices are addressed in either the T79 section or RTO section of the TSD				
TOC and HX stack testing requirements	These compliance standards for control devices are addressed in either the T79 section or RTO section of the TSD				
Record keeping and reporting					
Record keeping	None	Records of compliance with control device standards are addressed in the RTO and T79 sections of this TSD AND Records of HAP LDAR standards are addressed in LDAR section of this TSD	Records of mass limits [63.1259(b)(5(ii)] AND Records of compliance with control device standards are addressed in the RTO and T79 sections of this TSD AND Records of HAP LDAR standards are addressed in LDAR section of this TSD		Records of mass (TOC+HX) limits AND Records to demonstrate compliance with BACT limits (e.g., MACT monitoring data) and emission caps are addressed in the RTO and T79 sections and Change Mgmt section of this TSD AND Records of HAP LDAR standards are addressed in LDAR section of this TSD
Reporting	None	Reporting requirements for control device standards are addressed in the RTO and T79 sections of this TSD AND Reporting requirements for LDAR standards are addressed in LDAR section	Reporting requirements for control device standards are addressed in the RTO and T79 sections of this TSD AND Reporting requirements for LDAR standards are addressed in LDAR section of		Streamlined reporting requirements for control device standards are addressed in the RTO and T79 sections of this TSD AND Reporting requirements for LDAR standards [re addressed in LDAR section of this TSD

Affected Units:	Current applicable requirements				Streamlined applicable requirement
Solvents recovery operations	326 IAC 8-5-3 (Synthetic Pharma. RACT)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma. MACT)	326 IAC 2-2-3 (PSD BACT)	
	of this TSD	this TSD			

Other Federal Requirements

There are no other federal requirements that apply specifically to the BPM solvent recovery operations.

Other State Requirements

There are no other state requirements that apply specifically to the BPM solvent recovery operations.

Testing and Compliance Requirements

The compliance determination and compliance monitoring requirements for the BPM solvent recovery operations are described in the streamlining proposal above.

D.8: BPM Individual Drain Systems (IDSs)

Background and Description

BPM individual drain systems (IDSs) serve the BPM operations and BPM solvent recovery operations at Tippecanoe Labs. Individual drain systems supporting fermentation-type operations are outside the scope of this section. Individual drain systems are stationary systems used to convey waste streams to a waste management unit. Segregated stormwater sewer systems designed and operated for the sole purpose of collecting rainfall-runoff at a facility are not considered IDSs.

Types of Emission Units and Pollution Control Equipment

BPM IDSs operated above the applicability threshold established in the streamlining table below shall be routed to either the RTO or T79 fume incinerator at all times waste material is in the BPM IDS, unless it is necessary to use the opening for sampling or removal of material, or for equipment inspection, maintenance, or repair.

Insignificant Activities

The BPM IDSs qualify as insignificant activities pursuant to 326 IAC 2-7-1(21) because VOC emissions are equal to or less than 3 pounds per hour or 15 pounds per day.

Federal and State Rule Applicability Streamlining Proposal

The purpose of this streamlining proposal is to demonstrate that the requirements of 40 CFR 63, Subpart DD [the NESHAP for offsite waste and recovery operations] can be streamlined into more stringent applicable requirements found in 40 CFR 63, Subpart GGG [the Pharmaceutical MACT rules for IDSs] and the flexible PSD permit requirements that will be established in the Title V permit. To the extent possible, the flexible permit requirements will mirror the Pharmaceutical MACT requirements, thereby establishing the Pharmaceutical MACT requirements as the default most stringent requirements of the applicable rules.

Applicability
This proposal is applicable only to BPM IDSs containing waste from BPM operations at Tippecanoe Laboratories and/or waste from offsite sources that exceed the applicability threshold concentrations

addressed below in the streamlining table. IDSs supporting fermentation-type operations are outside the scope of this specific operating area.

Overview of applicable requirements

BPM IDSs supporting bulk pharmaceutical manufacturing operations and support operations are subject to the pharmaceutical manufacturing MACT rules for IDSs (40 CFR Part 63, Subpart GGG) and the off-site waste and recovery operations MACT rules for IDSs (40 CFR Part 63, Subpart DD). In addition to this streamlining proposal, Tippecanoe Laboratories is seeking a PSD permit applicable to this area of the plant site that will impose BACT limits on the BPM IDSs that will require more stringent control than those covered under the Pharmaceutical MACT requirements and Offsite Waste MACT requirements.

The most complex aspect of developing a streamlining proposal for waste storage containers is the different applicability thresholds and the types of waste streams covered for the various requirements of the rule.

Comparison of applicable requirements
According to the requirements of 326 IAC 2-7-24(b), any Permittee that seeks to streamline multiple applicable requirements must present a side-by-side comparison of the requirements and the proposed streamlining. The attached table presents a comparison of 40 CFR Part 63 Subpart GGG, 40 CFR 63 Subpart DD and the proposed flexible PSD permit requirements.

BPM Individual Drain Systems.

Affected Units: BPM Individual Drain Systems (IDs)	Applicable Rules			Streamlined Applicable Requirements
	Pharma MACT Standards - IDS (40 CFR Part 63, Subpart GGG)	Offsite Waste MACT Standards - IDS (40 CFR 63, Subpart DD)	PSD BACT Standards (326 IAC 2-2-3)	
Applicability				
	Affected wastewater or wastewater residuals containing: Partially soluble HAP annual avg. concentration > 1300 ppmw and total soluble and partially soluble HAP > 0.25 Mg/yr Partially soluble and/or soluble HAP annual avg. concentration > 5200 ppmw, and total soluble and partially soluble HAP > 0.25 Mg/yr [63.1256(a)(1)(i) and (ii)]	IDSs (i.e., transfer systems) containing off-site waste streams of HAP $\geq$ 1 Mg/year [63.680(b)(1), 63.680(c)(1) and 63.683(c)(2)]	All BPM IDSs containing waste streams of VOC > 0.25 Mg/year	All BPM IDSs containing waste streams of VOC > 0.25 Mg/yr and/or HAP > 0.25 Mg/yr
Notable exclusions	IDSs do not include a segregated stormwater sewer system, which is a drain and collection system designed and operated for the sole	IDSs do not include drains and collection systems that are designed and operated for the sole purpose of collecting rainfall runoff	Same exclusions allowed by other rules applied to BACT	BPM IDSs do not include drains and collection systems that are designed and operated for the sole purpose of collecting rainfall runoff

Affected Units: BPM Individual Drain Systems (IDs)	Applicable Rules			Streamlined Applicable Requirements
	Pharma MACT Standards - IDS (40 CFR Part 63, Subpart GGG)	Offsite Waste MACT Standards - IDS (40 CFR 63, Subpart DD)	PSD BACT Standards (326 IAC 2-2-3)	
	purpose of collecting rainfall-runoff at the facility, if it is segregated from all other IDSs [63.1251]	[63.681]		
Emission limits, control requirements, performance requirements, and work practices				
TOC Emission Limits and Standards	Wastewater streams > 1300 ppmw partially soluble HAP or > 5200 ppmw soluble and/or partially soluble HAP shall comply with the following requirements: Maintain IDS covers in closed position at all times except when necessary to use opening for sampling or removal, or for equipment inspection, maintenance, or repair [63.1256(e)(1)(i)(B)] OR If vented, route IDS vapors to a control device via a closed vent system	Off-site waste streams at the point of delivery (POD) that contain VOHAP concentration < 500 ppmw: No control device or cover is required AND Perform initial determination of average VOHAP concentration of each off-site material stream using procedures specified in 63.694(B) before waste streams placed in an IDS AND Review and update determination at least once every 12 months [63.683(b)(1)(iii)] _________________________ Off-site waste streams at the POD that contain VOHAP concentration $\geq$ 500 ppmw (*Lilly currently does not operate any of these*): All vented IDSs must be vented to a control device in accordance with 40 CFR 63, Subpart RR [63.689(b)] Maintain BPM IDS covers in closed position at all times except when necessary to use opening for sampling or removal, or for equipment inspection, maintenance, or repair [63.689]	BPM IDSs with waste streams at the point of delivery that contain VOHAP concentration < 500 ppmw or VOC concentration < 500 ppmw: No control device/cover required IF perform initial determination and annual review of average VOHAP concentration below thresholds ____ BPM IDSs with waste streams at the point of delivery that contain VOHAP concentration $\geq$ 500 ppmw or VOC concentration $\geq$ 500 ppmw: Vent IDSs to either the RTO system or T79 fume incinerator system via closed vent system at all times, except for sampling/removal of waste or for equipment inspection, maintenance, or repair	
Work Practice Standards – IDS	Initial/semiannual inspections of each cover for improper work practices/control device failures [63.1256(e)(2), 63.1258(g)(1), and Table 7]	Covers and closure devices on IDSs shall be visually inspected for defects initially and at least once per year [63.964(a)(1)(i)-(iv)] Detected defects must be repaired within 5/15 days, unless	Initial/semiannual inspections of each IDS cover for improper work practices and control device failures (access door open when not in use; cracks/gaps on gaskets, joints, lids, covers or doors) Repair shall be made within 5/15 days, except where delay of repair allowed	

<table>
<tr><td rowspan="2">Affected Units: BPM Individual Drain Systems (IDs)</td><td colspan="3">Applicable Rules</td><td rowspan="2">Streamlined Applicable Requirements</td></tr>
<tr><td>Pharma MACT Standards - IDS
(40 CFR Part 63, Subpart GGG)</td><td>Offsite Waste MACT Standards - IDS
(40 CFR 63, Subpart DD)</td><td>PSD BACT Standards
(326 IAC 2-2-3)</td></tr>
<tr><td></td><td>Repair leaks within 5/15 days, unless delay of repair allowed
[63.1256(e)(3) and 63.1256(i)]

AND

<u>IDS covers not under negative pressure:</u>
Initial M21 inspection and semiannual visual inspections for visible, audible, or olfactory indications of leaks
[63.1256(e)(1)(iii) and 63.1258(h)(2)(iii)]

Repair leaks within 5/15 days, unless delay of repair allowed
[63.1258(h)(4) and (h)(5)]

Inspections not required if unsafe or difficult to monitor
[63.1258(h)(6) and (h)(7)]

<u>IDS covers under negative pressure:</u>
Initial M21 or semiannual visual inspections NOT required
[63.1256(e)(1)(iv)]</td><td>delay of repair
[63.964(a)(1)(v) and (b)]</td><td colspan="2">AND

<u>IDS covers not under negative pressure:</u>
Initial M21 inspection and semiannual visual inspections for visible, audible, or olfactory indications of leaks for each IDS cover

Leaks must be repaired within 5/15 days, except where delay of repair allowed

Inspections not required if unsafe or difficult to monitor

OR

<u>IDS covers under negative pressure:</u>
Initial M21 or semiannual visual inspections NOT required</td></tr>
<tr><td colspan="5">Record keeping and reporting</td></tr>
<tr><td>Records</td><td>The following records shall be maintained for each IDS:

IDS inspections;
List unsafe to inspect facilities;
List difficult to inspect facilities;
Information on each inspection during which a leak is detected;
Date of each Method 21 inspection</td><td>The following records shall be maintained for each IDS:

IDS inspection plan, including drawings;
Dates each IDS inspection performed;
All defects detected during inspections
[63.964(b)(3) and 63.965(a)(3)]

Keep inspection records for period of 5 years
[63.10</td><td colspan="2">The following records shall be maintained for each waste IDS:

IDS inspections;
List of unsafe to inspect facilities;
List of difficult to inspect facilities;
Information on each inspection during which a leak is detected;
Date of each Method 21 inspection performed and statement that no leaks detected, if applicable;
Date of each visual inspection performed and statement that no leaks detected</td></tr>
</table>

Affected Units: BPM Individual Drain Systems (IDs)	Applicable Rules			Streamlined Applicable Requirements
	Pharma MACT Standards - IDS (40 CFR Part 63, Subpart GGG)	Offsite Waste MACT Standards - IDS (40 CFR 63, Subpart DD)	PSD BACT Standards (326 IAC 2-2-3)	
	performed and statement that no leaks detected, if applicable; Date of each visual inspection performed and statement that no leaks detected [63.1259(i)]			
Reports	Records of each inspection during which a leak is detected must be included in the next periodic report [63.1260(g)(2)(iii)]	None	Records of each inspection during which a leak is detected must be included in the next periodic report	

Other Federal Requirements

40 CFR 60, Subpart Kb – Volatile Organic Liquid Storage Vessels
The control requirements of this rule applies to storage tanks with a capacity greater than or equal to 40 cubic meters. The capacity of each BPM individual drain system is below the applicability threshold levels; therefore, the requirements of this rule do not apply to the individual drain systems.

Other State Requirements

326 IAC 8-5-3 – Synthesized Pharmaceutical Manufacturing Operations
The control requirements of 326 IAC 8-5-3 do not apply to the BPM individual drain systems because potential to emit from each individual drain system is less than 15 pounds per day.

Testing and Compliance Requirements

The compliance determination and compliance monitoring requirements for the BPM individual drain systems are described in the streamlining table above.

D.9 - BPM Solvent Storage Tanks

Background and Description

The BPM solvent storage tanks serve the bulk pharmaceutical manufacturing (BPM) operations at Tippecanoe Labs or store recovered solvent for other Lilly facilities. The BPM solvent storage tanks are located in Tank Modules T140, T143, T145, and T146.

Types of Emission Units and Pollution Control Equipment

The types of emission units subject to this specific operating area include solvent storage tanks that serve the BPM operations. Tanks supporting fermentation-type operations are outside the scope of this specific operating area because the tanks do not serve synthetic pharmaceutical operations and are not subject to 40 CFR 63, Subpart DD because the fermentation operations do not store or recover waste generated from offsite. The emissions from the BPM solvent storage tanks are controlled by one of two Regenerative Thermal Oxidizers equipped with caustic scrubbing systems (RTO system) or by one of two fume incinerators equipped with caustic scrubbing systems (T79 Fume Incinerator system).

Insignificant Activities

While some of the BPM solvent storage tanks may qualify as insignificant activities pursuant to 326 IAC 2-7-1, the PSD BACT requirements for tanks require that all BPM solvent storage tanks comply with the emission limitations and standards set forth in the Title V permit.

Federal and State Rule Applicability Streamlining Proposal

The purpose of this streamlining proposal is to demonstrate that the requirements of 326 IAC 8-5-3 [the Indiana RACT rule for synthesized pharmaceutical manufacturing operations, 40 CFR 60, Subpart Kb [the NSPS for volatile organic liquid storage vessels] can be streamlined into more stringent applicable requirements found in 40 CFR 63, Subpart GGG [the Pharmaceutical MACT rules for storage tanks] and the flexible PSD permit requirements that will be established in the Title V permit. To the extent possible, the flexible permit requirements will mirror the Pharmaceutical MACT requirements, thereby establishing the Pharmaceutical MACT requirements as the default most stringent requirements of the applicable rules.

Applicability
The following streamlining table is applicable only to storage tanks serving the BPM operations and storing raw material feedstocks or used solvent to be recovered that contain VOCs and/or VOHAP with a vapor pressure $\geq$ 3.5 kPa. Tanks supporting fermentation-type operations are outside the scope of this specific operating area because the tanks do not serve synthetic pharmaceutical manufacturing operations.

Overview of applicable requirements
Solvent storage tanks supporting bulk pharmaceutical manufacturing operations are subject to three potentially overlapping applicable requirements: an NSPS for solvent storage tanks (40 CFR Part 60, Subpart Kb), the pharmaceutical manufacturing MACT rules (40 CFR Part 63, Subpart GGG), and an Indiana RACT rule applicable to synthesized pharmaceutical manufacturing operations (326 IAC 8-5-3). Although two of the rules address volatile organic compound emissions (VOCs) and one rule addresses hazardous air pollutant emissions (HAP), the requirements will typically apply to the same tanks and require similar types of control measures. Because it is the most comprehensive and most stringent of the three rules, the Subpart GGG MACT rules generally serve as the basis for the streamlining proposal. In addition, Tippecanoe Laboratories is seeking a PSD permit applicable to this area of the plant site that will impose BACT limits on the tanks. To the extent possible, the BACT requirements will mirror the Pharmaceutical MACT requirements, which make up the most stringent requirements of the applicable rules.
The most complex aspect of developing a streamlining proposal for solvent storage tanks is the different applicability threshold for the various requirements of the rule. Requirements may vary depending on the year of construction or modification, the size of the tank, and the vapor pressure of the solvent material of the tank. In order to reduce complexity, this streamlining proposal applies only to tanks meeting the following criteria:

1. Storage tanks located in or supporting bulk pharmaceutical production operations. BPM pressure vessels greater than 204.9 kPa and vessels attached to motor vehicles are not storage tanks. Tanks supporting fermentation and extraction type operations are outside the scope of the PSD

permitting project; they are not subject to 326 IAC 8-5-3 and 40 CFR 63, Subpart GGG because the tanks do not serve synthetic pharmaceutical operations. The storage tanks supporting fermentation operations are identified separately under a different section of the Title V permit.

2. Storage tanks storing liquid VOC or volatile organic HAP (VOHAP) with a vapor pressure $\geq$ 3.5 kPa that are used as raw materials or storage systems for BPM production and BPM solvent recovery operations.

   Waste tanks, containers, and process tanks are subject to different applicable requirements than the solvent tanks in this proposal and are addressed under separate streamlining proposals in Sections D.10, D.11 and D.6 of the Title V permit, respectively.

3. Storage tanks with a fixed roof design and routed to a fume incinerator or a regenerative thermal oxidizer via an add-on closed vent system.

Even with the exclusion of waste tanks, containers, and process tanks, the applicability thresholds for the three rules vary greatly. As a further step for simplification, Lilly will generally propose to apply a requirement of a rule that would not otherwise apply to a particular tank.

Comparison of applicable requirements

According to the requirements of 326 IAC 2-7-24(b), any Permittee that seeks to streamline multiple applicable requirements must present a side-by-side comparison of the requirements and the proposed streamlining. The attached table presents a comparison of 40 CFR 60 Subpart Kb, 326 IAC 8-5-3, 40 CFR Part 63 Subpart GGG and the proposed flexible PSD permit requirements. Generally, Subpart GGG is the most stringent and extensive requirement and forms the basis of the streamlined requirement.

The fugitive emission control program for these operations is described in the specific operating area for LDAR for process and non-waste storage systems (Section E.1).

BPM Solvent Storage Tanks: Streamlining Table

Affected Units: BPM Solvent Storage Tanks	Applicable Requirements				Streamlined Applicable Requirement
	NSPS for VOL Storage Vessels (40 CFR Part 60,Kb)	State RACT rules for Synthesized Pharma. Mfg (326 IAC 8-5-3	MACT Standards for Pharma Storage Tanks (40 CFR Part 63, GGG)	PSD BACT Requirement (326 IAC 2-2)	
Applicability					
Date of construction	Tanks constructed, reconstructed, or modified after 7/23/84 [60.110b(a)]	Tanks constructed after November 1, 1980 [326 IAC 8-5-1(2)] Potential emissions of tank $\geq$ 15 lb/day [8-5-3(a)]	All new/existing/modified solvent tanks, regardless of construction date [63.1253]	All new/existing/modified solvent tanks, regardless of construction date	All BPM solvent storage tanks containing VOC or VOHAP, regardless of size or date of construction/ modification
Tank contents	Tanks $\geq$ 75m^3 storing VOL [60.110b(c) and 60.116b(a) and (b)]	Tanks storing liquid with any VOC content with vapor pressure $\geq$ 10 kPa @ 20C [8-5-3(b)(3)(B)]	Tanks storing liquids with organic HAP content with a vapor pressure $\geq$ 13.1 kPa [63.1253(a)]	Tanks storing VOC content	
Tank volume					

Affected Units: BPM Solvent Storage Tanks	Applicable Requirements				Streamlined Applicable Requirement
	NSPS for VOL Storage Vessels (40 CFR Part 60,Kb)	State RACT rules for Synthesized Pharma. Mfg (326 IAC 8-5-3	MACT Standards for Pharma Storage Tanks (40 CFR Part 63, GGG)	PSD BACT Requirement (326 IAC 2-2)	
	Tanks $\geq$ 75 m^3 (10,566 gallons) [60.110b(a)]	All volumes [8-5-3(b)(3)(B)]	Tanks $\geq$ 38 m^3 (10,039 gallons) [63.1253]	All volumes	
Notable exclusions	Pressure vessels > 204.9 kPa and without emissions to the atmosphere, vessels attached to motor vehicles, vessels used to store beverage alcohol [60.110b(d)]		Pressure vessels > 204.9 kPa, vessels attached to motor vehicles [63.1251] 240 hours planned routine maintenance allowed [63.1253(e)]	Tanks meeting these exclusions will not be listed as tanks subject to streamlined requirements	
Emission limits, control requirements, performance requirements, and work practices					
TOC Point Source Emission Limits and Standards	These incinerator limits are addressed in the RTO and T79 Incinerator sections of this TSD				
TOC Point Source Emission Limits and Standards requiring no control device	No control requirements for tanks < 75 m3 and tanks >75m3 - 151m3 storing VOLs with TVP < 15 kPa and tanks > 151 m3 storing VOLs with TVP < 3.5 kPa.	No control requirements for tanks with PTE < 15 lbs VOC/day		No control requirements for tanks with VP < 3.5 kPa:	
HX Point Source Emission Limits and Standards	The incineration limits are addressed in the RTO and T79 sections of this TSD				
Work Practice Standards – Tank Inspections	None Specified	All leaks observed running or dripping shall be repaired whenever equipment is off-line long enough to repair [8-5-3(b)(6)]	None Specified	Initial M21 for components not covered under LDAR on BPM solvent storage tanks not operated under negative pressure AND Semiannual visual inspections for all BPM solvent storage tanks > 3.5 kPa. These inspections not required if unsafe or difficult to monitor. Leaks must be repaired within 5/15 days, unless delay of repair This requirement consistent with BPM waste tank requirements addressed in Section D.10 to satisfy BACT requirements	
Work Practice Standards -	Closed vent system inspections are addressed in RTO and T79 sections of this TSD				

Affected Units: BPM Solvent Storage Tanks	Applicable Requirements				Streamlined Applicable Requirement
	NSPS for VOL Storage Vessels (40 CFR Part 60,Kb)	State RACT rules for Synthesized Pharma. Mfg (326 IAC 8-5-3	MACT Standards for Pharma Storage Tanks (40 CFR Part 63, GGG)	PSD BACT Requirement (326 IAC 2-2)	
Closed Vent System Inspections					
TOC Fugitive Emission Standards	LDAR conditions are addressed in the LDAR section of this TSD				
Compliance Demonstration Methods					
TOC and HX CMS Requirements	The control device compliance requirements are addressed in the RTO and T79 sections of the TSD				
TOC and HX Stack Testing Requirements	The control device compliance requirements are addressed in the RTO and T79 sections of this TSD				
CMS Monitoring Requirements for Closed Vent System	The control device compliance requirements are addressed in the RTO and T79 sections of this TSD				
Record keeping and Reporting					
Records	Tank dimensions & capacity for life of facility for tanks > 19812 gallons [75 m3] [60.116b(a) and (b)] Copy of operating plan for at least 2 years [60.115b and 60.115b(c)(1)] Records of measured values of parameters specified in operating plan for at least 2 years [60.115b(c)(2)] For variable mixtures, prior to initial filling, estimate maximum true vapor pressure the tank will see. If it is below control level, but above monitoring cutoff level, test initially and every 6 months. [60.116b(f)]	None specified	Records of equipment operation [63.10(b)(2)(vii) and (viii), 63.1259 and 63.1255(g)] Control device and closed vent system requirements addressed in RTO or T79 sections of this TSD	Tank dimensions & capacity for life of facility per Kb Fixed roof inspections and leaks found Delays of repair Records of nonapplicability Records of equipment operation Control device and closed vent system requirements addressed in RTO or T79 sections of this TSD Records necessary to demonstrate compliance with short term BACT limits (e.g., MACT monitoring data) and emission caps addressed in T79, RTO or Change Management sections of this TSD	

Affected Units: BPM Solvent Storage Tanks	Applicable Requirements				Streamlined Applicable Requirement
	NSPS for VOL Storage Vessels (40 CFR Part 60,Kb)	State RACT rules for Synthesized Pharma. Mfg (326 IAC 8-5-3	MACT Standards for Pharma Storage Tanks (40 CFR Part 63, GGG)	PSD BACT Requirement (326 IAC 2-2)	
Reports	Construction and startup notifications per Part 60 General Provisions	None specified	Periodic reports for excursions, bypasses and periods of planned routine maintenance. Notification of Process change—e.g., change in the use of a storage tank not covered by operating scenario	Pre-construction notice for storage tanks (per Kb) over 19,800 gallons, except if mass-produced and purchased in completed form Startup notice for storage tanks (per Kb) over 19,800 gallons Quarterly report of monthly emissions and quarterly deviation reports from BACT requirements addressed in RTO, T79, and Change Management sections of this TSD	

Other Federal Requirements

There are no other federal rules that apply to the BPM solvent storage tanks.

Other State Requirements

There are no other state rules that apply to the BPM solvent storage tanks.

Testing and Compliance requirements

The compliance determination and compliance monitoring requirements for BPM solvent storage tanks are described in the streamlining table above.

D.10: BPM Waste Storage Tanks

Background and Description

The BPM waste storage tanks serve the bulk pharmaceutical manufacturing (BPM) operations at Tippecanoe Labs, and may be used to store offsite waste from other Lilly facilities. The BPM waste tanks are located in Tank Modules T140, T142, T143, T145 and T146, outside in the T48 tank farm, and in the bulk pharmaceutical manufacturing buildings.

Types of Emission Units and Pollution Control Equipment

The types of emission units subject to this specific operating area include storage tanks containing waste from BPM operations at Tippecanoe Laboratories and/or storage tanks containing waste from offsite sources. Tanks supporting fermentation-type operations are outside the because the tanks do not serve synthetic pharmaceutical operations and are not subject to 40 CFR 63, Subpart DD because the fermentation operations do not store or recover waste generated from offsite. The emissions from the BPM waste tanks are controlled by one of two Regenerative Thermal Oxidizers equipped with caustic scrubbing systems (RTO system) or by one of two fume incinerators equipped with caustic scrubbing systems (T79 Fume Incinerator system).

Insignificant Activities

While some of the BPM waste tanks may qualify as insignificant activities pursuant to 326 IAC 2-7-1(21) because VOC emissions are equal to or less than 3 pounds per hour or 15 pounds per day, the PSD requirements for waste tanks require that all BPM waste tanks comply with the emission limitations and standards set forth in the Title V permit.

Federal and State Rule Applicability Streamlining Proposal

The purpose of this streamlining proposal is to demonstrate that the requirements of 326 IAC 8-5-3 [the Indiana RACT rule for synthesized pharmaceutical manufacturing operations, 40 CFR 60, Subpart Kb [the NSPS for volatile organic liquid storage vessels], 40 CFR 63, Subpart DD [the NESHAP for offsite waste and recovery operations] can be streamlined into more stringent applicable requirements found in 40 CFR 63, Subpart GGG [the Pharmaceutical MACT rules for wastewater tanks] and the flexible PSD permit requirements that will be established in the Title V permit. To the extent possible, the flexible permit requirements will mirror the Pharmaceutical MACT requirements, thereby establishing the Pharmaceutical MACT requirements as the default most stringent requirements of the applicable rules.

Applicability
The following streamlining table is applicable only to storage tanks containing waste from BPM operations at Tippecanoe Laboratories and/or storage tanks containing waste from offsite sources. Tanks supporting fermentation-type operations are outside the scope of this specific operating area because the tanks do not serve synthetic pharmaceutical operations and are not subject to 40 CFR 63, Subpart DD because the fermentation operations do not store or recover waste generated from offsite.

Overview of applicable requirements
Waste storage tanks supporting bulk pharmaceutical manufacturing operations are subject to four potentially overlapping applicable requirements: an NSPS for storage tanks (40 CFR Part 60, Subpart Kb), the pharmaceutical manufacturing MACT rules for wastewater tanks (40 CFR Part 63, Subpart GGG), waste tank standards for off-site waste and recovery operations MACT rules (40 CFR Part 63, Subpart DD), and an Indiana RACT rule applicable to synthesized pharmaceutical manufacturing operations (326 IAC 8-5-3). Although two of the rules address volatile organic compound emissions (VOCs) and two rules address hazardous air pollutant (HAP) emissions, the requirements will typically apply to the same tanks and require similar types of control measures. Because it is the most comprehensive and most stringent of the four rules, the Subpart GGG MACT rules for wastewater tanks generally serve as the basis for the streamlining proposal for all waste tanks. In addition to this streamlining proposal, Tippecanoe Laboratories is seeking a PSD permit applicable to this area of the plant site that will impose BACT limits on the tanks. To the extent possible, the BACT requirements will mirror the Pharmaceutical MACT requirements, which make up the most stringent requirements of the applicable rules.

The most complex aspect of developing a streamlining proposal for waste storage tanks is the different applicability thresholds and the types of waste streams covered for the various requirements of the rule. Requirements may vary depending on the year of construction or modification, the size of the tank, and the vapor pressure of the waste material of the tank, as well as the type of waste material stored in the tank. In order to reduce complexity, this streamlining proposal applies only to tanks meeting the following criteria:

1. Waste storage tanks located in or supporting bulk pharmaceutical manufacturing operations. BPM pressure vessels greater than 204.9 kPa and vessels attached to motor vehicles are not waste tanks. Waste tanks supporting fermentation-type operations are outside the scope of the PSD permitting project; are not subject to 326 IAC 8-5-3 and 40 CFR 63, Subpart GGG because the tanks do not serve synthetic pharmaceutical operations; and are not subject to 40 CFR 63, Subpart DD because the fermentation operations do not store or recover waste generated from offsite. The waste tanks supporting fermentation operations are identified separately under a different section of the Title V permit.

2. Waste storage tanks designed to contain an accumulation of waste material containing liquid VOCs with a vapor pressure ≥ 3.5 kPa or volatile organic HAPs.

   BPM solvent storage tanks, containers, and process tanks are subject to different applicable requirements than the BPM waste tanks in this proposal and are addressed under separate streamlining proposals in Sections D.9, D.11 and D.6 of the Title V permit, respectively.

3. Waste storage tanks with a fixed roof design and routed to a thermal oxidizer or a regenerative thermal oxidizer via a closed vent system.

Even with the exclusion of solvent storage tanks, the applicability thresholds for the four rules vary greatly. As a further step for simplification, Lilly will generally propose to apply a requirement of a rule that would not otherwise apply to a particular tank.

Comparison of applicable requirements
According to the requirements of 326 IAC 2-7-24(b), any Permittee that seeks to streamline multiple applicable requirements must present a side-by-side comparison of the requirements and the proposed streamlining. The attached table presents a comparison of 326 IAC 8-5-3, 40 CFR 60 Subpart Kb, 40 CFR Part 63 Subpart GGG, 40 CFR 63 Subpart DD and the proposed flexible PSD permit requirements. Generally, Subpart GGG is the most stringent and extensive requirement and forms the basis of the streamlined requirement.

BPM Waste Tanks: Streamlining Table

Affected Units: BPM Waste Storage Tanks - Fixed Roof Design	Applicable Requirements					Streamlined Applicable Requirement
	NSPS for VOL Storage Vessels (40 CFR Part 60, Kb)	RACT rules for Synthesized Pharma Mfg (326 IAC 8-5-3)	MACT Standards for Pharma Wastewater Tanks (40 CFR 63, GGG)	MACT Standards for OSWRO (40 CFR, DD)	PSD BACT Standards (40 CFR 52.21, 326 IAC 2-2)	
Applicability						
Date of Construction	Tanks constructed reconstructed, of modified after 7/23/84 [60.110b(a)]	Tanks constructed after January 1, 1980 [326 IAC 8-5-1(2)]	All new/existing/modified wastewater tanks, regardless of construction date [63.1251]	Any new/existing/ modified waste tank containing OSW [63.680]	All new/existing /modified solvent tanks, regardless of construction date	BPM waste tanks containing VOC and/or VOHAP, regardless of size or date of construction/ modification
Tank Contents	Tanks ≥ 75m3 to < 151m3 storing liquid with VP ≥ 15 kPa Tanks ≥ 151m3 storing liquid with VP ≥ 3.5kPa [60.110b(c) and 60.116b(a) and (b)]	Tanks storing liquid with any VOC content with vapor pressure ≥ 10 kPa [8-5-3(b)(3)(B)] Potential emissions of tank ≥ 15 lb/day [8-5-3(a)]	Tanks storing partially soluble HAP annual avg. concentration > 1300 ppmw and total soluble/ partially soluble HAP > 0.25 Mg/yr Tanks storing partially soluble and/or soluble HAP annual avg. concentration > 5200 ppmw, and total soluble and partially soluble HAP > 0.25 Mg/yr [63.1256(a)(1)(i) and (ii)]	Tanks storing off-site material with HAP content [63.680(b)(1)]		

Affected Units: BPM Waste Storage Tanks - Fixed Roof Design	Applicable Requirements					Streamlined Applicable Requirement
	NSPS for VOL Storage Vessels (40 CFR Part 60, Kb)	RACT rules for Synthesized Pharma Mfg (326 IAC 8-5-3)	MACT Standards for Pharma Wastewater Tanks (40 CFR 63, GGG)	MACT Standards for OSWRO (40 CFR, DD)	PSD BACT Standards (40 CFR 52.21, 326 IAC 2-2)	
Tank Volume	Tanks ≥ 75 m^3 (10,566 gallons) [60.110b(a)]	All volumes [8-5-3(b)(3)(B)]	All volumes [63.1256]	All volumes	All volumes	
Notable Exclusions	Pressure vessels > 204.9 kPa, vessels attached to motor vehicles, vessels used to store beverage alcohol [61.110(b)(d)]				Same exclusions allowed by other rules applied to BACT	Tanks meeting these exclusions will not be listed as tanks subject to streamlined requirements
Emission limits, Control requirements performance requirements and work practices						
TOC and HX Point Source Emission and Limits and Standards	The incineration limits are addressed in the RTO and T79 sections of this TSD					
TOC Point Source Emission and Limits and Standards requiring no control device	No control requirements for tanks ≥ 75 m3 storing VOL with TVP < 15 kpa or tanks > 151 m3 storing VOL with TVP < 3.5 kpa		Fixed roof only required for tanks <75 m3, ≥ 75 m^3 to < 151 m^3 @ VP ≤ 13.1 kPa, ≥ 151m^3 @ ≤ 5.2kPa [63.1256(b)(1), Table 6]	Closure device required for tanks ≤ 75 m^3 @ ≤ 76.6 kPa, ≥ 75 m^3 to < 151 m^3 @ ≤ 27.6 kPa, ≥ 151 m^3 @ ≤ 5.2 kPa [63.685(b)(1), (c)(2), and 63.902]	No control device required for BPM waste tanks with VP < 3.5 kPa	
Work Practice Standards – Tank Inspections	None Specified	All leaks observed running or dripping shall be repaired whenever equipment is off-line long enough to repair [8-5-3(b)(6)]	Initial/Semiannual tanks inspections for improper work practices Repair leaks within 5/45 days; 2 30-day extensions allowed Inspections not required if unsafe/difficult to monitor [63.1256(b)(7), (8)(i)(l), (8)(iii), (9), 63.1258(g) and Table 7); 63.1258(h)(6) and (7)] *AND* Tanks not under negative pressure: Initial M21 and semiannual visual	Tanks not under negative pressure: Initial and annual visual inspections Leaks must be repaired within 5/45 days with 2 30-day extensions allowed. [63.906(a) and 63.695(b)(3)(ii) and (b)(4)(i)]	Initial M21 for components not covered under LDAR on BPM waste tanks not operated under negative pressure AND Semiannual visual inspections for all waste tank tanks > 3.5 kPa. These inspections not required if unsafe or difficult to monitor. Leaks must be repaired within 5/15 days, unless delay of repair Initial Method 21 Inspections already completed for all existing tanks not operated under negative pressure	

Affected Units: BPM Waste Storage Tanks - Fixed Roof Design	Applicable Requirements					Streamlined Applicable Requirement
	NSPS for VOL Storage Vessels (40 CFR Part 60, Kb)	RACT rules for Synthesized Pharma Mfg (326 IAC 8-5-3)	MACT Standards for Pharma Wastewater Tanks (40 CFR 63, GGG)	MACT Standards for OSWRO (40 CFR, DD)	PSD BACT Standards (40 CFR 52.21, 326 IAC 2-2)	
			inspections of fixed roof and all openings. Repair leaks within 5/15 days, unless delay of repair Inspections not required if unsafe/difficult to monitor [63.1256(b)(3)(i)(A), 63.1258(h)(2)(iii), (4), (6), and (7)] Tanks under negative pressure: No initial M21/visual inspections required [63.1256(b)(3)(iv)]			
Work Practice Standards - Closed Vent System	Closed vent system requirements are addressed in the RTO and T79 sections of this TSD					
Fugitive Emission Standards	LDAR requirements are addressed in the LDAR section of this TSD					
Compliance demonstration methods						
TOC and HX CEMS Requirements	The control device compliance requirements are addressed in the RTO and T79 sections of this TSD					
TOC and HX CMS Requirements	The control device compliance requirements are addressed in the RTO and T79 sections of this TSD					
TOC and HX Stack Testing Requirements	The control device compliance requirements are addressed in the RTO and T79 sections of this TSD					
	These Compliance requirements are addressed in the RTO and T79 sections of this TSD					
Record Keeping and Reporting						
Record	Tank dimensions & capacity for life of facility [60.116b(a) and (b)] Copy of operating plan for at least 2 years [60.115b and (c)(1)] Records of measured values of parameters in operating plan [60.115b(c)(2)]	None Specified	The following records shall be kept in accordance with 63.10 for 5 years: SSM plan and Records CMS Operations Operating scenario logs Stack Test records Planned routine maintenance Inspections of closed vent systems & fixed roofs (as applicable) and any leaks found	The following records shall be kept in accordance with 63.10 for 5yrs: Annual inspections for each fixed roof and closure device Annual inspections and monitoring for each closed vent not	Records necessary to demonstrate compliance with short term BACT limits (e.g., MACT monitoring data) and emission caps	Records necessary to demonstrate compliance with short term BACT limits (e.g., MACT monitoring data) and emission caps. Keep records for minimum period of 5 years

Affected Units: BPM Waste Storage Tanks - Fixed Roof Design	Applicable Requirements					Streamlined Applicable Requirement
	NSPS for VOL Storage Vessels (40 CFR Part 60, Kb)	RACT rules for Synthesized Pharma Mfg (326 IAC 8-5-3)	MACT Standards for Pharma Wastewater Tanks (40 CFR 63, GGG)	MACT Standards for OSWRO (40 CFR, DD)	PSD BACT Standards (40 CFR 52.21, 326 IAC 2-2)	
	For variable waste mixtures, prior to initial filling, estimate maximum true VP seen by tank. if below control level, but above monitoring cutoff level, test initially and every 6 months. [60.11]		Flow indicator operation & bypasses detected Delays of repair [63.1259]	operated under negative pressure defect repair Planned routine maintenance periods Control device malfunctions [63.695(b), (c) and 63.696(e), (g), (h)]		Tank dimensions & capacity for life of facility per Kb
Reports	Construction and Startup notifications per Part 60 General Provisions	None Specified	Periodic reports for excursions, detail on all leaks detected on closed vent system or fixed roof, bypasses, and periods of planned routine maintenance. Notification of Process change—e.g., change in the use of a storage tank not covered by operating scenario SSM reports [63.1260 and 63.1255(h) (LDAR)]	SSM reports [63.10(d)(5) and 63.697(b)(3)] Semiannual summary report [63.10(e)(3), 63.697(b)(4)]	Quarterly report of monthly emissions and quarterly deviation reports from BACT requirements	MACT periodic reports, notification of process changes, and SSM reports Quarterly report of monthly emissions and quarterly deviation reports from BACT requirements Pre-construction notice for storage tanks (per Kb) over 19,800 gallons, except if mass-produced and purchased in completed form Startup notice for storage tanks (per Kb) over 19,800 gallons

Other Federal Requirements

There are no other federal rules that apply to the BPM waste storage tanks.

Other State Requirements

There are no other state rules that apply to the BPM waste storage tanks.

Testing and Compliance Requirements

The compliance determination and compliance monitoring requirements for the BPM waste storage tanks are described in the streamlining proposal above.

D.11: BPM Waste Containers

Background and Description

The BPM waste containers serve the bulk pharmaceutical manufacturing (BPM) operations at Tippecanoe Labs, as well as to store offsite waste from other Lilly facilities. Waste containers supporting fermentation-type operations are outside the scope of this section because the containers do not serve synthetic pharmaceutical operations and are not subject to 40 CFR 63, Subpart DD because the fermentation operations do not store or recover waste generated from offsite.

Types of Emission Units and Pollution Control Equipment

The BPM waste containers are categorized into small and large containers and contain waste material generated from the BPM operations at Tippecanoe Labs or contain waste material generated from offsite Lilly facilities. Small containers, such as drums, are currently located in the bulk pharmaceutical manufacturing buildings and in the T148 container storage building.

Large containers, such as tankers and melons, are currently used to transfer waste material from the BPM buildings to the waste tank storage area. Large containers are also used to transfer waste materials offsite for disposal or to transfer offsite waste materials onsite for disposal. Waste materials transferred onsite via large containers are unloaded either at the solvent recovery area or to the waste tank storage area. Large containers are loaded and unloaded via submerged fill pipe.

Insignificant Activities

The BPM waste containers qualify as insignificant activities pursuant to 326 IAC 2-7-1(21) because VOC emissions are equal to or less than 3 pounds per hour or 15 pounds per day.

Federal and State Rule Applicability Streamlining Proposal

The purpose of the streamlining table presented below is to demonstrate that the requirements of 40 CFR 63, Subpart DD [the NESHAP for offsite waste and recovery operations] can be streamlined into more stringent applicable requirements found in 40 CFR 63, Subpart GGG [the Pharmaceutical MACT rules for wastewater containers] and the flexible PSD permit requirements that will be established in the Title V permit. To the extent possible, the flexible permit requirements will mirror the Pharmaceutical MACT requirements, thereby establishing the Pharmaceutical MACT requirements as the default most stringent requirements of the applicable rules. IDEM has reviewed the streamlining proposal and has determined it meets the requirements of 326 IAC 2-7-24.

Applicability

The following streamlining table applies to waste storage containers containing waste from BPM operations at Tippecanoe Laboratories and/or waste storage containers containing waste from offsite sources. Waste containers supporting fermentation-type operations are outside the scope of this specific operating area because these containers do not serve synthetic pharmaceutical operations, are not part of the flexible PSD permit scope, and are not subject to 40 CFR 63, Subpart DD because the fermentation operations do not store or recover waste generated from offsite.

Overview of applicable requirements

Waste storage containers supporting bulk pharmaceutical manufacturing operations are subject to the pharmaceutical manufacturing MACT rules for wastewater containers (40 CFR Part 63, Subpart GGG) and the waste container standards for off-site waste and recovery operations MACT rules (40 CFR Part 63, Subpart DD. Because it is the more comprehensive and more stringent, the Subpart GGG MACT rules for wastewater containers generally serve as the basis for the streamlining proposal for all waste containers. In addition to the streamlining aspects of the Title V permit, Tippecanoe Laboratories is seeking a PSD permit applicable to this area of the plant site that will impose BACT limits on the waste containers. that mirrors the Pharmaceutical MACT requirements.

The most complex aspect of developing a streamlining proposal for waste storage containers is the different applicability thresholds and the types of waste streams covered for the various requirements of the rule. Requirements may vary depending on the size of the container, the vapor pressure of the waste material in the container, and the type of waste material stored in the container.

Comparison of applicable requirements

According to the requirements of 326 IAC 2-7-24(b), any Permittee that seeks to streamline multiple applicable requirements must present a side-by-side comparison of the requirements and the proposed streamlining. The attached table presents a comparison of 40 CFR Part 63 Subpart GGG, 40 CFR 63 Subpart DD and the proposed flexible PSD permit requirements. Generally, Subpart GGG is the most stringent and extensive requirement and forms the basis of the streamlined requirement.

BPM Waste Containers: Streamlining Table

Affected Units: BPM Waste Containers	Applicable Requirements			Streamlined Applicable Requirement
	MACT Standards for Pharma Wastewater containers (40 CFR, Subpart GGG)	MACT Standards for OSWRO Containers (40 CFR 63, Subpart DD)	PSD BACT Standards (326 IAC 2-2)	
Applicability				
Date of Construction	All new/existing/modified wastewater containers, regardless of construction date [63.1250(a)]	Any new/existing/ modified waste container containing OSW [63.680]	All new/existing/modified waste containers	
Waste container contents	Waste containers storing affected wastewater or wastewater residuals containing: Partially soluble HAP annual avg. concentration > 1300 ppmw and total soluble and partially soluble HAP > 0.25 Mg/yr Partially soluble and/or soluble HAP annual avg. concentration > 5200 ppmw & total	Waste containers storing off-site waste material with HAP content $\geq$ 500 ppmw [63.680(b)(1)]	Waste containers storing VOC-containing waste material $\geq$ 500 ppmv	

Affected Units: BPM Waste Containers	Applicable Requirements			Streamlined Applicable Requirement
	MACT Standards for Pharma Wastewater containers (40 CFR, Subpart GGG)	MACT Standards for OSWRO Containers (40 CFR 63, Subpart DD)	PSD BACT Standards (326 IAC 2-2)	
	soluble/partially soluble HAP > 0.25 Mb/yr [63.1256(a)(1)(i) and (ii)]			
Waste container volume	Any portable waste management unit (waste container) ≥ 0.1 m^3 (26.4 gallons) [63.1251]	Waste containers ≥ 0.1 m^3 (26.4 gallons) [63.688(a)(1)]	Waste containers ≥ 0.1 m^3 (26.4 gallons)	
Notable exclusions	Opening allowed for filling, removal, inspection, sampling or pressure relief events related to safety considerations [63.1256(d)(1)(iii)]	Opening of closure device allowed for filling, removal, inspection, sampling or pressure relief events related to safety considerations [63.922(d)(1)-(5)]	Same exclusions allowed by other rules applied to BACT	Opening allowed for filling, removal, inspection, sampling or pressure relief events related to safety considerations
Emission limits, control requirements, performance requirements, and work practices				
TOC Emission Limits and Standards for Small Waste Containers	Control Options for wastewater containers >0.1 m^3 to < 0.42 m^3: DOT compliant container (Lilly's compliance strategy); OR Maintain cover/openings without leaks. [63.1256(d)(1)(ii)(A) and (B)]	Container Level 1 Controls required for ≥ 0.1 m^3 to ≤ 0.46 m^3 and > 0.46 m^3 not in light-material service [63.688(b)(1)(i) and 63.888(b)(2)]: DOT compliant container; OR Cover/closure device secured on container; OR Organic vapor-suppressing barrier on open-top container. [63.922(b)]	Waste containers > 0.1 m3 to ≤ 0.42 m^3 not operated under negative pressure: Utilize DOT containers; AND Maintain cover and all openings in a closed position at all times except for filling, removal, inspection, sampling or pressure relief events related to safety considerations.	
TOC Emission Limits and Standards for Large Waste Containers	Control Options for wastewater containers > 0.42 m^3: Maintain cover/openings without leaks [63.1256(d)(1)(i)] AND Use submerged fill pipe for filling operations (Lilly's compliance strategy);	Container Level 2 Controls for ≥ 0.46 m^3, in light-material service [63.688(b)(3)]: DOT compliant container; OR	Waste containers > 0.42 m^3 not operated under negative pressure: Maintain cover and all openings without leaks; Maintain cover and all openings in a closed position at all times except for filling, removal, inspection, sampling or pressure relief events related to safety considerations; AND	

Affected Units: BPM Waste Containers	Applicable Requirements			Streamlined Applicable Requirement
	MACT Standards for Pharma Wastewater containers (40 CFR, Subpart GGG)	MACT Standards for OSWRO Containers (40 CFR 63, Subpart DD)	PSD BACT Standards (326 IAC 2-2)	
	OR Locate container within an enclosure with closed-vent system that routes to control; OR Use closed-vent system to vent displaced organic vapors from container to control device or back to equipment from which wastewater is transferred. [63.1256(d)(2)(i)]	Operate with no detectable organic emissions; OR Vapor tight container demonstration. [63.923(b)]	Use submerged fill pipe for filling operations for Containers > 0.42 m^3	
Exceptions	No inspection requirements for containers operated under negative pressure. All wastewater containers maintained in closed position at all times except for filling, removal, inspection, sampling or pressure relief events related to safety considerations [63.1256(d)(1)(iii)]	No inspection requirements for containers operated under negative pressure.	No inspection requirements for containers operated under negative pressure.	
Work Practice Standards – Small Waste Container Inspections	Inspections for DOT compliant wastewater containers > 0.1 m^3 to $\leq$ 0.42 m^3, not operated under negative pressure: Initial and semiannual visual inspections for improper work practices (i.e., open hatch that is not in use) and control equipment failures (i.e., gaps, cracks or cover is broken) Repairs shall be initiated within 5 days and completed within 15 days after identification, unless delay of repair allowed [63.1256(d)(1)(ii)(A), 63.1258(h)(2)(iii), 63.1256(d)(5)] --------------------------------- All inspections that are unsafe or difficult to monitor are not subject to inspection requirements [63.1258(h)(6) and (7)]	Initial visual inspection, if container not emptied within 24 hours after container arrives at facility, for visible cracks, holes, gaps, or other open spaces into the interior of the container. Annual visual inspections for visible cracks, holes, gaps or other open spaces into the interior of the container Repair of defects shall be initiated within 24 hours and completed within 5 days after detection; otherwise must remove regulated material from container until defect is repaired [63.922(e), 63.923(e), and 63.926(a)]	Inspections for DOT compliant Waste Containers > 0.1 m^3 to $\leq$ 0.42 m^3: Initial and semiannual visual inspections for improper work practices and control equipment failures. Repairs shall be initiated within 24 hours and completed within 5 days after identification. ____ NOTE: Inspections that are unsafe or difficult to monitor are not subject to inspection requirements ____ No inspection requirements for containers operated under negative pressure.	

Affected Units: BPM Waste Containers	Applicable Requirements			Streamlined Applicable Requirement
	MACT Standards for Pharma Wastewater containers (40 CFR, Subpart GGG)	MACT Standards for OSWRO Containers (40 CFR 63, Subpart DD)	PSD BACT Standards (326 IAC 2-2)	
Work Practice Standards – Large Waste Container Inspections	Inspections for Containers > 0.42 m^3, not operated under negative pressure: Initial Method 21 testing; Semiannual visual inspections for visible, audible, or olfactory indications of leaks; AND Initial and semiannual visual inspections for improper work practices and control equipment failures. Repairs shall be initiated within 5 days and completed within 15 days after identification, unless delay of repair allowed [63.1256(d)(1)(i), 63.1258(h)(2)(iii), and 63.1256(d)(5)] _________________________ All inspections that are unsafe or difficult to monitor are not subject to inspection requirements [63.1258(h)(6) and (7)]	Initial visual inspection, if container not emptied within 24 hours after container arrives at facility, for visible cracks, holes, gaps, or other open spaces into the interior of the container. Annual visual inspections for visible cracks, holes, gaps or other open spaces into the interior of the container Repair of defects shall be initiated within 24 hours and completed within 5 days after detection; otherwise must remove regulated material from container until defect is repaired [63.922(e), 63.923(e), and 63.926(a)] AND For pressure-vacuum relief valves on containers, must demonstrate that it is designed to operate with no detectable emissions [63.922(d)(4) and 63.925(a)]	Inspections for Waste Containers > 0.42 m^3: Initial Method 21 testing; Semiannual visual inspections for visible, audible, or olfactory indications of leaks; AND Initial and semiannual visual inspections for improper work practices and control equipment failures. Repairs shall be initiated within 24 hours and completed within 5 days after identification ____ NOTE: Inspections that are unsafe or difficult to monitor are not subject to inspection requirements ____ No inspection requirements for containers operated under negative pressure.	
Record Keeping and Reporting				
Record	The following records shall be maintained for each waste container: Inspections for the container, control device, seal gap	Keep inspection records for period of 5 years. [63.10]	The following records shall be maintained for each waste container: inspection was performed for the container, control device, seal gap measurement, if applicable; unsafe to inspect facilities;	

Affected Units: BPM Waste Containers	Applicable Requirements			Streamlined Applicable Requirement
	MACT Standards for Pharma Wastewater containers (40 CFR, Subpart GGG)	MACT Standards for OSWRO Containers (40 CFR 63, Subpart DD)	PSD BACT Standards (326 IAC 2-2)	
	measurement, if applicable; unsafe to inspect facilities; difficult to inspect facilities; information on each inspection during which a leak is detected; date of each Method 21 inspection performed and statement that no leaks detected, if applicable; date of each visual inspection performed and statement that no leaks detected. [63.1259(i)]		difficult to inspect facilities; information on each inspection during which a leak is detected; date of each Method 21 inspection performed and statement that no leaks detected, if applicable; date of each visual inspection performed and statement that no leaks detected	
Reports	Records of each inspection during which a leak is detected must be included in the next periodic report [63.1260(g)(2)(iii)]	None	Records of each inspection during which a leak is detected must be included in the next periodic report	

Other Federal Requirements

40 CFR 60, Subpart Kb – Volatile Organic Liquid Storage Vessels – While the definition of a storage vessel includes containers, this rule only applies to containers greater than or equal to 75 cubic meters. The largest containers utilized at Tippecanoe Laboratories are tanker trucks used to transport liquid material to and from the site. These containers have a capacity of 25,000 liters, or 25 cubic meters. Therefore, the requirements of this rule do not apply to the BPM waste containers.

Other State Requirements

326 IAC 8-5-3 – Synthesized Pharmaceutical Manufacturing Operations –
The control requirements of 326 IAC 8-5-3 do not apply to the BPM waste containers because potential to emit from each container is less than 15 pounds per day.

Testing and Compliance Requirements

The compliance determination and compliance monitoring requirements for the BPM waste containers are described in the streamlining table above.

Appendix A

Indiana Department of Environmental Management

Office of Air Quality

Technical Support Document (TSD) for a Part 70 Operating Permit Renewal

Section D.12 - Section D.20

D.12: T49 Liquid Waste Incinerator

Background and Description

The T49 liquid waste incinerator is designed to treat high Btu liquids (primary waste) and low Btu liquids (secondary waste).

Types of Emission Units and Pollution Control Equipment

The T49 liquid waste incinerator consists of a primary combustion chamber and vertical up-fired secondary combustion chamber (SCC), a wet quench system, a condenser/absorber, a Hydrosonic scrubber and a stack with continuous emissions monitoring.

Insignificant Activities

The T49 liquid waste incinerator is not considered an insignificant activity pursuant to 326 IAC 2-7-1.

Existing Approvals

Description	Permit No.	Date
Operating Permits		
Title V permit	T157-6879-00006	Issued February 27, 2004

Unpermitted Emission Units and Pollution Control Devices

There are no unpermitted emission units associated with the T49 liquid waste incinerator.

Federal Rule Applicability

New Source Performance Standards:

There are no New Source Performance Standards (NSPS) that apply to the incinerator project.

<u>40 CFR 60, Subpart Cb: Emission Guidelines and Compliance Times for Large Municipal Waste Combustors That are Constructed On or Before September 20, 1994</u> – This rule does not apply because the T49 liquid waste incinerator does not have the capability to combust solid wastes and therefore does not combust municipal waste.

40 CFR 60, Subpart Ce: Emission Guidelines and Compliance Times for Hospital / Medical / Infectious Waste Incinerators – This rule does not apply because the T49 liquid waste incinerator does not have the capability to combust solid wastes and therefore will not combust hospital, medical, or infectious waste.

40 CFR 60, Subpart E: Standards of Performance for Incinerators – This rule does not apply because the T49 liquid waste incinerator does not have the capability to combust solid wastes and therefore will not combust solid waste as defined in 60.51(b).

40 CFR 60, Subpart Ea: Standards of Performance for Municipal Waste Combustors for Which Construction Commenced After December 20, 1989 and On or Before September 20, 1994 – This rule does not apply because the T49 liquid waste incinerator has a permit under section 3005 of the Solid Waste Disposal Act. Any combustor required to have a permit under section 3005 of the Solid Waste Disposal Act is not subject to this subpart.

40 CFR 60, Subpart Eb: Standards of Performance for Large Municipal Waste Combustors for Which Construction is Commenced After September 20, 1994 or for Which Modification or Reconstruction is Commenced After June 19, 1996 – This rule does not apply because the T49 liquid waste incinerator has a permit under section 3005 of the Solid Waste Disposal Act. Any combustor required to have a permit under section 3005 of the Solid Waste Disposal Act is not subject to this subpart.

40 CFR 60, Subpart Ec: Standards of Performance for Hospital / Medical / Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996 – This rule does not apply because the T49 liquid waste incinerator has a permit under section 3005 of the Solid Waste Disposal Act. Any combustor required to have a permit under section 3005 of the Solid Waste Disposal Act is not subject to this subpart.

40 CFR 60, Appendix B, Performance Specification 16 - Predictive Emission Monitoring Systems - This rule does not apply to the T49 incinerator because permit condition D.12.15(a) requires operation of continuous parametric monitoring systems, including combustion air flow rate. Because the T49 combustion air flow rate monitor is part of a parametric monitoring system, instead of a predicative emission monitoring system, it is not subject to Performance Specification 16.

National Emission Standards for Hazardous Air Pollutants (NESHAP):

40 CFR 61, Subpart C: National Emission Standard for Beryllium – Although Subpart C is applicable to incinerators, USEPA has determined that this rule applies only to incinerators burning beryllium containing waste that was generated by a foundry, extraction plant, ceramic plant, propellant plant, or machine shop which is subject to Subpart C. [See, May 22, 1997, memorandum from R. Douglas Neeley of U.S. EPA, Region 4].

Since the beryllium-containing wastes that may be combusted in the incinerator do not originate from one of the five sources listed 40 CFR 61, Subpart C, the rule does not apply.

40 CFR 61, Subpart E: National Emission Standard for Mercury – 40 CFR 61, Subpart E, National Emission Standard for Mercury, does not apply because the T49 liquid waste incinerator does not incinerate wastewater treatment plant sludge.

40 CFR 63, Subpart I: National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks – Although the source is a major source of hazardous air pollutants (HAPs), 40 CFR 63, Subpart I, does not apply because the incinerator is not associated with any of the applicable processes listed under 40 CFR 63.190(b)(1) through (b)(6).

40 CFR 63, Subpart DD: National Emission Standards for Off-Site Waste and Recovery Operations – The requirements of 40 CFR 63, Subpart DD applies to the T49 liquid waste incinerator because the plant site is a major source of HAP emissions, off-site material as specified in 40 CFR 63.680(b) will be received, and the waste management operation is one of the operations specified in 40 CFR 63.680(a)(2)(i) through (a)(2)(vi).

40 CFR 63, Subpart EEE: National Emission Standards for Hazardous Air Pollutants from Hazardous Waste Combustors – The T49 liquid waste incinerator is subject to the requirements of 40 CFR 63, Subpart EEE because this incinerator burns hazardous waste. The source shall comply with all applicable requirements under this rule.

State Rule Applicability

326 IAC 1-6-3 (Preventive Maintenance Plan) – The T49 liquid waste incinerator is required to have a preventive maintenance plan (PMP) pursuant to 326 IAC 1-6-3. The Operation and Maintenance Plan (O&M Plan) required under the HWC MACT standards shall satisfy the requirements of the PMP.

326 IAC 2-2 (Prevention of Significant Deterioration) – As part of the Title V permitting process, the source underwent PSD review for its BPM operations and BPM support operations, which includes the T49 liquid waste incinerator. The best available control technology (BACT) and modeling analyses are required under the PSD requirements are discussed in Attachment C of this TSD. The following table summarizes the BACT for the T49 liquid waste incinerator:

Facility	PSD Pollutants	BACT Control Devices	BACT Limits
T49 liquid waste incinerator	VOC	Good combustion practice; HWC MACT	10 ppmvdc
	CO	Good combustion practice; HWC MACT	100 ppmvdc
	NOx	Good combustion practice	975 ppmvdc
	SO2	Caustic scrubber	500 ppmvdc
	Fluorides	Caustic scrubber	98% control efficiency, measured as HCl

326 IAC 5-1-2 (Opacity Limitations) – Opacity shall not exceed an average of 40% in any one 6 minute averaging period. Opacity shall not exceed 60% for more than a cumulative total of fifteen minutes.

326 IAC 4-2 – 326 IAC 4-2 does not apply because the incinerator is subject to emission limitations in 40 CFR 63, Subpart EEE.

326 IAC 6-3 (Process Operations) – 326 IAC 6-3 does not apply because the T49 liquid waste incinerator is exempted under 326 IAC 6-3-1(a).

326 IAC 7 (Sulfur Dioxide Emission Limitations) – 326 IAC 7 applies to the T49 liquid waste incinerator because the SO_2 potential to emit exceeds 25 tons per year. Pursuant to 326 IAC 7-1.1-2 (SO_2 Rules), the SO_2 emissions shall not exceed 0.5 pounds per million British thermal units (lbs/MMBtu).

326 IAC 8-5-3 (Miscellaneous Operations: Synthesized Pharmaceutical Manufacturing Operations) – 326 IAC 8-5-3 does not apply to the T49 liquid waste incinerator because it is not listed as one of the emission unit types defined in 326 IAC 8-5-3(a).
326 IAC 8-1-6 (State BACT Requirements) – As part of the Title V permitting process, the source elected to undergo PSD review for its BPM operations. The best available control technology (BACT) required under the PSD requirements of 326 IAC 2-2 are discussed in Attachment C of this TSD. These federal requirements satisfy the requirements of 326 IAC 8-1-6.

326 IAC 9 and 40 CFR 52, Subpart P (Carbon Monoxide Rules) – 326 IAC 9-1-2 does not apply because the incinerator is subject to carbon monoxide emission limitations in 40 CFR 63, Subpart EEE.

326 IAC 11-6 (Hospital/Medical/Infectious Waste Incinerators) – This rule does not apply to the T49 liquid waste incinerator because it does not combust hospital/medical/infectious waste as defined in 40 CFR 60, Subpart Ec.

326 IAC 11-7 (Municipal Waste Combustors) – This rule does not apply to the T49 liquid waste incinerator because it does not combust municipal waste as defined in 40 CFR 60, Subpart Cb.

326 IAC 15 (Lead Rules) – This rule does not apply to the source because the plant operations are not classified as one of the source types listed in 326 IAC 15-1-2.

Compliance Requirements

The following compliance activities are required for the T49 liquid waste incinerator:

1. Conduct performance tests;

2. Operate CEMS for CO, SO2, and NOx;

3. Continuously monitor the following operating parameters:

    (a) Atomizing air media pressure;
    (b) Primary and secondary waste feed viscosity;
    (c) Primary and secondary waste feed rate;
    (d) Combustion temperature;
    (e) Combustion air flow rate;
    (f) Mercury, semi-volatile metals and low-volatile metals feed rate;
    (g) Chlorine feed rate;
    (h) ash federate;
    (i) condenser/absorber flow rate, differential pressure drop, pH and percent solid; and
    (j) hydro-sonic scrubber flow rate and equivalent differential pressure.

D.13: T149 Solid-Liquid Waste Incinerator

Background and Description

The T 149 solid-liquid waste incinerator, provides treatment of Lilly hazardous and non-hazardous waste to support its operational requirements. The solid-liquid waste incinerator is designed to treat containerized waste (hazardous and non-hazardous), high Btu liquids (primary waste), low Btu liquids (secondary waste), and wastewater treatment sludge.

Types of Emission Units and Pollution Control Equipment

The solid-liquid waste incinerator consists of a rotary kiln incinerator, an emergency backup motor to the rotary kiln drive system, and ancillary equipment. The solid-liquid waste incinerator consists of a rotary kiln and vertical up-fired secondary combustion chamber (SCC), a wet ash handling system, a NO_x abatement system, a wet quench system, a condenser/absorber, a particulate matter scrubber, an induced draft (ID) fan, and a stack with continuous emissions monitoring. Ancillary equipment consists of a containerized waste receiving, storage, and handling area, two wastewater treatment plant sludge holding tanks, and containerized waste, sludge, and liquid feed systems. Primary and secondary wastes are stored and handled in existing waste holding tanks.

Insignificant Activities

The solid-liquid waste incinerator is not considered an insignificant activity pursuant to 326 IAC 2-7-1.

Existing Approvals

Description	Permit No.	Date
Operating Permits		
Title V permit	T157-6879-00006	Issued February 27, 2004

Unpermitted Emission Units and Pollution Control Devices

There are no unpermitted emission units associated with the rotary kiln incinerator.

Federal Rule Applicability

New Source Performance Standards:

There are no New Source Performance Standards (NSPS) that apply to the incinerator project.

<u>40 CFR 60, Subpart Cb: Emission Guidelines and Compliance Times for Large Municipal Waste Combustors That are Constructed On or Before September 20, 1994</u> – This rule does not apply because the solid-liquid waste incinerator does not combust municipal waste and the construction date was after the applicable date of September 20, 1994.

<u>40 CFR 60, Subpart Ce: Emission Guidelines and Compliance Times for Hospital / Medical / Infectious Waste Incinerators</u> – This rule does not apply because the solid-liquid waste incinerator does not combust hospital, medical, or infectious waste.

40 CFR 60, Subpart E: Standards of Performance for Incinerators – This rule does not apply because the incinerator does not combust solid waste as defined in 60.51(b).

40 CFR 60, Subpart Ea: Standards of Performance for Municipal Waste Combustors for Which Construction Commenced After December 20, 1989 and On or Before September 20, 1994 – This rule does not apply because the T149 solid-liquid waste incinerator has a permit under section 3005 of the Solid Waste Disposal Act. Any combustor required to have a permit under section 3005 of the Solid Waste Disposal Act is not subject to this subpart.

40 CFR 60, Subpart Eb: Standards of Performance for Large Municipal Waste Combustors for Which Construction is Commenced After September 20, 1994 or for Which Modification or Reconstruction is Commenced After June 19, 1996 – This rule does not apply because the T149 solid-liquid waste incinerator has a permit under section 3005 of the Solid Waste Disposal Act. Any combustor required to have a permit under section 3005 of the Solid Waste Disposal Act is not subject to this subpart.

40 CFR 60, Subpart Ec: Standards of Performance for Hospital / Medical / Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996 – This rule does not apply because the T149 solid-liquid waste incinerator has a permit under section 3005 of the solid waste disposal Act. Any combustor required to have a permit under section 3005 of the Solid Waste Disposal Act is not subject to this subpart.

40 CFR 60, Appendix B, Performance Specification 16 - Predictive Emission Monitoring Systems - This rule does not apply to the T149 solid-liquid waste incinerator, because the T149 solid-liquid waste incinerator does not operate any predictive emission monitoring systems (PEMS)

National Emission Standards for Hazardous Air Pollutants (NESHAP):

40 CFR 61, Subpart C: National Emission Standard for Beryllium – Although Subpart C is applicable to incinerators, USEPA has determined that this rule applies only to incinerators burning beryllium containing waste that was generated by a foundry, extraction plant, ceramic plant, propellant plant, or machine shop which is subject to Subpart C. [See, May 22, 1997, memorandum from R. Douglas Neeley of U.S. EPA, Region 4".

Since the beryllium-containing wastes that may be combusted in the incinerator do not originate from one of the five sources listed 40 CFR 61, Subpart C, the rule does not apply.

40 CFR 61, Subpart E: National Emission Standard for Mercury – 40 CFR 61, Subpart E, National Emission Standard for Mercury, does not apply because the solid-liquid waste incinerator does not incinerate wastewater treatment plant sludge.

40 CFR 63, Subpart I: National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks – Although the source is a major source of hazardous air pollutants (HAPs), 40 CFR 63, Subpart I, does not apply because the solid-liquid waste incinerator is not any of the applicable processes listed under 40 CFR 63.190(b)(1) through (b)(6).

40 CFR 63, Subpart DD: National Emission Standards for Off-Site Waste and Recovery Operations – 40 CFR 63, Subpart DD applies to the solid-liquid waste incinerator because the plant site is a major source of HAP emissions, off-site material as specified in 40 CFR 63.680(b) is received, and the waste management operation is one of the operations specified in 40 CFR 63.680(a)(2)(i) through (a)(2)(vi).

40 CFR 63, Subpart EEE: National Emission Standards for Hazardous Air Pollutants from Hazardous Waste Combustors – The solid-liquid waste incinerator is subject to the

requirements of 40 CFR 63, Subpart EEE because the incinerator is a hazardous waste incinerator. The source shall comply with all applicable requirements under this rule.

State Rule Applicability

326 IAC 1-6-3 (Preventive Maintenance Plan) – The source is required to have a preventive maintenance plan pursuant to 326 IAC 1-6-3.

326 IAC 2-2 (Prevention of Significant Deterioration) – As part of the Title V permitting process, the source underwent PSD review for its BPM operations and BPM support operations, which includes the solid-liquid waste incinerator. The best available control technology (BACT) and modeling analyses are required under the PSD requirements are discussed in Attachment C of this TSD. The following table summarizes the BACT for the solid-liquid waste incinerator:

Facility	PSD Pollutants	BACT Control Devices	BACT Limits
T 140 Solid-Liquid Waste Incinerator	VOC	Good combustion practice; HWC MACT	10 ppmvdc
	CO	Good combustion practice; HWC MACT	100 ppmvdc
	NOx	Selective Non-catalytic reduction	170 ppmvdc
	SO2	Caustic scrubber	400 ppmvdc
	Fluorides	Caustic scrubber	98% control efficiency

326 IAC 5-1-2 (Opacity Limitations) – Opacity shall not exceed an average of 40% in any one 6 minute averaging period. Opacity shall not exceed 60% for more than a cumulative total of fifteen minutes.

326 IAC 4-2 – 326 IAC 4-2 does not apply because the incinerator is subject to emission limitations in 40 CFR 63, Subpart EEE.

326 IAC 6-3 (Process Operations) – 326 IAC 6-3 does not apply because the solid-liquid waste incinerator is exempted under 326 IAC 6-3-1(a).

326 IAC 7 (Sulfur Dioxide Emission Limitations) – 326 IAC 7 applies to the solid-liquid waste incinerator because the kiln SO_2 potential to emit exceeds 25 tons per year. Pursuant to 326 IAC 7-1.1-2 (SO_2 Rules), the SO_2 emissions from the combustion of fuel oil during the deslagging process in the solid-liquid waste incinerator shall not exceed 0.5 pounds per million British thermal units (lbs/MMBtu).

326 IAC 8-5-3 (Miscellaneous Operations: Synthesized Pharmaceutical Manufacturing Operations) – 326 IAC 8-5-3 does not apply to the solid-liquid waste incinerator because it is not defined as any of the emission unit types listed in 326 IAC 8-5-3(a).

326 IAC 8-1-6 (State BACT Requirements) – As part of the Title V permitting process, the source elected to undergo PSD review for its BPM operations. The best available control technology (BACT) required under the PSD requirements of 326 IAC 2-2 are discussed in Attachment C of this TSD. These federal requirements satisfy the requirements of 326 IAC 8-1-6.

326 IAC 9 (Carbon Monoxide Rules) – 326 IAC 9-1-2 does not apply because the incinerator is subject to carbon monoxide emission limitations in 40 CFR 63, Subpart EEE.

326 IAC 11-6 (Hospital/Medical/Infectious Waste Incinerators) – This rule does not apply to the rotary solid-liquid waste incinerator because it has a permit under section 3005 of the Solid Waste Disposal Act. Any combustor required to have a permit under section 3005 of the Solid Waste Disposal Act is not subject to this subpart.

326 IAC 11-7 (Municipal Waste Combustors) – This rule does not apply to the solid-liquid waste incinerator because it does not combust municipal waste as defined in 40 CFR 60, Subpart Cb.

326 IAC 15 (Lead Rules) – This rule does not apply to the source because the plant operations are not classified as one of the source types listed in 326 IAC 15-1-2.

Compliance Requirements

The following compliance activities are required for the solid-liquid waste incinerator:

1. Conduct performance tests;
2. Operate CEMS for CO, SO2, and NOx;
3. Sampling and analysis of fuel oil; and
4. Continuously monitor the following operating parameters:

   (a) primary and secondary waste feed to primary combustion chamber;
   (b) solid feed rate;
   (c) primary combustion chamber temperature;
   (d) primary and secondary waste feed to secondary combustion chamber;
   (e) stack gas flow rate;
   (f) waste feed viscosity;
   (g) waste atomizing pressure;
   (h) mercury, semi-volatile metal and low-volatile metal feed rate in all feed streams;
   (i) low-volatile metal feed rate in all pumpable feed streams;
   (j) ash feed rate;
   (k) total chlorine feed rate;
   (l) condenser/absorber pressure drop, liquid feed pressure, scrubber water pH, scrubber liquid flow rate; and
   (m) Hydo-sonic scrubber equivalent pressure drop, conductivity, feed rate, and pH.

D.14: RTO Control System Operations

Background and Description

Tippecanoe Laboratories utilizes an extensive emission control system to reduce point source emissions from bulk pharmaceutical manufacturing (BPM) and parts of the BPM support operations. The system consists of two major elements. One is an elaborate fume transport system, also known as a closed-vent system, which consists of a series of large-diameter fiberglass ductwork, fans, and instrumentation. This system provides the transport of the fumes from the manufacturing building roof vents and tank modules to the second system, the Regenerative Thermal Oxidizers (RTO). The plantsite operates two identical RTO systems. It is typical for one RTO to be in operation while the other is in a maintenance shutdown or on standby.

Types of Emission Units and Pollution Control Equipment

The RTOs control VOC and VOHAP emissions from the fume streams exhausted from the bulk pharmaceutical manufacturing and support equipment. In addition, the RTOs oxidize carbon monoxide emissions that may be emitted by BPM process equipment. Good combustion design and practices minimize carbon monoxide and nitrogen oxide emissions. The RTOs are also equipped with caustic scrubbing systems used to control hydrogen halide and halogen emissions from the BPM production and support operations as well as hydrogen halides and halogens formed during combustion. The combustion chamber of each RTO and its associated scrubber make up the RTO control system.

Insignificant Activities

The RTO control system is not considered an insignificant activity pursuant to 326 IAC 2-7-1(21)(E).

Federal and State Rule Applicability/Streamlining Strategy

The RTO control system is the primary mechanism for Tippecanoe Laboratories to comply with multiple state and federal air pollution control requirements, including MACT standards, RACT rules, and New Source Performance Standards. These rules have similar standards and performance objectives which provide an opportunity for the Title V permit to consolidate the requirements into streamlined permit terms that comprehensively address all the requirements. Streamlining of overlapping requirements is authorized pursuant to 326 IAC 2-7-24.

Applicability
The following streamlining table applies to the RTO control system. Currently, the emissions from the BPM production buildings (T27, T28, T29, T31, T31A, T99, and T100) and one storage tank module(T146) shall comply with the RTO control system requirements established in this Title V permit section.

Overview of applicable requirements
The RTO control system is utilized to meet the requirements of the following air pollution control requirements dealing with volatile organic compound emissions (VOC), volatile organic hazardous air pollutant emissions (VOHAP), and/or hydrogen halides and halogens (HX): 326 IAC 8-5-3 [an Indiana RACT rule applicable to synthesized pharmaceutical manufacturing facilities], 40 CFR 63 Subpart DD [the NESHAP for offsite waste and recovery operations], 40 CFR 63 Subpart GGG [the Pharmaceutical MACT rules], and 40 CFR 60 Subpart Kb [the NSPS for volatile organic liquid vessels]. Upon issuance of this permit, the permittee will also be subject to BACT and flexible permit requirements established in this permit.

<u>Comparison of applicable requirements</u>
Pursuant to 326 IAC 2-7-24(b), any permittee that seeks to streamline multiple applicable requirements must present a side-by-side comparison of the requirements and the streamlined requirement. The following RTO streamlining table presents a comparison of 326 IAC 8-5-3, 40 CFR 60 Subpart Kb, 40 CFR 63 Subpart DD, 40 CFR 63 Subpart GGG, and the flexible PSD permit requirements, and includes the IDEM approved streamlined requirements established in the Title V permit. To the extent possible, the flexible PSD permit requirements mirror the Pharmaceutical MACT requirements. The streamlining table contains the following sections and subsections:

Emission Limits and Standards
- TOC Point Source Emission Limits and Standards

- HX and Fluorides Point Source Emission Limits and Standards

- CO/NOx/SO2 Point Source Emission Limits and Standards

- Work Practice Standards – Closed Vent Systems

- Work Practice Standards – Bypass Systems in Closed Vent Systems

- Exceptions to Control Device and Closed Vent System Standards

Compliance Demonstration Methods

- TOC Continuous Emissions Monitoring Systems (CEMS) and parametric Continuous Monitoring System (CMS) Requirements (if complying with 20 ppmv TOC alternative standard)

- HX CEMS requirements (if complying with 20 ppmv HX alternative standard)

- CO/NOx/SO2 CEMS Requirements

- TOC Stack Testing Requirements (if complying with DRE standard)

- HX Stack Testing Requirements (if complying with DRE standard)

- RTO Parametric CMS and Other Parametric Monitoring Requirements

- Scrubber Parametric CMS Requirements

- Closed Vent System and Bypass System parametric CMS and Other Parametric

RTO Control System Operations: Streamlining Table

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 8-5-3 (Synthetic Pharma RACT)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
Emission Limits and Standard						
TOC Point Source Emission Limits and Standards						
BPM Process Vent (D.6 – Process, D.7 – Recovery)	For reactors, distillation operations, crystallizers, centrifuges and vacuum dryers: Condensers must meet maximum outlet gas temperature requirement or equivalent controls [326 IAC 8-5-3(b)(1)] ________________ For air dryers and production equipment exhaust systems (local exhaust vents): Achieve at least 90% controls for uncontrolled VOC emissions ≥ 330 lb/day [326 IAC 8-5-3(b)(2)(A)] Reduce VOC emissions to 15 lbs/day or less for uncontrolled VOC emissions < 330 lb/day [326 IAC 8-5-3(b)(2)(B)]	N/A	20 ppm TOC, corrected to 3%O2 achieved from a stack test *AND* establish min temp from stack test [63.690(b), 63.693(f)(1)(i)(B) or (f)(1)(ii)(B), and 63.693(f)(3)(i)] OR Alternative operating parameter: 20 ppmv TOC avg. over 24-hr period via CEMS [63.690(b), 63.693(f)(1)(i)(B) or (f)(1)(ii)(B), and 63.693(f)(3)(iii)] 95% DRE (individual vent percent reduction standard) *AND* establish min temp from stack test [63.690(b), 63.693(f)(1)(i)(A) or (f)(1)(ii)(A), and 63.693(f)(3)(ii)] OR Maintain temp ≥ 760 F *AND* residence time ≥ 0.5 sec [63.690(b) and 63.693(f)(1)(iii)]	93% DRE for process vents in a process ≤ 25 tpy *AND* establish 24-hr avg. for min temp and max %LEL determined from worst case compliant stack test [63.1254(a)(1)(i) and 63.1258(b)(1)(vii)] OR 98% DRE for individual vents > 25 tpy AND establish 24-hr avg. for min temp and max % LEL determined from worst-case compliant stack test [63.1254(a)(3)(i) and 63.1258(b)(1)(vii)] OR 20 ppmv TOC, as calibrated on methane, avg. over 24-hr period, corrected to 3% O2 [63.1254(c), 63.1257(a)(3), 63.1258(b)(2)] OR 20 ppmv TOC avg. over 24-hr period *AND* min time of ≥ 0.75 sec (or flowrate) and min temp of ≥ 816 C [63.1254(c), 63.1258(b)(2) and 63.1258(b)(5)(ii)(A)]	20 ppm TOC (measured as methane) average over 24-hr period *AND* residence time ≥ 0.75 sec and temp ≥ 816C (1500F) OR 98% TOC DRE *AND* establish 24-hr average parameters for min temp and max % LEL determined from worst-case compliant stack test	

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 8-5-3 (Synthetic Pharma RACT)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM Solvent Tanks (D.9)		Control Device Emission Limit Options: 95% DRE OR Time ≥ 0.75 sec and temp ≥ 816C OR Other parameters determined from a design analysis [60.112b(a) and (a)(3)(iii), and 60.113b(c)(1)(i)]	N/A	90% DRE achieved via stack testing *AND* establish min temp and max % LEL from worst case compliant stack test for tanks ≥38 to <75 m3 & VP ≥13.1 kPa [63.1253(b)(1) and 63.1258(b)(1)(vii)] *OR* Maintain time ≥ 0.5 sec AND temp ≥760 C for tanks ≥38 to <75 m3 & VP ≥13.1 kPa [63.1253(b)(2) and 63.1258(b)(1)(vii)] OR 95% DRE *AND* min temp and max % LEL from worst case stack test for tanks ≥75 m3, VP ≥13.1kPa [63.1253(c)(1)(i)] *OR* Maintain time ≥ 0.5 sec *AND* temp ≥ 760 C for solvent tanks ≥75 m3, VP ≥13.1kPa [63.1253(c)(2)] OR 20 ppmv TOC avg. over 24-hr period *AND* min time of ≥ 0.5 sec (or flowrate) and min temp of ≥ 760 C [63.1253(d), 63.1258(b)(2) and 63.1258(b)(5)(ii)(A)]		

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 8-5-3 (Synthetic Pharma RACT)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM Waste Tanks (D.10)	For reactors, distillation operations, crystallizers, centrifuges and vacuum dryers: Condensers must meet maximum outlet gas temperature requirement or equivalent controls [326 IAC 8-5-3(b)(1)] _______________ For air dryers and production equipment exhaust systems (local exhaust vents): Achieve at least 90% controls for uncontrolled	Control Device Emission Limit Options: 95% DRE OR Min time of ≥ 0.75 sec and min temp of ≥ 816 C OR Other parameters determined from a design analysis [60.112b(a) and (a)(3)(iii), and 60.113b(c)(1)(i)]	For the waste tanks and IDSs described in their respective individual "D" sections that require the facility to be vented through a closed-vent system to a control device [63.685(b)(1) and (4), 63.685(c)(2) and 63.902(b)(3)(ii), 63.685(d)(3), and 63.689(b) and 63.962(a)(3)] shall comply with one of the following control standards: 20 ppm TOC, corrected to 3%O2 achieved from a stack test *AND* establish min temp from stack test [63.962(a)(3)(ii), 63.962(b)(3)(ii)(A), 63.693(f)(1)(i)(B) or (f)(1)(ii)(B), and 63.693(f)(3)(ii)] OR Alternative operating parameter: 20 ppmv TOC avg. over 24-hr period via CEMS	95% DRE achieved via stack testing *AND* establish min temp from stack test[63.1256(b)(2), 62.1256(e)(1)(ii), and 63.1256(h)(2)(i)(A)] OR 20 ppmv achieved via stack testing *AND* establish min temp from stack test [63.1256(b)(3)(ii), 63.1256(e)(1)(ii), and 63.1256(h)(2)(i)(B)] OR Maintain residence time ≥ 0.5 sec *AND* temp ≥ 760C [63.1256(b)(3)(ii), 63.1256(e)(1)(ii), and 63.1256(h)(2)(i)(C)]	20 ppm TOC (measured as methane) average over 24-hr period *AND* residence time ≥ 0.75 sec and temp ≥ 816C (1500F). The following maximum flowrate may be used to demonstrate the residence time is ≥ 0.75 sec: Max Flowrate, cfm = volume of retention chamber, scf / residence time, sec Max Flowrate, cfm = 2504.7 scf / 0.75 sec Max Flowrate, cfm = 3340 scf/sec OR 98% TOC DRE *AND* min temp and max % LEL determined from worst-case compliant stack test	

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 8-5-3 (Synthetic Pharma RACT)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM Individual Drain Systems (IDSs) to Control Device (D.8)		N/A				

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 8-5-3 (Synthetic Pharma RACT)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
HX Point Source Emission Limits and Standards						
BPM Process Vent (D.6 – Process, D.7 – Recovery)	N/A	N/A	N/A	20 ppmv HX, which includes fluorides as HF, (measured as HCl) avg. over 24-hr period, corrected to 3% O2 [63.1254(c), 63.1257(a)(3), 63.1258(b)(2)] OR 20 ppmv HX, which includes fluorides as HF, (measured as HCl) avg. over 24-hr period [63.1254(a)(1)(ii)(A), 63.1258(b)(2), (b)(5)(ii)(A)] OR <u>Process vents in a process < 25 tpy</u>: 93% DRE *AND* min scrubber pH, min recirculation flow rate, and max caustic flow rate from worst case compliant HCl stack test [63.1254(a)(1)(i), 63.1257(d), and 63.1258(b)(1)(ii)] OR <u>Individual vents > 25 tpy:</u> 98% DRE *AND* min scrubber pH, min recirculation flow rate, and max caustic flow rate from worst case compliant HCl stack test [63.1254(a)(3)(i), 63.1257(d), and 63.1258(b)(1)(ii)]	20 ppmv HX, which includes fluorides as HF (measured as HCl), averaged over 24-hr period, using an HCl CEMS OR 98% HX DRE, which includes fluorides as HF, *AND* min scrubber liquid pH min recirculation flow rate, and max caustic flow rate determined from worst-case compliant HCl stack test	

<table>
<tr><th rowspan="2">Affected Units Controlled by RTO Control System</th><th colspan="5">Potentially Applicable Regulations</th><th rowspan="2">Streamlined Requirements</th></tr>
<tr><th>326 IAC 8-5-3 (Synthetic Pharma RACT)</th><th>40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)</th><th>40 CFR 63, Subpart DD (Offsite Waste MACT)</th><th>40 CFR 63, Subpart GGG (Pharma MACT)</th><th>326 IAC 2-2 (PSD BACT for RTO System)</th></tr>
<tr><td>BPM Solvent Tanks (D.9)</td><td>N/A</td><td>N/A</td><td>N/A</td><td>20 ppmv HX (measured as HCl) avg. over 24-hr period [63.1253(d) and 63.1258(b)(5)(ii)(A)]

OR

<u>Tanks >38 m3 to<75 m3, >13.1kPa:</u>
90% DRE for total HAP (VOHAP + HX) and min temp via worst case stack test AND establish min recirculation flow rate, min scrubber pH, and max caustic flow rate [63.1253(b)(1), 63.1257(c), 63.1258(b)(1)(ii)]

OR

<u>Tanks >75 m3, >13.1kPa:</u>
95% DRE and min temp via worst case stack test AND establish min recirculation flow rate, min scrubber pH, and max caustic flow rate [63.1253(c)(1)(i) and 63.1258(b)(1)(ii)]</td><td rowspan="3"></td><td rowspan="3"></td></tr>
<tr><td>BPM Waste Tanks (D.10)</td><td>N/A</td><td>N/A</td><td>N/A</td><td rowspan="2">95% DRE achieved via stack testing AND establish min recirculation flow rate, min scrubber pH, and max caustic flow rate [63.1256(b)(3)(ii), 63.1256(e)(1)(ii), 63.1256(h)(2)(iv), and 63.1258(b)(1)(ii)]

OR

20 ppmv HX avg. over 24-hr period, using an HCl CEMS [63.1256(b)(3)(ii), 63.1256(e)(1)(ii), 63.1256(h)(2)(iv) and 63.1258(b)(1)(ii)]]</td></tr>
<tr><td>BPM IDSs to Control Device (D.8)</td><td>N/A</td><td>N/A</td><td>N/A</td></tr>
<tr><td colspan="7">CO/NOx/SO2 Point Source Emission Limits and Standards</td></tr>
</table>

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 8-5-3 (Synthetic Pharma RACT)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM Process Vent (D.6 – Process, D.7 – Recovery) BPM Solvent Tanks (D.9) BPM Waste Tanks (D.10) BPM IDS to Control Device (D.8)	N/A	N/A	N/A	N/A	Each RTO system shall be limited to 73 ppmv CO average over a 24-hr period Each RTO system shall be limited to 91 ppmv NOx average over a 24-hr period Each RTO system shall be limited to 100 ppmv SO2 average over a 24-hr period	
Work Practice Standards – Closed-vent Systems (CVSs)						
BPM Process Vent (D.6 – Process, D.7 – Recovery)	N/A	N/A	<u>CVSs NOT under negative pressure:</u> Initial Method 21 inspections [63.683(c), 63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.690(b), 63.693(b)(5), 63.693(c)(1)(i) and 63.695(c)(1)(i)] Annual visual inspections on CVSs [63.683(c), 63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.693((b)(5) and 63.695(c)(1)(ii)(A)] Repair defects within 5/45 days [63.683(c), 63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.690(b), 63.693(c)(1)(i), 63.695(c)(1)(iiii) and 63.695(c)(3)(i)] Any time a component is repaired or replaced, conduct a Method 21 inspection to demonstrate < 500 ppmv [63.683(c), 63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.690(b),	None Specified	<u>Closed-vent systems NOT operated under negative pressure:</u> - Initial Method 21 inspections on closed vent systems - Annual visual inspections for defects on closed vent systems - Repair detected defects within 5/15 days, except where delay of repair is allowed - Any time a component is repaired or replaced, conduct a Method 21 inspection to demonstrate < 500 ppmv <u>Closed-vent systems operated under negative pressure:</u> - Annual visual inspections for defects such as visible cracks/holes/gaps in	
BPM Solvent Tanks (D.9)	N/A	N/A		None Specified		
BPM Waste Tanks (D.10)	N/A	N/A		<u>CVSs NOT under negative pressure:</u> Initial Method 21 inspections Annual visual inspections for visible, audible or olfactory indications of leaks on closed vent systems that are		

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 8-5-3 (Synthetic Pharma RACT)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM IDSs to Control Device (D.8)	N/A	N/A	63.695(c)(1)(ii)(A)] CVSs under negative pressure: Annual visual inspections for visible cracks, holes, or gaps in ductwork or piping; loose connections; or broken or missing caps or other closure devices [63.683(c), 63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.690(b), 63.693(c)(1)(ii) and 63.695(c)(2)] Repair defects within 5/45 days [63.683(c), 63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.690(b), 63.693(c)(1)(ii), 63.695(c)(2)(iii), (3)(i)] NOTE: These requirements do not apply to solvent tanks. Solvent tanks are not regulated under the Offsite Waste MACT.	hard-piped [1256(b)(3)(iii), 63.1256(e)(1)(iii), 63.1258(h)(2)(i) and 63.1258(h)(10)] Repair detected defects within 5/15 days, except where delay of repair allowed (technically infeasible without shutdown, or emissions resulting form immediate repair would be greater than the fugitive emissions resulting from delay of repair. Must be complete by end of next shutdown) [63.1258(h)(4) and (5)] Closed-vent systems operated under negative pressure: No inspections required [1256(b)(3)(iv) and 63.1256(e)(1)(iv)] __________________________________ Not required to inspect if unsafe/difficult to monitor [63.1258(h)(6) and (7)]	ductwork/piping; loose connections; or broken/missing caps - Repair detected defects within 5/15 days, except where delay of repair allowed __________________________________ Not required to test or inspect if unsafe or difficult to monitor	
Work Practice Standards – Bypass Systems in Closed Vent System						
BPM Process Vent (D.6 – Process, D.7 – Recovery)	N/A	N/A	Nothing Referenced	Continuous flow indicator at inlet of bypass line at least once every 15 minutes. Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and pressure relief valves needed for safety purposes are not subject to this requirement [63.1252(b)(1), 63.1253(b) and (c), Table 4, 63.1258(b)(1)(xi)]	The Pharma MACT work practice requirements serve as the PSD BACT and streamlined requirements: Continuous flow indicator at inlet of bypass line at least once every 15 minutes. Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and	
BPM Solvent Tanks (D.9)	N/A	N/A	N/A			

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 8-5-3 (Synthetic Pharma RACT)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM Waste Tanks (D.10)	N/A	N/A	Continuous flow indicator at inlet of bypass [63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.693(c)(2)(i)] OR Monthly visual inspection of seal or locking device on the mechanism by which the bypass device position is controlled to ensure the device is in the closed position and that the seal is not broken [63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.693(c)(2)(ii)]	OR Monthly visual inspection of seal or locking device on the mechanism by which the bypass device position is controlled to ensure the device is in the closed position and that the seal is not broken [63.1252(b)(2), 63.1253(b) and (c), Table 4, 63.1258(b)(1)(xi)]	pressure relief valves needed for safety purposes are not subject to this requirement OR Monthly visual inspection of seal or locking device on the mechanism by which the bypass device position is controlled to ensure the device is in the closed position and that the seal is not broken	
BPM IDSs (D.8)	N/A	N/A				
Exceptions to Control Device (RTO System) and Closed-Vent System Standards						
BPM Process Vent (D.6 – Process, D.7 – Recovery)	N/A	N/A	The control device may be bypassed for purposes of correcting a malfunction of the closed vent system or control device [63.690((b) and 63.693(b)(3)(ii)]	Control except for SSM events, if SSM plan is followed [63.1260(g)]	Control except for SSM events, if SSM plan is followed	
BPM Solvent Tanks (D.9)	N/A	N/A	N/A			
BPM Waste Tanks (D.10)	N/A	N/A	Opening of a safety device, as defined in 63.681 is allowed at any time conditions require it to do so to avoid an unsafe condition [63.685(g)(2)(ii) and 63.681] The control device may be bypassed for purposes of correcting a malfunction of the closed vent system or control device [63.693(b)(3)(ii)]			
BPM IDSs (D.8)	N/A	N/A				

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
Compliance Demonstration Methods						
TOC Continuous emissions monitoring (CEMS) and Continuous monitoring system (CMS) requirements (if complying with 20 ppmv TOC alternative standard)						
BPM Process Vent (D.6 – Process, D.7 – Recovery)	<u>CEMS Monitoring Requirements [3-5-1(c)(1) and (d)]:</u> - Install/monitor VOC CEMS that meets PS 8 set forth in 40 CFR 60, Appx B	N/A	The rule allows the source to demonstrate compliance using CEMS: - Meet requirements of PC 8 or 9 of Appx B of CFR 60 [63.693(f)(3)(iii) or (iv)] - O&M for CMSs [63.8(c)(1)]	The following CEMS requirements apply when demonstrating compliance with the 20 ppmv alternative standard [63.1253(d) and 63.1254(c)]: <u>Initial Compliance Procedures</u>: *Initial compliance demonstration*		The Pharma MACT requirements for process vents and solvent tanks shall serve as the streamlined requirement when demonstrating compliance with the 20 ppmv alternative standard: <u>Initial Compliance Procedures</u>:

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM Solvent Tanks (D.9)	[326 IAC 3-5-2(1)] - Measure/record VOC for each successive 15 minute measuring period [326 IAC 3-5-2(2)(B) - Daily CD check [326 IAC 3-5-5(a) and 40 CFR 60, Appx F, Proc 1] - Quarterly cylinder gas audits [3-5-5(e), 40 CFR 60, Appx F, Proc 1] - Annual RATA [3-5-5(e) and 40 CFR 60, Appx F, Proc 1]		N/A	*detailed in the Relative Accuracy Test Audit (RATA) Compliance Reports submitted to IDEM on October 17, 2002 for RTO1 and August 28, 2002 for RTO2* [63.1254(a), 63.1257(a)(5), (b), and (d)(1)(iv)] <u>TOC CEMS Monitoring Requirements</u>: - Meet requirements of Performance Spec (PC) 8 of Appx B of 40 CFR 60 [63.1258(b)(1)(x), 63.1258(b)(5)(i)(A), 63.8(c)(2)] - Monitor/record outlet TOC and HX concentration every 15 min during periods which device is operating on waste [63.1258(b)(1)(x), (b)(5)(i) and 63.8(c)(4)(ii)] - Daily calibration drift (CD) check [63.1258(b)(1)(x), 40 CFR 60, Appx F, Procedure 1, and 63.8(c)(6)] - Quarterly cylinder gas audits [63.1258(b)(5)(i)(A) and 40 CFR 60, Appx F, Procedure 1] - Annual RATA [63.1258(b)(1)(x) and 40 CFR 60, Appx F, Procedure 1] - Monitoring values taken during periods in which the control devices are not functioning in controlling emissions, as indicated by periods of no flow, not considered in emissions averaging. If flow to the device could be intermittent, install/calibrate/operate a flow indicator to identify periods of no flow [63.1258(b)(2)(iii)] - O&M and QC for CMSs [63.1258(b)(1)(x), (b)(5)(i)(A), and 63.8(c)(1) and (d)]	*Initial compliance demonstration detailed in the Relative Accuracy Test Audit (RATA) Compliance Reports submitted to IDEM on October 17, 2002 for RTO1 and August 28, 2002 for RTO2* [63.1254(a), 63.1257(a)(5), (b), and (d)(1)(iv)] <u>TOC CEMS Monitoring Requirements</u>: - Meet requirements of Performance Spec (PC) 8 of Appx B of 40 CFR 60 [63.1258(b)(1)(x), 63.1258(b)(5)(i)(A), 63.8(c)(2)] - Monitor/record outlet TOC and HX concentration every 15 min during periods which device is operating on waste [63.1258(b)(1)(x), (b)(5)(i) and 63.8(c)(4)(ii)] - Daily calibration drift (CD) check [63.1258(b)(1)(x), 40 CFR 60, Appx F, Procedure 1, and 63.8(c)(6)] - Quarterly cylinder gas audits [63.1258(b)(5)(i)(A) and 40 CFR 60, Appx F, Procedure 1] - Annual RATA [63.1258(b)(1)(x) and 40 CFR 60, Appx F, Procedure 1] - Monitoring values taken during periods in which the control devices are not functioning in controlling emissions, as indicated by periods of no flow, not considered in emissions averaging. If flow to the device could be intermittent, install/calibrate/operate a flow indicator to identify periods of	

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	Streamlined Requirements
BPM Waste Tanks (D.10)			The rule allows the source to demonstrate compliance using CEMS: - Meet requirements of PC 8 or 9 of Appx B of CFR 60 [63.693(f)(3)(iii) or (iv)] - O&M for CMSs [63.8(c)(1)]	No CEMS required for these types of operations	no flow [63.1258(b)(2)(iii)] - O&M and QC for CMSs [63.1258(b)(1)(x), (b)(5)(i)(A), and 63.8(c)(1) and (d)]	
BPM IDSs to control device (D.8)						
HX Continuous CEMS requirements (if complying with 20 ppmv HX alternative standard)						
BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery)	This rule does not address CEMS for HX or HCl [3-5]	N/A	N/A	The following CEMS requirements apply when demonstrating compliance with the 20 ppmv HCl alternative standard [63.1253(d) and 63.1254(c)]: Initial Compliance Procedures – *Initial compliance demonstration detailed in the Relative Accuracy Test Audit (RATA) Compliance Reports submitted to IDEM on October 17, 2002 for RTO1 and August 28, 2002 for RTO2* [63.1253(a), 63.1254(a), 63.1257(b), 63.1257(c)(4), 63.1257(d)(1)(iv) and 63.1257(a)(5)] HCl CEMS Monitoring Requirements – - Meet PS 15 of Appx B of part 60; or any other CEMS capable of	The following Pharma MACT compliance determination requirements for process vents and solvent tanks shall satisfy the PSD BACT requirements for fluorides and serve as the streamlined requirement when demonstrating compliance with the 20 ppmv concentration standard: Initial Compliance Procedures – *Initial compliance demonstration detailed in the Relative Accuracy Test Audit (RATA) Compliance Reports submitted to IDEM on October 17, 2002 for RTO1 and August 28, 2002 for RTO2* [63.1253(a), 63.1254(a), 63.1257(b), 63.1257(c)(4), 63.1257(d)(1)(iv) and	

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM Solvent Tanks (D.9)				measuring HCl for which a PS has been promulgated in appx B of part 60; or CEMS for which a PS has not been promulgated, if Permittee prepares/submits a monitoring plan to the agency for approval [63.1258(b)(5)(i)(A) and (B) and 63.8(b)(ii)] - Monitor and record outlet TOC and HX concentration every 15 min during periods which device is operating [63.1258(b)(5)(i) and 63.8(c)(4)(ii)]Quarterly cylinder gas audits [63.1258(b)(5)(i)(A)] - Annual RATA - Monitoring values taken during periods in which the control devices are not functioning in controlling emissions shall not be considered in emissions averaging. Lilly will determine these periods by control device operating status [63.1258(b)(2)(iii)] - O&M and QC for CMSs [63.1258(b)(1)(x), (b)(5)(i)(A), and 63.8(c)(1) and (d)]	63.1257(a)(5)] HCl CEMS Monitoring Requirements – - Meet PS 15 of Appx B of part 60; or any other CEMS capable of measuring HCl for which a PS has been promulgated in appx B of part 60; or CEMS for which a PS has not been promulgated, if Permittee prepares/submits a monitoring plan to the agency for approval [63.1258(b)(5)(i)(A) and (B) and 63.8(b)(ii)] - Monitor and record outlet TOC and HX concentration every 15 min during periods which device is operating [63.1258(b)(5)(i) and 63.8(c)(4)(ii)]Quarterly cylinder gas audits [63.1258(b)(5)(i)(A)] - Annual RATA - Monitoring values taken during periods in which the control devices are not functioning in controlling emissions shall not be considered in emissions averaging. Lilly will determine these periods by control device operating status [63.1258(b)(2)(iii)] - O&M and QC for CMSs [63.1258(b)(1)(x), (b)(5)(i)(A), and 63.8(c)(1) and (d)]	
BPM Waste Tanks (D.10)				No CEMS required for these types of operations		

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	Streamlined Requirements
BPM IDSs (D.8)						
CO/NOx/SO2 CEMS requirements						
BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery) BPM Solvent Tanks (D.9) BPM Waste Tanks (D.10)	<u>CEMS Monitoring Requirements [3-5-1(d)]:</u> - Install/monitor VOC CEMS that meets PS 4 or 4A for CO and PS 2 for NOx and SO2 set forth in 40 CFR 60, Appx B [326 IAC 3-5-2(1)] - Measure/record VOC for each successive 15 minute measuring period [326 IAC 3-5-2(2)(B) - Daily CD check [326 IAC 3-5-5(a) and 40	N/A	N/A	N/A	The following CEMS determination requirements of 326 IAC 3-5 shall satisfy the PSD BACT for CO/NOx/SO2 and serve as the streamlined requirement. Monitoring data is only required when burning fume streams: - Install/monitor VOC CEMS that meets PS 4 or 4A for CO and PS 2 for NOx and SO2 set forth in 40 CFR 60, Appx B [326 IAC 3-5-2(1)] - Measure/record VOC for each successive 15 minute measuring period [326 IAC 3-5-2(2)(B) - Daily CD check [326 IAC 3-5-5(a) and 40 CFR 60, Appx F,	

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM IDSs (D.8)	CFR 60, Appx F, Proc 1] - Quarterly cylinder gas audits [3-5-5(e), 40 CFR 60, Appx F, Proc 1] - Annual RATA [3-5-5(e) and 40 CFR 60, Appx F, Proc 1] - Initial monitor system certifications within 180 days upon startup (permit issuance date) [3-5-3(1)(A)] - Monitor system certifications of monitor replacement or significant monitor repair within 45 days following the change [3-5-3(1)(B)]					Proc 1] - Quarterly cylinder gas audits [3-5-5(e), 40 CFR 60, Appx F, Proc 1] - Annual RATA [3-5-5(e) and 40 CFR 60, Appx F, Proc 1] - Initial monitor system certifications within 180 days upon startup (permit issuance date) [3-5-3(1)(A)] - Monitor system certifications of monitor replacement or significant monitor repair within 45 days following the change [3-5-3(1)(B)]
TOC Stack Testing requirements (if complying with DRE standard)						
BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery)	When demonstrating compliance with the DRE standard, facilities subject to NSPS or NESHAP shall be tested under conditions specified in that applicable provision [326 IAC 3-6-3]		<u>The following stack test procedures apply if demonstrating compliance with the DRE standard [63.693(f)(2)(i)]:</u> - Method 1 or 1A of 40 CFR 60, Appx A for selection of sampling sites - Method 2, 2A, 2C, or 2D of 40 CFR 60, Appx A for gas volumetric flowrate - Method 18 of 40 CFR 60, Appx A or method validated according to procedures in Method 301 in 40 CFR 63, Appx A to demonstrate compliance with control device DRE requirement	<u>The following stack testing requirements apply when demonstrating compliance with the DRE standard:</u> - Submit site-specific plan prior to testing as required by 63.7 and 63.1260(l) - Conduct test under worst-case conditions or hypothetical worst-case conditions via max load to control device - Measure gas stream volumetric		The following stack testing requirements for TOC under the Pharma MACT satisfy the PSD BACT for VOC and streamlined requirements when demonstrating compliance with the DRE standard: - Submit site-specific plan prior to testing as required by 63.7 and 63.1260(l) - Conduct test under worst-case conditions or hypothetical worst-case conditions via max

<table>
<tr><th rowspan="2">Affected Units Controlled by RTO Control System</th><th colspan="5">Potentially Applicable Regulations</th><th rowspan="2">Streamlined Requirements</th></tr>
<tr><th>326 IAC 3 (Monitoring Requirements)</th><th>40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)</th><th>40 CFR 63, Subpart DD (Offsite Waste MACT)</th><th>40 CFR 63, Subpart GGG (Pharma MACT)</th><th>326 IAC 2-2 (PSD BACT for RTO System)</th></tr>
<tr><td>BPM Solvent Tanks (D.9)</td><td rowspan="3"></td><td rowspan="3"></td><td rowspan="3">[63.694(l)(1)(i), 63.694(l)(3)]

<u>The following stack test procedures apply if demonstrating compliance with the concentration standard via stack test [63.693(f)(2)(i)]:</u>

- Method 1 or 1A of 40 CFR 60, Appx A for selection of sampling sites
- Method 2, 2A, 2C, or 2D of 40 CFR 60, Appx A for gas volumetric flowrate
- Method 18 of 40 CFR 60, Appx A or method validated according to procedures in Method 301 in 40 CFR 63, Appx A to demonstrate compliance with control device concentration limit [63.694(l)(1)(ii), 63.694(l)(4)]

NOTE: These requirements do not apply to solvent tanks. Solvent tanks are not regulated under Offsite Waste MACT.</td><td>flow rates at least every 15 minutes
- Perform testing on inlet and outlet of control device [63.1257(c)(1)(iii), 63.1257(d)(1)(ii)(A), 63.1257(d)(3)(ii), 63.1257(b)(8)]

<u>Measure and record the following parameters during stack test to develop operating parameter limits</u>:

- Organic concentration in FTS measured as % LEL
- Temperature</td><td rowspan="3" colspan="2">load to control device
- Measure gas stream volumetric flow rates at least every 15 minutes
- Perform testing on inlet and outlet of control device [63.1257(c)(1)(iii), 63.1257(d)(1)(ii)(A), 63.1257(d)(3)(ii), 63.1257(b)(8)]

<u>Measure and record the following parameters during stack test to develop operating parameter limits</u>:

- Organic concentration in FTS measured as % LEL
- Temperature</td></tr>
<tr><td>BPM Waste Tanks (D.10)</td><td rowspan="2"><u>The following stack testing requirements apply when demonstrating compliance with the DRE standard:</u>

- Method 1 or 1A of 40 CFR 60, Appx A for selection of sampling sites
- Method 2, 2A, 2C, or 2D of 40 CFR 60, Appx A for gas volumetric flowrate
- Method 18 of 40 CFR 60, Appx A or method validated according to procedures in Method 301 in 40 CFR 63, Appx A to demonstrate compliance with control device percent reduction requirement [63.1257(e)(3)(i)(A)-(J)]</td></tr>
<tr><td>BPM IDSs to control device (D.8)</td></tr>
<tr><td colspan="7">HX Stack Testing requirements (if complying with DRE standard)</td></tr>
</table>

<table>
<tr><th rowspan="2">Affected Units Controlled by RTO Control System</th><th colspan="5">Potentially Applicable Regulations</th><th rowspan="2">Streamlined Requirements</th></tr>
<tr><th>326 IAC 3 (Monitoring Requirements)</th><th>40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)</th><th>40 CFR 63, Subpart DD (Offsite Waste MACT)</th><th>40 CFR 63, Subpart GGG (Pharma MACT)</th><th>326 IAC 2-2 (PSD BACT for RTO System)</th></tr>
<tr><td>BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery)</td><td rowspan="4">When demonstrating compliance with the DRE standard, facilities subject to NSPS or NESHAP shall be tested under conditions specified in that applicable provision [326 IAC 3-6-3]</td><td rowspan="4">N/A</td><td rowspan="4">N/A</td><td rowspan="2">The following HCl stack testing requirements apply when demonstrating compliance with the DRE standard:

- Submit site-specific plan prior to testing as required by 63.7 and 63.1260(l)
- Conduct test under worst-case conditions or hypothetical worst-case conditions via max load to control device
- Measure gas stream volumetric flow rates at least every 15 minutes
- Perform testing on inlet and outlet of control device [63.1257(c)(1)(iii), 63.1257(d)(1)(ii)(A), 63.1257(d)(3)(ii), 63.1257(b)(8)]

Measure and record the following parameters during stack test to develop operating parameter limits:

- Scrubber pH
- Recirculation flow rate
- Caustic flow rate</td><td colspan="2" rowspan="4">The following stack testing requirements for hydrogen halides and halogens under the Pharma MACT shall satisfy the fluorides compliance determination requirements and serve as the streamlined requirement when demonstrating compliance with the DRE standard:

- Submit site-specific plan prior to testing as required by 63.7 and 63.1260(l)
- Conduct test under worst-case conditions or hypothetical worst-case conditions via max load to control device
- Measure gas stream volumetric flow rates at least every 15 minutes
- Perform testing on inlet and outlet of control device [63.1257(c)(1)(iii), 63.1257(d)(1)(ii)(A), 63.1257(d)(3)(ii), 63.1257(b)(8)]
- Measure and record scrubber pH
- Measure recirculation flow rate
- Measure caustic flow rate</td></tr>
<tr><td>BPM Solvent Tanks (D.9)</td></tr>
<tr><td>BPM Waste Tanks (D.10)</td><td rowspan="2">None Specified</td></tr>
<tr><td>BPM IDSs to control device (D.8)</td></tr>
<tr><td colspan="7">RTO Parametric Continuous Monitoring System (CMS) and other monitoring requirements</td></tr>
</table>

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery) BPM Solvent Tanks (D.9) BPM Waste Tanks (D.10) BPM IDSs to control device (D.8)	Parametric CMS Monitoring Requirements: No parametric CMS requirements under 3-5 Air Flow Monitor Requirements: - Measure/record each successive 15-minute measuring period [326 IAC 3-5-2(2)(B)] - Annual RATA [3-5-5(e) and 40 CFR 60, Appx F, Proc 1] - Initial monitor system certifications within 180 days upon startup (permit issuance date) [3-5-3(1)(A)] - Monitor system certifications of monitor replacement or significant monitor repair within 45 days following the change [3-5-3(1)(B)] - QC requirements [3-5-5(d)]	N/A	Temperature CMS requirements, if complying with the TOC DRE standard: - Measure and record a data point at least once every 15 minutes when burning fume streams [63.693(b)(4), (f)(3)(i)] - O&M for CMSs [63.8(c)(1)] NOTE: These requirements do not apply to solvent tanks. Solvent tanks are not regulated under the Offsite Waste MACT	Temperature CMS requirements, if complying with the DRE standard or the 20 ppmv TOC alternative standard [63.1258(b)(1)(vii)]: - Measure and record a data point at least once every 15 minutes when burning fume streams - Monitor device must be accurate to within ±0.75% of C temp or ±2.5C, whichever is greater - Calibrate annually - O&M and quality control for CMSs [63.1258(b)(1)(x), (b)(5)(i)(A), and 63.8(c)(1), (d)] Residence time (or flowrate) CMS requirements, if complying with the 20 ppmv TOC alternative std [63.1258(a) and (b)(5)(i)(A), and 63.1260(e)]: No performance specifications referenced (See Precompliance Report)	Temperature CMS requirements under the Pharma MACT shall serve as the streamlined requirement: - Measure and record a data point at least once every 15 minutes when burning fume streams - Monitor device must be accurate to within ±0.75% of C temp or ±2.5C, whichever is greater - Calibrate annually - O&M and quality control for CMSs The flow monitor CMS requirements under 326 IAC 3-5 shall serve as the streamlined requirement to demonstrate compliance with residence time: - Measure/record each successive 15-minute measuring period [326 IAC 3-5-2(2)(B)] - Annual RATA [3-5-5(e) and 40 CFR 60, Appx F, Proc 1] - Initial monitor system certifications within 180 days upon startup (permit issuance date) [3-5-3(1)(A)] - Monitor system certifications of monitor replacement or significant monitor repair within 45 days following the change [3-5-3(1)(B)] - QC requirements [3-5-5(d)]	
Scrubber Parametric CMS and other monitoring requirements						

<table>
<tr><th rowspan="2">Affected Units Controlled by RTO Control System</th><th colspan="5">Potentially Applicable Regulations</th><th rowspan="2">Streamlined Requirements</th></tr>
<tr><th>326 IAC 3 (Monitoring Requirements)</th><th>40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)</th><th>40 CFR 63, Subpart DD (Offsite Waste MACT)</th><th>40 CFR 63, Subpart GGG (Pharma MACT)</th><th>326 IAC 2-2 (PSD BACT for RTO System)</th></tr>
<tr><td>BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery)</td><td rowspan="3"><u>Parametric CMS Monitoring Requirements</u>:

No parametric CMS requirements under 3-5</td><td rowspan="3">N/A</td><td rowspan="3">N/A</td><td rowspan="3"><u>Scrubber liquid flow rate CMS requirements [63.1258(b)(1)(ii)]:</u>

- Measure and record a data point at least once/15 minutes when process is in operation
- Monitor must be certified by the mfr to be accurate within ±10% of design scrubber liquid flowrate
- Calibrate annually
- O&M and QC for CMSs [63.1258(b)(1)(x), (b)(5)(i)(A), and 63.8(c)(1) and (d)]

<u>Effluent scrubber liquid pH monitoring requirements [63.1257(b)(8), 63.1258(b)(1)(ii) and 63.1260(e)]:</u>

- Measure effluent scrubber liquid</td><td rowspan="3" colspan="2">When applying the control efficiency standard, the following streamlined compliance demonstration requirements shall satisfy the hydrogen halides/halogens requirements under Pharma MACT and the PSD BACT requirements for fluorides:

<u>Scrubber liquid flow rate, effluent scrubber liquid pH, and caustic liquid flow rate CMS requirements in accordance with 63.8(c)(1) and (d) and as outlined in the NOC:</u>

- Measure and record a data point at least once/15 minutes when process is in operation
- Monitor must be certified by</td></tr>
<tr><td>BPM Solvent Tanks (D.9)</td></tr>
<tr><td>BPM Waste Tanks (D.10)</td></tr>
</table>

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM IDSs to control device (D.8)						

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
Record Keeping and Reporting Requirements						
Record Keeping Requirements						
BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery)	<u>CEMS (includes flow monitor for CERMS data) Record keeping Requirements [3-5-6]</u>: - raw data; - design/installation/testing - corrective action or compliance plan, if applicable - maintenance logs - calibration checks and other QA activities - corrective and preventive action - facility downtime periods and reason for each downtime <u>CMS Record keeping Requirements</u>:	N/A	NOTE: The solvent storage tanks are not subject to these conditions <u>CMS (includes CEMS) and Control Device Records [63.693(b)(7), 63.696(b)]:</u> - Occurrence/duration records of each malfunction [63.696(h)] - Duration of each period during a malfunction when fumes continue to vent to the control device - Actions taken during periods of malfunction to restore control device to normal operation - All maintenance performed on control device equipment [63.10(b)(2)] - Current and superseded versions of SSM Plan stored at plantsite [63.6(e)(3)(v)] - Each SSM occurrence/duration [63.10(b)(2)] - Actions taken during SSM when different from SSM plan [63.10(b)(2)] - Info to demonstrate conformance with	<u>CMS (includes CEMS) and Control Device (RTO) Records:</u> - Occurrence/duration records of each malfunction of RTO and CMS [63.1259(a)(3)(i) and (ii)] - Control device operating parameter data [63.1259(b)(1)] - Description of worst-case operating conditions, if complying with DRE standard [63.1259(b)(9)] - Control device maintenance records [63.1259(b)(13)] - CMS data [63.1259(a)(4)] - CMS calibration checks and maintenance records [63.1259(b)(3)] - Malfunctioning/inoperative CMS periods - All required CMS measurements to demonstrate compliance with a standard - Current and superseded versions of SSM Plan stored at plantsite [63.1259(a)(3)] - Info to demonstrate conformance with SSM plan are consistent with procedures in the plan [63.1259(a)(3)(iii)] - Actions taken during SSM when different from SSM plan [63.1259(a)(3)(iii)] - Info to demonstrate conformance with SSM plan are consistent with procedures in the plan ***NOTE:*** Although the Pharma MACT recordkeeping requirements do not apply to NOx/SOx/CO CEMS and flow monitor, the Permittee shall comply		
BPM Solvent Tanks (D.9) BPM Waste Tanks (D.10)		- Maintain record of operating plan that describes parameters monitored to demonstrate compliance with control device standards [60.115b(c)(1)] - Records of all measured values/parameters monitored [60.115b(c)(2)]				

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM IDSs to control device (D.8)		N/A				

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
Reporting Requirements						
BPM Process Vent (D.6 – Process, D.7 – Recovery)	CEMS (includes flow monitor for CERMS data) Periodic Reporting Requirements: - Notifications 35-days prior to gaseous monitor system certification [3-5-3(2)(B)] - Notifications 35 days	N/A	NOTE: The solvent storage tanks are not subject to these conditions CMS (includes CEMS) and Control Device Reporting Requirements [63.697]: - Notification of CMSs at least 60 days prior to performance evaluation date [63.9(g)(1)] - SSM reports if actions are not consistent with SSM plan [63.697(b)(3)	CMS(includes CEMS) and Control Device Reporting Requirements [63.1260(g)]: - Notification of CMSs (includes CEMS) at least 60 days prior to performance evaluation date [63.9(g)(1)] - If total duration of excess emissions, parameter exceedances, or excursions is 1%	Control Device and CVS Reporting Requirements: The control device and closed vent system reporting requirements under the Pharma MACT rules shall serve as the streamlined reporting requirement. CMS/CEMS Reporting Requirements:	
BPM Solvent Tanks (D.9)		None Specified				
BPM Waste Tanks (D.10)						

Affected Units Controlled by RTO Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM IDSs to control device (D.8)		N/A				

D.15: T79 Control System Operations

Background and Description

Tippecanoe Laboratories utilizes an extensive emission control system to reduce point source emissions from bulk pharmaceutical manufacturing (BPM) and parts of the BPM support operations. The system consists of two major elements. One is an elaborate fume transport system, also known as a closed-vent system, which consists of a series of large-diameter fiberglass ductwork, fans, and instrumentation. This system provides the transport of the fumes from the solvent recovery vents and tank modules to the second system, the T79 control system. The plantsite operates two identical T79 control systems. It is typical for one unit to be in operation while the other is in a maintenance shutdown or on standby.

Types of Emission Units and Pollution Control Equipment

The redundant T79 control systems control VOC and VOHAP emissions from the fume streams exhausted from the BPM solvent recovery operations and support equipment. In addition, the T79 control systems are equipped with caustic scrubbing systems used to control hydrogen halide and halogen emissions from the BPM production and support operations as well as hydrogen halides and halogens formed during combustion. The combustion chamber of each T79 combustion chamber and its associated scrubber make up the T79 control system.

Insignificant Activities

The T79 fume incinerator control system is not considered an insignificant activity pursuant to 326 IAC 2-7-1(21)(E).

Federal and State Rule Applicability/Streamlining Strategy

The T79 control system is used to comply with multiple state and federal air pollution control requirements, including MACT standards, RACT rules, and New Source Performance Standards. These rules have similar standards and performance objectives which provide an opportunity for the Title V permit to consolidate the requirements into streamlined permit terms that comprehensively address all the requirements. Streamlining of overlapping requirements is authorized pursuant to 326 IAC 2-7-24.

Applicability
The following streamlining table applies to the T79 control system. Currently, the emissions from the BPM storage tank modules (T140, T143, and T145) and the BPM solvent recovery operations (T19, T52, and T61) shall comply with the T79 control system requirements established in this Title V permit section.

Overview of applicable requirements
The T79 control system is utilized to meet the requirements of the following air pollution control requirements dealing with volatile organic compound emissions (VOC), volatile organic hazardous air pollutant emissions (VOHAP), and/or hydrogen halides and halogens (HX): 326 IAC 8-5-3 [an Indiana RACT rule applicable to synthesized pharmaceutical manufacturing facilities], 40 CFR 63 Subpart DD [the NESHAP for offsite waste and recovery operations], 40 CFR 63 Subpart GGG [the Pharmaceutical MACT rules], and 40 CFR 60 Subpart Kb [the NSPS for volatile organic liquid vessels]. Upon issuance of this permit, the Permittee will also be subject to BACT for VOCs and flexible permit requirements established in this permit.

Comparison of applicable requirements

Pursuant to 326 IAC 2-7-24(b), any Permittee that seeks to streamline multiple applicable requirements must present a side-by-side comparison of the requirements and the streamlined requirement. The following RTO streamlining table presents a comparison of 326 IAC 8-5-3, 40 CFR 60 Subpart Kb, 40 CFR 63 Subpart DD, 40 CFR 63 Subpart GGG, and the flexible PSD permit requirements, and includes the IDEM approved streamlined requirements established in the Title V permit. To the extent possible, the flexible PSD permit requirements mirror the Pharmaceutical MACT requirements. The streamlining table contains the following sections and subsections:

Emission Limits and Standards

- TOC Point Source Emission Limits and Standards
- HX and Fluorides Point Source Emission Limits and Standards
- Work Practice Standards – Closed Vent Systems
- Work Practice Standards – Bypass Systems in Closed Vent Systems
- Exceptions to Control Device and Closed Vent System Standards

Compliance Demonstration Methods

- TOC Stack Testing Requirements (if complying with DRE standard)
- HX Stack Testing Requirements (if complying with DRE standard)
- T79 Parametric CMS and Other Parametric Monitoring Requirements
- Scrubber Parametric CMS Requirements
- Closed Vent System and Bypass System Parametric CMS and Other Parametric Monitoring Requirements

Record Keeping and Reporting Requirements

T79 Control System Operations: Streamlining Table

Affected Units Controlled by T79 Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 8-5-3 (Synthetic Pharma RACT)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
Emission Limits and Standard						
TOC Point Source Emission Limits and Standards						
BPM Process Vent (D.6 – Process, D.7 – Recovery)	For reactors, distillation operations, crystallizers, centrifuges and vacuum dryers: Condensers must meet maximum outlet gas temperature requirement or equivalent controls [326 IAC 8-5-3(b)(1)] _______________ For air dryers and production equipment exhaust systems (local exhaust vents): Achieve at least 90% controls for uncontrolled VOC emissions ≥ 330 lb/day [326 IAC 8-5-3(b)(2)(A)] Reduce VOC emissions to 15 lbs/day or less for uncontrolled VOC emissions < 330 lb/day [326 IAC 8-5-3(b)(2)(B)]	N/A	20 ppm TOC, corrected to 3%O2 achieved from a stack test *AND* establish min temp from stack test [63.690(b), 63.693(f)(1)(i)(B) or (f)(1)(ii)(B), and 63.693(f)(3)(i)] OR Alternative operating parameter: 20 ppmv TOC avg. over 24-hr period via CEMS [63.690(b), 63.693(f)(1)(i)(B) or (f)(1)(ii)(B), and 63.693(f)(3)(iii)] 95% DRE (individual vent percent reduction standard) *AND* establish min temp from stack test [63.690(b), 63.693(f)(1)(i)(A) or (f)(1)(ii)(A), and 63.693(f)(3)(ii)] OR Maintain temp ≥ 760 F *AND* residence time ≥ 0.5 sec [63.690(b) and 63.693(f)(1)(iii)]	93% DRE for process vents in a process ≤ 25 tpy *AND* establish 24-hr avg. for min temp and max %LEL determined from worst case compliant stack test [63.1254(a)(1)(i) and 63.1258(b)(1)(vii)] OR 98% DRE for individual vents > 25 tpy AND establish 24-hr avg. for min temp and max % LEL determined from worst-case compliant stack test [63.1254(a)(3)(i) and 63.1258(b)(1)(vii)] OR 20 ppmv TOC, as calibrated on methane, avg. over 24-hr period, corrected to 3% O2 [63.1254(c), 63.1257(a)(3), 63.1258(b)(2)] OR 20 ppmv TOC avg. over 24-hr period *AND* min time of ≥ 0.75 sec (or flowrate) and min temp of ≥ 816 C [63.1254(c), 63.1258(b)(2) and 63.1258(b)(5)(ii)(A)]	98% TOC DRE *AND* establish 24-hr average parameters for min temp and max % LEL determined from worst-case compliant stack test	

Affected Units Controlled by T79 Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 8-5-3 (Synthetic Pharma RACT)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM Solvent Tanks (D.9)		Control Device Emission Limit Options: 95% DRE OR Time ≥ 0.75 sec and temp ≥ 816C OR Other parameters determined from a design analysis [60.112b(a) and (a)(3)(iii), and 60.113b(c)(1)(i)]	N/A	90% DRE achieved via stack testing *AND* establish min temp and max % LEL from worst case compliant stack test for tanks ≥38 to <75 m3 & VP ≥13.1 kPa [63.1253(b)(1) and 63.1258(b)(1)(vii)] *OR* Maintain time ≥ 0.5 sec AND temp ≥760 C for tanks ≥38 to <75 m3 & VP ≥13.1 kPa [63.1253(b)(2) and 63.1258(b)(1)(vii)] OR 95% DRE *AND* min temp and max % LEL from worst case stack test for tanks ≥75 m3, VP ≥13.1kPa [63.1253(c)(1)(i)] *OR* Maintain time ≥ 0.5 sec *AND* temp ≥ 760 C for solvent tanks ≥75 m3, VP ≥13.1kPa [63.1253(c)(2)] OR 20 ppmv TOC avg. over 24-hr period *AND* min time of ≥ 0.5 sec (or flowrate) and min temp of ≥ 760 C [63.1253(d), 63.1258(b)(2) and 63.1258(b)(5)(ii)(A)]		

<table>
<tr><th rowspan="2">Affected Units Controlled by T79 Control System</th><th colspan="5">Potentially Applicable Regulations</th><th rowspan="2">Streamlined Requirements</th></tr>
<tr><th>326 IAC 8-5-3
(Synthetic Pharma RACT)</th><th>40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)</th><th>40 CFR 63, Subpart DD
(Offsite Waste MACT)</th><th>40 CFR 63, Subpart GGG
(Pharma MACT)</th><th>326 IAC 2-2 (PSD BACT for RTO System)</th></tr>
<tr><td>BPM Waste Tanks (D.10)</td><td rowspan="2">For reactors, distillation operations, crystallizers, centrifuges and vacuum dryers:

Condensers must meet maximum outlet gas temperature requirement or equivalent controls [326 IAC 8-5-3(b)(1)]
____

For air dryers and production equipment exhaust systems (local exhaust vents):

Achieve at least 90% controls for uncontrolled VOC emissions ≥ 330 lb/day [326 IAC 8-5-3(b)(2)(A)]; OR

Reduce VOC emissions to 15 lbs/day or less for uncontrolled VOC emissions < 330 lb/day [326 IAC 8-5-3(b)(2)(B)]</td><td>Control Device Emission Limit Options:

95% DRE

OR

Min time of ≥ 0.75 sec and min temp of ≥ 816 C

OR

Other parameters determined from a design analysis [60.112b(a) and (a)(3)(iii), and 60.113b(c)(1)(i)]</td><td rowspan="2">For the waste tanks and IDSs described in their respective individual "D" sections that require the facility to be vented through a closed-vent system to a control device [63.685(b)(1) and (4), 63.685(c)(2) and 63.902(b)(3)(ii), 63.685(d)(3), and 63.689(b) and 63.962(a)(3)] shall comply with one of the following control standards:

20 ppm TOC, corrected to 3%O2 achieved from a stack test AND establish min temp from stack test [63.962(a)(3)(ii), 63.962(b)(3)(ii)(A), 63.693(f)(1)(i)(B) or (f)(1)(ii)(B), and 63.693(f)(3)(ii)]

OR

Alternative operating parameter: 20 ppmv TOC avg. over 24-hr period via CEMS [63.962(a)(3)(ii), 63.962(b)(3)(ii)(A), 63.693(f)(1)(i)(B) or (f)(1)(ii)(B), and 63.693(f)(3)(iii)]

OR

95% DRE (individual vent percent reduction standard) AND establish min temp from stack test [63.962(a)(3)(ii), 63.962(b)(3)(ii)(A), 63.693(f)(1)(i)(A), and 63.693(f)(3)(iii)]

OR

Maintain temp ≥ 760 F AND residence time ≥ 0.5 sec [63.962(a)(3)(ii), 63.962(b)(3)(ii)(A), and 63.693(f)(1)(iii)]</td><td rowspan="2">95% DRE achieved via stack testing AND establish min temp from stack test[63.1256(b)(2), 62.1256(e)(1)(ii), and 63.1256(h)(2)(i)(A)]

OR

20 ppmv achieved via stack testing AND establish min temp from stack test [63.1256(b)(3)(ii), 63.1256(e)(1)(ii), and 63.1256(h)(2)(i)(B)]

OR

Maintain residence time ≥ 0.5 sec AND temp ≥ 760C [63.1256(b)(3)(ii), 63.1256(e)(1)(ii), and 63.1256(h)(2)(i)(C)]</td><td rowspan="2" colspan="2">98% TOC DRE AND min temp and max % LEL determined from worst-case compliant stack test</td></tr>
<tr><td>BPM Individual Drain Systems (IDSs) to Control Device (D.8)</td><td>N/A</td></tr>
</table>

Affected Units Controlled by T79 Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 8-5-3 (Synthetic Pharma RACT)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
HX Point Source Emission Limits and Standards						
BPM Process Vent (D.6 – Process, D.7 – Recovery)	N/A	N/A	N/A	20 ppmv HX, which includes fluorides as HF, (measured as HCl) avg. over 24-hr period, corrected to 3% O2 [63.1254(c), 63.1257(a)(3), 63.1258(b)(2)] OR 20 ppmv HX, which includes fluorides as HF, (measured as HCl) avg. over 24-hr period [63.1254(a)(1)(ii)(A), 63.1258(b)(2), (b)(5)(ii)(A)] OR Process vents in a process < 25 tpy: 93% DRE *AND* min scrubber pH, min recirculation flow rate, and max caustic flow rate from worst case compliant HCl stack test [63.1254(a)(1)(i), 63.1257(d), and 63.1258(b)(1)(ii)] OR Individual vents > 25 tpy: 98% DRE *AND* min scrubber pH, min recirculation flow rate, and max caustic flow rate from worst case compliant HCl stack test [63.1254(a)(3)(i), 63.1257(d), and 63.1258(b)(1)(ii)]		98% HX DRE, which includes fluorides as HF, *AND* min scrubber liquid pH, min recirculation flow rate, and max caustic flow rate determined from worst-case compliant HCl stack test

Affected Units Controlled by T79 Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 8-5-3 (Synthetic Pharma RACT)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM Solvent Tanks (D.9)	N/A	N/A	N/A	20 ppmv HX (measured as HCl) avg. over 24-hr period [63.1253(d) and 63.1258(b)(5)(ii)(A)] OR Tanks >38 m3 to<75 m3, >13.1kPa: 90% DRE for total HAP (VOHAP + HX) and min temp via worst case stack test *AND* establish min recirculation flow rate, min scrubber pH, and max caustic flow rate [63.1253(b)(1), 63.1257(c), 63.1258(b)(1)(ii)] OR Tanks >75 m3, >13.1kPa: 95% DRE and min temp via worst case stack test *AND* establish min recirculation flow rate, min scrubber pH, and max caustic flow rate [63.1253(c)(1)(i) and 63.1258(b)(1)(ii)]		
BPM Waste Tanks (D.10)	N/A	N/A	N/A	95% DRE achieved via stack testing *AND* establish min recirculation flow rate, min scrubber pH, and max caustic flow rate [63.1256(b)(3)(ii), 63.1256(e)(1)(ii), 63.1256(h)(2)(iv), and 63.1258(b)(1)(ii)] OR 20 ppmv HX avg. over 24-hr period, using an HCl CEMS [63.1256(b)(3)(ii), 63.1256(e)(1)(ii), 63.1256(h)(2)(iv) and 63.1258(b)(1)(ii)]]		
BPM IDSs to Control Device (D.8)	N/A	N/A	N/A			

<table>
<tr><th rowspan="2">Affected Units Controlled by T79 Control System</th><th colspan="5">Potentially Applicable Regulations</th><th rowspan="2">Streamlined Requirements</th></tr>
<tr><th>326 IAC 8-5-3 (Synthetic Pharma RACT)</th><th>40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)</th><th>40 CFR 63, Subpart DD (Offsite Waste MACT)</th><th>40 CFR 63, Subpart GGG (Pharma MACT)</th><th>326 IAC 2-2 (PSD BACT for RTO System)</th></tr>
<tr><td colspan="7">Work Practice Standards – Closed-vent Systems (CVSs)</td></tr>
<tr><td>BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery)</td><td>N/A</td><td>N/A</td><td rowspan="2"><u>CVSs NOT under negative pressure:</u>

Initial Method 21 inspections [63.683(c), 63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.690(b), 63.693(b)(5), 63.693(c)(1)(i) and 63.695(c)(1)(i)]

Annual visual inspections on CVSs [63.683(c), 63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.693((b)(5) and 63.695(c)(1)(ii)(A)]

Repair defects within 5/45 days [63.683(c), 63.685(g)(1)(iv), 63.962(a)(3)(ii),</td><td>None Specified</td><td colspan="2" rowspan="2"><u>Closed-vent systems NOT operated under negative pressure:</u>

- Initial Method 21 inspections on closed vent systems
- Annual visual inspections for defects on closed vent systems
- Repair detected defects within 5/15 days, except where delay of repair is allowed</td></tr>
<tr><td>BPM Solvent Tanks (D.9)</td><td>N/A</td><td>N/A</td><td>None Specified</td></tr>
</table>

Affected Units Controlled by T79 Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 8-5-3 (Synthetic Pharma RACT)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
BPM Waste Tanks (D.10)	N/A	N/A	63.690(b), 63.693(c)(1)(i), 63.695(c)(1)(iiii) and 63.695(c)(3)(i)] Any time a component is repaired or replaced, conduct a Method 21 inspection to demonstrate < 500 ppmv [63.683(c), 63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.690(b), 63.695(c)(1)(ii)(A)] <u>CVSs under negative pressure:</u> Annual visual inspections for visible cracks, holes, or gaps in ductwork or piping; loose connections; or broken or missing caps or other closure devices [63.683(c), 63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.690(b), 63.693(c)(1)(ii) and 63.695(c)(2)] Repair defects within 5/45 days [63.683(c), 63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.690(b), 63.693(c)(1)(ii), 63.695(c)(2)(iii), (3)(i)] ***NOTE:*** These requirements do not apply to solvent tanks. Solvent tanks are not regulated under the Offsite Waste MACT.	<u>CVSs NOT under negative pressure:</u> Initial Method 21 inspections Annual visual inspections for visible, audible or olfactory indications of leaks on closed vent systems that are hard-piped [1256(b)(3)(iii), 63.1256(e)(1)(iii), 63.1258(h)(2)(i) and 63.1258(h)(10)] Repair detected defects within 5/15 days, except where delay of repair allowed (technically infeasible without shutdown, or emissions resulting form immediate repair would be greater than the fugitive emissions resulting from delay of repair. Must be complete by end of next shutdown) [63.1258(h)(4), (5)] <u>Closed-vent systems operated under negative pressure:</u> No inspections required [1256(b)(3)(iv) and 63.1256(e)(1)(iv)] ___________________________________ Not required to inspect if unsafe/difficult to monitor [63.1258(h)(6) and (7)]	- Any time a component is repaired or replaced, conduct a Method 21 inspection to demonstrate < 500 ppmv <u>Closed-vent systems operated under negative pressure:</u> - Annual visual inspections for defects such as visible cracks/holes/gaps in ductwork/piping; loose connections; or broken/missing caps - Repair detected defects within 5/15 days, except where delay of repair allowed ___________________________ Not required to test or inspect if unsafe or difficult to monitor	
BPM IDSs to Control Device (D.8)	N/A	N/A				

<table>
<tr><th rowspan="2">Affected Units Controlled by T79 Control System</th><th colspan="5">Potentially Applicable Regulations</th><th rowspan="2">Streamlined Requirements</th></tr>
<tr><th>326 IAC 8-5-3
(Synthetic Pharma RACT)</th><th>40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)</th><th>40 CFR 63, Subpart DD
(Offsite Waste MACT)</th><th>40 CFR 63, Subpart GGG
(Pharma MACT)</th><th>326 IAC 2-2 (PSD BACT for RTO System)</th></tr>
<tr><td colspan="7">Work Practice Standards – Bypass Systems in Closed Vent System</td></tr>
<tr><td>BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery</td><td>N/A</td><td>N/A</td><td>Nothing Referenced</td><td rowspan="4">Continuous flow indicator at inlet of bypass line at least once every 15 minutes. Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and pressure relief valves needed for safety purposes are not subject to this requirement [63.1252(b)(1), 63.1253(b) and (c), Table 4, 63.1258(b)(1)(xi)]

OR

Monthly visual inspection of seal or locking device on the mechanism by which the bypass device position is controlled to ensure the device is in the closed position and that the seal is not broken
[63.1252(b)(2), 63.1253(b) and (c), Table 4, 63.1258(b)(1)(xi)]</td><td colspan="2" rowspan="4">The Pharma MACT work practice requirements serve as the PSD BACT and streamlined requirements:

Continuous flow indicator at inlet of bypass line at least once every 15 minutes. Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and pressure relief valves needed for safety purposes are not subject to this requirement

OR

Monthly visual inspection of seal or locking device on the mechanism by which the bypass device position is controlled to ensure the device is in the closed position and that the seal is not broken</td></tr>
<tr><td>BPM Solvent Tanks (D.9)</td><td>N/A</td><td>N/A</td><td>N/A</td></tr>
<tr><td>BPM Waste Tanks (D.10)</td><td>N/A</td><td>N/A</td><td rowspan="2">Continuous flow indicator at inlet of bypass
[63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.693(c)(2)(i)]

OR
Monthly visual inspection of seal or locking device on the mechanism by which the bypass device position is controlled to ensure the device is in the closed position and that the seal is not broken
[63.685(g)(1)(iv), 63.962(a)(3)(ii), 63.693(c)(2)(ii)]</td></tr>
<tr><td>BPM IDSs (D.8)</td><td>N/A</td><td>N/A</td></tr>
</table>

Affected Units Controlled by T79 Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 8-5-3 (Synthetic Pharma RACT)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
Exceptions to Control Device and Closed-Vent System (T79 Fume Incinerator System) Standards						
BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery)	N/A	N/A	The control device may be bypassed for purposes of correcting a malfunction of the closed vent system or control device [63.690((b) and 63.693(b)(3)(ii)]	Control except for SSM events, if SSM plan is followed [63.1260(g)]	Control except for SSM events, if SSM plan is followed	
BPM Solvent Tanks (D.9)	N/A	N/A	N/A			
BPM Waste Tanks (D.10)	N/A	N/A	Opening of a safety device, as defined in 63.681 is allowed at any time conditions require it to do so to avoid an unsafe condition [63.685(g)(2)(ii) and 63.681] The control device may be bypassed for purposes of correcting a malfunction of the closed vent system or control device [63.693(b)(3)(ii)]			
BPM IDSs (D.8)	N/A	N/A				

<table>
<tr><th rowspan="2">Affected Units Controlled by T79 Control System</th><th colspan="5">Potentially Applicable Regulations</th><th rowspan="2">Streamlined Requirements</th></tr>
<tr><th>326 IAC 3
(Monitoring Requirements)</th><th>40 CFR 60, Subpart Kb
(Volatile Organic Liquid Storage Vessels)</th><th>40 CFR 63, Subpart DD
(Offsite Waste MACT)</th><th>40 CFR 63, Subpart GGG
(Pharma MACT)</th><th>326 IAC 2-2
(PSD BACT for RTO System)</th></tr>
<tr><td colspan="7">Compliance Demonstration Methods</td></tr>
<tr><td colspan="7">TOC Stack Testing requirements</td></tr>
<tr><td>BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery)</td><td rowspan="4">Facilities subject to NSPS or NESHAP shall be tested under conditions specified in that applicable provision
[326 IAC 3-6-3]</td><td rowspan="4"></td><td rowspan="4"><u>The following stack test procedures apply to demonstrate compliance with the DRE standard [63.693(f)(2)(i)]:</u>

- Method 1 or 1A of 40 CFR 60, Appx A for selection of sampling sites
- Method 2, 2A, 2C, or 2D of 40 CFR 60, Appx A for gas volumetric flowrate
- Method 18 of 40 CFR 60, Appx A or method validated according to procedures in Method 301 in 40 CFR 63, Appx A to demonstrate compliance with control device DRE requirement
[63.694(l)(1)(i), 63.694(l)(3)]

<u>The following stack test procedures apply to demonstrate compliance with the concentration standard via stack test [63.693(f)(2)(i)]:</u>

- Method 1 or 1A of 40 CFR 60, Appx A for selection of sampling sites
- Method 2, 2A, 2C, or 2D of 40 CFR 60, Appx A for gas volumetric flowrate
- Method 18 of 40 CFR 60, Appx A or method validated according to procedures in Method 301 in 40 CFR 63, Appx A to demonstrate compliance with control device concentration limit
[63.694(l)(1)(ii), 63.694(l)(4)]
____
NOTE: These requirements do not apply to solvent tanks. Solvent tanks are not regulated under the Offsite Waste MACT.</td><td rowspan="2"><u>The following stack testing requirements apply to demonstrate compliance with the DRE standard:</u>

- Submit site-specific plan prior to testing as required by 63.7 and 63.1260(l)
- Conduct test under worst-case conditions or hypothetical worst-case conditions via max load to control device
- Measure gas stream volumetric flow rates at least every 15 minutes
- Perform testing on inlet and outlet of control device
[63.1257(c)(1)(iii), 63.1257(d)(1)(ii)(A), 63.1257(d)(3)(ii), 63.1257(b)(8)]

<u>Measure and record the following parameters during stack test to develop operating parameter limits</u>:

- Organic concentration in FTS measured as % LEL
Temperature</td><td colspan="2" rowspan="4">The following stack testing requirements for TOC under the Pharma MACT satisfy the PSD BACT for VOC and streamlined requirements to demonstrate compliance with the DRE standard:

- Submit site-specific plan prior to testing as required by 63.7 and 63.1260(l)
- Conduct test under worst-case conditions or hypothetical worst-case conditions via max load to control device
- Measure gas stream volumetric flow rates at least every 15 minutes
- Perform testing on inlet and outlet of control device
[63.1257(c)(1)(iii), 63.1257(d)(1)(ii)(A), 63.1257(d)(3)(ii), 63.1257(b)(8)]

<u>Measure and record the following parameters during stack test to develop operating parameter limits</u>:

- Organic concentration in FTS measured as % LEL
- Temperature</td></tr>
<tr><td>BPM Solvent Tanks (D.9)</td></tr>
<tr><td>BPM Waste Tanks (D.10)</td><td rowspan="2"><u>The following stack testing requirements apply to demonstrate compliance with the DRE standard:</u>

- Method 1 or 1A of 40 CFR 60, Appx A for selection of sampling sites
- Method 2, 2A, 2C, or 2D of 40 CFR 60, Appx A for gas volumetric flowrate
- Method 18 of 40 CFR 60, Appx A or method validated according to procedures in Method 301 in 40 CFR 63, Appx A to demonstrate compliance with control device percent reduction requirement
[63.1257(e)(3)(i)(A)-(J)]</td></tr>
<tr><td>BPM IDSs to control device (D.8)</td></tr>
</table>

<table>
<tr><th rowspan="2">Affected Units Controlled by T79 Control System</th><th colspan="5">Potentially Applicable Regulations</th><th rowspan="2">Streamlined Requirements</th></tr>
<tr><th>326 IAC 3 (Monitoring Requirements)</th><th>40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)</th><th>40 CFR 63, Subpart DD (Offsite Waste MACT)</th><th>40 CFR 63, Subpart GGG (Pharma MACT)</th><th>326 IAC 2-2 (PSD BACT for RTO System)</th></tr>
<tr><td colspan="7">HX Stack Testing requirements</td></tr>
<tr><td>BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery)</td><td rowspan="4">Facilities subject to NSPS or NESHAP shall be tested under conditions specified in that applicable provision
[326 IAC 3-6-3]</td><td rowspan="4">N/A</td><td rowspan="4">N/A</td><td rowspan="2"><u>The following HCl stack testing requirements apply to demonstrate compliance with the control efficiency standard:</u>

- Submit site-specific plan prior to testing as required by 63.7 and 63.1260(l)
- Conduct test under worst-case conditions or hypothetical worst-case conditions via max load to control device
- Measure gas stream volumetric flow rates at least every 15 minutes
- Perform testing on inlet and outlet of control device
[63.1257(c)(1)(iii), 63.1257(d)(1)(ii)(A), 63.1257(d)(3)(ii), 63.1257(b)(8)]

<u>Measure and record the following parameters during stack test to develop operating parameter limits</u>:

- Scrubber pH
- Recirculation flow rate
- Caustic flow rate</td><td colspan="2" rowspan="4"><u>The following stack testing requirements for hydrogen halides and halogens under the Pharma MACT shall satisfy the fluorides compliance determination requirements and serve as the streamlined requirement to demonstrate compliance with the control efficiency standard:</u>

- Submit site-specific plan prior to testing as required by 63.7 and 63.1260(l)
- Conduct test under worst-case conditions or hypothetical worst-case conditions via max load to control device
- Measure gas stream volumetric flow rates at least every 15 minutes
- Perform testing on inlet and outlet of control device
[63.1257(c)(1)(iii), 63.1257(d)(1)(ii)(A), 63.1257(d)(3)(ii), 63.1257(b)(8)]
- Measure and record scrubber pH
- Measure recirculation flow rate
- Measure caustic flow rate</td></tr>
<tr><td>BPM Solvent Tanks (D.9)</td></tr>
<tr><td>BPM Waste Tanks (D.10)</td><td rowspan="2">None Specified</td></tr>
<tr><td>BPM IDSs to control device (D.8)</td></tr>
</table>

Affected Units Controlled by T79 Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
T79 Fume Incinerator Parametric Continuous Monitoring System (CMS) and other monitoring requirements						
BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery) BPM Solvent Tanks (D.9) BPM Waste Tanks (D.10) BPM IDSs to control device (D.8)	<u>Parametric CMS Monitoring Requirements</u>: No parametric CMS requirements under 3-5 <u>Air Flow Monitor Requirements:</u> - Measure/record each successive 15-minute measuring period [326 IAC 3-5-2(2)(B)] - Annual RATA [3-5-5(e) and 40 CFR 60, Appx F, Proc 1] - Initial monitor system certifications within 180 days upon startup (permit issuance date) [3-5-3(1)(A)] - Monitor system certifications of monitor replacement or significant monitor repair within 45 days following the change [3-5-3(1)(B)] - QC requirements [3-5-5(d)]	N/A	<u>Temperature CMS requirements, if complying with the TOC DRE standard</u>: - Measure and record a data point at least once every 15 minutes when burning fume streams [63.693(b)(4), (f)(3)(i)] - O&M for CMSs [63.8(c)(1)] NOTE: These requirements do not apply to solvent tanks. Solvent tanks are not regulated under the Offsite Waste MACT	<u>Temperature CMS requirements, if complying with the DRE standard or the 20 ppmv TOC alternative standard [63.1258(b)(1)(vii)]:</u> - Measure and record a data point at least once every 15 minutes when burning fume streams - Monitor device must be accurate to within ±0.75% of C temp or ±2.5C, whichever is greater - Calibrate annually - O&M and quality control for CMSs [63.1258(b)(1)(x), (b)(5)(i)(A), and 63.8(c)(1), (d)] <u>Residence time (or flowrate) CMS requirements, if complying with the 20 ppmv TOC alternative std [63.1258(a) and (b)(5)(i)(A), and 63.1260(e)]</u>: No performance specifications referenced (See Precompliance Report)	Temperature CMS requirements under the Pharma MACT shall serve as the streamlined requirement: - Measure and record a data point at least once every 15 minutes when burning fume streams - Monitor device must be accurate to within ±0.75% of C temp or ±2.5C, whichever is greater - Calibrate annually - O&M and quality control for CMSs The flow monitor CMS requirements under 326 IAC 3-5 shall serve as the streamlined requirement to demonstrate compliance with residence time: - Measure/record each successive 15-minute measuring period [326 IAC 3-5-2(2)(B)] - Annual RATA [3-5-5(e) and 40 CFR 60, Appx F, Proc 1] - Initial monitor system certifications within 180 days upon startup (permit issuance date) [3-5-3(1)(A)] - Monitor system certifications of monitor replacement or significant monitor repair within 45 days following the change [3-5-3(1)(B)] - QC requirements [3-5-5(d)]	

<table>
<tr><th rowspan="2">Affected Units Controlled by T79 Control System</th><th colspan="5">Potentially Applicable Regulations</th><th rowspan="2">Streamlined Requirements</th></tr>
<tr><th>326 IAC 3 (Monitoring Requirements)</th><th>40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)</th><th>40 CFR 63, Subpart DD (Offsite Waste MACT)</th><th>40 CFR 63, Subpart GGG (Pharma MACT)</th><th>326 IAC 2-2 (PSD BACT for RTO System)</th></tr>
<tr><td colspan="7">Scrubber Parametric CMS and other monitoring requirements</td></tr>
<tr><td>BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery)</td><td rowspan="4"><u>Parametric CMS Monitoring Requirements</u>:

No parametric CMS requirements under 3-5</td><td rowspan="4">N/A</td><td rowspan="4">N/A</td><td rowspan="4"><u>Scrubber liquid flow rate CMS requirements [63.1258(b)(1)(ii)]:</u>

- Measure and record a data point at least once/15 minutes when process is in operation
- Monitor must be certified by the mfr to be accurate within ±10% of design scrubber liquid flowrate
- Calibrate annually
- O&M and QC for CMSs [63.1258(b)(1)(x), (b)(5)(i)(A), and 63.8(c)(1) and (d)]

<u>Effluent scrubber liquid pH monitoring requirements [63.1257(b)(8), 63.1258(b)(1)(ii) and 63.1260(e)]:</u>

- Measure effluent scrubber liquid pH once per day</td><td colspan="2" rowspan="4">When applying the control efficiency standard, the following streamlined compliance demonstration requirements shall satisfy the hydrogen halides/halogens requirements under Pharma MACT and the PSD BACT requirements for fluorides:

<u>Scrubber liquid flow rate, effluent scrubber liquid pH, and caustic liquid flow rate CMS requirements in accordance with 63.8(c)(1) and (d):</u>

- Measure and record a data point at least once/15 minutes when process is in operation
- Monitor must be certified by the mfr to be accurate within ±10% of design scrubber liquid flowrate
- Calibrate annually
- O&M and QC for CMSs</td></tr>
<tr><td>BPM Solvent Tanks (D.9)</td></tr>
<tr><td>BPM Waste Tanks (D.10)</td></tr>
<tr><td>BPM IDSs to control device (D.8)</td></tr>
</table>

Affected Units Controlled by T79 Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	
Record Keeping and Reporting Requirements						
Record Keeping Requirements						
BPM Process Vent (D.6 – Process Operation s, D.7 – Solvent Recovery) BPM Solvent Tanks (D.9) BPM Waste Tanks (D.10)	<u>CEMS (includes flow monitor for CERMS data) Record keeping Requirements [3-5-6]</u>: - raw data; - design/installation/ testing - corrective action or compliance plan, if applicable - maintenance logs - calibration checks and other QA activities - corrective and preventive action - facility downtime periods and reason for each downtime <u>CMS Record keeping Requirements</u>: No parametric CMS requirements under 326 IAC 3-5 <u>Performance Testing Record keeping Requirements</u>: Keep records of all test protocols, raw testing and support	N/A (BPM Process Vent) - Maintain record of operating plan that describes parameters monitored to demonstrate compliance with control device standards [60.115b(c)(1)] - Records of all measured values/parameters monitored [60.115b(c)(2)]	NOTE: The solvent storage tanks are not subject to these conditions <u>CMS and Control Device Records [63.693(b)(7), 63.696(b)]:</u> - Occurrence/duration records of each malfunction [63.696(h)] - Duration of each period during a malfunction when fumes continue to vent to the control device - Actions taken during periods of malfunction to restore control device to normal operation - All maintenance performed on control device equipment [63.10(b)(2)] - Current and superseded versions of SSM Plan stored at plantsite [63.6(e)(3)(v)] - Each SSM occurrence/duration [63.10(b)(2)] - Actions taken during SSM when different from SSM plan [63.10(b)(2)] - Info to demonstrate conformance with SSM plan are consistent with procedures in the plan [63.10(b)(2)(v)] - Malfunctioning/inoperative CMS periods [63.10(b)(2)(vi)] - All required CMS measurements to demonstrate compliance with a standard [63.10(b)(2)(vii) <u>Performance Test Records:</u> - Results of control device performance tests & CMS performance evaluations	<u>CMS and Control Device (T79) Records:</u> - Occurrence/duration records of each malfunction of RTO and CMS [63.1259(a)(3)(i) and (ii), 63.6(e)(3)(iii)] - Control device operating parameter data [63.1259(b)(1)] - Description of worst-case operating conditions, if complying with DRE standard [63.1259(b)(9)] - Control device maintenance records [63.1259(b)(13)] - CMS data [63.1259(a)(4), 63.10(c)] - CMS calibration checks and maintenance records [63.1259(b)(3)] - Malfunctioning/inoperative CMS periods [63.10(b)(2)(vi)] - All required CMS measurements to demonstrate compliance with a standard [63.10(b)(2)(vii)] - Current and superseded versions of SSM Plan stored at plantsite [63.1259(a)(3), 63.6(e)(3)(v)] - Info to demonstrate conformance with SSM plan are consistent with procedures in the plan [63.1259(a)(3)(iii), 63.6(e)(3)(iii)] - Actions taken during SSM when different from SSM plan [63.1259(a)(3)(iii), 63.6(e)(3)(iv)] - Info to demonstrate conformance with SSM plan are consistent with procedures in the plan [63.10(b)(2)(v)] ***NOTE:*** Although the Pharma MACT recordkeeping requirements do not apply to NOx/SOx/CO CEMS and flow monitor, the Permittee shall comply with these more stringent record keeping requirements to satisfy 326 IAC 2-7-5(3). <u>Performance Test Records:</u> - Results of control device performance tests & CMS performance evaluations [63.7(g)(3), 63.10(b)(2)(viii)] <u>Closed Vent System Records:</u> - Hourly records of bypass flow indicator operating status and the time/duration of all diversions detected by bypass flow indicator, if complying via this method [63.1252(b)(1) and 63.1259(i)(6)(i)]		

Affected Units Controlled by T79 Control System	Potentially Applicable Regulations					Streamlined Requirements
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	

BPM IDSs to control device (D.8)	data, emission test results, and emission test reports for a minimum of 5 years.
	
	General Record keeping Requirements [3-5]:
	
	- Retain monitoring data and supporting info for 5 years [3-5-6(a)]
	- Maintain SOP for all CEMS [3-5-4(a)]
		N/A	[63.7(g)(3), 63.10(b)(2)(viii)]
			
			Closed Vent System Records:
			
			- Closed vent inspections [63.693(b)(7), 63.695(c)(1)(iv), (2)(iv), 63.696(b), 63.10(b)(1)]
			- Repair records of defects detected during inspections [63.695(c)(3)(ii)] and 63.696]
			
			General Record keeping Requirements [63.693(b)(7), 63.696(b)]:
			
			- Maintain records for 5 yrs [63.10(b)(1)]
				- Monthly visual inspection records of bypass line valves and the occurrence of all periods the valve position has changed, if complying via this method [63.1252(b)(2), 63.1259(i)(6)(ii)]
				- For CVSs not under negative pressure, record all parts of CVS designated as unsafe/difficult to inspect, explanation of why unsafe/difficult to inspect, and plan for inspecting [63.1259(i)(4), (5)]
				- For CVSs not under negative pressure, record following information if no leaks detected during initial M21 inspection or annual visual inspections [63.1259(i)(2), (8), and (9)]:
				  - Date inspection performed
				  - Declaration that no leaks detected
				- For CVSs not under negative pressure, record following information for all leaks detected during initial M21 inspection [63.1259(i)(7)]:
				  - Identification of leaking equipment
				  - Instrument ID and operator name/initials
				  - Date leak detected and date of first attempt to repair leak
				  - Max instrument reading after leak from initial M21 is successfully repaired or nonrepairable
				  - Record 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
				- For CVSs not under negative pressure, record following information for all leaks detected from annual visual inspection:
				  - Record that leak was detected and identification of leaking equipment
				  - Date leak detected and date first attempt to repair
				  - Record 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
				
				General Record keeping Requirements
				
				- Keep records for 5 years [63.1259(a)(1), 63.10(b)(1)]
				- Records of operating scenarios [63.1259(c)]
				- Maintain SOP for all CMSs [63.8(d)]		

<table>
<tr><th rowspan="2">Affected Units Controlled by T79 Control System</th><th colspan="5">Potentially Applicable Regulations</th><th rowspan="2">Streamlined Requirements</th></tr>
<tr><th>326 IAC 3 (Monitoring Requirements)</th><th>40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)</th><th>40 CFR 63, Subpart DD (Offsite Waste MACT)</th><th>40 CFR 63, Subpart GGG (Pharma MACT)</th><th>326 IAC 2-2 (PSD BACT for RTO System)</th></tr>
<tr><td colspan="7">Reporting Requirements</td></tr>
<tr><td>BPM Process Vent (D.6 – Process Operation s, D.7 – Solvent Recovery)</td><td rowspan="3"><u>Flow Monitor Periodic Reporting Requirements:</u>

- Notifications 35-days prior to gaseous monitor system certification [3-5-3(2)(B)]
- Notifications 35 days prior to RATA [3-5-5(f)]
- Submit performance spec test and performance evaluation report within 45 days following test [3-5-2(7)(C) and 3-5-3(3)]
- Submit SOP if required by NSPS or NESHAP within 90 days after monitor installation and if revisions made, updates submitted biennially [3-5-4(a)]
- Quarterly reports of performance audit results (cylinder gas audit or RATA) to be submitted within 30 days following quarter [3-5-5(d)]
- Quarterly excess</td><td>N/A</td><td rowspan="3">NOTE: The solvent storage tanks are not subject to these conditions

<u>CMS and Control Device Reporting Requirements [63.697]:</u>

- Notification of CMSs at least 60 days prior to performance evaluation date [63.9(g)(1)]
- SSM reports if actions are not consistent with SSM plan [63.697(b)(3) and 63.10(d)(5)]
- Prepare/submit semiannual reports for each control device including excess emissions summary and CMS performance summary [63.10(e)(3)]
- CMS excursions occur if have <75% valid operating hours. A valid operating hour requires data in each 15-minute segment of the hour. If the control device is operated for less than 4 hours in a day, then an excursion occurs have more than one invalid hour.

<u>Performance Test Requirements:</u>

- Waiver of performance test at least 60 days prior to test date [63.7(h), 63.9(e)]
- Notification of performance tests 60 days prior to test date [63.7(b)(1)]
- Upon request, submit site specific test plan 60 days prior to test [63.7(c)(2)(iv)]
- Performance test reports within 60 days following test [63.7(g)(1), 63.10(d)(2)]</td><td rowspan="3"><u>CMS and Control Device Reporting Requirements [63.1260(g)]:</u>

- Notification of CMSs at least 60 days prior to performance evaluation date [63.9(g)(1)]
- 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 15-minute data and daily averages for all operating days out of range; duration of excursions; operating logs and operating scenarios for all operating days out of range.
- Report, when applicable, no excess emissions, no exceedances, no excursions, and no CMS has been inoperative, out of control, repaired or adjusted [63.1260(g)(v)]
- Prepare/submit periodic reports for each control device including excess emissions summary and CMS performance summary [63.10(e)(3)]
- SSM reports if actions are not consistent with SSM plan [63.10(d)(5)]
- Report each new operating scenario that has been operated since last report [63.1260(g)(2)(vii)]

<u>Performance Test Requirements:</u>

- Waiver of performance test at least 60 days prior to test date [63.7(h), 63.9(e)]
- Notification of performance tests 60 days prior to test date [63.7(b)(1)]
- Upon request, submit site specific test plan 60 days prior to test [63.7(c)(2)(iv)]
- Performance test reports, and performance evaluation upon request, within 60 days following test [63.7(g)(1), 63.8(e), 63.10(d)(2)]
- Report each new operating scenario that has</td><td colspan="2" rowspan="3"><u>CMS and Control Device Reporting Requirements:</u>

The control device and CMS reporting requirements under the Pharma MACT rules shall satisfy the PSD BACT requirements and shall serve as the streamlined reporting requirement.

- Notification of CMSs at least 60 days prior to performance evaluation date [63.9(g)(1)]
- 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 15-minute data and daily averages for all operating days out of range; duration of excursions; operating logs and operating scenarios for all operating days out of range.
- Report, when applicable, no excess emissions, no exceedances, no excursions, and no CMS has been inoperative, out of control, repaired or adjusted [63.1260(g)(v)]
- Prepare/submit periodic reports for each control device including excess emissions summary and CMS performance summary [63.10(e)(3)]
- SSM reports if actions are not consistent with SSM plan [63.10(d)(5)]
- Report each new operating scenario that has been operated since last report [63.1260(g)(2)(vii)]</td></tr>
<tr><td>BPM Solvent Tanks (D.9)</td><td rowspan="2">None Specified</td></tr>
<tr><td>BPM Waste Tanks (D.10)</td></tr>
</table>

Affected Units Controlled by T79 Control System	Potentially Applicable Regulations					
	326 IAC 3 (Monitoring Requirements)	40 CFR 60, Subpart Kb (Volatile Organic Liquid Storage Vessels)	40 CFR 63, Subpart DD (Offsite Waste MACT)	40 CFR 63, Subpart GGG (Pharma MACT)	326 IAC 2-2 (PSD BACT for RTO System)	Streamlined Requirements
BPM IDSs to control device (D.8)		N/A				

D.16: BPM Research and Development Operations

Background and Description

The research and development operations at the plant site are located in building T71. The equipment in the research and development area mimics the equipment in the production buildings, but on a much smaller scale. These facilities are not used to manufacture products for sale, rather the primary purpose of the research and development facilities is to conduct research and development into new processes and products. The following summary of the research and development operations has been prepared to document technical information used to prepare the Title V permit conditions and to demonstrate compliance with the Title V permit requirements.

Types of Emission Units and Pollution Control Equipment

The research and development operations consist of process tanks, charge tanks and dryers. This equipment is of much smaller scale than the production equipment. For example a typical production tank is 2000 gallons, while a typical production tank in building T71 is only 50 gallons. Thus, the emissions generated from the research and development operations are much lower. There are no controls on these operations.

Insignificant Activities

All of the emission units in the T71 research and development operations are considered "insignificant activities" as defined in 326 IAC 2-7-1(21)(E).

Federal Rule Applicability

40 CFR 60, Subpart Kb – Volatile Organic Liquid Storage Vessels
The tanks in the T71 research and development operations are not subject to Subpart Kb because the individual tank capacities are equal to or less than 40 cubic meters (10,566 gallons).

NSPS 40 CFR 60, Subpart VV – Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry – The storage tank in the T71 research and development operations is not subject to this rule because it stores a waste stream, which is not regulated under this rule.

40 CFR 63, Subpart GGG – Pharmaceutical MACT
The emission units associated with research and development operations are not subject to the requirements of the Pharmaceutical MACT standards because these operations are not associated with the manufacture of pharmaceutical products pursuant to 40 CFR 63.1250(a) and 63.1251.

State Rule Applicability

326 IAC 8-1-6 – VOC BACT Rule
The storage tanks associated with the T71 research and development equipment are not subject to 326 IAC 8-1-6 because the VOC emissions from the equipment are limited to less than 25 tons per year.

326 IAC 8-6-1 – Organic Solvent Rule
The waste storage tanks associated with the T71 research and development equipment are not subject to the requirements of 326 IAC 8-6-1 because the tanks were installed after January 1, 1980.

326 IAC 8-5-3 – Synthesized Pharmaceutical Manufacturing Operations – The emission units associated with the T71 research and development operations are not subject to the requirements of this rule because these operations are not associated with the manufacturing operations.

Compliance Requirements

The emission units associated with the T71 research and development operations are not subject to any compliance determination or compliance monitoring requirements.

D.17: BPM General Wastewater Requirements

Background and Description

The general wastewater requirements in this Title V permit section are driven by the Pharmaceutical MACT standards. There are no existing air construction approvals or other applicable air rules that regulate wastewater itself. There are regulatory requirements on equipment that handle wastewater which are addressed in the equipment sections of the Title V permit.

This section of the permit is intended to be an informational section that first defines a wastewater stream and identifies the transfer and treatment alternatives of the wastewater streams. The following information has been incorporated into the Title V permit to address the Pharmaceutical MACT [40 CFR 63, Subpart GGG] requirements that apply to wastewater streams:

<u>Definition of Wastewater [40 CFR 63.1251, 63.1256(a)(1)(i)]</u> – Wastewater is defined as any water that is discarded from a pharmaceutical manufacturing process unit through a single point of determination (POD) that contains an annual average concentration of partially soluble and/or soluble HAP compounds of at least 5 parts per million by weight and a load of at least 0.05 kg/yr. Wastewater does not include stormwater from segregated sewers; water from fire-fighting and deluge systems, including testing of such systems; spills; water from safety showers; samples of a size not greater than reasonably necessary for the method of analysis that is used; equipment leaks; wastewater drips from procedures such as disconnecting hoses after clearing lines; noncontact cooling water; and primary waste (waste with a net positive heating value).

Point of determination (POD) is defined as the point where a wastewater stream exits the process, storage tank, or last recovery device. If soluble and/or partially soluble HAP compounds are not recovered from water before discharge, the discharge point from the process equipment or storage tank is a POD. If water streams are routed to a recovery device, the discharge from the recovery device is a POD. There can be more than one POD per process or pharmaceutical manufacturing process unit. [40 CFR 63.1251]

<u>Definition of Affected Wastewater [40 CFR 63.1251, 63.1256(a)(1)(i)(A) and (B)]</u> – Affected wastewater is defined as any wastewater stream containing partially soluble HAP compounds at an annual average concentration greater than 1300 ppmw, and the total soluble and partially soluble HAP load in all wastewater from the PMPU exceeds 0.25 Mg/yr; or any wastewater stream containing partially soluble and/or soluble HAP compounds at an annual average concentration greater than 5200 ppmw, and the total soluble and partially soluble HAP load in all wastewater from the PMPU exceeds 0.25 Mg/yr.

<u>Maintenance Wastewater [40 CFR 63.1256(a)(4)(iii)]</u>

The Permittee shall prepare a maintenance wastewater plan and implement this plan as part of the Startup, Shutdown, and Malfunction (SSM) Plan for maintenance wastewater as required under 40 CFR 63.6(e)(3). Maintenance wastewater is not considered an affected wastewater stream.

<u>Storage and Transfer of Affected Wastewater [40 CFR 63.1256(b), (d), and (e)]</u> – BPM containers, individual drain systems and storage tanks may be used to store or transfer affected wastewater from the BPM operations. The regulatory requirements for these storage and transfer equipment are described in Sections D.11, D.8, and D.10 of this TSD.

Treatment of Affected Wastewater [40 CFR 63.1256] – The affected wastewater shall be treated using an enhanced biological treatment system, waste incinerator or an offsite treatment facility. The regulatory requirements for these treatment options are described in Sections D.18, D.12, D.13 and D.19 of this TSD.

D.18: BPM Chemical Wastewater Treatment Plant

Background and Description

The BPM chemical wastewater treatment plant serves the BPM operations. The following summary has been prepared to document technical information used to prepare the Title V permit conditions and to demonstrate compliance with the Title V permit requirements.

Types of Emission Units and Pollution Control Equipment

The chemical wastewater treatment plant operations consist of a series of clarifiers and activated sludge tanks. Sludge is transferred to sludge tanks and the treated wastewater is discharged to the river.

Insignificant Activities

With the exception of the activated sludge tanks, all other emission units associated with the chemical wastewater treatment plant are considered “insignificant activities” as defined in 326 IAC 2-7-1(21)(E).

Federal Rule Applicability

40 CFR 63, Subpart GGG – Pharmaceutical MACT

The BPM enhanced biological treatment components (activated sludge tanks) of the BPM chemical wastewater treatment plant may be used to treat affected wastewater streams except for mixed wastewater streams greater than 5200 ppmw, where the partially soluble HAP component is equal to or greater than 50 ppmw or wastewater streams containing combined partially soluble HAPs greater than 1300 ppmw.

To demonstrate compliance with the enhanced biological treatment system, the Permittee shall maintain a minimum mixed liquor volatile suspended solids concentration of 1 kg/cubic meter (942 mg/l) of the mixed liquor in the enhanced biological treatment system.

State Rule Applicability

326 IAC 8-1-6 – VOC BACT Rule
The BPM chemical wastewater treatment plant is not subject to 326 IAC 8-1-6 because the potential VOC emissions from the facility are less than 25 tons per year.

326 IAC 8-5-3 – Synthesized Pharmaceutical Manufacturing Operations – The T147 tank module only serves the fermented products manufacturing area. Products manufactured in the fermented products area are based on fermentation principles, not by chemical synthesis. Therefore, the storage tanks associated with T147 tank module are not subject to this requirement.

326 IAC 2-2 – Prevention of Significant Deterioration – CP 157-3319 established VOC emission limits on tank modules T143, T145, T146, and T147 to avoid the requirements of PSD. This permit requires the use of VOC controls to satisfy emission netting done in the permit. Tank modules T143, T145, and T146 are associated with the BPM operations, while tank module T147 is dedicated to fermented products operations.

Compliance Requirements
The BPM enhanced biological treatment components (activated sludge tanks) of the BPM chemical wastewater treatment plant shall measure the total suspended solids, chemical oxygen demand, and

biomass concentration at least once per week and record the weekly average data to demonstrate compliance with the Pharmaceutical MACT requirements.

D.19: BPM Transfer of Affected Wastewater for Offsite Treatment

Background and Description

The requirements for the transfer of affected wastewater for offsite treatment are driven by the Pharmaceutical MACT standards. There are no existing air construction approvals or other applicable air rules that regulate these transfer activities. The transfer of affected wastewater for offsite treatment relates to either of the shipment of affected wastewater generated onsite to an offsite treatment facility or receipt of an offsite affected wastewater to be treated onsite.

This section of the permit is intended to be an informational section that first defines a wastewater stream and identifies the transfer and treatment alternatives of the wastewater streams. The following information has been incorporated into the Title V permit to address the Pharmaceutical MACT [40 CFR 63, Subpart GGG] requirements that apply to these transfer activities:

Shipment of Affected wastewater to an offsite treatment facility – 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.

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.

Receipt of Offsite Affected Wastewater for Onsite Treatment [40 CFR 63.1256(a)(5)] – 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)]. The Permittee may revoke its certification as allowed under 40 CFR 63.1256(a)(5)(iii).

D.20: Utilities Operations.

Description

The following emissions units are subject to applicable requirements described in this TSD:

Emissions Unit ID	Emissions Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
Building T26					
BLR006	Natural Gas/Fuel Oil Boiler No. 6	S-T26-BLR006	156.1	MMBtu/hr	None
BLR007	Natural Gas/Fuel Oil Boiler No. 7	S-T26-BLR007	156.1	MMBtu/hr	None
T26-GEN-7500A	Diesel Powered Emergency Generator	S-T26- GEN-7500A	150	KW	None
T26-COMP	Diesel Powered	S-T26- COMP	125	Hp	None

5600A	Emergency Air Compressor	5600A			

* Emission units marked with a single asterisk are insignificant activities as defined in 326 IAC 2-7-1(21).

326 IAC 5-1-2 (Opacity Limitations)
When starting up or shutting down Boilers No. 6 and No.7, opacity may exceed the applicable limit. However, opacity levels shall not exceed sixty percent (60%) for any six (6)-minute averaging period. Opacity in excess of the applicable limit established in 326 IAC 5-1-2 shall not continue for more than two (2) six (6)-minute averaging periods in any twenty-four (24) hour period.

326 IAC 7-1.12 (Sulfur Dioxide (SO2) Limitation)

(a) Pursuant to 326 IAC 7-1.1 (SO_2 Emission Limitations), 326 IAC 12, and 40 CFR 60, Subpart Db (Standards of Performance for Industrial-Commercial-Institutional Steam Generating Units):

  (1) The SO_2 emission rate from Boilers No. 6 and No.7 shall not exceed 0.32 pounds per million Btu heat input; or

  (2) The fuel oil shall contain no more than 0.3 weight percent sulfur.

  (3) If the Permittee burns either natural gas or very low sulfur oil, the Permittee shall be in compliance with Conditions D.20.3(a)(1) and (2).

(b) Pursuant to 40 CFR 60 Subpart Db, the fuel oil sulfur content or sulfur dioxide emission limit applies at all times, including periods of startup, shutdown, and malfunction.

Nitrogen Oxides (NOx) Limitations
Pursuant to 40 CFR 60.44b(a), the NOx emission rate from Boilers No. 6 and No.7 shall not exceed 0.2 lb per MMBtu per boiler. The NOx emission limit shall be based on a 30-day rolling average. The NOx emission limit applies at all times, including periods of startup, shutdown, and malfunction.

326 IAC 6-2-4 (Particulate Matter (PM) Limitations)
Pursuant to 326 IAC 6-2-4(a), the PM emission rate from each of Boilers No. 6 and No.7 shall not exceed 0.19 pounds per MMBtu heat input.

326 IAC 2-2 (Prevention of Significant Deterioration (PSD))

(a) The total carbon monoxide emissions from Boilers No. 6 and No.7 shall be less than 98 tons per twelve consecutive month period with the compliance determined at the end of each month.

During the first twelve (12) months after startup of either Boilers No. 6 or No. 7, the total carbon monoxide emissions divided by the accumulated months of operation shall not exceed 8.17 tons up to a maximum total of 98 tons for the first twelve (12) months of operation of the boilers.

(b) The hours of operation of the emergency air compressor shall be limited to 500 hours per year. The Permittee shall monitor the operating hours of the emergency air compressor with a non-resettable hour meter, as required by 40 CFR 60.4209(a).

Compliance with the CO emission limit of Boilers No. 6 and No. 7, and the hours of operation of the emergency air compressor will render 326 IAC 2-2 (Prevention of Significant Deterioration) not applicable to this modification.

(c) The amount of very low sulfur oil with a maximum sulfur content of 0.3%, burned in each of Boilers No. 6 and No. 7 shall be less than 976,740 gallons per twelve consecutive month period with compliance determined at the end of each month.

Compliance with the fuel oil consumption limit will render 326 IAC 2-2 (Prevention of Significant Deterioration) not applicable to this modification

Compliance Requirements

The following compliance activities are required for the utilities operations associated with D.20 of the permit:

1. Burn only natural gas or very low sulfur fuel oil; and
2. Demonstrate that the oil burned meets the definition of very low sulfur fuel oil; and
3. Continuously monitor NOx and CO.

Appendix A

Indiana Department of Environmental Management
Office of Air Quality
Technical Support Document (TSD) for a Part 70 Operating Permit Renewal

Section E: LDAR Program

Background and Description

Section E of the permit identifies the leak detection and repair [LDAR] and other fugitive emission control requirements for leaks involving volatile organic hazardous air pollutants and volatile organic compounds (VOHAP/VOC). These emissions occur primarily from small leaks in piping systems, including pumps, valves, open-ended valves or lines, connectors, instrumentation systems, and closed vent systems. This section of the TSD describes the LDAR program that will be employed by the Permittee.

Types of Emission Units and Pollution Control Equipment

Fugitive VOHAP/VOC emissions occur throughout the BPM facilities. Fugitive emissions can be expected from several elements of the solvent/solvent waste distribution and handling systems, including pumps, valves and flanges. LDAR programs are the most widely used systems to control fugitive emissions from these components.

Insignificant Activities

While individual components of piping systems that cause fugitive VOHAP/VOC emissions have low enough emissions to be classified as insignificant activities, this permit looks at such emissions in their entirety. On that basis, they are not classified as insignificant activities.

Existing Approvals

Description	Permit No.	Date
Operating Permits		
Title V permit	T157-6879-00006	Issued February 27, 2004

Federal Rule Applicability

The fugitive VOHAP/VOC emissions in BPM areas are subject to the three federal Clean Air Act LDAR requirements listed below. These requirements are described in greater detail later in this section of the TSD.

Applicable federal LDAR requirements:
1. 40 CFR 63.1255, Pharmaceutical Production (Pharma) MACT
2. 40 CFR 63.691, Off-site Waste and Recovery Operations (OSWRO) MACT
3. 40 CFR Subpart I, the Negotiated Regulation for Equipment Leaks

The Pharmaceutical MACT rules provide that a source may comply with the Subpart I requirements by complying with the Pharma MACT LDAR requirements. The Pharma MACT LDAR requirements at 40 CFR 63.1255 apply to process vents and storage tanks under the Pharma MACT rule, but, like the

Hazardous Organic NESHAP (the HON) from which it is derived, the LDAR program does not include wastewaters. In addition, a source may comply with the OSWRO MACT LDAR requirements by complying with 40 CFR 61 Subpart V (National Emission Standard for Equipment Leaks). The OSWRO MACT currently applies only to equipment that receives off-site material as defined in that rule; such equipment constitutes part, but not all, of the “BPM waste systems.” As described below, the source will use the Pharmaceutical MACT LDAR program for all “BPM process systems” to satisfy not only the Pharma MACT requirements, but also to satisfy PSD BACT requirements under 326 IAC 2-2. All “BPM waste systems” will follow the 40 CFR 61 Subpart V program to satisfy the OSWRO MACT requirements, as well as PSD BACT requirements.

Other Federal rules governing fugitive emissions were examined, and all were found to be comparable to either the Pharmaceutical MACT (i.e., the HON, or derived from the HON, with industry-appropriate adjustments), or to 40 CFR Part 61, Subpart V. For example, 40 CFR Part 63, Subpart CC, the National Emission Standards for Hazardous Air Pollutants from Petroleum Refineries, provides that new sources comply with the HON (40 CFR Part 63, Subpart H), except that periodic monitoring of connectors is not mandated.

State Rule Applicability

The fugitive VOHAP/VOC emissions in BPM areas are subject to the two state fugitive emission control requirements listed below. These requirements are described in greater detail later in this section of the TSD.

Applicable LDAR requirements:

1. Synthesized pharmaceutical manufacturing rule [326 IAC 8-5-3]
2. PSD Best Available Control Technology Requirements [326 IAC 2-2]

The source has demonstrated that compliance with federal LDAR requirements satisfies the requirements of both these state requirements. Therefore, the source may satisfy the state fugitive emission control requirements by complying with the Pharmaceutical MACT and 40 CFR 61 Subpart V. As described below, the source will use the Pharmaceutical MACT LDAR requirements for “BPM process systems” and the Subpart V requirements for “BPM waste systems”.

Testing and Compliance Requirements

An LDAR program does not employ any testing and compliance requirements beyond the inspections and monitoring within the program itself.

Multiple Requirement Streamlining Proposal and BACT Determination

Industrial volatile organic hazardous air pollutant and/or volatile organic compound (VOHAP/VOC) emissions occur either as point source emissions or as fugitive emissions. Fugitive emissions occur in such a way as to render it difficult or impossible to duct them except as a very low concentration portion of the general ventilation system. This characteristic of extremely low VOC concentration at a high gas flow rate means that the use of add-on control equipment is nearly always prohibitively expensive, and often technologically futile.

Two basic approaches are used to minimize fugitive VOHAP/VOC emissions from industrial process equipment and its associated supply and waste treatment systems. Both approaches are included in regulated leak detection and repair (LDAR) programs. Such programs represent Best Available Control Technology (BACT) for sources of fugitive VOC emissions.

The first approach is to use design specifications to reduce leaks in solvent areas. For example, closed purge sampling systems are used, open pipe ends are capped or blinded, and rupture disks replace pressure relief valves.

The second approach used in LDAR is periodic monitoring of fugitive emission components. Periodic monitoring includes:

1. Identifying the equipment components;
2. Monitoring of components for VOHAP/VOC emissions using a defined test methods. 40 CFR Part 60, Appendix A, Test Method 21 is used for instrumental quantification of leaks. The test methods at 40 CFR 63.180(f) and (g) are used for pressure testing. Visual, audible and olfactory detection of leaks do not have a specified methodology;
3. Defining the frequency for monitoring components;
4. Repairing or replacing leaking components; and
5. Maintaining records of the tests, results, and repairs.

Since 1978, EPA has promulgated a number of LDAR regulations. These fall into two basic categories. One category, the Pharma MACT LDAR Program, takes as its model the HON under 40 CFR 63, Subpart H, while the other is exemplified by the regulations at 40 CFR Part 61, Subpart V and 40 CFR 264 and 265, Subpart BB (RCRA BB). Lilly will apply the Pharmaceutical MACT LDAR program to components from the arrival of raw materials at the plant to the RCRA point of generation (POG) or the Pharmaceutical MACT point of determination (POD) (the POG and POD coincide where both exist on a given stream). Lilly will apply the Subpart V/RCRA BB program to all components after the POG or POD.

40 CFR 63, Subpart GGG – LDAR Program for Process Systems

40 CFR 63, Subpart GGG (National Emission Standards for Pharmaceutical Production, “Pharma MACT”) was originally promulgated in 1998 and most recently amended in 2005. 40 CFR 63.1255 contains the description and details of the LDAR program. The LDAR program in this rule applies to fugitive emissions of VOHAP from the point of arrival of raw materials to the point at which wastes exit the pharmaceutical manufacturing process unit. This exit point corresponds in practice to the point of generation for RCRA and to the point of determination, where applicable, under the Pharma MACT (40 CFR 63.1256). This Title V permit applies the LDAR requirements under Subpart GGG to both VOHAP and VOC for the same areas to satisfy MACT and BACT requirements.

As with all other LDAR programs, Subpart GGG includes both design specifications and periodic monitoring. Regardless of whether a component complies by design or by periodic monitoring, if it is observed to be leaking at any time it must be repaired.

In general, a source must make an initial attempt to repair within 5 days after observing the leak and to complete the repair within 15 days of discovery. Repair may be delayed if the component is taken out of service, or if other requirements are met. For example, if repair parts are not available on site but are promptly ordered, delay of repair may be justifiable. Each delay of repair must be reported in the periodic report. This also satisfies the requirements of 326 IAC 8-5-3 to repair visible leaks of VOC.

Subpart GGG also provides for the use of an alternative means of emission limitation for all processes and for supply lines between storage and processing areas. The specifications are found at 40 CFR 63.178. This alternative allows an owner or operator to use pressure, vacuum, or liquid testing to demonstrate compliance with all applicable LDAR requirements. Although not everything can physically be pressure, vacuum, or liquid tested, Tippecanoe Labs complies through the use of this alternative in many of the processing areas in the plant. The necessary permit conditions for this alternative are as explained in 40 CFR 63.178.

The pressure, vacuum, or liquid test alternative provides that each process must conduct a pressure, vacuum, or liquid test on reconfiguration or once a year, whichever is more frequent. Tests on reconfiguration must be conducted before the VOHAP/VOC is fed to the equipment and the equipment is placed in VOHAP/VOC service. The leak repair provisions for this alternative provide that if the equipment fails the first test, then a second test must be conducted before start-up of the process. If the process fails the second test, but the equipment is placed in VOHAP/VOC service, the leak must be repaired as soon as practicable but not later than 30 days afterwards. As long as a successful pressure vacuum, or liquid test is conducted prior to placing the equipment in VOHAP/VOC service, no leak is reported.

Table 1 summarizes the requirements for BPM process system component types generally managed by design specifications, periodic monitoring or other monitoring.

40 CFR 61, Subpart V/RCRA BB – LDAR Program for BPM Waste Systems

Although 40 CFR 61, Subpart V (National Emission Standard for Equipment Leaks) was promulgated in 1984 and RCRA BB in 1990, these are substantially similar to the more recent Subpart TT, the Generic MACT promulgated in 1999. Subpart V is also prescribed as an accepted compliance method under the more recent Offsite Waste and Recovery Operations (OSWRO) MACT rule, 40 CFR 63.691. This Title V permit applies LDAR requirements under Subpart V to both VOHAP and VOC for the same areas to satisfy MACT and BACT requirements.

As with all other LDAR programs, Subpart V includes both design specifications and periodic monitoring. Regardless of whether a component complies by design or undergoes periodic monitoring, if it is observed to be leaking at any time it must be repaired.

In general, you are required to do an initial attempt of repair within 5 days after observing the leak and complete the repair within 15 days of discovery. Repair may be delayed if the component is taken out of service, or if other requirements are met. For example, if repair parts are not available on site but are promptly ordered, delay of repair may be justifiable. Each delay of repair must be reported in the periodic report. This also satisfies the requirements of 326 IAC 8-5-3 to repair visible leaks of VOC.

Table 2 summarizes the requirements for BPM waste system component types generally managed by design specification, periodic monitoring or other monitoring.

Recordkeeping and Reporting Requirements

The following table summarizes the different BPM process and waste system equipment record keeping and reporting requirements that apply.

Equipment Description	**Record Keeping and Reporting According to:**
BPM Process Systems	40 CFR 63, Subpart GGG
BPM Waste Systems	40 CFR 61, Subpart V

Table 1: Summary LDAR Program for Process Systems

General exemptions: Lines and equipment not containing process fluids, per 40 CFR 63.1255(a)(5).
Bench-scale processes per 40 CFR 63.1255(a)(6).
Equipment in VOC/VOHAP service < 300 hours/year per 40 CFR 63.1255(a)(1), if properly identified per 40 CFR 63.1255(g)(9).
Equipment in vacuum service per 40 CFR 63.1255(a)(8).

Component Types	Standards	Leak Definition	Repair	Exemptions
Design Specifications:				
Pressure Relief Devices in Gas/Vapor Service 40 CFR 63.165	No detectable emissions 40 CFR 63.165(a) or Rupture disk 40 CFR 63.165(d)(1)	No detectable emissions (less than 500 ppm above background) 40 CFR 63.165(a)&(b) N/A for rupture disk	No Rupture Disk: After each release, return to no detectable emissions, measured by monitoring, within 5 calendar days 40 CFR 63.165(b)(1) Rupture Disk: After each release, replace rupture disk within 5 calendar days 40 CFR 63.165(d)(2)	Equipment operated in VOC/VOHAP service less than 300 hours per year 40 CFR 63.1255(a)(1) Equipment in vacuum service 40 CFR 63.1255(a)(8)
Compressors 40 CFR 63.164	Either use a seal with barrier fluid system inspected daily or alarmed, 40 CFR 63.164(a) or Equip with a closed-vent system to capture & transport compressor drive shaft seal back to a process, a fuel gas system, or a control device meeting 40 CFR 63..172 40 CFR 63.164(h) or use leakless design that is < 500 ppmv monitored annually 40 CFR 63.164(i)	Sensor indicates failure of seal system, barrier fluid system, or both 40 CFR 63.164(f) or leakless design $\geq$ 500 ppmv 40 CFR 63.164(i)(2) N/A for closed vent system alternative	5/15 40 CFR 63.164(g)(1) & (2) N/A for closed vent system alternative	Equipment operated in VOC/VOHAP service less than 300 hours per year 40 CFR 63.1255(a)(1) Equipment in vacuum service 40 CFR 63.1255(a)(8)

Component Types	Standards	Leak Definition	Repair	Exemptions
Sampling Connection Systems 40 CFR 63.166	Use a closed purge or closed vent system that either returns the fluid to the process or collects and recycles the purged fluid 40 CFR 63.166(b)(1) & (2) or Captures and transports all purged fluids to a compliant control device 40 CFR 63.166(b)(3) or Collects, stores and transports the purged process fluid to an appropriate waste management system or facility, such as a RCRA TSD 40 CFR 63.166(b)(4) *Gases displaced during filling of samples are not required to be collected or captured 40 CFR 63.166(a)	N/A	N/A	Equipment operated in VOC/VOHAP service less than 300 hours per year 40 CFR 63.1255(a)(1) Equipment in vacuum service 40 CFR 63.1255(a)(8) In-situ sampling systems and sampling systems without purges 40 CFR 63.166(c)
Open-Ended Valves or Lines 40 CFR 63.1255(d)	Equip with cap, blind flange, plug or second valve to seal open end at all times, except when operations requires flow through open end or during maintenance and repair 40 CFR 63.1255(d)(1)(ii) Closure must be in place within one hour after the end of allowed activities. No record is required 40 CFR 63.1255(d)(1)(ii) *Second valves: Must close valve on process fluid and prior to closing second valve 40 CFR 63.1255(d)(2) *Double Block and Bleed System: may remain open during operations that require venting the line between the block valves 40 CFR 63.1255(d)(3)	N/A	N/A	Equipment operated in VOC/VOHAP service less than 300 hours per year 40 CFR 63.1255(a)(1) Equipment in vacuum service 40 CFR 63.1255(a)(8) Open ended valves and lines, in an emergency shutdown system, that are designed to open automatically in the event of a process upset. Certain other open ended valves or lines that would create a safety hazard if closed. 40 CFR 63.1255(d)(4)-(6)

Component Types	Standards	Leak Definition	Repair	Exemptions
Periodic Monitoring:				
Valves in Gas/Vapor Service and Light Liquid Service 40 CFR 63.1255(e)	Complete initial monitoring survey by 10/21/03, or within 1 year after compliance date 40 CFR 63.1255(e)(2) Subsequently monitor at a frequency determined by % leakers calculated per the equation in the rule. Frequencies range from monthly to every 2 years. 40 CFR 63.1255(e)(4)(1)-(v) Valves may be assigned to subgroups, as long as the percent leakers in the subgroup remains at less than 2 percent, and may be reassigned under certain conditions 40 CFR 63.1255(e)(5)	500 ppmv	5/15 40 CFR 63.1255(e)(7)(i) & (ii) and remonitor the valve within 3 months after repair	Equipment operated in VOC/VOHAP service less than 300 hours per year 40 CFR 63.1255(a)(1) Equipment in vacuum service 40 CFR 63.1255(a)(8) Unsafe to monitor and difficult to monitor: see section on unsafe, difficult, and inaccessible components below.
Pumps in Light Liquid Service 40 CFR 63.1255(c)	Monitor quarterly and visually inspect weekly. If the greater of 10% or 3 of the pumps in a group of processes leak on a 1year rolling average, then must monitor monthly 40 CFR 63.1255(c)(2)(1)(iii) & (c)(4)(ii) No monitoring or visual inspections required for pumps designed with no external actuated shaft penetrating the housing 40 CFR 63.1255(c)(6) No monitoring required for dual mechanical seal pumps, with specific design requirements, including a barrier fluid system, with weekly visual inspections 40 CFR 63.(c)(5)(iv) No monitoring required for pumps equipped with closed vent system that ducts either to a control device or back to the process. 40 CFR 63.1255(c)(7)	2,000 ppmv 40 CFR 63.1255(c)(2)(ii)(B) Visual: Indications of liquids dripping from pump seal; monitor to confirm or eliminate visual indications of liquids dripping 40 CFR 63.1255(c)(2)(iii)40 CFR 63.1255(c)(5)(iv) Dual mechanical seal: if visual indication of liquids dripping exceeds established criteria, or sensor indicates leak 40 CFR 63.1255(c)(5)(vi)	5/15 40 CFR 63.1255(c)(3)	Equipment operated in VOC/VOHAP service less than 300 hours per year 40 CFR 63.1255(a)(1) Equipment in vacuum service 40 CFR 63.1255(a)(8) If more than 90% of the pumps in a group of processes are either dual mechanical seal or no external actuated shaft, then no periodic monitoring is required 40 CFR 63.1255(c)(9) Unsafe to monitor and difficult to monitor: see section on unsafe, difficult, and inaccessible components below.

Component Types	Standards	Leak Definition	Repair	Exemptions
Connectors in Gas/Vapor Service or Light Liquid Service 40 CFR 63.1255(b)(4)(iii) and 40 CFR 63.174	Complete initial monitoring survey by 10/21/03, or one year after compliance date 40 CFR 63.1255(b)(4)(iii) & 40 CFR 63.174 (b) Subsequently monitor at a frequency determined by % leakers calculated per the equation in the rule. Frequencies range from once a year to once every 8 years 40 CFR 63.1255(b)(4)(iii) The number of non-repairable connectors are set to zero; thus opened connectors are not required to be monitored within 3 months of being returned to service 40 CFR 63.174(c)(2) Screwed connectors will comply as ordinary connectors; the alternative at 40 CFR 64.172(c)(2) will not be used.	500 ppmv 40 CFR 63.174(a)(1)	5/15 40 CFR 63.174(d)	Equipment operated in VOC/VOHAP service less than 300 hours per year 40 CFR 63.1255(a)(1) Equipment in vacuum service 40 CFR 63.1255(a)(8) Inaccessible, unsafe to monitor:, ceramic or ceramic-lined connectors: see section on unsafe, difficult, and inaccessible components below.
Agitators in Gas/Vapor Service or Light Liquid Service 40 CFR 63.1255(c)	Monitor quarterly and visually inspect weekly 40 CFR 63.1255(c)(2)(1)(iii) No monitoring or visual inspections required for agitators designed with no external actuated shaft penetrating the housing 40 CFR 63.1255(c)(6) No monitoring required for dual mechanical seal agitators, with specific design requirements, including a barrier fluid system, with weekly visual inspections 40 CFR 63.(c)(5)(iv) No monitoring required for agitators equipped with closed vent system that ducts either to a control device or back to the process. 40 CFR 63.1255(c)(7)	10,000 ppm 40 CFR 63.1255(c)(2)(ii)(A) Visual: Indications of liquids dripping from agitators seal; monitor to confirm or eliminate visual indications of liquids dripping 40 CFR 63.1255(c)(2)(iii)40 CFR 63.1255(c)(5)(iv) Dual mechanical seal: if visual indication of liquids dripping exceeds established criteria, or sensor indicates leak 40 CFR 63.1255(c)(5)(vi)	5/15 40 CFR 63.1255(c)(3)	Equipment operated in VOC/VOHAP service less than 300 hours per year 40 CFR 63.1255(a)(1) Equipment in vacuum service 40 CFR 63.1255(a)(8) Unsafe to monitor and difficult to monitor: see section on unsafe, difficult, and inaccessible components below.

Component Types	Standards	Leak Definition	Repair	Exemptions
Other Monitoring:				
Pumps, valves, connectors, and agitators in heavy liquid service; instrumentation systems; and pressure relief devices in light and heavy liquid services 40 CFR 63.169	Monitor within 5 calendar days if there is visual, audible, or olfactory evidence of a leak 40 CFR 63.169(a) A leak may be declared without monitoring 40 CFR 63.139(a)	10,000 ppm for agitators, 2000 ppm for pumps, and > 500 ppm for others 40 CFR 63.169(b)	5/15 days 40 CFR 63.169(c)(1) & (2) If a leak has been detected without monitoring, repair means that the visual, audible, olfactory or other indications of a leak to the atmosphere have been eliminated; that no bubbles are observed at potential leak sites during a leak check using soap solution; or that the system will hold a test pressure. 40 CFR 63.169(c)(3)	Equipment operated in VOC/VOHAP service less than 300 hours per year 40 CFR 63.1255(a)(1) Equipment in vacuum service 40 CFR 63.1255(a)(8)
Closed vent systems and control devices 40 CFR 63.172	Conditions in Sections D.14 and D.15 of this permit are equivalent to or more stringent than 40 CFR 63.172 and are therefore are the relevant requirements.			Portions of a closed vent system which are designated as unsafe to inspect or difficult to inspect: see section on unsafe, difficult and inaccessible components below.
Unsafe, difficult, or inaccessible components [40 CFR 63.1255(f)]:				
Valves, connectors, agitators, pumps and closed vent systems designated as unsafe to monitor or unsafe to inspect 40 CFR 63.1255(f)(2)		As per component-specific standard elsewhere in this table.		
Valves, agitators, pumps and closed vent systems designated as difficult to monitor or difficult to inspect 40 CFR 63.1255(f)(3)		As per component-specific standard elsewhere in this table.		
Inaccessible, ceramic, or ceramic-lined connectors 40 CFR 63.1255(f)(4)		As per component-specific standard elsewhere in this table.	15 days	

Component Types	Standards	Leak Definition	Repair	Exemptions
Delay of Repair:				
All component types			Delay of repair is allowed if the repair is technically infeasible without a process shutdown. Repair shall occur by the end of the next scheduled process shutdown. 40 CFR 63.1255(b)(4)(i)(A) Delay of repair is allowed if the owner or operator determines that repair personnel would be exposed to an immediate danger if attempting to repair without a process shutdown. Equipment repair shall occur at end of next scheduled process shutdown. 40 CFR 63.1255(b)(4)(i)(B) Delay of repair is allowed if the equipment is isolated from the process and does not remain in VOC/VOHAP service. 40 CFR 63.171(b)	
Valves, connectors and agitators			Delay of repair allowed for these components if owner/operator determines emissions of purged material resulting from immediate repair would be greater than fugitive emissions likely to result from delay of repair, and when repairs are made, the purged material is collected/ destroyed, or recovered in control device. 40 CFR 63.171(c) Delay of repair, beyond a process unit shutdown, is allowed for valves if valve assembly replacement is necessary during the process unit shutdown, valve assembly supplies have been depleted, and valve assembly supplies had been sufficiently stocked before the supplies were depleted. Delay of repair beyond the second process unit shutdown is not allowed unless the third process unit shutdown occurs within 6 months after the first process unit shutdown. 40 CFR 63.71(e)	

Component Types	Standards	Leak Definition	Repair	Exemptions
Pumps			Delay of repair allowed if repair requires replacing existing seal design with dual mechanical seal pump, or with a pump with no externally actuated shaft penetrating the pump housing, or ducting the seal emissions via a closed-vent system to a control, and repair is completed as soon as practicable and not later than 6 months after leak detected. 40 CFR 63.171(d)	
Pressure, Vacuum, or Liquid Testing Alternative:				
All component types; all equipment designated as following this alternative 40 CFR 63.1255(b)(4)(iv)(A) and 40 CFR 63.178(a), (b) and (d)	Each time that equipment is reconfigured for production of a different product, or intermediate, the equipment is to be pressure tested for leaks before VOHAP/VOC is first fed into the equipment. 40 CFR 63.178(b)(1) Pressure testing after reconfiguration is required only for the new or disturbed equipment when the equipment train is reconfigured. 40 CFR 63.178(b)(1)(i) If equipment is not reconfigured, it must still be tested at least once per calendar year. 40 CFR 63.178(b)(1)(ii) Test methods per 63.180(f) and (g)	40 CFR 63.178(b)(2) specifies test methods at 40 CFR 63.180(f), (g). For pressure tests using a liquid, a leak is detected if indications of dripping liquid or other evidence of fluid loss . 40 CFR 63.178(b)(3)(ii) For pressure or vacuum tests, a leak is detected if rate of change in pressure is > 6.9kPa in 1 hour; or if visible, audible or olfactory evidence of fluid loss. 40 CFR 63.178(b)(3)(i)	When leaks are detected, repairs must be made and a retest conducted before startup of the process. 40 CFR 63.178(b)(4)(i) If it fails this retest or the second of 2 consecutive pressure tests, and is placed in VOHAP/VOC service, the equipment must be repaired as soon as practicable but not later than 30 calendar days after the second pressure test. 40 CFR 63.178(b)(4)(ii)	Pressure testing is not required for routine seal breaks, such as changing hoses and filters, which are not part of the reconfiguration to produce a different product or intermediate. 40 CFR 63.178(b)(1)(iii)

Definitions:

In VOC/VHAP Service means that a piece of equipment either contains or contacts a fluid (liquid or gas) that is at least 5 percent by weight a volatile hazardous air pollutant (VHAP). 40 CFR 63.1251

Connector means flanged, screwed or other joined fittings used to connect two pipelines or a pipeline and a piece of equipment. For purposes of reporting and recordkeeping, connector means joined fittings not inaccessible ceramic or ceramic lined. 40 CFR 63.1251

In vacuum service means that equipment is operating at an internal pressure which is at least 5 kPa below ambient pressure. 40 CFR 63.1251

Monitor means to measure by the methods described at 40 CFR 63.180(b) and applies to this table only.

Repaired means that equipment is adjusted to eliminate a leak as defined in the applicable paragraphs of 40 CFR 63.1255, and monitored as specified in 40 CFR 63.180(b) and (c), or 63.180(f) or (g), as appropriate, to verify that the emissions from the equipment is below the applicable leak definition. 40 CFR 63.1251

Table 2: Summary LDAR Program for Waste Systems

Component Types	Standards	Leak Definition	Repair	Exemptions
Leakless Design:				
Pressure Relief Devices in Gas/Vapor Service 40 CFR 61.242-4	No detectable emissions 40 CFR 61.2423-4(a)	No detectable emissions (less than 500 ppm above background) 40 CFR 61.242-4(a)	After each release return to no detectable emissions within 5 calendar days & monitor 40 CFR 61.242-4(b) or Where a rupture disc is installed upstream of a pressure relief device, after each pressure release, a new rupture disc shall be installed upstream of the pressure relief device as soon as practicable, but no later than 5 calendar days after each pressure release. 40 CFR 61.242-4(d) or Vent the pressure relief device to a process or fuel gas system or equip it with a closed-vent system capable of capturing and transporting leakage from the pressure relief device to a control device. 40 CFR 61.242-4(c)	Equipment in vacuum service 40 CFR 61.242-1(e)
Compressors 40 CFR 61.242-3	Either use a seal with barrier fluid system inspected daily or alarmed, 40 CFR 61.242-3(a)-(f) or Equip with a closed-vent system to capture & transport compressor drive shaft seal back to a process, a fuel gas system, or a control device meeting 61.242-11 40 CFR 61.242-3(h) or Use leakless design that is < 500 ppmv monitored annually 40 CFR 61.242-3(i)	Sensor indicates failure of seal system, barrier fluid system, or both 40 CFR 61.242-3(e) &f) or leakless design $\geq$ 500 ppmv 40 CFR 61.242-3(i) N/A for closed vent system alternative 40 CFR 61.242-3	5/15 40 CFR 61.242-3(g) N/A for closed vent system	Equipment in vacuum service

Component Types	Standards	Leak Definition	Repair	Exemptions
Sampling Connection Systems 40 CFR 61.242-5	Use a closed purge or closed vent system that either returns the fluid to the process or collects and recycles the purged fluid 40 CFR 61.242-5(b)(1) &(2) or Captures and transports all purged fluids to a compliant control device 40 CFR 61.242-5(b)(3) or Collects, stores and transports the purged process fluid to an appropriate waste management system or facility, such as a RCRA TSD 40 CFR 61.242-5(b)(4) *Gases displaced during filling of samples are not required to be collected or captured 40 CFR 61.242-5(a)	N/A	N/A	Equipment in vacuum service In-situ sampling systems and systems without purges 40 CFR 61.242-5(c)
Open-Ended Valves or Lines 40 CFR 61.242-6	Equip with cap, blind flange, plug or second valve to seal open end at all times, except when operations requires flow through open end or during maintenance and repair 40 CFR 40 CFR 61.242-6(a) *Second valves: Must close valve on process fluid and prior to closing second valve 40 CFR 61.242-6(b) *Double Block and Bleed System: may remain open during operations that require venting the line between the block valves 40 CFR 61.242-6(c)	N/A	N/A	Equipment in vacuum service Open ended valves and lines, in an emergency shutdown system, that are designed to open automatically in the event of a process upset. Certain other open ended valves or lines that would create a safety hazard if closed. 40 CFR 61.242-6(d) & (e)

Component Types	Standards	Leak Definition	Repair	Exemptions
Periodic Monitoring:				
Valves in Gas/Vapor Service or Light Liquid Service 40 CFR 61.242-7 and 40 CFR 61.243-1 and 40 CFR 61.243-2	Monitor each valve monthly 40 CFR 61.242-6(a) After 2 consecutive months of no leaks on a given valve, that valve may be monitored during the first month of each quarter, as long as it does not leak. If it leaks, it returns to monthly monitoring until a leak is not detected for 2 successive months. 40 CFR 61.242-6(c) Or Monitor according to 40 CFR 61.242-6(a) and (c). Then, on notice to the Administrator, after 2 consecutive quarters with ≤ 2% leakers per process unit, monitor all valves in the process unit semiannually 40 CFR 61.243-2(b)(2); or after 5 consecutive quarters with ≤ 2% leakers per process unit, monitor all valves in process unit annually. 40 CFR 61.243-2(b)(3) In either case, if the process unit exceeds 2% leaking valves in any monitoring period, all valves revert to individual schedules under 61.242-6, but may elect to skip again when requalified. 40 CFR 61.243-2(b)(4) Or Performance test all valves within a process unit annually and within one calendar week, or as requested by the Administrator. Percent leaking must be ≤ 2.0. This option may be initiated or terminated upon notification to the agency. 40 CFR 61.243-1 No detectable emission valves must be designed with any external actuating mechanism in contact with the process fluid. These valves shall be monitored initially, annually, and as requested by the Administrator. 61.242-7(f) Valves designated unsafe-to-monitor must be monitored according to a written plan to monitor as frequently as practicable during safe-to-monitor times 61.242-7(g) Valves designated difficult to monitor must be monitored according to a written plan that requires monitoring of the valve at least once/ yr. 40 CFR 61.242-7(h)	10,000 ppmv 40 CFR 61.242-7(b) 500 ppmv for no detectable emission valves	5/15 40 CFR 61.242-7(d)	Equipment in vacuum service

Component Types	Standards	Leak Definition	Repair	Exemptions
Pumps in Light Liquid Service 40 CFR 61.242-2	Monitor monthly and visually inspect weekly 40 CFR 61.242-1(a) No monitoring required for dual mechanical seal pumps, with specific design requirements, including a barrier fluid system, with weekly visual inspections 40 CFR 61.242-1(d) Pumps designed with no external actuated shaft penetrating the housing may instead be monitored initially, annually, and as requested by the Administrator to confirm no detectable emissions. 40 CFR 61.242-1(e) No monitoring required for pumps equipped with closed vent system that ducts either to a control device or back to the process. 40 CFR 61.242-1(f) Pumps designated unsafe-to-monitor must be monitored according to a written plan to monitor as frequently as practicable during safe-to-monitor times 61.242-1(g)	10,000 ppmv 40 CFR 61.242-1(b)(1) Visual: Indications of liquids dripping from pump seal 40 CFR 61.242-1(b)(2) Dual mechanical seal: if visual indication of liquids dripping is confirmed by monitoring which indicates the presence of the process fluid, or VOC/VOHAP in excess of 10,000 ppmv, or sensor indicates leak 40 CFR 61.242-1(d)(4)-(6) 500 ppmv for no detectable emissions pumps 40 CFR 61.242-1(e)(2)	5/15 40 CFR 61.242-1(c) 40 CFR 61.242-1(d)(6)(iii) & (iv) 40 CFR 61.242-1(g)(2)	Equipment in vacuum service
Other Monitoring:				
Pressure Relief Devices in Liquid Service 40 CFR 61.242-8	If visual, audible, or olfactory evidence of a leak, either: Monitor within 5 calendar days or Repair without monitoring 40 CFR 61.242-8(a)	10,000 ppmv 40 CFR 61.242-8(b)	5/15 40 CFR 61.242-8(c) If a leak is declared without monitoring, repair means that the visual, audible, olfactory or other indication of a leak has been eliminated. 40 CFR 61.242-8(a)(2)	Equipment in vacuum service
Connectors 40 CFR 61.242-8	If visible, audible, or olfactory evidence of a leak, either: Monitor within 5 calendar days or Repair without monitoring 40 CFR 61.242-8(a)	10,000 ppmv 40 CFR 61.242-8(b)	5/15 40 CFR 61.242-8(c) If a leak declared without monitoring, repair means that the visual, audible, olfactory or other indication of a leak has been eliminated. 40 CFR 61.242-8(a)(2)	Equipment in vacuum service

Component Types	Standards	Leak Definition	Repair	Exemptions
Closed vent systems and control devices 40 CFR 61.242-11	Conditions in Sections D.14 and D.15 of this permit are equivalent to or more stringent than 40 CFR 61.242-11(c), (e), and (f) and are therefore are the relevant requirements. 40 CFR 61.242-11(b) and (d) do not apply, Portions of a closed vent system which are designated as designated unsafe to inspect must be inspected according to a written plan to monitor as frequently as practicable during safe-to-monitor times 40 CFR 61.242-11(j) Portions of a closed vent system which are designated as difficult to inspect must be inspected according to a written plan that requires monitoring of the closed vent system at least once every 5 years.. 40 CFR 61.242-11(k)	500 ppmv or visual 40 CFR 61.242-11(g)	5/15 40 CFR 61.242-11(g)	Closed vent system portions that are operated under a vacuum. 40 CFR 61.242-11(k)
Delay of Repair [40 CFR 61.242-10]				
All component types			Delay of repair is allowed if the repair is technically infeasible without a process shutdown. Repair shall occur by the end of the next scheduled process shutdown. 40 CFR 61.242-10(a) Delay of repair is allowed if the equipment is isolated from the process and does not remain in VOC/VOHAP service. 40 CFR 61.242-10(b)	

Component Types	Standards	Leak Definition	Repair	Exemptions
Valves			Delay of repair allowed if owner/operator determines that emissions of purged material resulting from immediate repair would be greater than the fugitive emissions likely to result fro delay of repair, and when the repairs are made, the purged material is collected and destroyed, or recovered in a control device. 40 CFR 61.242-10(c) Delay of repair, beyond a process unit shutdown, is allowed if valve assembly replacement is necessary during the process unit shutdown, valve assembly supplies have been depleted, and valve assembly supplies had been sufficiently stocked before the supplies were depleted. Delay of repair beyond the next process unit shutdown is not allowed unless the next process unit shutdown occurs within 6 months after the first process unit shutdown. 40 CFR 61.242-10(e)	
Pumps			Delay of repair is allowed if repair requires replacing the existing seal design with a dual mechanical seal pump and repair is completed as soon as practicable and not later than 6 months after the leak was detected. 40 CFR 61.242-10(d)	

Definitions:

In VOC/VHAP Service means that a piece of equipment either contains or contacts a fluid (liquid or gas) that is at least 10 percent by weight a Volatile hazardous air pollutant (VHAP).

Connector means flanged, screwed, or other joined fittings used to connect two pipelines or a pipeline and a piece of equipment. For purposes of reporting and recordkeeping, connector means joined fittings not covered by insulation or other materials that prevent location of the fittings.

In vacuum service means that equipment is operating at an internal pressure which is at least 5 kPa below ambient pressure.

Appendix B
Technical Support Documentation for
Advance Source Modification Approval

Overview

This section of the TSD describes the elements of this permit that provide the Permittee with the flexibility to make changes at the plant site more quickly and with fewer administrative requirements. This flexible permit is based on provisions in Indiana's air permit regulations and guidance issued by USEPA.

The additional flexibility will exist while assuring compliance with Clean Air Act requirements and protecting air quality. Lilly proposes several flexible permit concepts which have been created or advocated under USEPA's P4 (Pollution Prevention Permitting Pilot) permitting program and other flexible permitting programs. These flexible permit concepts are based on the use of three elements:

1) Advance identification of the types of changes that will occur under the flexible permit, and the requirements that will apply to those changes;
2) Requiring highly effective emission control systems to assure compliance with applicable emission standards; and
3) Limiting emissions through BACT emission limits to assure protection of air quality.

The permit provides a higher level of flexibility and simplicity because of these features. It also establishes a higher level of environmental performance than would otherwise be required under Clean Air Act requirements applicable to the site. The permit requires Best Available Control Technology be used on the Bulk Pharmaceutical Manufacturing (BPM) operations and support areas – when applicable requirements would not otherwise require as high a level of controls. In particular, Lilly will control VOC and volatile organic HAPs by 98% or greater, and it will control sulfur dioxide and fluorides by greater than 97.5%. In some cases the site committed to additional upgrades of its emission control equipment beyond what existing rules or a traditional PSD permit would require. In addition, the emission limits that will limit overall BPM and support area emissions represent a significant reduction in the level of emissions the site could legally emit. Furthermore, Tippecanoe Laboratories has committed to utilize continuous emission monitoring systems (CEMs) to a much greater extent than would have been required by existing requirements.

The flexible permit also simplifies ongoing compliance and administrative requirements. The permit will streamlines similar regulatory requirements into a single set of requirements. The streamlined permit conditions replace dozens of older permit conditions that established different performance requirements, compliance demonstration requirements, and record keeping/reporting obligations.

Background and description

Tippecanoe Laboratories serves several roles in Lilly's overall product development and manufacturing system. The site is involved in the research and development of the manufacturing process that will be used to produce new medicines. It also serves as the site where new products are first made and where existing products continue to be made. The source maintains extra capacity to back up other sites if manufacturing at another site cannot occur.

Because of these varying roles, the production facilities at Tippecanoe Laboratories must be capable of making frequent changes with minimal delay. In a typical year, Tippecanoe Laboratories will make more than 20 process and product changes. A flexible permit enables Tippecanoe Laboratories to make the necessary changes with minimal delay, and assures that air pollution control standards will be achieved and air quality will be protected.

In order to fulfill the various roles of Tippecanoe Laboratories in Lilly's manufacturing strategy, Lilly would expect six types of changes that potentially would trigger air permitting requirements and/or changes in the applicable emission standards. More specific descriptions of these changes are described in greater detail:

- Production of new medicine compounds or intermediate compounds
- Process change for an existing product or intermediate
- Replacement of existing equipment in the pharmaceutical production unit
- Addition of new equipment to a pharmaceutical production unit
- Replacement of existing production buildings with new production buildings
- Expansion of production operations

In order to understand the nature of each of these changes, it is important to understand the nature of bulk pharmaceutical manufacturing. Synthesizing a pharmaceutical product or intermediate is the result of a series of chemical reactions and physical treatments (separations, filtrations, centrifugations, and drying) of a mixture of solvents and other raw materials. It is similar to following the recipe for making an elaborate food. Sometimes you can create the final product through a few chemical reactions and treatments. More often the process calls for multiple intermediate production steps where the process of chemical reactions and physical treatment occurs several times to transform the raw materials into a final bulk pharmaceutical product that is sent to another site for formulation into pills, capsules, vials, and other forms for human ingestion or injection.

The process takes place in a group of equipment commonly referred to as a production unit or rig. A rig generally consists of vessels or tanks where the chemical reactions take place and several other types of equipment to separate the desirable intermediate or final product from the unreacted or spent material. The separation is achieved through various means such as distillation, washing, centrifugation and drying.

While the general process of manufacturing a pharmaceutical product is relatively consistent, the specific process to make an individual product or intermediate is unique. The number of reactions that must take place will be different. The solvents and other raw materials may be different. The time, temperature and other variables of the chemical reactions are process specific. As a result, the emissions generated by any individual process will be different too.

Below is a more specific description of the types of changes that may occur at Tippecanoe Laboratories that under traditional permitting schemes may trigger air-permitting requirements.

New products: As the primary facility for developing full scale manufacturing processes and launching production of new products, Tippecanoe Laboratories sees many new products each year. On average, Tippecanoe Laboratories will be involved in the process development or production of 5 to 10 new pharmaceutical products each year.

Process changes: Synthesizing a pharmaceutical intermediate or final product is a complex science that must be implemented with speed in order to compete in the current market. Due to these factors, it is common for the initial synthetic route for making a product or intermediate to be less than ideal. Therefore, most process changes are implemented with the purpose of improving the overall yield of the active pharmaceutical ingredient in the final product or the cycle time associated with making the product. Frequently the process changes will reduce raw material, energy usage, waste generation and emissions. The changes may involve anything from changing solvents and other raw materials to adjusting process control parameters such as reaction temperature and reaction time. In some instances the process changes will change the emissions profile of a process.

Equipment replacement: The process vessels (tanks) in which the chemical synthesis occurs are subjected to harsh conditions. The solvents and raw materials used in the synthesis and the by-products of the synthesis can corrode or otherwise wear away the tank. Temperature changes involved in driving a chemical reaction or generated by the reaction can also affect the safety and performance of a tank. FDA requirements establish strict purity standards for pharmaceutical products. As a result, Tippecanoe

Laboratories has an aggressive tank integrity-testing program that requires frequent replacement of process tanks. Generally the new tanks will be the same size as the old tank, thus assuring the process capacity does not change. In some cases the material of construction for the new tank will be newer or more durable. The chemistry of a new process can also impact the material of construction for a tank. This assures the widest degree of production flexibility for the tank in the future.

New equipment: Tippecanoe Laboratories' production facilities are designed to accommodate a wide variety of raw materials and process operations, and this aspect enables the site to use existing equipment to a great extent to manufacture both existing products and new products. In some instances, however, it may be necessary to add additional equipment to a process rig in order to implement a process change or to make a new product. For example, the new equipment might be another tank to handle an additional reaction or process step or centrifuge that is larger to handle a larger amount of wetcake created by the process.

While the potential emissions attributed to the new equipment could be above various permitting thresholds, typically this type of project has little impact on the site overall VOC and HAP emissions.

Replacement of production buildings with new buildings: Over time, production buildings may be replaced in order to modernize production operations. This process involves shutting down existing production rigs and other operations, and constructing new operations in its place. In some cases, a single building may be replaced by more than one smaller building. The new operations are more automated and require less manual intervention.

These aspects generally result in more efficient production and lower environmental impact. For example, new drying equipment combines both centrifugation/filtration with drying in a single step. This type of equipment reduces fugitive emissions because the centrifuge is not opened up for manual removal of the product before transfer into a dryer. Because of the increased efficiency, the new operations typically entail less physical capacity than the current operations. This will reduce the overall potential to emit of the plant site.

The new buildings would be subject to the appropriate applicable requirements (i.e., RACT or MACT rules), and the same BACT requirements as the existing operations. Essentially, the new operations would be subject to the same applicable requirements as the existing operations. Since the existing source MACT and new source MACT requirements of the Pharmaceutical MACT rules require the same level of controls (20 ppm TOC or 98% DRE), advance approval of this type of change is easier to manage.

Expansion: An expansion to the bulk pharmaceutical manufacturing facilities would consist of adding significant quantities of new equipment to increase production capacity or to enable production of an entirely new product. The expansion could take several forms. The site could build an entirely new production building that would consist of several production rigs. Adding a new wing consisting of one or two new rigs to an existing building would be another form of expansion. In some cases, common operation types such as drying could undergo expansion by construction of a new building or wing devoted to that unit operation. Expansion occurs infrequently. The last major construction project in BPM occurred in the early 1990s when Building T29 was demolished and replaced with a new T29. Long term, Tippecanoe Laboratories may replace existing buildings or add additional production capacity. This permit will not allow construction of new process buildings without undergoing traditional New Source Review.

Flexible permit concept and scope

The flexible permit is based on the concept of pre-approval of changes with known standards for emissions control technology, emission limitations and compliance assurance. Although the production operations will change, the applicable regulatory requirements, the emission control systems to comply with those requirements, and the compliance assurance systems will not change. By approving in advance the types of changes that will likely occur at the site and linking them to the known compliance obligations those changes will entail, the permit can provide flexibility by reducing the administrative burdens of individual pre-approvals.

The Tippecanoe Laboratories' flexible permit consists of the following elements:

- Advance approval of anticipated types of changes;
- A requirement to utilize Best Available Control Technology to reduce emissions of the pollutants that would potentially increase above PSD significance thresholds as a result of the changes;
- A requirement to conduct an air quality assessment if a plant expansion would cause a significant net emission increase in emissions from boiler operations;
- A limit on emissions (emissions cap) applicable to the areas subject to the flexible permit provisions to ensure compliance with NAAQS and PSD increments;
- Provisions to measure and estimate actual emissions to verify compliance with the emissions cap;
- Monitoring requirements to demonstrate compliance with emissions performance requirements and emission caps.
- Condensing various Clean Air Act requirements that establish similar requirements for the same equipment into a streamlined, common requirement; and
- A commitment to reduce air emissions and solid and liquid waste generation through pollution prevention efforts.

The table that appears at the end of this section of the TSD summarizes the flexible permit.

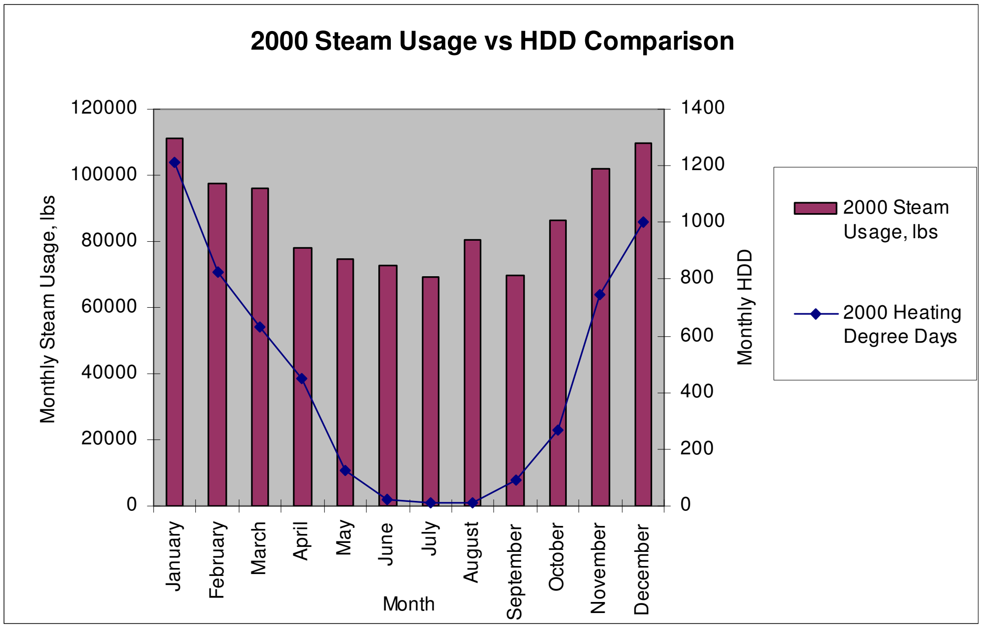
Scope of the flexible permit: As discussed earlier in this TSD, the Permittee will be issued a PSD permit for future modifications to the BPM facilities at Tippecanoe Laboratories. In addition to the potential increase in emissions of carbon monoxide (CO), fluorides (F^-) and volatile organic compounds (VOC) directly from the modifications, the permit allows the permittee to emit additional quantities of those three pollutants from operations supporting and relating to the BPM operations. These support operations include solvent storage, solvent recovery, waste solvent storage, wastewater treatment (encompasses both pretreatment and wastewater treatment facilities), and waste incineration.

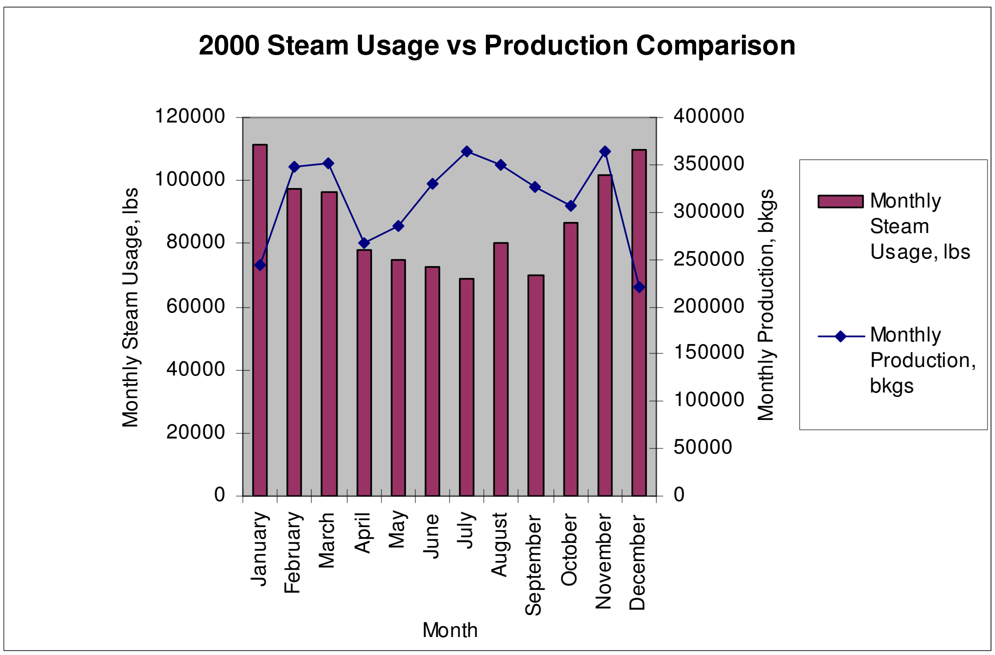
The modifications to BPM include manufacture of new products and intermediates, process changes, equipment replacement, and equipment additions to existing operations in process research/manufacturing buildings T27, T28, T29, T31/T31A, T99 and T100. In addition, the modifications would also include process changes, equipment replacement, equipment additions to existing solvent and waste storage tank modules (T140, T142, T143, T145, and T146), and solvent recovery operations (T19, T52, and T61). Lilly anticipates there will be other physical changes or changes in the method of operation to the waste incinerators, such as upgrade, replacement or repair of incinerator components. Some BPM production buildings or operations could be replaced with entirely new operations.

The Fermentation Products operations and the site utility systems are outside the scope of the flexible permit. The Fermented Products operations manufacture pharmaceutical products, primarily for animals, by fermenting and purifying medicines. The products made in this area are not related to products made in BPM. Emissions in Fermented Products will not change due to any of the possible changes made in BPM. Therefore, the Fermented Products area is not within the scope of the flexible elements of this permit.

Except in the case of an expansion to the plant site, the Permittee does not anticipate an increase in demand for steam from the boilers or an increase other utility support operations as a result of the changes proposed under the flexible permit. Steam produced at the site is used for several purposes including general heating of buildings and process steam. Steam demand, however, is driven primarily by weather – cold weather. The Permittee has analyzed the relationship of steam production to weather conditions and BPM production levels, and that analysis demonstrates that steam demand is directly correlated to weather. The relationship between production rates and steam demand cannot be correlated. The following graphs illustrate this finding.

The first graph shows the relationship between steam production levels and heating degree-days for the year 2000. The graph shows that steam production rose and fell as heating degree days rose and fell. The second graph shows no discernible relationship between production rates and steam usage.





Advance approval: The concept of advance approval is the key mechanism for providing flexibility in the permit. Instead of requiring case-by-case administrative review of individual changes proposed by Tippecanoe Laboratories, the advance approval features of the permit condense those many future reviews into a single review that occurs well in advance of the change. As a result, instead of waiting up to several months for the permitting authority to review and approve a change before it can be made, the changes falling within the scope of the advance approval can be made immediately or after a notice is submitted to the permitting authority.

Advance approval works well when the applicable Clean Air Act requirements can be determined for each type of change and described adequately as a requirement in the permit. Because the applicable requirements for pharmaceutical manufacturing operations and prospective changes are readily known and easily described as permit terms, Tippecanoe Laboratories is a good candidate for advance approval terms.

The Clean Air Act and the USEPA and IDEM regulations implementing the Act have created several programs that require prior approval from an agency before a change can proceed. These programs include pre-construction permitting programs such as Major and Minor New Source Review, the Part 61 NESHAP and Part 63 MACT pre-construction approval provisions, Section 112(g) case-by-case MACT determinations, and the Title V operating permit program.

Of these prior approval requirements, the Permittee will use advance approval provisions to address prior approval requirements of Indiana's Minor NSR program and the Title V operating permit program. In addition, because the flexible permit is being reviewed pursuant to a PSD review process that will establish BACT emission control requirements and federally enforceable emission limits, future changes within the scope of the advance approvals will not trigger major NSR. The advance approval provisions will also require Lilly to follow any pre-construction requirements of the NSPS, NESHAP, and MACT general provisions if applicable.

Advance approvals are specifically authorized under Indiana's Title V program rules at 326 IAC 2-7-5(16) and alternative operating scenarios are authorized pursuant to 326 IAC 2-7-5(9). The advance approval provisions found at 326 IAC 2-7-5(16) also authorize the use of advance approvals in Title V permits as a mechanism to eliminate review procedures of the minor New Source Review requirements of 326 IAC 2-7-10.5. Emission limits or other standards that would be applicable under minor NSR remain applicable.

The permit will allow the use of advance approval provisions for the following types of modifications to take place in the existing BPM and BPM support operations: production of new products and intermediates; process changes for existing products; replacement of existing production equipment with similar equipment, new equipment additions to existing process operations, and replacement of existing production buildings.

The permit will allow the types of changes listed below (and others meeting the requirements of the permit) to occur under the advance approval scheme.

(a) BPM Process Operations:

(1) A change in bulk pharmaceutical products or intermediate products manufactured;
(2) A change in raw materials stored and utilized;
(3) A change in the method of operation to a process or existing equipment;
(4) Piping changes, including but not limited to, process piping, waste piping and fume transport piping;
(5) A physical change to existing equipment;
(6) Reconstruction or replacement of existing equipment, including but not limited to, process tanks, crystallizers, distillation operations, filters, centrifuges, and dryers;
(7) Installation of new equipment, including but not limited to, process tanks, crystallizers, distillation operations, filters, centrifuges, and dryers; and
(8) Reconstruction or replacement of existing production buildings.

(b) BPM Support Operations:

(1) A change in solvent material recovered;
(2) A change in raw materials stored and utilized;
(3) A change in the method of operation to a process or existing equipment;
(4) Piping changes, including but not limited to, process piping, waste piping and fume transport piping;
(5) A physical change to existing equipment;
(6) Reconstruction or replacement of existing equipment, including but not limited to, process tanks, receivers, stills, storage tanks, and container transfer operations;
(7) Installation of new equipment, including but not limited to, process tanks, receivers, stills, storage tanks, and container transfer operations;

(8) Reconstruction or replacement of existing solvent recovery operations, storage tanks, storage tank modules, and distillation operations; and
(9) Installation of new solvent recovery operations, storage tanks, storage tank modules, and distillation operations.

(c) T49 liquid waste incinerator and T149 solids-liquid waste incinerator:

(1) A change in waste materials disposed in the incinerators that does not affect compliance with 40 CFR 63, Subpart EEE or RCRA Part B permit requirements;
(2) A change in the use of portable containers, including but not limited to, drums, melons, and tank trailers;
(3) A change in the method of operation that does not affect compliance with 40 CFR 63, Subpart EEE;
(4) Piping changes;
(5) A physical change that does not affect compliance with 40 CFR 63, Subpart EEE;
(6) Reconstruction or replacement of incinerator components and support equipment, including but not limited to, cooling towers and waste container management;
(7) Installation of new incinerator equipment components, support equipment or emission control equipment.

Condition F.1.2 establishes the basic elements of the advance approval program (types of changes, applicable requirements for the changes) in the permit. Condition F.1.11 establishes the record keeping requirements for changes made pursuant to the flexible permit provisions. Condition F.1.12 establishes the notification requirements for advance approved changes.

BACT Requirements:
The use of the BACT determination for anticipated future changes depends on two factors. First, under the Indiana PSD regulations, modifications must occur without an interruption of greater than 18 months in order for the BACT determination to remain valid for the future changes. Tippecanoe Laboratories expects to make modifications on a fairly regular basis and does not expect 18 months to pass between any modifications.

Second, the BACT determination would expire at the end of the flexible permit term. As part of a Title V permit, the flexible permit would expire in five years. As part of the Title V permit renewal process, Lilly will reevaluate the BACT determination for the areas of the site undergoing modifications in the future. Upon expiration of the Title V permit, the major NSR rules in effect at that time would govern the applicability and requirements to changes made at the site.

The BACT determination for this permit is described in greater detail elsewhere in this TSD. The BACT controls also assure compliance with other applicable requirements that apply to BPM and the associated operations. For example, the Regenerative Thermal Oxidizers (RTOs), which control VOC and organic HAP emissions from the BPM production buildings, not only constitute BACT, but also assure Tippecanoe Laboratories will comply with the Pharmaceutical Production MACT (40 CFR Part 63, Subpart GGG), and an Indiana VOC RACT regulation for synthesized pharmaceutical manufacturing operations (326 IAC 8-5-3).

The BACT requirements of the permit can be found in the specific sections of the permits establishing emission limitations for operating areas.

Emission Limits: The flexible permit utilizes emission limits for the three pollutants CO, F^- and VOC as a mechanism to establish boundaries on the extent of the changes that can occur under the advance approval provisions. The limits apply to all the areas under the flexible permit that could expect to see emission increases as a result of modifications that would occur in the BPM production areas and support operations. The limits will apply to emissions from BPM production buildings, solvent storage and recovery, waste solvent storage, BPM wastewater treatment, and the liquid/solid waste incinerators.

The emission limits are set at levels that assure protection of the National Ambient Air Quality Standards and PSD increments. Compliance with these requirements is discussed in greater detail in the Air Quality Analysis section of this TSD.

The emission limits are based on Lilly's estimate of the emission increases that could be expected under various product mixes and production rates. In order to assure the greatest flexibility for Tippecanoe Laboratories, the limits apply to all the emission units under the flexible permit in the aggregate. This approach will allow the greatest flexibility to the site operations and assure air quality standards are still protected.

Tippecanoe Laboratories will demonstrate compliance with the emission limits through a variety of techniques, including continuous emissions monitoring systems (CEMS), stack testing, and engineering calculations. Approximately two-thirds of the potential emissions under the limit will be measured using CEMS.

The emission limits are in Condition F.1.1 of the permit. The compliance demonstration systems are described in Conditions F1.3 through F1.7. Record keeping and reporting requirements for the emission caps are in Condition F.1.9.

Pharmaceutical MACT change management system: The Pharmaceutical MACT rule created a unique change management scheme to assure sources subject to it could document compliance with the appropriate requirements depending on which equipment was being operated and how the equipment was being operated. This permit includes several provisions to implement the MACT change management requirements. Condition F.1.10 describes the evaluation process Lilly will use to identify the applicable requirements and compliance methods for each operating scenario. Because the site will utilize MACT "alternative" compliance method (20 ppm TOC limit) for the BPM production operations, and a "worst case" control scenario for the BPM support operations, the complexity of complying with this standard is greatly reduced. These compliance methods require the least amount of evaluation for each change, because the compliance method assumes that all operating scenarios will require the highest level of controls and the control equipment is capable of meeting that level of controls. Conditions F.1.11 and F.1.13 include notification, record keeping and reporting requirements for the MACT change management system.

Streamlining of requirements: The fundamental aspects of the Tippecanoe Laboratories flexible permit are the advance approval provisions, the Clean Building requirement, and the emission limits. These features work in conjunction to provide flexibility and assure compliance with applicable requirements and air quality standards.

In addition to providing the flexibility to make changes quickly, the Title V permit will also reduce or eliminate administrative duplication and promote simplicity for compliance. This will be accomplished in part by condensing or streamlining similar emission limitations and standards that apply to the same emission units. This concept is recognized by USEPA in Title V Implementation White Paper 2 and in Indiana's Title V regulations at 326 IAC 2-7-24.

For example, the BPM production buildings are subject to three regulatory and permit requirements that require the use of high efficiency emission control systems: (1) BACT requirements of this flexible permit; (2) 326 IAC 8-5-3; and (3) Pharmaceutical Production MACT. All three of these requirements establish control requirements for VOC or organic HAP emissions. By distilling the multiple and overlapping requirements into a single requirement that represents the most stringent requirements, the permit will assure compliance with all three requirements. The specific streamlining actions are described in greater detail in the TSDs for the specific operating areas utilizing this program.

This permit will also eliminate several synthetic minor emission limits established in past construction permits through the PSD review process. Because the potential emission increases that might occur as a result of eliminating these old limits will undergo PSD review, the elimination of these limits is consistent with 40 CFR 52.21(r)(4).

Pollution prevention commitment: This flexible permit has been designed under the auspices of EPA's P4 permitting program. As an element of participating in the P4 program, Tippecanoe Laboratories proposes to make certain commitments regarding pollution prevention. These requirements are found in Condition F.1.18.

Tippecanoe Laboratories is committed to pollution prevention and has been honored by receiving the Vice-President's Green Chemistry Award and by three times receiving the Indiana Governor's Pollution Prevention Award. Tippecanoe Laboratories plays an important role in implementing pollution prevention principles for manufacturing throughout the company. As the site that is responsible for ramping up synthetic production processes from pilot plant to full-scale production, the scientists and engineers at Tippecanoe Laboratories work to assure the process not only provides high yields of the pharmaceutical ingredient, but also takes into account raw material and energy usage and waste generation. This knowledge can be transferred to other manufacturing sites when they are making compounds originating at the site.

Flexible Permit Summary

Operating area/emission units	Types of changes	Pollutant	Control device(s)	Applicable requirements	Emissions cap (tpy)*	Compliance assurance
Bulk Pharmaceutical Manufacturing (BPM) production buildings Operations include ■ Process vessels (tanks) ■ Filters ■ Centrifuges ■ Dryers ■ Fugitive emission components (pumps, valves, etc.)	**Changes in existing equipment** ■ Production of new products/intermediates ■ Process changes for existing processes **Installation of new equipment** ■ Replacement of existing equipment ■ Installation of new equipment (small projects)	VOC point	RTOs	BACT limits/RTO 326 IAC 8-5-3(b)	300	TOC monitor
		VOC fugitive	LDAR	BACT (LDAR)		Mass Balance
		CO	RTOs	BACT limits (RTOs)	150	CO monitor
		Fluorides	RTO scrubbers	BACT limits/RTO scrubbers	6	HCl Monitor
		HAPs	RTOs/RTO scrubbers	Pharmaceutical MACT SOCMI HON Subpart I	NA	TOC monitor HCl monitor
BPM support operations Solvent recovery Solvent and waste storage BPM waste water treatment Equipment includes: ■ Solvent recovery tanks and columns ■ Storage tanks (raw material, solvent recovery and waste storage)	**Changes in existing equipment** ■ Storage, recovery, and treatment of new or different solvents/solvent wastes ■ Change in location of storage or recovery of solvent/solvent wastes ■ Changes to solvent recovery processes **Installation of new equipment** ■ Replacement of existing equipment ■ Installation of new equipment (small projects) ■ Addition of new storage tank modules **Building replacement** ■ Replacement of production unit/rig ■ Replacement of production building Site expansions **Addition of new storage tank module solvent recovery system**	VOC point	T79	BACT limit/T79 NSPS Subpart Kb 326 IAC 8-5-3(b)	300	Calculation /stack test T79 temperature monitoring (for BACT/ NSPS/Rule 8-5-3)
		VOC fugitive	LDAR	LDAR		Mass Balance
		CO	Good combustion practice - T79	Sub-cap limit = 30 tpy	150	Calculation
		Fluorides	T79 scrubbers	Sub-cap limit = 2 tpy	6	Calculation Scrubber parametric monitoring
		HAPs	T79/scrubbers	Pharmaceutical MACT SOCMI HON Subpart I Off-site Waste MACT	NA	Stack test/temperature monitoring
T49 liquid waste incineration (Control device - scrubbers)	**Changes in existing equipment** Upgrade, replacement and repair of incinerator components	VOC point	Good combustion practice	BACT limit/good combustion HWC combustor MACT	300	CO monitor as surrogate
		CO	Good combustion practice	BACT limit/good combustion HWC combustor MACT 326 IAC 9	150	CO monitor
		Fluorides	Scrubbers	BACT limit/scrubbers HWC combustor MACT	6	Calculation HCl monitoring as surrogate

Operating area/emission units	Types of changes	Pollutant	Control device(s)	Applicable requirements	Emissions cap (tpy)*	Compliance assurance
		HAPs	Good combustion practice/scrubbers	HWC combustor MACT	NA	HWC MACT requirements
T149 Liquid/solid waste incineration - kiln (Control device - scrubbers, SNCR)	**Changes in existing equipment** Upgrade, replacement and repair of incinerator components	VOC point	Good combustion practice	BACT limit/good combustion HWC combustor MACT	300	CO monitor as surrogate
		CO	Good combustion practice	BACT limit/good combustion HWC combustor MACT 326 IAC 9	150	CO monitor
		Fluorides	Scrubbers	BACT limit/scrubbers HWC combustor MACT	6	Calculation HCl monitoring as surrogate
		HAPs	Good combustion practice/scrubbers	HWC combustor MACT	NA	HWC MACT requirements

* Emission limits are the sum of all of the emission points identified above.

Appendix D – BACT Analyses

Indiana Department of Environmental Management
Office of Air Quality

Technical Support Document (TSD)
Best Available Control Technology

Source Background and Description

Source Name:	**Eli Lilly and Company - Tippecanoe Laboratories**
Source Location:	**1650 Lilly Road, Lafayette, IN 47909**
County:	**Tippecanoe**
SIC Code:	**2833, 2879 and 4953**
Operation Permit No.:	**T 157-6879-00006**
Operation Permit Issuance Date:	**February 27, 2004**
Significant Source Modification No.:	**157-26577-00006**
Title V Operating Permit Renewal No.:	**T 157-26575-00006**
Permit Reviewer:	**Josiah Balogun**

Proposed Expansion

Eli Lilly and Company (Lilly) is a research-based company that discovers, develops, manufactures and markets pharmaceutical products for people and animals. In this preventive of Significant Deterioration (PSD)/Flexible Permit, Eli Lilly proposed to modify Tippecanoe Laboratories through a series of product and process changes, replacement of existing production equipment and installation of new production equipment. This proposal is essentially an extension of the existing flexible permit of Tippecanoe Laboratories except that the PSD application will cover only three pollutants: carbon monoxide (CO), volatile organic compounds (VOC) and fluorides (F^-). In lieu of evaluating future changes for PSD applicability, and potentially requiring time and resource-consuming permit reviews for each individual change, Lilly proposes to evaluate the parts of the existing plant site affected by the changes and the types of changes it intends to make in the future under the Prevention of Significant Deterioration (PSD) program (326 IAC 2-2). This approach is allowed under provisions in Indiana's air permit regulations (326 IAC 2-2 and 326 IAC 2-7-5(16)) and guidance issued by USEPA in its draft White Paper 3 on implementing the Title V operating permit program. The PSD permit will allow Lilly to make changes in the future with minimal administrative requirements and will assure compliance with all applicable Clean Air Act requirements.

Eli Lilly and Company - Tippecanoe Laboratories, located at 1650 Lilly Road, Lafayette, Indiana, in Tippecanoe County submitted a PSD application and Title V Flexible Permit Renewal to IDEM, OAQ on May 20, 2008.

Requirement for Best Available Control Technology (BACT)

326 IAC 2-2 requires a best available control technology (BACT) review to be performed on the proposed modification because the modification has the potential to emit of VOC, CO and F emissions greater than 40, 100 and 3 tons per year, respectively, which exceeds the significant level for these pollutants.

Emission Units Subject to BACT Requirements for VOC, CO and F:

The following emission units have the potential to emit Volatile Organic Compounds (VOC), carbon monoxide (CO) and Fluorides (F-); therefore, a Best Available Control Technology analyses for VOC, CO and Fluorides was performed for these units:

(1) BPM Operations – VOC, CO and Fluorides

(2) BPM Support Operations – VOC

(3) T49 Liquid Waste Incinerator – VOC, CO and Fluorides

(4) T149 Rotary Kiln Incinerator – VOC, CO and Fluorides

Requirement for VOC, CO and Fluoride (F-) BACT

The BPM Operations, BPM Support Operations, T49 Liquid Waste Incinerator and T149 Rotary Kiln Incinerator operations has the total potential to emit of volatile organic compounds (VOC), carbon monoxide (CO) and Fluorides (F-) greater than 40, 100 and 3 tons per year, respectively; therefore, Best Available Control Technology analyses for VOC, CO and Fluorides (F-) were performed for BPM Operations, BPM Support Operations, T49 Liquid Waste Incinerator and T149 Rotary Kiln Incinerator.

Summary of the Best Available Control Technology (BACT) Process

BACT is a mass emission limitation based on the maximum degree of pollution reduction of emissions, which is achievable on a case-by-case basis. BACT analysis takes into account the energy, environmental, and economic impacts on the source. These reductions may be determined through the application of available control techniques, process design, work practices, and operational limitations. Such reductions are necessary to demonstrate that the emissions remaining after application of BACT will not cause or contribute significantly to air pollution, thereby protecting public health and the environment.

Federal guidance on BACT requires an evaluation that follows a “top down” process. In this approach, the applicant identifies the best-controlled similar source on the basis of controls required by regulation or permit, or controls achieved in practice. The highest level of control is then evaluated for technical feasibility.

The five (5) basic steps of a top-down BACT analysis are listed below:

Step 1: Identify Potential Control Technologies

The first step is to identify potentially “available” control options for each emission unit and for each pollutant under review. Available options should consist of a comprehensive list of those technologies with a potentially practical application to the emissions unit in question. The list should include lowest achievable emission rate (LAER) technologies, innovative technologies, and controls applied to similar source categories.

Step 2: Eliminate Technically Infeasible Options

The second step is to eliminate technically infeasible options from further consideration. To be considered feasible, a technology must be both available and applicable. It is important in this step that any presentation of a technical argument for eliminating a technology from further consideration be clearly documented based on physical, chemical, engineering, and source-specific factors related to safe and successful use of the controls. Innovative control means a control that has not been demonstrated in a commercial application on similar units. Innovative controls are normally given a waiver from the BACT requirements due to the uncertainty of actual control efficiency. A control technology is considered available when there are sufficient data indicating that the technology results in a reduction in emissions of regulated pollutants.

Step 3: Rank the Remaining Control Technologies by Control Effectiveness

The third step is to rank the technologies not eliminated in Step 2 in order of descending control effectiveness for each pollutant of concern. The ranked alternatives are reviewed in terms of environmental, energy, and economic impacts specific to the proposed modification. If the analysis determines that the evaluated alternative is not appropriate as BACT due to any of the impacts, then the next most effective is evaluated. This process is repeated until a control alternative is chosen as BACT. If the highest ranked technology is proposed as BACT, it is not necessary to perform any further technical or economic evaluation, except for the environmental analyses.

Step 4: Evaluate the Most Effective Controls and Document the Results

The fourth step entails an evaluation of energy, environmental, and economic impacts for determining a final level of control. The evaluation begins with the most stringent control option and continues until a technology under consideration cannot be eliminated based on adverse energy, environmental, or economic impacts.

Step 5: Select BACT

The fifth and final step is to select as BACT the most effective of the remaining technologies under consideration for each pollutant of concern. For the technologies determined to be feasible, there may be several different limits that have been set as BACT for the same control technology. The permitting agency has to choose the most stringent limit as BACT unless the applicant demonstrates in a convincing manner why that limit is not feasible. The final BACT determination would be the technology with the most stringent corresponding limit that is economically feasible. BACT must, at a minimum, be no less stringent than the level of control required by any applicable New Source Performance Standard (NSPS) and National Emissions Standard for Hazardous Air Pollutants (NESHAP) or state regulatory standards applicable to the emission units included in the permits.

The Office of Air Quality (OAQ) makes BACT determinations by following the five steps identified above.

Volatile Organic Compounds (VOC) BACT – BPM Operations

Step 1: Identify Potential Control Technologies

The volatile organic compounds (VOC) emissions can be controlled by the followings:

(1) Destruction Processes;

(2) Reclamation Processes; and /or

(3) Combination of Reclamation and Destruction Technologies.

Destruction technologies reduce VOC concentration by high temperature oxidation into carbon dioxide and water vapor. Reclamation is the capture of VOCs for reuse or disposal.

Step 2: Eliminate Technically Infeasible Options

The test for technical feasibility of any control option is whether it is both available and applicable to reducing VOC emissions from emissions units at BPM operation. The control technologies listed in the previous section are discussed and evaluated below for their technical feasibility.

Destruction Control Methods

The destruction of organic compounds usually requires temperatures ranging from 1,200^{0}F to 2,000^{0}F for direct thermal incinerators or 600^{0}F to 1,200^{0}F for catalytic systems. Combustion temperature depends on the chemical composition and the desired destruction efficiency. Carbon dioxide and water vapor are the typical products of complete combustion. Turbulent mixing and combustion chamber retention times of 0.5 to 1.0 seconds are needed to obtain high destruction efficiencies.

Combustion control technologies include recuperative thermal incineration, regenerative thermal incineration, recuperative catalytic incineration, regenerative catalytic incineration, and flares.

Combustion control technologies include:

Recuperative Thermal Oxidation: Recuperative thermal incinerators are add-on control devices used to control VOC emissions by introducing solvent-laden fume to the oxidizer. The stream is pre-heated by exiting flue gas from the same system in a heat exchanger or recuperator. A burner then heats the air to the required temperature. The air is then passed through an oxidation chamber where the solvent-laden air is converted to carbon dioxide and water. These are then passed through the heat exchanger where incoming fume is preheated by the heat of the exiting flue gas. Finally the clean flue gas is discharged to the atmosphere. The recuperative thermal oxidizer is appropriate for waste streams with a relatively high solvent content and/or consistent pollutant loading. Variation in pollutant loading will require a longer retention time in the oxidizer in order to properly destroy VOC emissions. Eli Lilly's streams do not have high solvent content or consistent pollutant loading. Based on a review of the RBLC, this type of control has been used for controlling VOC emissions from other sources, but has not been typically used for pharmaceutical processes. This would not be an appropriate control method for low VOC exhaust stream from the BPM operations

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a Recuperative Thermal Oxidation is not a technically feasible option for the BPM Operation at this source.

Regenerative Thermal Oxidation: Regenerative thermal oxidizers (RTOs) are add-on control devices used to control VOC emissions by simple reaction of the harmful air pollutants with oxygen and heat. RTO uses a direct contact heat exchanger. These direct contact heat exchangers consist of a bed of porous ceramic packing or other structured, high heat capacity media. These systems can handle variable and low-concentration VOC waste streams.

The inlet gas first passes through a hot ceramic bed thereby heating the stream (and cooling the bed) to its ignition temperature. The hot gases then react (releasing energy) in the combustion chamber and while passing through another ceramic bed, thereby heating it to the combustion chamber outlet temperature. The process flows are then switched, now feeding the inlet stream to the hot bed. This cyclic process affords very high energy recovery (up to 95%). The higher capital costs associated with these high-performance heat exchangers and combustion chambers may be offset by the increased auxiliary fuel savings to make such a system economical

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a Regenerative thermal oxidizer is a technically feasible option for the BPM Operation at this source.

Recuperative and Regenerative Catalytic Oxidation: Catalytic incinerators are add-on control devices used to control VOC emissions by using a bed of catalyst that facilitates the oxidation of the combustible gases. The catalyst increases the reaction rate and allows the conversion of VOC at lower temperatures than thermal incinerators. Catalytic oxidation can be used for low-concentration VOC waste streams; however, certain compounds present in waste stream gas may foul the catalyst. It may also be necessary to remove particulate prior to catalytic oxidation as well.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a Recuperative and Regenerative Catalytic Oxidation is not a technically feasible option for the BPM Operation at this source.

Flares: Flaring is used to control VOC emissions by piping VOCs to a remote, usually elevated location and burning them in an open flame in the open air using a specially designed burner tip, auxiliary fuel, and steam or air to promote mixing for nearly complete (> 98%) VOC destruction. While flares are designed to eliminate waste gas streams, they can cause safety and operational problems and the exhaust stream concentration must be high enough to sustain combustion.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a flare is not a technically feasible option for the BPM Operation at this source.

Reclamation Control Methods

Organic compounds may be reclaimed by one of three possible methods; adsorption, absorption (scrubbing) or condensation. In general, the organic compounds are separated from the emission stream and reclaimed for reuse or disposal. Depending on the nature of the contaminant and the inlet concentration of the emission stream, recovery technologies can reach efficiencies of 98%.

Adsorption: is a surface phenomenon where attraction between the carbon and VOC molecules binds the pollutants to the carbon surface. Both carbon and VOC are chemically intact after adsorption. The VOCs may be removed, or desorbed, from the carbon bed reclaimed and destroyed. Adsorption can be used for relatively low VOC exhaust streams. Pollutants present in the gas streams can reduce adsorber efficiency, increase pressure drop and eventually plug the bed. Adsorption processes can be used to capture VOCs in low concentration exhaust; however, it is typically only used for exhaust that is not loaded with other pollutants which can plug the bed. Based on a review of the RBLC, this type of control has been used in the printing and petroleum refinery industries. This type of control is not typically used in pharmaceutical industries and based on the pollutant loading of the exhaust stream, adsorption is not considered technically feasible for the BPM operations as plugging of the adsorption media would likely occur.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of adsorption is not technically feasible option for the BPM Operation at this source.

Absorption: is a unit operation where components of a gas phase mixture (Pollutants) are selectively transferred to a relatively nonvolatile liquid, usually water. Sometimes, organic liquids, such as mineral oil or nonvolatile hydrocarbons, are suitable absorption solvents. The choice of solvent depends on cost and solubility of the pollutant in the solvent. Absorption is commonly used to recover products or purify gas streams that have high concentrations of organic compounds. Absorption processes are typically used to recover products or purify gas streams with high concentrations of organic compounds such as in the ethanol production and soybean oil refinery industries. However, it is not considered a technically feasible application for VOC control of emissions from the pharmaceutical operations due to the low concentration of VOC in the exhaust.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of absorption is not technically feasible option for the BPM Operation at this source.

Condensation: is the separation of VOCs from an emission stream through a phase change, by increasing the system pressure or, more commonly, lowering the system temperature below the dew point of the VOC vapor. When condensers are used for air pollution control, they usually operate at the pressure of the emission stream, and typically require a refrigeration unit to obtain the temperature necessary to condense the VOCs from the emission stream. These systems are frequently used prior to other control devices (e.g., oxidizers or absorbers) to remove components that may be corrosive or damaging to other parts of the system. Refrigerated condensers are used as air pollution control devices for treating emission streams with high VOC concentrations (usually > 5,000 ppmv). Condensers may be used to control VOC emissions with high VOC concentrations (usually greater than 5,000 ppmv). The RBLC shows that this type of control has been used for botanical extraction processes and petroleum refineries. Condensers are not typically used in the pharmaceutical industries for VOC control and are not considered technically feasible for the application of controlling VOC emissions from the pharmaceutical operations due to the low concentration of VOC in the exhaust.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of condensation is not technically feasible option for the BPM Operation at this source.

Combinations of Reclamation and Destruction Control Methods

In some cases, a combination of control technologies offers the most efficient and cost effective VOC control.

The combination of carbon adsorption with recuperative thermal incineration is available commercially. This system concentrates the VOC stream by using carbon adsorption to remove low concentration VOCs in an emission stream and then uses a lower volume of hot air, commonly one-tenth the original flow, to desorb the pollutants. A recuperative incinerator for destroying pollutants in the concentrated stream is much smaller and has lower supplemental fuel requirement than an incinerator sized for the full emission stream volume.

Absorption systems can also be used to concentrate emission streams to reduce the size of destruction equipment. The concentration effect is not as extreme as with carbon adsorption, a concentrated exhaust stream one quarter the volume of the inlet stream seems to be the practical limit. Absorption concentrators are typically suited for batch processes or to equalize pollutant concentrations in a variable stream. The physical characteristics that drive the absorption of pollutants into a liquid also limit the opportunity to remove those pollutants from the liquid stream.

Fume incinerators typically need supplemental fuel. Concentrated VOC streams with high heat contents obviously require less supplementary fuel than more dilute streams. VOC streams sometimes have a heat content high enough to be self-sustaining, but a supplemental fuel firing rate equal to about 5% of the total incinerator heat input is usually needed to stabilize the burner flame. Natural gas is the most common fuel for VOC incinerators, but fuel oil is an option in some circumstances.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a Combinations of Reclamation and Destruction Control Methods is not a technically feasible option for the BPM Operation at this source.

Step 3: Rank the Remaining Control Technologies by Control Effectiveness

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of Regenerative Thermal oxidizer has been identified for control of VOC resulting from BPM operations at the Eli Lilly and Company, Tippecanoe Laboratories.

(1) Regenerative Thermal Oxidizer - 98 % destruction efficiency

Step 4: Evaluate the Most Effective Controls and Document the Results

The following table lists the proposed VOC BACT determination along with the existing VOC BACT determinations for BPM operations. All data in the table is based on the information obtained from the permit application submitted by Eli Lilly and Company - Tippecanoe Laboratories, the U.S. EPA RACT/BACT/LAER Clearinghouse (RBLC), and electronic versions of permits available at the websites of other permitting agencies.

Table 1: Existing VOC BACT Limits – BPM Operations			
Company Name / Operation	**Process Description**	**Control Type**	**Control Efficiency**
PROPOSED BACT FOR BPM Operations			
Eli Lilly and Company, Tippecanoe Laboratories - **Lafayette,** IN (Proposed permit 157-26575-00006) Proposed date, 2008	BPM Operations	Regenerative Thermal Oxidation (RTO) and leak detection and repair (LDAR) Program	98% control of VOC/VOHAP or 20 ppmv based on 24-hour daily average
COMPARABLE BACT DETERMINATIONS (List in Top-Down Order by Control Efficiency)			
ICN Pharmaceuticals (CA-0348)	Drying Ovens (4)	Carbon Adsorption	65 lb/day (control efficiency not specified) (BACT)

Table 1: Existing VOC BACT Limits – BPM Operations

Company Name / Operation	Process Description	Control Type	Control Efficiency
Kelco-Division of Merck, Inc (CA-0570)	Biogum Processing Line	Water Scrubbers	95% (BACT)
American Cyanamid Co. (CT-0037)	Pharmaceutical Material Generation	Activated carbon Adsorption	90% (BACT)
Pfizer (CT-0108)	Pharmaceuticals Manufacturing Equipments	Regenerative Oil Adsorption System	93% (BACT)
Pfizer (CT-0108)	Coater	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0108)	Dryer	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0108)	Dryer	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0108)	Pharmaceuticals Manufacturing Equipments	Surface Condensers	95% (BACT)
Pfizer (CT-0108)	Pharmaceuticals Manufacturing Equipments	Scrubber and /or Carbon Adsorption	85% (BACT)
Pfizer (CT-0108)	Coater	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0108)	Dryer	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0108)	Dryer	Catalytic Oxidizer	95% (BACT)
Eli Lilly and Company (IN-0035)	Insulin Manufacturing	Low Temperature Vent Condensers	97% (BACT)
Upjohn (MI-0201)	Filter, Pressure for product drying	2 Nitrogen recycle Drying System	98% (LAER)
Dow Chemical (MI-0223)	Reactor, Distillation, Crystallizer, Centrifuge, Vacuum Dryer and Filter	Condenser followed by wet scrubber	90% for isopropyl Alcohol and 95% for Ethyl Alcohol
Upjohn (MI-0235)	Expansion of HF Chemistry	Refrigerated Condenser	94.7% (BACT)
Pfizer (MI-0276)	Pharmaceutical Production.	Thermal Oxidizer	99.9% (BACT)
Wyckoff Chemicals Co., Inc (MI-0107)	Pharmaceutical Mfg.	Caustic scrubber/Demister, carbon Adsorption System	95% (BACT)
Wyckoff, Inc (MI-0312)	Reactors, et. al	Scrubber and Condenser	94%
Eli Lilly and Company (IN-0098)	Monensin Process	Carbon Adsorber	95% (BACT)
Eli Lilly and Company (Permit No. T157-6879-00006)	BPM	RTO	98% control or 20ppmv

The most stringent VOC emission limitation contained in the pharmaceutical summary is 99.99% control on a pharmaceutical production operation. The most stringent control requirement for wastewater operations includes permit that indicate VOC control using thermal incineration to 99% control and benzene control using carbon adsorption to 99.5%.

In evaluating BACT for VOC control of pharmaceutical operations, it is important to note that the control efficiency anticipated for a given emission unit/control equipment combination is dependent upon the uncontrolled VOC emission rate of the emission unit. Even though a unit may be listed with a high control efficiency in RBLC, the same control equipment would be expected to have a lower control efficiency if the uncontrolled emission rate is lower. Lilly has focused its BACT evaluation on the extent to which the selected control equipment corresponds to the control equipment type utilized at the best-controlled facility identified in RBLC.

The RBLC entry with the highest indicated VOC control efficiency is an entry for Pfizer in Holland, Michigan that is described in RBLC as "three 22,500 cfm thermal oxidizers (that) will destroy VOC and combustibles at 99.99% guaranteed efficiency". Due to the high control efficiency noted in RBLC for this unit, a more detailed discussion of this permit is provided. Lilly notes that Pfizer Holland plant is no longer in operation. The Pfizer permit did not have a permit condition or limit that required 99.99% control of VOC emissions, but rather a mass emission rate of 0.84 pounds of VOC per hour (for all units combined). Lilly determined that the oxidizers at Pfizer were simple afterburners manufactured by Callidus, followed by waste heat boilers. They were not regenerative or recuperative type thermal oxidizers, and operated with no internal heat recovery. No information was available on the inlet VOC concentration for this unit.

Vendor data indicate that neither a recuperative nor a regenerative type of oxidizer can be expected to meet a very stringent DRE of 99.99%. No manufacturer of these devices will guarantee such a high efficiency since they need to leave themselves a safety margin below the highest efficiency that can reasonably be obtained. The only type of oxidizer that is utilized for applications requiring this degree of efficiency is an afterburner, or a simple incinerator without any heat recovery, that can operate at combustion temperatures as high as 2500°F. To achieve such a limit, Lilly would have to install an afterburner that operated at a much higher temperature than a regenerative oxidizer.

Lilly has performed an analysis of the cost to add an afterburner to the VOC control system for the BPM exhaust stream using cost equations contained in the EPA document *Control Technologies for Hazardous Air Pollutants* (EPA/625/6-91/014). Based on an air flow rate of 60,000 cfm and an inlet VOC concentration of 20 ppmv, Lilly estimates capital and operating costs for such a system to be:

- Capital cost = $3,300,000
- Operating costs = $54,000,000 per year
- Cost effectiveness = $735,000 per ton of VOC controlled

The cost effectiveness to add an afterburner to the BPM operations is clearly beyond the level that would be considered economically reasonable under state and federal guidelines for BACT

Lilly concludes that the RBLC entry for the Pfizer facility was based on different control technology than proposed by Lilly. The permit for the Pfizer unit did not require a 99.99% DRE for VOCs, but rather specified an outlet emission rate. Lilly believes that the limit proposed in its BACT analysis represents the lowest limit that a regenerative thermal oxidizer is reasonably capable of meeting. In order for Lilly to meet an emission rate comparable to that required for Pfizer, an afterburner would have to be added to the existing control system for BPM. Given the low level of additional VOC removal that this would provide (in comparison with estimated capital and operating costs), Lilly believes that this option would not be considered to be BACT for this unit. Since this unit is not comparable to the Lilly operation, the most stringent applicable limit for

VOC emissions from pharmaceutical operations is the BACT limit for BPM contained in the original Flexible Permit.

(a) **Proposal**: **Eli Lilly and Company, Tippecanoe Laboratories** – Lafayette, IN
The following has been proposed as BACT for VOC for BPM Operations:

(a) VOC point source emissions: Regenerative Thermal Oxidizer (RTO) to control VOC emissions to a volumetric concentration of 20 parts per million (ppmv) based on a 24 - hour daily average, or 98 % of VOC/VOHAP emissions.

(b) VOC fugitive emissions: Leak Detection and Repair (LDAR) Program

Step 5: Select BACT

Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed VOC BACT of 20 parts per million (ppmv) based on a 24 - hour daily average, or 98 % of VOC/VOHAP emissions for the BPM Operation. The BACT determination is based on the following facts and findings:

(1) BPM Operations

(a) The emission rates represent the most stringent applicable regulatory requirement;

(b) With the exception of the Pfizer facility in Holland, Michigan, the most stringent listing in the RBLC is consistent with the proposed BACT limit proposed by the source.

(c) The installation of an afterburner is considered economically infeasible. In order for Lilly to meet a control efficiency comparable to that required for Pfizer in Holland, Michigan, an afterburner would have to be installed after the RTO control system. The cost effectiveness to add an afterburner to the existing RTO control system is $735,000 per ton of additional VOC removed using accepted cost equations contained in the EPA document *Control Technologies for Hazardous Air Pollutants* (EPA/625/6-91/014).

(2) Fugitive Emissions
IDEM, OAQ has approved the proposed LDAR program to satisfy the fugitive VOC BACT in the BPM process operations area based on the following facts and findings:

(a) The proposed LDAR program is consistent with the most stringent regulatory standards. These standards are described in detail in Appendix A – Section E (LDAR Program) of the TSD; and

(b) There were no control requirements listed in the RBLC database that addressed fugitive emissions.

Regulatory Limits: The most stringent VOC emission limitation applicable to this emission unit is the MACT standard for pharmaceutical operations. This rule requires organic HAP emissions to be controlled by 93 to 98% or to 20 ppm. This rule also contains requirements for leak detection and repair programs for components in organic HAP service. There are no emission limits for similar sources that would create any more stringent emission limits for pharmaceutical operations.

Permit Limits: The most stringent permit limit contained in RBLC for a comparable unit is the existing BPM BACT limit of 98% control or 20 ppmv.

Feasibility of Control Technology: VOC emissions may be controlled by a variety of control technologies, however there is no technology that would be expected to achieve an overall control efficiency (or outlet VOC emission rate) more stringent than the existing BACT limit for BPM.

Carbon Monoxide (CO) BACT - BPM Operations

Step 1: Identify Potential Control Technologies

Emissions of carbon monoxide (CO) are generally controlled by oxidation.

Step 2: Eliminate Technically Infeasible Options

The test for technical feasibility of any control option is whether it is both available and applicable to reducing VOC emissions from emissions units at BPM operation. The control technologies listed in the previous section are discussed and evaluated below for their technical feasibility.

Carbon Monoxide (CO) is formed through the incomplete oxidation of organic material to carbon dioxide (CO2). Factors that may lead to the formation of carbon monoxide include inadequate air flow rates, inadequate mixing of air and fuel, and improper temperatures in combustion zones. CO emission control is achieved by design optimization in combustion equipment to minimize CO formation or by the use of add-on control units that will facilitate the further oxidation of CO to CO2.

Thermal Oxidizers

The thermal oxidizer is a nozzle-stabilized flame maintained by a combination of auxiliary fuel, waste gas compounds, and supplemental air added when necessary. This technology is typically applied for destruction of organic vapors, nevertheless it is also considered as a technology for controlling CO emissions. Upon passing through the flame, the waste gas containing CO is heated from its inlet temperature to its ignition temperature (It is the temperature at which the combustion reaction rate (and consequently the energy production rate) exceeds the rate of heat losses, thereby raising the temperature of the gases to some higher value). Thus, any CO/air mixture will ignite if its temperature is raised to a sufficiently high level. The CO-containing mixture ignites at some temperature between the preheat temperature and the reaction temperature. The ignition occurs at some point during the heating of a waste stream as it passes through the nozzle-stabilized flame regardless of its concentration. The mixture continues to react as it flows through the combustion chamber.

The required level of CO destruction of the waste gas that must be achieved within the time that it spends in the thermal combustion chamber dictates the reactor temperature. The shorter the residence time, the higher the reactor temperature must be. Most thermal units are designed to provide no more than 1 second of residence time to the waste gas with typical temperatures of 1,200 to 2,000^{o}F. Once the unit is designed and built, the residence time is not easily changed, so that the required reaction temperature becomes a function of the particular gaseous species and the desired level of control.

(a) Recuperative Thermal Oxidizer

The Recuperative Thermal Oxidizer is comprised of the combustion chamber and heat exchanger. After leaving the combustion chamber, the exhaust gas enters a heat exchanger where it transfers heat to the waste gas through conduction. The waste gas is thus preheated.

Considerable fuel savings can be achieved by using the exhaust gas to preheat the incoming waste gas, combustion air, or both via a heat exchanger. These heat exchangers can recover up to 70% of the energy (enthalpy) in the product gas. Most heat exchangers are not designed to withstand high temperatures, so that most of the energy needed to reach ignition is supplied by the combustion of fuel in the combustion chamber and only moderate preheat temperatures are sought in practice ($<1200^{o}$F). Eli Lilly's stream has high temperature.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a thermal oxidizer is a technically feasible option for the BPM Operation at this source.

(b) Regenerative Thermal Oxidizer

Regenerative Thermal Oxidizer consists of direct contact heat exchangers constructed of a ceramic material that can tolerate the high temperatures needed to achieve ignition of the waste stream.

The inlet gas first passes through a hot ceramic bed thereby heating the stream (and cooling the bed) to its ignition temperature. The hot gases then react (releasing energy) in the combustion chamber and while passing through another ceramic bed, thereby heating it to the combustion chamber outlet temperature. The process flows are then switched, now feeding the inlet stream to the hot bed. This cyclic process affords very high energy recovery (up to 95%). The higher capital costs associated with these high-performance heat exchangers and combustion chambers may be offset by the increased auxiliary fuel savings to make such a system economical.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a thermal oxidizer is a technically feasible option for the BPM Operation at this source.

(c) Catalytic Oxidizers

Catalytic oxidation is also a widely used control technology to control pollutants where the waste gas is passed through a flame area and then through a catalyst bed for complete combustion of the waste in the gas. This technology is typically applied for destruction of organic vapors, nevertheless it is considered as a technology for controlling CO emissions. A catalyst is an element or compound that speeds up a reaction at lower temperatures compared to thermal oxidation without undergoing change itself. Catalytic oxidizers operate at 650°F to 1000°F and approximately require 1.5 to 2.0 ft^3 of catalyst per 1000 standard ft^3 per gas flow rate.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a catalytic oxidizer is not a technically feasible option for the BPM Operation at this source.

Step 3: Rank the Remaining Control Technologies by Control Effectiveness

(1) Recuperative Thermal Oxidizer - 98 % destruction efficiency

(2) Regenerative Thermal Oxidizer - 98 % destruction efficiency

Step 4: Evaluate the Most Effective Controls and Document the Results

Company (RBLC Entry Number)	Process Description	Control Type	Control Efficiency
Eli Lilly	BPM	Combustion Controls (RTOs)	73 ppmv
Anniston Army Depot (AL-0135)*	Liquid Incinerator	Quench tower, venturi scrubber, demister, clean fuel	100 ppmv @ 7% O2
Anniston Army Depot (AL-0137)*	Metal Parts Furnace	Quench tower, venturi scrubber, demister, clean fuel	100 ppmv @ 7% O2
Aptus, Inc. (UT-0044)	Kiln	Not Specified	100 ppm @ 7% O2 (BACT)
BASF Corporation Acrylic Acid (TX-0266)	Incinerator	None	40.39 lb/hr, 101.82 tpy (BACT)
Huntsville Solid Waste Authority (AL-0029)	Boiler, RDF, 2 Each	Pollution Prevention (Combustion Design)	50 ppm at 12%CO2, 7.6 lb/hr (BACT)
Ogden Martin Systems of Indianapolis (IN-0026)	Incinerator, Mass Burn, 3 Each	Pollution Prevention (Combustion Controls)	135 ppmv at 12% CO2 (BACT)
Dow Chemical Company (MI-0329)	Incinerator, Rotary Kiln, Hazardous Waste	Pollution Prevention	100 ppmv at 7% O2 (MACT)
BASF Freeport (TX-0418)	Hazardous Waste Incinerator	Pollution Prevention (Good Combustion Practices)	66.65 lb/hr, 291.93 tpy, 100 ppm at 7% O2 (BACT)
Eli Lilly and Company (Permit T157-6879-00006)	T49	Combustion Controls	100 ppmvdc
Eli Lilly and Company (Permit T157-6879-00006)	T149	Combustion Controls	100 ppmvdc

* Pollutant not listed in RBLC; information obtained from actual permits.

There are no CO limits contained in RBLC for Pharmaceutical operations.

(a) **Proposal**: **Eli Lilly and Company, Tippecanoe Laboratories** – Lafayette, IN
The following has been proposed as BACT for VOC for BPM Operations:

(1) Combustion controls to limit CO emissions to 73 ppmvdc, based on a 24-hour daily average.

Step 5: Select BACT

Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed CO BACT of 78 ppmvdc based on a 24 - hour daily average. The BACT determination is based on the following facts and findings:

(1) Because average CO emissions are less than 4 ppmv on a daily average, the quantity of CO which would be controlled in reducing peak hourly emissions from 73 ppmv to 10 ppmv is very small, while the cost to control these emissions would be significant (both in regards to the capital cost to treat an air stream of up to 120,000 acfm and the operating costs for supplemental fuel).

(2) In addition to the fact that little CO would actually be controlled, significant additional NOx emissions would be expected from the combustion control system.

Regulatory Limits: There are no regulatory limits for CO emissions for pharmaceutical operations.

Permit Limits: There are no CO limits contained in RBLC for pharmaceutical operations. The CO BACT limit for the existing Flexible Permit is 73 ppmvdc.

Feasibility of Control Technology: CO emissions are generally controlled by proper combustion techniques. Add-on controls are not feasible for this operation.

Fluorides (F-) BACT – BPM Operations

Step 1: Identify Potential Control Technologies

Fluorides can be controlled by scrubbers:

Step 2: Eliminate Technically Infeasible Options

The test for technical feasibility of any control option is whether it is both available and applicable to reducing fluorides emissions from emissions units at BPM operation.

Fluorides Technologies Considered Feasible

The presence of halogens such as fluorine or chlorine in a fuel or waste stream exposed to high temperatures will result in the creation of acid gases such as hydrogen fluoride or hydrogen chloride. Fluoride and chloride emissions are generally controlled in much the same manner as chloride emissions are generally controlled in much the same manner as for sulfur dioxide. Fuel or process modifications may be possible to limit the quantity of these materials in fuel or process streams. Add-on controls may also be used to physically remove these materials from exhaust gases. Systems used to control sulfur dioxide emissions will also capture and control halogen emissions. Fluoride compounds tend to react with chemical reagents most rapidly, followed by chloride compounds and sulfur dioxide. Thus, a control system for sulfur dioxide will by its nature remove most fluoride and chloride compounds.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a fluorides technology is not a technically feasible option for the BPM Operation at this source

Step 3: Rank the Remaining Control Technologies by Control Effectiveness

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of Sodium hydroxide (NaOH) injection with 98 % control efficiency is the only viable technology for controlling fluorides (F-) emissions resulting from the BPM operations at the Eli Lilly and Company, Tippecanoe Laboratories.

Sodium hydroxide (NaOH) Injection - 98% control efficiency

Step 4: Evaluate the Most Effective Controls and Document the Results

There are no Fluorides limits contained in RBLC for Pharmaceutical operations.

(a) **Proposal**: **Eli Lilly and Company, Tippecanoe Laboratories** – Lafayette, IN
The following has been proposed as BACT for Fluorides for BPM Operations:

(1) NaOH injection to achieve 98% removal of hydrogen halide and halogen emissions, or 20 ppmv of hydrogen halide and halogen emissions over a 24 - hour daily average.

Step 5: Select BACT

Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed Fluorides (F-) BACT of NaOH injection to achieve 98% removal of hydrogen halide and halogen emissions, or 20 ppmv of hydrogen halide and halogen emissions over a 24 - hour daily average. The BACT determination is based on the following facts and findings:

(1) There are no applicable regulations or RBLC entries limiting fluoride emissions from this type of operation.

(2) This level of control is as stringent as the Pharmaceutical MACT limit for hydrogen chloride.

Regulatory Limits: There are no regulatory limits for fluoride emissions for pharmaceutical operations.

Permit Limits: There are no fluoride limits contained in RBLC for pharmaceutical operations. The BACT limit in the existing Flexible Permit for BPM is 98% removal or 20 ppmv of hydrogen halide and halogen emissions.

Feasibility of Control Technology: Fluoride emissions may be controlled through the use of a scrubbing system.

Volatile Organic Compounds (VOC) BACT – BPM SUPPORTS

Step 1: Identify Potential Control Technologies

The volatile organic compounds (VOC) emissions can be controlled by the followings:

(1) Destruction Processes;

(2) Reclamation Processes; and /or

(3) Combination of reclamation and destruction technologies.

Destruction technologies reduce VOC concentration by high temperature oxidation into carvon dioxide and water vapor. Reclamation is the capture of VOCs for reuse or disposal.

Step 2: Eliminate Technically Infeasible Options

The test for technical feasibility of any control option is whether it is both available and applicable to reducing VOC emissions from emissions units at BPM operation.

Destruction Control Methods

The destruction of organic compounds usually requires temperatures ranging from 1,200^{0}F to 2,000^{0}F for direct thermal incinerators or 600^{0}F to 1,200^{0}F for catalytic systems. Combustion temperature depends on the chemical composition and the desired destruction efficiency. Carbon dioxide and water vapor are the typical products of complete combustion. Turbulent mixing and combustion chamber retention times of 0.5 to 1.0 seconds are needed to obtain high destruction efficiencies.

Combustion control technologies include recuperative thermal incineration, regenerative thermal incineration, recuperative catalytic incineration, regenerative catalytic incineration, and flares.

Combustion control technologies include:

Recuperative Thermal Oxidation: Recuperative thermal incinerators are add-on control devices used to control VOC emissions by introducing solvent-laden fume to the oxidizer. The stream is pre-heated by exiting flue gas from the same system in a heat exchanger or recuperator. A burner then heats the air to the required temperature. The air is then passed through an oxidation chamber where the solvent-laden air is converted to carbon dioxide and water. These are then passed through the heat exchanger where incoming fume is preheated by the heat of the exiting flue gas. Finally the clean flue gas is discharged to the atmosphere. The recuperative thermal oxidizer is appropriate for waste streams with a relatively high solvent content and/or consistent pollutant loading. Variation in pollutant loading will require a longer retention time in the oxidizer in order to properly destroy VOC emissions. Eli Lilly's streams do not have high solvent content or consistent pollutant loading. Based on a review of the RBLC, this type of control has been used for controlling VOC emissions from other sources, but has not been typically used for pharmaceutical processes. This would not be an appropriate control method for low VOC exhaust stream from the BPM support.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a Recuperative Thermal Oxidation is not a technically feasible option for the BPM support at this source.

Regenerative Thermal Oxidation: Regenerative thermal oxidizers (RTOs) are add-on control devices used to control VOC emissions by simple reaction of the harmful air pollutants with oxygen and heat. RTO uses a direct contact heat exchanger. These direct contact heat exchangers consist of a bed of porous ceramic packing or other structured, high heat capacity media. These systems can handle variable and low-concentration VOC waste streams.

The inlet gas first passes through a hot ceramic bed thereby heating the stream (and cooling the bed) to its ignition temperature. The hot gases then react (releasing energy) in the combustion chamber and while passing through another ceramic bed, thereby heating it to the combustion chamber outlet temperature. The process flows are then switched, now feeding the inlet stream to the hot bed. This cyclic process affords very high energy recovery (up to 95%). The higher capital costs associated with these high-performance heat exchangers and combustion chambers may be offset by the increased auxiliary fuel savings to make such a system economical

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a Regenerative thermal oxidizer is a technically feasible option for the BPM support at this source.

Recuperative and Regenerative Catalytic Oxidation: Catalytic incinerators are add-on control devices used to control VOC emissions by using a bed of catalyst that facilitates the oxidation of the combustible gases. The catalyst increases the reaction rate and allows the conversion of VOC at lower temperatures than thermal incinerators. Catalytic oxidation can be used for low-concentration VOC waste streams; however, certain compounds present in waste stream gas may foul the catalyst. It may also be necessary to remove particulate prior to catalytic oxidation as well.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a Recuperative and Regenerative Catalytic Oxidation is not a technically feasible option for the BPM support at this source.

Flares: Flaring is used to control VOC emissions by piping VOCs to a remote, usually elevated location and burning them in an open flame in the open air using a specially designed burner tip, auxiliary fuel, and steam or air to promote mixing for nearly complete (> 98%) VOC destruction. While flares are designed to eliminate waste gas streams, they can cause safety and operational problems and the exhaust stream concentration must be high enough to sustain combustion.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a flare is not a technically feasible option for the BPM support at this source.

Reclamation Control Methods

Organic compounds may be reclaimed by one of three possible methods; adsorption, absorption (scrubbing) or condensation. In general, the organic compounds are separated from the emission stream and reclaimed for reuse or disposal. Depending on the nature of the contaminant and the inlet concentration of the emission stream, recovery technologies can reach efficiencies of 98%.

Adsorption: is a surface phenomenon where attraction between the carbon and VOC molecules binds the pollutants to the carbon surface. Both carbon and VOC are chemically intact after adsorption. The VOCs may be removed, or desorbed, from the carbon bed reclaimed and destroyed. Adsorption can be used for relatively low VOC exhaust streams. Pollutants present in the gas streams can reduce adsorber efficiency, increase pressure drop and eventually plug the bed. Adsorption processes can be used to capture VOCs in low concentration exhaust; however, it is typically only used for exhaust that is not loaded with other pollutants which can plug the bed. Based on a review of the RBLC, this type of control has been used in the printing and petroleum refinery industries. This type of control is not typically used in pharmaceutical industries and based on the pollutant loading of the exhaust stream, adsorption is not considered technically feasible for the BPM operations as plugging of the adsorption media would likely occur.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of adsorption is not technically feasible option for the BPM support at this source.

Absorption: is a unit operation where components of a gas phase mixture (Pollutants) are selectively transferred to a relatively nonvolatile liquid, usually water. Sometimes, organic liquids, such as mineral oil or nonvolatile hydrocarbons, are suitable absorption solvents. The choice of solvent depends on cost and solubility of the pollutant in the solvent. Absorption is commonly used to recover products or purify gas streams that have high concentrations of organic compounds. Absorption processes are typically used to recover products or purify gas streams with high concentrations of organic compounds such as in the ethanol production and soybean oil refinery industries. However, it is not considered a technically feasible application for VOC control of emissions from the pharmaceutical operations due to the low concentration of VOC in the exhaust.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of absorption is not technically feasible option for the BPM support at this source.

Condensation: is the separation of VOCs from an emission stream through a phase change, by increasing the system pressure or, more commonly, lowering the system temperature below the dew point of the VOC vapor. When condensers are used for air pollution control, they usually operate at the pressure of the emission stream, and typically require a refrigeration unit to obtain the temperature necessary to condense the VOCs from the emission stream. These systems are frequently used prior to other control devices (e.g., oxidizers or absorbers) to remove components that may be corrosive or damaging to other parts of the system. Refrigerated condensers are used as air pollution control devices for treating emission streams with high VOC concentrations (usually > 5,000 ppmv). Condensers may be used to control VOC emissions with high VOC concentrations (usually greater than 5,000 ppmv). The RBLC shows that this type of control has been used for botanical extraction processes and petroleum refineries. Condensers are not typically used in the pharmaceutical industries for VOC control and are not considered technically feasible for the application of controlling VOC emissions from the pharmaceutical operations due to the low concentration of VOC in the exhaust.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of condensation is not technically feasible option for the BPM support at this source.

Combinations of Reclamation and Destruction Control Methods

In some cases, a combination of control technologies offers the most efficient and cost effective VOC control.

The combination of carbon adsorption with recuperative thermal incineration is available commercially. This system concentrates the VOC stream by using carbon adsorption to remove low concentration VOCs in an emission stream and then uses a lower volume of hot air, commonly one-tenth the original flow, to desorb the pollutants. A recuperative incinerator for destroying pollutants in the concentrated stream is much smaller and has lower supplemental fuel requirement than an incinerator sized for the full emission stream volume.

Absorption systems can also be used to concentrate emission streams to reduce the size of destruction equipment. The concentration effect is not as extreme as with carbon adsorption, a concentrated exhaust stream one quarter the volume of the inlet stream seems to be the practical limit. Absorption concentrators are typically suited for batch processes or to equalize pollutant concentrations in a variable stream. The physical characteristics that drive the absorption of pollutants into a liquid also limit the opportunity to remove those pollutants from the liquid stream.

Fume incinerators typically need supplemental fuel. Concentrated VOC streams with high heat contents obviously require less supplementary fuel than more dilute streams. VOC streams sometimes have a heat content high enough to be self-sustaining, but a supplemental fuel firing rate equal to about 5% of the total incinerator heat input is usually needed to stabilize the burner flame. Natural gas is the most common fuel for VOC incinerators, but fuel oil is an option in some circumstances.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a Combinations of Reclamation and Destruction Control Methods is not a technically feasible option for the BPM support at this source.

Step 3: Rank the Remaining Control Technologies by Control Effectiveness

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of T79 fume Incinerator with 98 % control efficiency is the only viable technology for controlling VOC emissions resulting from the BPM Support at the Eli Lilly and Company, Tippecanoe Laboratories.

T79 Fume Incinerator - 98% control efficiency.

Step 4: Evaluate the Most Effective Controls and Document the Results

The following table lists the proposed CO BACT determination along with the existing VOC BACT determinations for BPM Support. All data in the table is based on the information obtained from the permit application submitted by Eli Lilly and Company, Tippecanoe Laboratories, the U.S. EPA RACT/BACT/LAER Clearinghouse (RBLC), and electronic versions of permits available at the websites of other permitting agencies.

Table 2: Existing VOC BACT Limits – BPM Support

Company Name / Operation	**Process Description**	**Control Type**	**Control Efficiency**
PROPOSED BACT FOR BPM Support			
Eli Lilly and Company, Tippecanoe Laboratories - **Lafayette,** IN (Proposed permit 157-26577-00006) Proposed date, 2008	BPM Support	T79 fume Incineration and leak detection and repair (LDAR) Program	98% control of VOC
COMPARABLE BACT DETERMINATIONS (List in Top-Down Order by Control Efficiency)			
ICN Pharmaceuticals (CA-0348)	Drying Ovens (4)	Carbon Adsorption	65 lb/day (control efficiency not specified) (BACT)
Kelco-Division of Merck, Inc (CA-0570)	Biogum Processing Line	Water Scrubbers	95% (BACT)
American Cyanamid Co. (CT-0037)	Pharmaceutical Material Generation	Activated carbon Adsorption	90% (BACT)

Table 2: Existing VOC BACT Limits – BPM Support			
Company Name / Operation	**Process Description**	**Control Type**	**Control Efficiency**
Pfizer (CT-0108)	Pharmaceuticals Manufacturing Equipments	Regenerative Oil Adsorption System	93% (BACT)
Pfizer (CT-0108)	Coater	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0108)	Dryer	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0108)	Dryer	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0108)	Pharmaceuticals Manufacturing Equipments	Surface Condensers	95% (BACT)
Pfizer (CT-0108)	Pharmaceuticals Manufacturing Equipments	Scrubber and /or Carbon Adsorption	85% (BACT)
Pfizer (CT-0108)	Coater	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0108)	Dryer	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0108)	Dryer	Catalytic Oxidizer	95% (BACT)
Eli Lilly and Company (IN-0035)	Insulin Manufacturing	Low Temperature Vent Condensers	97% (BACT)
Upjohn (MI-0201)	Filter, Pressure for product drying	2 Nitrogen recycle Drying System	98% (LAER)
Dow Chemical (MI-0223)	Reactor, Distillation, Crystallizer, Centrifuge, Vacuum Dryer and Filter	Condenser followed by wet scrubber	90% for isopropyl Alcohol and 95% for Ethyl Alcohol
Upjohn (MI-0235)	Expansion of HF Chemistry	Refrigerated Condenser	94.7% (BACT)
Pfizer (MI-0276)	Pharmaceutical Production.	Thermal Oxidizer	99.9% (BACT)
Wyckoff Chemicals Co., Inc (MI-0107)	Pharmaceutical Mfg.	Caustic scrubber/Demister, carbon Adsorption System	95% (BACT)
Wyckoff, Inc (MI-0312)	Reactors, et. al	Scrubber and Condenser	94%
Eli Lilly and Company (IN-0098)	Monensin Process	Carbon Adsorber	95% (BACT)
Eli Lilly and Company (Permit No. T157-6879-00006)	BPM	RTO	98% control or 20ppmv

The most stringent VOC emission limitation contained in the pharmaceutical summary is 98% control on a product drying operation, 97% on an insulin manufacturing operation, and 99.99% on pharmaceutical manufacturing consisting of reactor and process vents, storage tanks, wastewater treatment, and solvent recovery. The variation in control efficiency is in part dependent on the uncontrolled VOC emission rate of the emissions unit. Even though a unit may be listed with a high control efficiency, the same control equipment will have lower control efficiency if the uncontrolled emission rate is lower.

The 99.99% VOC control efficiency for pharmaceutical manufacturing as identified in RBLC was for Pfizer in Holland, Michigan. This permit does not have a permit condition or limit that requires 99.99% control of VOC emissions, but rather a mass emission rate of 0.84 pounds of VOC per hour (for all units combined). The control is not regenerative thermal oxidizer, but simple afterburners manufactured by Callidus, followed by waste heat boilers.

(a) **Proposal**: **Eli Lilly and Company, Tippecanoe Laboratories** – Lafayette, IN
The following has been proposed as BACT for VOC for BPM Support:

(a) VOC point source emissions: 98% control of VOC emissions.

(b) VOC fugitive emissions: Leak Detection and Repair (LDAR) Program

Step 5: Select BACT

Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed VOC BACT of 98% control of VOC emissions for the BPM Support. The BACT determination is based on the following facts and findings.

(a) The most stringent VOC emission limitation applicable to this emission unit is the MACT standard for pharmaceutical operations. This rule requires organic HAP emissions to be controlled by 93% to 98% or to 20 ppm. For the BPM support operations, the MACT rule requires 95% control of point source organic HAP emissions. This rule also contains requirements for leak detection and repair programs for components in organic HAP service. There are no emission limits for similar sources that would create any more stringent emission limits for pharmaceutical operations.

(b) In order for Lilly to meet a control efficiency comparable to that required for Pfizer in Holland, Michigan, an afterburner would have to be installed after the T79 fume incinerator. The cost effectiveness to add an afterburner to the existing T79 control system is $735,000 per ton of additional VOC removed using accepted cost equations contained in the EPA document *Control Technologies for Hazardous Air Pollutants* (EPA/625/6-91/014). Therefore, it is not economically feasible to install afterburner after the existing T79 fume incineration system.

(c) With the exception of the Pfizer facility in Holland, Michigan, the most stringent listing in the RBLC is consistent with the proposed BACT limit proposed by the source.

Fugitive Emissions

IDEM, OAQ has approved the proposed LDAR program to satisfy the fugitive VOC BACT in the BPM process operations area. This conclusion is based on the following facts and findings:

(1) The proposed LDAR program is consistent with the most stringent regulatory standards. These standards are described in detail in Appendix A – Section E (LDAR Program) of the TSD; and

(2) There were no control requirements listed in the RBLC database.

Regulatory Limits: The most stringent VOC emission limitation applicable to this emission unit is the MACT standard for pharmaceutical operations. This rule requires organic HAP emissions to be controlled by 93% to 98% or to 20 ppm. For the BPM support operations, the MACT rule requires 95% control of point source organic HAP emissions. This rule also contains requirements for leak detection and repair programs for components in organic HAP service. There are no emission limits for similar sources that would create any more stringent emission limits for pharmaceutical operations.

Feasibility of Control Technology: VOC emissions are currently controlled through the use of the T79 fume incineration system. VOC emissions may be controlled by a variety of control technologies, however there is no technology that would be expected to achieve an overall control efficiency (or outlet VOC emission rate) more stringent than that contained in the MACT standard.

Volatile Organic Compounds (VOCs) BACT – Waste Incineration T49

Step 1: Identify Potential Control Technologies

Add-No control is feasible.

Step 2: Eliminate Technically Infeasible Options

VOC emissions are generally limited from incineration operations through the use of good combustion. Add-on controls are not feasible for combustion operations with low concentrations.

Step 3: Rank the Remaining Control Technologies by Control Effectiveness

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the good combustion practice and compliance with CO limit is the only viable technology for controlling VOC emissions resulting from the Waste incinerator at the Eli Lilly and Company, Tippecanoe Laboratories.

Step 4: Evaluate the Most Effective Controls and Document the Results

The are no listings in the U.S. EPA RACT/BACT/LAER Clearinghouse (RBLC), that contained stack limitations or concentration limits for VOC emissions from incineration operations.

(a) **Proposal**: **Eli Lilly and Company, Tippecanoe Laboratories** – Lafayette, IN
The following has been proposed as BACT for VOC for Waste Incineration (T49 liquid waste incinerator):

(1) VOC: Good combustion practice and compliance with CO limit.

There were no listings in the RBLC that contained stack limitations or concentration limits for VOC emissions from incineration operations. The RBLC did contain listings that contained DRE requirements for requirements, with most DRE requirements at 99.99%. The existing Flexible Permit specifies that BACT for VOC emissions from T49 is compliance with the CO limit of 100 ppmvdc.

Step 5: Select BACT

Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed VOC BACT for the T49 is good combustion practices and compliance with the 100 ppmvdc CO limit.

The IDEM agrees that the VOC BACT for both the T49 liquid waste incinerator is a good combustion practice and compliance with CO limit.

Regulatory Limits: There are no regulatory limits for VOC emissions from incineration operations with the exception of the hazardous waste incineration MACT standard (Subpart EEE), which limits Total Hydrocarbon (THC) emissions to 10 ppm (or requires CO emission control to 100 ppm) and requires a destruction removal efficiency (DRE) for organic materials of 99.99% for each principle organic hazardous constituent.

Permit Limits: There were no listings in the RBLC that contained stack limitations or concentration limits for VOC emissions from incineration operations. The RBLC did contain listings that contained DRE requirements for requirements, with most DRE requirements at 99.99%. The existing Flexible Permit specifies that BACT for VOC emissions from T49 is compliance with the CO limit of 100 ppmvdc.

Feasibility of Control Technology: VOC emissions are generally limited from incineration operations through the use of good combustion. Add-on control systems are not feasible for combustion operations with low VOC concentrations.

Carbon Monoxide (CO) BACT - T49 Waste Incineration

Step 1: Identify Potential Control Technologies

Emissions of carbon monoxide (CO) are generally controlled by oxidation.

Step 2: Eliminate Technically Infeasible Options

The test for technical feasibility of any control option is whether it is both available and applicable to reducing CO emissions from the T49 waste incinerator.

CO Technologies Considered Feasible

Carbon Monoxide (CO) is formed through the incomplete oxidation of organic material to carbon dioxide (CO2). Factors that may lead to the formation of carbon monoxide include inadequate air flow rates, inadequate mixing of air and fuel, and improper temperatures in combustion zones. CO emission control is achieved by design optimization in combustion equipment to minimize CO formation or by the use of add-on control units that will facilitate the further oxidation of CO to CO2.

Good Combustion Practices

Combustion equipment design focuses on proper air to fuel ratios, good mixing of air and fuel, and control of combustion chamber temperatures to minimize CO emissions. In situations where CO is generated by process activities (such as chemical reactions) or where combustion equipment design are inadequate to achieve the desired level of control, add-on- controls may be necessary to limit CO emissions. Add-on-control equipment for CO includes thermal or catalytic oxidation techniques to convert CO to CO_2. The choice of controls is based upon several factors, including the degree of control desired, the concentration of carbon monoxide in the air stream, and other physical characteristics of the air stream (including the presence of other pollutants).

Oxidation Catalyst
An oxidation catalyst uses a precious metal based catalyst to promote the oxidation of CO to $CO_{2.}$ The oxidation of CO to CO_2 utilizes the excess air present in the gases; the activation energy required for the reaction to proceed is lowered in the presence of the catalyst. Technical factors relating to this technology include catalyst reactor design, optimum-operating temperature,

backpressure loss to the system and catalyst life. Oxidation catalyst reactors operate in a temperature range of 700°F to 900°F. At temperature lower that this range CO conversion to CO_2 reduces rapidly. Cost of an oxidation catalyst can be high with the largest cast associated with the catalyst itself. Catalyst life varies, but typically a 3 to 6 year life can be expected.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of oxidation catalyst is not a technically feasible option for the T49 Waste Incineration at this source.

Step 3: Rank the Remaining Control Technologies by Control Effectiveness

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the good combustion practice to control CO emissions to 100 ppmvdc based on a 1-hour block period is the only viable technology for controlling CO emissions resulting from the Waste incinerator at the Eli Lilly and Company, Tippecanoe Laboratories.

Step 4: Evaluate the Most Effective Controls and Document the Results

There are several regulatory limits for CO emissions from incineration units. The MACT standards within 40 CFR Part 63, Subpart EEE limit CO emissions to 100 ppm (or VOC emissions to 10 ppm).The only CO emission limit for any type of incineration operation that is more stringent than this limit is the limit for Hospital/Medical/Infectious Waste Combustors found in 40 CFR Part 60, Subpart Ec. This standard limits CO emissions to 40 ppm.

There are a few CO limits in RBLC for hazardous waste incinerators and other waste incinerators. The most stringent CO emission limit contained in RBLC for incineration is 100 ppm. The existing Flexible Permit specifies that BACT for T49 is 100 ppmvdc.

Step 5: Select BACT

Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed CO BACT for the T49 as good combustion practices to control CO emissions to 100 ppmvdc based on a 1-hour block period. The BACT determination is based on the following facts and findings:

The CO BACT for the T49 incinerator has proper combustion to limit CO emissions to no more than 100 ppmvdc, based on a 1-hour average. This is equivalent to the CO MACT limit contained in 40 CFR Part 63, Subpart EEE.

IDEM, OAQ believes that the hospital/medical/infectious waste incineration limit is not appropriate for hazardous waste incineration units for the following reasons:

(a) Incinerators of the type regulated under Subpart Ec are typically much smaller than units such as T49; and

(b) The waste stream for these units of the type regulated under Subpart Ec is generally more uniform than that encountered in T49.

Regulatory Limits: There are several regulatory limits for CO emissions from incineration units. The MACT standards within 40 CFR Part 63, Subpart EEE limit CO emissions to 100 ppm (or VOC emissions to 10 ppm). The only CO emission limit for any type of incineration operation that is more stringent than this limit is the limit for Hospital/Medical/Infectious Waste Combustors found in 40 CFR Part 60, Subpart Ec. This standard limits CO emissions to 40 ppm.

Permit Limits: There are a few CO limits in RBLC for hazardous waste incinerators and other waste incinerators. The most stringent CO emission limit contained in RBLC for incineration is 100 ppm. The existing Flexible Permit specifies that BACT for T49 is 100 ppmvdc.

Feasibility of Control Technology: CO emissions are generally controlled by proper combustion techniques. Add-on controls are not appropriate for the control of CO emissions from incineration

Fluorides (F-) BACT – T49 Waste incinerator

Step 1: Identify Potential Control Technologies

Fluorides can be controlled by scrubbers:

Step 2: Eliminate Technically Infeasible Options

The test for technical feasibility of any control option is whether it is both available and applicable to reducing fluorides emissions from the waste incinerator.

Fluorides Technologies Considered Feasible

The presence of halogens such as fluorine or chlorine in a fuel or waste stream exposed to high temperatures will result in the creation of acid gases such as hydrogen fluoride or hydrogen chloride. Fluoride and chloride emissions are generally controlled in much the same manner as chloride emissions are generally controlled in much the same manner as for sulfur dioxide. Fuel or process modifications may be possible to limit the quantity of these materials in fuel or process streams. Add-on controls may also be used to physically remove these materials from exhaust gases. Systems used to control sulfur dioxide emissions will also capture and control halogen emissions. Fluoride compounds tend to react with chemical reagents most rapidly, followed by chloride compounds and sulfur dioxide. Thus, a control system for sulfur dioxide will by its nature remove most fluoride and chloride compounds.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a fluorides technology is not a technically feasible option for the BPM Operation at this source

Step 3: Rank the Remaining Control Technologies by Control Effectiveness

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of sodium hydroxide (NaOH) injection with 98% control efficiency is the only viable technology for controlling Fluorides (F-) emissions resulting from the Waste incinerator at the Eli Lilly and Company, Tippecanoe Laboratories.

Sodium hydroxide (NaOH) Injection - 98% control efficiency

Step 4: Evaluate the Most Effective Controls and Document the Results

The following table lists the proposed PM/PM_{10} BACT determination along with the existing Fluoride (F-) BACT determinations for Waste Incineration. All data in the table is based on the information obtained from the permit application submitted by Eli Lilly and Company, Tippecanoe Laboratories, the U.S. EPA RACT/BACT/LAER Clearinghouse (RBLC), and electronic versions of permits available at the websites of other permitting agencies.

Table 3: Existing VOC BACT Limits – T49			
Company Name / Operation	**Process Description**	**Control Type**	**Control Efficiency**
PROPOSED BACT FOR T49			
Eli Lilly and Company, Tippecanoe Laboratories - **Lafayette,** IN (Proposed permit 157-26577-00006) Proposed date, 2008	Waste Incineration-T49 liquid waste incineration	NaOH Injection	98% control of HCl
COMPARABLE BACT DETERMINATIONS (List in Top-Down Order by Control Efficiency)			
NRG Recovery Group (FL-0038)	Refuse Incinerator, 2 ea 250 t/d	Acid gas control	1.5 gr/dscf (BACT)
Pasco County (FL-0039)	Refuse Incinerator, 120 t/d	Dry Scrubber/baghouse	90% control; 0.008 lb/mmBtu (BACT)
Lee County Energy Recovery Facility (FL-0067)	Boiler, Municipal waste incineration (3) 660 tpd	Spry dryer (lime dry scrubber)/fabric filter	5 ppm fluorides at 7% O2 (BACT)
Central Wayne Energy Recovery Limited Partnership (MI-0252)	Municipal Waste Combustors (3 units)	Dry Scrubber	5 ppmdv (BACT)
Mercer and Atlantic Co. Resource recovery Facility (NJ-0020)	Municipal Waste Combustor 833.8 tpd	Dryer absorber	90% (BACT)
San Juan Resource Recovery Facility (PR-0001)	Mass Burn Combustor, 3 1040 t/d	Dry scrubber	90% (BACT)
Ogden Martin Systems of Fairfax, Inc (VA-0055)	Incineration, 4 ea 750 t/d	Dry scrubber	90% (BACT)
Lee County Solid Waste Division (FL-0258)	Combustor, MSW	Dry scrubber	3.5 ppmvd at 7% (BACT)
Riley Energy System of Lisbon Corp (CT-0144)	Municipal Waste Combustors (2)	SNCR, Fabric Filter	0.41 lb/hr, 2,081 ug/dscm, 2.5 ppm at12% CO2 (BACT)
Wheelabrator Gloucster County RRF (NJ-0039 draft determination)	Water wall incinerator (2)	Semi-Dry Scrubber	90% 0.002 lb/mmBtu, 0.018 lb/ton (BACT)
Dade County Dept of Solid waste management (FL-0.164)	Municipal Waste Combustors 4 units	None	840 ug/dscm at 7% O2, 7.3 lb/mmBtu (Other)
Wheelabrator South Broward, Inc (FL-0169)	Municipal Waste Combustors	Spray Dryer Absorber	0.004 lb/mmbtu, 1.21 lb/hr, 5.29 tpy (BACT and NSPS)

Table 3: Existing VOC BACT Limits – T49			
Company Name / Operation	**Process Description**	**Control Type**	**Control Efficiency**
Wheelabrator North Broward, Inc (FL-0170)	Municipal Waste Combustors	Spray Dryer Absorber	5.66 tpy, 0.004 lb/mmbtu, 1.29 lb/hr, (NSPS)
Hillsborough County Resources Facility (FL-0165)	Municipal Waste Combustors	Spray Dryer Absorber	6.74 mg/dscm at 7% O2, 0.0059 lb/mmbtu, 1 lb/hr, 5.29 tpy (Other)
Eli Lilly and Company (permit T157-6879-00006)	T49	NaOH Injection	98% Control of HCl
Eli Lilly and Company (permit T157-6879-00006)	T149	NaOH Injection	98% Control of HCl

There are no permit limits in RBLC for fluoride emissions from hazardous waste combustion units. There are several listings in RBLC for fluoride/fluorine/hydrogen fluoride emission limits from municipal waste combustors. The most stringent such limit for municipal waste combustors is 5 ppm. The existing Flexible Permit specifies that BACT for fluoride emissions from T49 is 98% control of HCl emissions. This permit also contains a fluoride emission limit of 77 ppmvdc

(a) **Proposal**: **Eli Lilly and Company, Tippecanoe Laboratories** – Lafayette, IN
The following has been proposed as BACT for Fluorides for the Waste Incineration (T49 liquid Waste incineration) is:

(1) NaOH injection to achieve 98% removal efficiency of hydrogen Chloride (HCl).

Step 5: Select BACT

Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed Fluorides (F-) BACT of NaOH injection to achieve 98% removal of hydrogen Chloride (HCl).

The fluorides BACT for the T49 incinerator is caustic scrubbing with NaOH to achieve 98% removal efficiency of HCl. This 98% removal efficiency corresponds to an outlet concentration of 77 ppmvdc. IDEM, OAQ believes that this level of control is as stringent as or more stringent than any limit contained in applicable rules or permits for comparable emission units.

Regulatory Limits: There are no regulatory limits for fluoride emissions that are applicable to hazardous waste incinerators, including the MACT standard for hazardous waste incineration units. There are regulatory limits for hydrogen chloride emissions from several types of incinerators, with emission limits that vary from 15 to 62 ppm, depending upon the specific type of unit regulated. The combined hydrogen chloride/chlorine limit from hazardous waste incinerators (40 CFR Part 63, Subpart EEE) is 32 ppmvdc for existing units and 21 ppmvdc for new units.

Permit Limits: There are no permit limits in RBLC for fluoride emissions from hazardous waste combustion units. There are several listings in RBLC for fluoride/fluorine/hydrogen fluoride emission limits from municipal waste combustors. The most stringent such limit for municipal waste combustors is 5 ppm. The existing Flexible Permit specifies that BACT for fluoride emissions from T49 is 98% control of HCl emissions. This permit also contains a fluoride emission limit of 32 ppmv dry corrected to 7% oxygen, expressed as HCl equivalent.

Feasibility of Control Technology: Fluoride emissions may be controlled through the use of a wet or dry scrubbing system.

Volatile Organic Compounds (VOCs) BACT – 149 Solid-Liquid Waste Incinerator

Step 1: Identify Potential Control Technologies

Add-No control is feasible.

Step 2: Eliminate Technically Infeasible Options

VOC emissions are generally limited from incineration operations through the use of good combustion. Add-on controls are not feasible for combustion operations with low concentrations.

Step 3: Rank the Remaining Control Technologies by Control Effectiveness

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the good combustion practice and compliance with CO limit is the only viable technology for controlling VOC emissions resulting from the Waste incinerator at the Eli Lilly and Company, Tippecanoe Laboratories.

Step 4: Evaluate the Most Effective Controls and Document the Results

The are no listings in the U.S. EPA RACT/BACT/LAER Clearinghouse (RBLC), that contained stack limitations or concentration limits for VOC emissions from incineration operations.

Proposal: **Eli Lilly and Company, Tippecanoe Laboratories** – Lafayette, IN
The following has been proposed as BACT for VOC for Waste Incineration (T149 Rotary kiln incinerator):

(1) VOC: Good combustion practice and compliance with CO limit.

There were no listings in the RBLC that contained stack limitations or concentration limits for VOC emissions from incineration operations. The RBLC did contain listings that contained DRE requirements for requirements, with most DRE requirements at 99.99%.

Step 5: Select BACT

Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed VOC BACT for the T149 is good combustion practices and compliance with the 10 ppmvdc.

The IDEM agrees that the VOC BACT for T149 Rotary Kiln incinerator may be established as 10 ppmvdc.

Regulatory Limits: There are no regulatory limits for VOC emissions from incineration operations with the exception of the hazardous waste incineration MACT standard (Subpart EEE), which limits THC emissions to 10 ppm (or requires CO emissions to 100 ppm) and requires a destruction removal efficiency (DRE) for organic materials of 99.99% for each principle organic hazardous constituent.

Permit Limits: There were no listings in the RBLC that contained stack limitations or concentration limits for VOC emissions from incineration operations. The RBLC did contain listings that contained DRE requirements for requirements, with most DRE requirements at 99.99%. The existing Flexible Permit contains a VOC BACT limit for T149 of 10 ppmvdc.

Feasibility of Control Technology: VOC emissions are generally limited from incineration operations through the use of good combustion. Add-on control systems are not feasible for combustion operations with low VOC concentrations.

Carbon Monoxide (CO) BACT - T149 Solid-Liquid Waste Incinerator

Step 1: Identify Potential Control Technologies

Emissions of carbon monoxide (CO) are generally controlled by oxidation.

Step 2: Eliminate Technically Infeasible Options

The test for technical feasibility of any control option is whether it is both available and applicable to reducing CO emissions from the T149 Solid-Liquid Waste incinerator.

CO Technologies Considered Feasible

Carbon Monoxide (CO) is formed through the incomplete oxidation of organic material to carbon dioxide (CO2). Factors that may lead to the formation of carbon monoxide include inadequate air flow rates, inadequate mixing of air and fuel, and improper temperatures in combustion zones. CO emission control is achieved by design optimization in combustion equipment to minimize CO formation or by the use of add-on control units that will facilitate the further oxidation of CO to CO2.

Good Combustion Practices

Combustion equipment design focuses on proper air to fuel ratios, good mixing of air and fuel, and control of combustion chamber temperatures to minimize CO emissions. In situations where CO is generated by process activities (such as chemical reactions) or where combustion equipment design are inadequate to achieve the desired level of control, add-on- controls may be necessary to limit CO emissions. Add-on-control equipment for CO includes thermal or catalytic oxidation techniques to convert CO to CO_2. The choice of controls is based upon several factors, including the degree of control desired, the concentration of carbon monoxide in the air stream, and other physical characteristics of the air stream (including the presence of other pollutants).

Oxidation Catalyst

An oxidation catalyst uses a precious metal based catalyst to promote the oxidation of CO to CO_2. The oxidation of CO to CO_2 utilizes the excess air present in the gases; the activation energy required for the reaction to proceed is lowered in the presence of the catalyst. Technical factors relating to this technology include catalyst reactor design, optimum-operating temperature, backpressure loss to the system and catalyst life. Oxidation catalyst reactors operate in a temperature range of 700^{o}F to 900^{o}F. At temperature lower that this range CO conversion to CO_2 reduces rapidly. Cost of an oxidation catalyst can be high with the largest cast associated with the catalyst itself. Catalyst life varies, but typically a 3 to 6 year life can be expected.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of oxidation catalyst is not a technically feasible option for the T149 Rotary Kiln Incinerator at this source.

Step 3: Rank the Remaining Control Technologies by Control Effectiveness

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the good combustion practice to control CO emissions to 100 ppmvdc based on a 1-hour block period is the only viable technology for controlling CO emissions resulting from the Rotary kiln incinerator at the Eli Lilly and Company, Tippecanoe Laboratories.

Step 4: Evaluate the Most Effective Controls and Document the Results

There are several regulatory limits for CO emissions from incineration units. The MACT standards within 40 CFR Part 63, Subpart EEE limit CO emissions to 100 ppm (or VOC emissions to 10 ppm).The only CO emission limit for any type of incineration operation that is more stringent than this limit is the limit for Hospital/Medical/Infectious Waste Combustors found in 40 CFR Part 60, Subpart Ec. This standard limits CO emissions to 40 ppm.

There are a few CO limits in RBLC for hazardous waste incinerators and other waste incinerators. The most stringent CO emission limit contained in RBLC for incineration is 100 ppmvdc. The existing Flexible Permit specifies that BACT for T49 is 100 ppmvdc.

Step 5: Select BACT

Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed CO BACT for the T149 is good combustion practices to control CO emissions to 100 ppmvdc based on a 1-hour block period. The BACT determination is based on the following facts and findings:

The CO BACT for the T149 rotary kiln incinerator has proper combustion to limit CO emissions to no more than 100 ppmvdc, based on a 1-hour average. This is equivalent to the CO MACT limit contained in 40 CFR Part 63, Subpart EEE.

Regulatory Limits: There are several regulatory limits for CO emissions from incineration units. The MACT standards within 40 CFR Part 63, Subpart EEE limit CO emissions to 100 ppm (or VOC emissions to 10 ppm). The only CO emission limit for any type of incineration operation that is more stringent than this limit is the limit for Hospital/Medical/Infectious Waste Combustors found in 40 CFR Part 60, Subpart Ec. This standard limits CO emissions to 40 ppm.

Permit Limits: There are a few CO limits in RBLC for hazardous waste incinerators and other waste incinerators. The most stringent CO emission limit contained in RBLC for incineration is 100 ppm. The existing Flexible Permit specifies that BACT for CO emissions from T149 is 100 ppmvdc.

Feasibility of Control Technology: CO emissions are generally controlled by proper combustion techniques. Add-on controls are not appropriate for the control of CO emissions from incineration.

Fluorides (F-) BACT – T149 Soli-Liquid Waste Incinerator

Step 1: Identify Potential Control Technologies

Fluorides can be controlled by scrubbers:

Step 2: Eliminate Technically Infeasible Options

The test for technical feasibility of any control option is whether it is both available and applicable to reducing fluoride emissions from the Incinerator.

Fluorides Technologies Considered Feasible

The presence of halogens such as fluorine or chlorine in a fuel or waste stream exposed to high temperatures will result in the creation of acid gases such as hydrogen fluoride or hydrogen chloride. Fluoride and chloride emissions are generally controlled in much the same manner as chloride emissions are generally controlled in much the same manner as for sulfur dioxide. Fuel or process modifications may be possible to limit the quantity of these materials in fuel or process streams. Add-on controls may also be used to physically remove these materials from exhaust gases. Systems used to control sulfur dioxide emissions will also capture and control halogen emissions. Fluoride compounds tend to react with chemical reagents most rapidly, followed by chloride compounds and sulfur dioxide. Thus, a control system for sulfur dioxide will by its nature remove most fluoride and chloride compounds.

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of a fluorides technology is not a technically feasible option for the Rotary kiln Incineration operation at this source

Step 3: Rank the Remaining Control Technologies by Control Effectiveness

Based on the information reviewed for this BACT determination, IDEM, OAQ has determined that the use of sodium hydroxide (NaOH) injection with 98% control efficiency is the only viable technology for controlling Fluorides (F-) emissions resulting from the Waste incinerator at the Eli Lilly and Company, Tippecanoe Laboratories.

Sodium hydroxide (NaOH) Injection - 98% control efficiency

Step 4: Evaluate the Most Effective Controls and Document the Results

The following table lists the proposed PM/PM_{10} BACT determination along with the existing Fluoride (F-) BACT determinations for Waste Incineration. All data in the table is based on the information obtained from the permit application submitted by Eli Lilly and Company, Tippecanoe Laboratories, the U.S. EPA RACT/BACT/LAER Clearinghouse (RBLC), and electronic versions of permits available at the websites of other permitting agencies.

Table 4: Existing VOC BACT Limits – T149			
Company Name / Operation	**Process Description**	**Control Type**	**Control Efficiency**
PROPOSED BACT FOR T149			
Eli Lilly and Company, Tippecanoe Laboratories - **Lafayette,** IN (Proposed permit 157-26577-00006) Proposed date, 2008	T149 Rotary kiln incineration	NaOH Injection	98% control of HCl
COMPARABLE BACT DETERMINATIONS (List in Top-Down Order by Control Efficiency)			
NRG Recovery Group (FL-0038)	Refuse Incinerator, 2 ea 250 t/d	Acid gas control	1.5 gr/dscf (BACT)
Pasco County (FL-0039)	Refuse Incinerator, 120 t/d	Dry Scrubber/baghouse	90% control; 0.008 lb/mmBtu (BACT)
Lee County Energy Recovery Facility (FL-0067)	Boiler, Municipal waste incineration (3) 660 tpd	Spry dryer (lime dry scrubber)/fabric filter	5 ppm fluorides at 7% O2 (BACT)
Central Wayne Energy Recovery Limited Partnership (MI-0252)	Municipal Waste Combustors (3 units)	Dry Scrubber	5 ppmdv (BACT)
Mercer and Atlantic Co. Resource recovery Facility (NJ-0020)	Municipal Waste Combustor 833.8 tpd	Dryer absorber	90% (BACT)
San Juan Resource Recovery Facility (PR-0001)	Mass Burn Combustor, 3 1040 t/d	Dry scrubber	90% (BACT)

Table 4: Existing VOC BACT Limits – T149			
Company Name / Operation	**Process Description**	**Control Type**	**Control Efficiency**
Ogden Martin Systems of Fairfax, Inc (VA-0055)	Incineration, 4 ea 750 t/d	Dry scrubber	90% (BACT)
Lee County Solid Waste Division (FL-0258)	Combustor, MSW	Dry scrubber	3.5 ppmvd at 7% (BACT)
Riley Energy System of Lisbon Corp (CT-0144)	Municipal Waste Combustors (2)	SNCR, Fabric Filter	0.41 lb/hr, 2,081 ug/dscm, 2.5 ppm at12% CO2 (BACT)
Wheelabrator Gloucster County RRF (NJ-0039 draft determination)	Water wall incinerator (2)	Semi-Dry Scrubber	90% 0.002 lb/mmBtu, 0.018 lb/ton (BACT)
Dade County Dept of Solid waste management (FL-0.164)	Municipal Waste Combustors 4 units	None	840 ug/dscm at 7% O2, 7.3 lb/mmBtu (Other)
Wheelabrator South Broward, Inc (FL-0169)	Municipal Waste Combustors	Spray Dryer Absorber	0.004 lb/mmbtu, 1.21 lb/hr, 5.29 tpy (BACT and NSPS)
Wheelabrator North Broward, Inc (FL-0170)	Municipal Waste Combustors	Spray Dryer Absorber	5.66 tpy, 0.004 lb/mmbtu, 1.29 lb/hr, (NSPS)
Hillsborough County Resources Facility (FL-0165)	Municipal Waste Combustors	Spray Dryer Absorber	6.74 mg/dscm at 7% O2, 0.0059 lb/mmbtu, 1 lb/hr, 5.29 tpy (Other)
Eli Lilly and Company (permit T157-6879-00006)	T49	NaOH Injection	98% Control of HCl
Eli Lilly and Company (permit T157-6879-00006)	T149	NaOH Injection	98% Control of HCl

There are no permit limits in RBLC for fluoride emissions from hazardous waste combustion units. There are several listings in RBLC for fluoride/fluorine/hydrogen fluoride emission limits from municipal waste combustors. The most stringent such limit for municipal waste combustors is 5 ppm. The existing Flexible Permit specifies that BACT for fluoride emissions from T49 is 98% control of HCl emissions. This permit also contains a fluoride emission limit of 77 ppmvdc

(a) **Proposal**: **Eli Lilly and Company, Tippecanoe Laboratories** – Lafayette, IN
The following has been proposed as BACT for Fluorides for Waste Incineration (T149 Rotary Kiln incineration):

(1) NaOH injection to achieve 98% removal efficiency of hydrogen Chloride (HCl).

Step 5: Select BACT

Pursuant to 326 IAC 2-2-3 (Prevention of Significant Deterioration (PSD), IDEM, OAQ has approved the proposed Fluorides (F-) BACT of NaOH injection to achieve 98% removal of hydrogen Chloride (HCl).

The fluorides BACT for the T149 incinerator is caustic scrubbing with NaOH to achieve 98% removal efficiency of HCl. This 98% removal efficiency corresponds to an outlet concentration of 77 ppmvdc. IDEM, OAQ believes that this level of control is as stringent as or more stringent than any limit contained in applicable rules or permits for comparable emission units.

Regulatory Limits: There are no regulatory limits for fluoride emissions that are applicable to hazardous waste incinerators, including the MACT standard for hazardous waste incineration units. There are regulatory limits for hydrogen chloride emissions from several types of incinerators, with emission limits that vary from 15 to 62 ppm, depending upon the specific type of unit regulated. The combined hydrogen chloride/chlorine limit from hazardous waste incinerators (40 CFR Part 63, Subpart EEE) is 32 ppmvdc for existing units.

Permit Limits: There are no permit limits in RBLC for fluoride emissions from hazardous waste combustion units. There are several listings in RBLC for fluoride/fluorine/hydrogen fluoride emission limits from municipal waste combustors. The most stringent such limit for municipal waste combustors is 5 ppm. The existing Flexible Permit specifies that BACT for fluorides is 98% control of HCl emissions. The permit also limits fluoride emissions to 32 ppmv dry corrected to 7% oxygen, expressed as HCl equivalent.

Feasibility of Control Technology: Fluoride emissions may be controlled through the use of a wet or dry scrubbing system.

Best Available Control Technology during Startup and Shutdown

Startup and Shutdown (SU/SD) conditions are short duration events during which the emission unit is in non steady-state mode. During these events the emission control equipment for the emission units cannot operate at optimum level of performance due to large variations in flow and concentration. Consequently, it is unreasonable to set emission limits that are as stringent as those determined to be BACT under normal operating conditions. Nonetheless, New Source Review guidance requires that emissions be set that assure no violation of the National Ambient Air Quality Standard (NAAQS).

If the compliance with steady state BACT limits is not feasible during startup and shutdown, then the PSD permit must include other limitations or work practices that protect the NAAQS and PSD increment.

The following analysis of the proposed permit supports that the permit includes provisions to protect the NAAQS and PSD increments:

Carbon dioxide (CO) Emissions:
The NAAQS for CO are a one-hour average and an eight-hour average. The permit includes an annual emission limit of 150 tons per year CO for the units subject to PSD requirements. The PSD permit review included a worst case assessment that if all 150 tons of CO were emitted from the T49 incinerator, the CO NAAQS would not be violated. CO emissions that occur during periods of startup and shutdown will be included in the determination of compliance with the 150 ton per year limit. [Note: The T49 incinerator would have to emit CO at a rate 4.5 times higher than its MACT/BACT limit of 100 ppmv for an entire year to emit 150 tons per year.] In order for the T49 incinerator to exceed the one-hour CO NAAQS, it would have to emit 51,900 ppmv of CO for an hour under the worst meteorological conditions. This is more than 500 times the MACT/BACT CO limit. Likewise, T49 would have to emit 45,000 ppmv of CO for eight hours under the worst meteorological conditions to cause concentrations to exceed the eight-hour CO NAAQS. During startup and shutdown of the RTOs and incinerators, these units will be burning only natural gas, which results in low CO emissions except for the brief periods of ignition of the gas. When process fumes or waste are first introduced to the combustion chambers of these units [also considered a startup activity], CO emissions will be momentarily higher than normal, but nowhere near the emission levels needed to cause NAAQS violations. Shutdowns of the T149 incinerator include the process of clearing the kiln of solid waste and could last as long as 30 minutes. Lilly operates T149 in a normal manner until the waste is cleared from the kiln. Emissions are normal during this period.

Fluorides (F-) Emissions:
There is no NAAQS for fluorides. Nonetheless, fluoride emissions during startup and shutdown will be lower than during periods of normal operation because fluoride emissions are due solely to combustion of fluorine-containing process fumes or wastes. These materials will not be burned during startup and

shutdown of the RTOs and incinerators. When process fumes or waste are first introduced to the combustion chambers of these units [also considered a startup activity], fluoride emissions are expected to be within BACT emission limits. Shutdowns of the T149 incinerator include the process of clearing the kiln of solid waste and could last as long as 30 minutes. Lilly operates T149 in a normal manner until the waste is cleared from the kiln. Emissions are normal during this period.
Volatile Organic Compounds (VOCs)/Ozone Emissions:

The NAAQS for ozone is an 8-hour average. The permit includes an annual emission limit of 300 tons per year VOC for the units subject to PSD requirements. The PSD permit review included an assessment that VOC emissions would not cause or significantly contribute to a violation of the ozone NAAQS. VOC emissions that occur during periods of startup and shutdown will be included in the determination of compliance with the 300 ton per year limit. Furthermore, the VOC BACT limits for the RTOs and waste incinerators reflect burning fume streams or waste streams with solvent content. During startup and shutdown of the RTOs and incinerators, these units will be burning only natural gas, which will cause lower VOC emissions. When process fumes or waste are first introduced into the combustion chambers of these units [also considered a startup activity], VOC may momentarily be higher than normal, but generally emissions are expected to be within BACT emission limits. Shutdowns of the T149 incinerator include the process of clearing the kiln of solid waste and could last as long as 30 minutes. Lilly operates T149 in a normal manner until the waste is cleared from the kiln. Emissions are normal during this period.

Appendix C

Air Quality Analysis

Eli Lilly & Company Tippecanoe Laboratories

Lafayette, Indiana (Tippecanoe County)

Tracking and Plant ID: 157-26577-00006

Proposed Project

Eli Lilly & Company Tippecanoe Laboratories (Eli Lilly) has submitted a request for a renewal of their flexible operating permit for Carbon Monoxide (CO) and Fluorides at the Lafayette pharmaceutical manufacturing facility.

ERM, prepared the permit application for Eli Lilly. The Modeling Section in the Office of Air Quality (QAQ) received the permit application August 2008. This technical support document provides the air quality analysis review of the permit application.

Analysis Summary

Based on the net emissions after controls, a PSD air quality analysis was triggered for CO and Fluorides. The significant impact analysis for CO determined that modeling concentrations did not exceed the significant impact levels. Pre-construction monitoring requirements are satisfied using area wide air quality analysis. An additional impact analysis was conducted and showed no significant impact.

Air Quality Impact Objectives

The purpose of the air quality impact analysis in the permit application is to accomplish the following objectives. Each objective is individually addressed in this document in each section outlined below.

A. Establish which pollutants require an air quality analysis based on PSD significant emission rates.

B. Provide analyses of actual stack heights with respect to Good Engineering Practice (GEP), the meteorological data used, a description of the model used in the analysis, and the receptor grid utilized for the analyses.

C. Determine the significant impact level, the area impacted by the source's emissions and background air quality levels.

D. Perform a Hazardous Air Pollutant (HAP) screening for informational purposes.

E. Perform a qualitative analysis of the source's impact on general growth, soils and vegetation in the impact area with emphasis on any Class I areas. The nearest Class I area is Kentucky's Mammoth Cave National Park.

F. Summarize the Air Quality Analysis.

Section A - Pollutants Analyzed for Air Quality Impact

Applicability

The PSD requirements, 326 IAC 2-2, apply in attainment and unclassifiable areas and require an air quality impact analysis of each regulated pollutant emitted in significant amounts by a major stationary source or modification. Significant emission levels for each pollutant are defined in 326 IAC 2-2-1 and in the Code of Federal Regulations (CFR) 52.21(b) (23) (i).

Proposed Project Emissions

Carbon Monoxide is the pollutant that will be emitted from Eli Lilly. The emissions for this project are summarized below in Table 1.

TABLE 1
Significant Emission Rates for PSD

POLLUTANT	SOURCE EMISSION RATE (tpy)	SIGNIFICANT EMISSION RATE (tpy)	PRELIMINARY AIR QUALITY ANALYSIS REQUIRED?
CO	150	100	Yes

These are emission rates that are taken from their permit application. These emission rates are the permitted limits for the whole facility. Worst-case emission rates for were modeled for comparison with short-term impact standards.

Section B – Good Engineering Practice (GEP), Met Data, Model Used, Receptor Grid and Terrain

Stack Height Compliance with Good Engineering Practice (GEP)

Applicability

Stacks should comply with GEP requirements established in 326 IAC 1-7-4. If stacks are lower than GEP, excessive ambient concentrations due to aerodynamic downwash may occur. Dispersion modeling credit for stacks taller than 65 meters (213 feet) are limited to GEP for the purpose of establishing emission limitations. The GEP stack height takes into account the distance and dimensions of nearby structures, which would affect the downwind wake of the stack. The downwind wake is considered to extend five times the lesser of the structure's height or width. A GEP stack height is determined for each nearby structure by the following formula:

$$Hg = H + 1.5L$$

Where: Hg is the GEP stack height
H is the structure height
L is the structure's lesser dimension (height or width)

New Stacks

Since the stack heights for Eli Lilly are below GEP stack height, the effect of aerodynamic downwash will be accounted for in the air quality analysis for the project.

Meteorological Data

The meteorological data used in AERMOD consisted of 1988 through 1992 surface data from the Indianapolis, Indiana and upper air measurements taken at Peoria, IL. The meteorological data was downloaded from Lakes Environmental and preprocessed using AERMET.

Model Description

ERM used AERMOD, Version 07026. OAQ used the same model version to determine maximum off-property concentrations or impacts for each pollutant. All regulatory default options were utilized in the U.S. EPA approved model, as listed in the 40 Code of Federal Register Part 51, Appendix W “Guideline on Air Quality Models”.

Receptor Grid

OAQ modeling used the same receptor grids generated by ERM. The receptor grid contains 3647 individual receptors.

- 100 meter spacing along the facility’s property boundary,
- 100 meter spacing from 0 to 1,500 meters from the facility,
- 250 meters spacing from 1,500 to 3,000 meters from the facility,
- 500 meters spacing from 3,000 to 5,000 meters from the facility.
- 1000 meters spacing from 5,000 to 10,000 meters from the facility.

Treatment of Terrain

Receptor terrain elevation inputs were interpolated from DEM (Digital Elevation Model) data obtained from the USGS. DEM terrain data was preprocessed using AERMAP.

Section C - Significant Impact Level/Area (SIA) and Background Air Quality Levels

A significant impact analysis was conducted to determine if the source would exceed the PSD significant impact levels (concentrations). If the source's concentrations exceed these levels, further air quality analysis is required. Refined modeling for CO was not required because the results did not exceed significant impact levels. Significant impact levels are defined by the following time periods in Table 2 below with all maximum-modeled concentrations from the worst case operating scenarios.

TABLE 2
Significant Impact Analysis

POLLUTANT	TIME AVERAGING PERIOD	MAXIMUM MODELED IMPACTS (ug/m^3)	SIGNIFICANT IMPACT LEVEL (ug/m^3)	REFINED AQ ANALYSIS REQUIRED

CO	1 hour*	127.2	2000	No
CO	8 hour*	50.5	500	No

*First highest values per EPA NSR manual October 1990. Impacts are from the Eli Lilly only.

Pre-construction Monitoring Analysis

Applicability

The PSD rule, 326 IAC 2-2-4, requires an air quality analysis of the new source or the major modification to determine if the pre-construction monitoring threshold is triggered. In most cases, monitoring data taken from a similar geographic location can satisfy this requirement if the pre-construction monitoring threshold has been exceeded. Also, post construction monitoring could be required if the air quality in that area could be adversely impacted by applicant's emissions.

Modeling Results

The modeling results were compared to the PSD preconstruction monitoring thresholds. The results are shown in the table below.

TABLE 3
Preconstruction Monitoring Analysis

POLLUTANT	TIME AVERAGING PERIOD	MAXIMUM MODELED IMPACTS (ug/m^3)	DEMINIMIS LEVEL (ug/m3)	ABOVE DE MINIMIS LEVEL
Fluorides	24-hour	1.26	0.25	Yes
CO	8 hour*	127.2	575	No

*First highest values per EPA NSR manual October 1990. Maximum modeled impacts are from Eli Lilly only.

CO did not trigger the preconstruction monitoring threshold level. Fluorides did trigger the preconstruction monitoring threshold limit. Based on the "Ambient Monitoring Guidelines for Prevention of Significant Deterioration (EPA 450/4-87-007, May 1987), air dispersion modeling is an acceptable substitute for air monitoring for non-criteria pollutants such as fluorides. ERM used this approach as an alternative to preconstruction monitoring for ambient fluorides. This method was approved by IDEM for the original flexible operating permit.

Background Concentrations

IDEM provided ERM with an inventory of fluoride sources in the Tippecanoe County area. These sources were used for an area wide air quality dispersion analysis. Since fluorides do not have any air quality standards under the Clean Air Act, ERM and Eli Lilly compared the ambient modeled concentration

to air quality standards that have been adopted by some individual states. The most stringent state standard is from New York (AQS Part 257) with a 24-hour concentration of 2.85 ug/m^3. The highest 24-hour modeled concentration is 1.26 ug/m^3. This is below the most stringent state standard.

Part D – HAPs Analysis

OAQ currently requests data concerning the emission of 189 HAPs listed in the 1990 Clean Air Act Amendments (CAAA) that are either carcinogenic or otherwise considered toxic and may be used by industries in the State of Indiana. These substances are listed as air toxic compounds on the State of Indiana, Department of Environmental Management, Office of Air Quality's construction permit application Form GSD-08.

The total potential emissions for all HAPs are 309.76 tons per year. Methylene Chloride has the potential to emit 102 tons per year. Potential emissions of fluorides are limited to 6 tons per year. Due to lack of air quality standards, the estimated fluoride concentrations will be considered as a HAP.

For Eli Lilly, a full HAP analysis was completed comparing the maximum estimated concentrations of each pollutant with the Unit Risk Factor (URF) or Inhalation Unit Risk and the Reference Concentration (RfC). This analysis offers a refined, up to date site specific analysis that takes into account the different potencies and health effects that each pollutant presents to the public.

The Unit Risk Factor (URF) is the upper-bound excess lifetime cancer risk estimated to result from continuous inhalation exposure to a pollutant over a 70 year lifetime. Multiplying the estimated concentration by the URF will produce a cancer risk estimate. The cancer risk estimate is the conservative probability of developing cancer from exposure to a pollutant or a mixture of pollutants over a 70 year lifetime, usually expressed as the number of additional cancer cases in a given number of people, e.g., one in a million. For screening purposes at Eli Lilly, the cancer estimates for each pollutant are considered to be additive when deriving the cumulative maximum individual cancer risk.

Non-cancer health effects are determined using the Reference Concentration (RfC). The RfC is an estimate of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Dividing the estimated pollutant concentration by the RfC will determine the pollutant’s Hazard Quotient (HQ). All of the HAPs’ Hazard Quotients were added together to determine Eli Lilly’s Hazard Index (HI).

This HAP screening analysis uses health protective assumptions that overestimate the actual risk associated with emissions from Eli Lilly. Estimates 1) assume a 70 year exposure time, 2) assume that all carcinogens cause the same type of cancer, 3) assume that all non-carcinogens have additive health effects, 4) assume maximum permit allowable emissions from the facility, and 5) use conservatively derived dose-response information. The risk analysis cannot accurately predict whether there will be observed health problems around Eli Lilly; rather it identifies possible avenues of risk.

The results of the HAP modeling are in Table 4.

TABLE 4
Hazardous Air Pollutant Modeling Results

Compound	Potential Emissions	Annual Concentration	Cancer	Cancer Risk	Non-Cancer	Hazard Quotient
	TPY	(ug/m3)	URF, $(ug/m^3)^{-1}$		Chronic RfC, (ug/m^3)	
1,1,2-Trichloroethane	5.00E-04	6.91E-06	1.6E-05	1.11E-10	400.00	0.000
1,2,4-Trichlorobenzene	8.50E-04	1.18E-05	1.0E-06	1.18E-11	200.00	0.000

Compound	Potential Emissions	Annual Concentration	Cancer	Cancer Risk	Non-Cancer	Hazard Quotient
1,3-Butadiene	2.00E-04	2.76E-05	3.0E-05	8.28E-10	2.00	0.000
1,3-trans dichloropropene	2.00E-04	3.46E-06	3.7E-05		0.02	
1,3-Dinitrobenzene	8.50E-04	1.18E-05			0.35	0.000
1,4-Dichlorobenzene	1.05E-03	1.45E-05	6.9E-06	9.95E-11	800.00	0.000
2,4,6-Trichlorophenol	1.30E-03	1.80E-05	3.1E-06	5.58E-11	0.35	0.000
2,4-Dinitrotoluene	1.35E-03	1.87E-05	8.9E-05	1.66E-09	7.00	0.000
2,6-Dinitrotoluene	1.05E-03	1.45E-05	1.9E-01	2.81E-10	3.50	0.000
2-chloroacetophenone	2.30E-03	3.18E-05			0.03	0.001
3,3'-Dichlorobenzidine	5.55E-03	7.67E-05	3.4E-04	2.61E-08		
Acetaldehyde	3.95E-03	5.46E-05	2.2E-06	1.20E-10	9.00	0.000
Acetonitrile	99.36	1.37E+00			60.00	0.023
Acetophenone	3.75E-03	5.18E-05				
Acrylonitrile	6.60E-03	9.12E-05	6.8E-05	6.20E-09	2.00	0.000
Antimony Compounds	2.05E-03	2.83E-05			0.20	0.000
Arsenic compounds	3.50E-04	4.84E-06	4.3E-03	2.08E-08	0.03	0.000
Benzene	9.00E-04	1.24E-05	7.8E-06	9.67E-11	30.00	0.000
Beryllium compounds	2.00E-04	2.76E-06	2.4E-03	6.62E-09	20.00	0.000
bis(2-Chloroethyl)ether	8.00E-04	1.10E-05	3.3E-04	3.63E-09		
bis(2-Ethylhexyl)phthalate	1.39E-02	1.92E-04	2.4E-06	4.61E-10	10.00	0.000
Bromoform	5.00E-04	6.90E-06	1.1E-06	7.59E-12		
Cadmium compounds	1.55E-03	2.14E-05	1.8E-03	3.85E-08	0.02	0.001
Carbon disulfide	6.50E-04	8.99E-06			700.00	0.000
Carbon tetrachloride	5.00E-04	6.91E-06	1.5E-05	1.04E-10	2.00	0.000
Chlordane	5.00E-05	6.91E-07	1.0E-04	6.91E-11	0.70	0.000
Chlorine	2.75	3.80E-02			0.20	0.190
Chlorobenzene	5.00E-04	6.91E-06			1000.00	0.000
Chlorobenzilate	1.00E-04	1.38E-06	7.8E-05	1.08E-10		
Chloroform	4.34E-01	6.00E-03	2.3E-05	1.38E-07	0.30	0.020
Chloromethane (Methyl chloride)	4.35E-03	6.01E-05	1.8E-06	1.08E-10	90.00	0.000
Chromium (VI) compounds	9.00E-04	1.24E-05	1.2E-02	1.49E-07	0.10	0.000
Cumene	2.50E-04	3.46E-06			400.00	0.000
Dimethyl formamide	2.43E-02	3.35E-04			30.00	0.000
Di-n-octyl phthalate	1.55E-03	2.14E-05			70.00	0.000
Chloroethane (Ethyl Chloride)	7.50E-04	1.04E-05	1.3E-07	1.38E-12	10000.00	0.000
Ethylbenzene	2.00E-04	2.76E-06			1000.00	0.000
Ethylene dibromide (1,2-dibromoethane)	7.50E-04	1.04E-05	6.0E-04	6.24E-09	9.00	0.000
Ethylene dichloride (1,2-dichloroethane)	3.70E-03	5.12E-05	2.6E-05	1.33E-09	4.90	0.000
Ethylene glycol	1.00E-02	1.38E-04			400.00	0.000
Fluoride	6	2.52e-1			13.00	0.019
Formaldehyde	1.19E-02	1.65E-04	1.3E-05	2.15E-09	9.80	0.000

Compound	Potential Emissions	Annual Concentration	Cancer	Cancer Risk	Non-Cancer	Hazard Quotient
Hexachlorobenzene	8.00E-04	1.10E-05	4.6E-04	5.06E-09	2.80	0.000
Hexachlorobutadiene	1.25E-03	1.73E-05	2.2E-05	3.81E-10	90.00	0.000
Hexachlorocyclopentadiene	1.01E-02	1.39E-04			0.20	0.001
Hexachloroethane	1.65E-03	2.28E-05	4.0E-06	9.12E-11	80.00	0.000
Hydrochloric Acid	26	3.59E-01			20.00	0.018
Hydrofluoric acid	14.36	1.99E-01			20.00	0.010
Lead compounds	7.95E-03	1.10E-04	1.2E-05	1.32E-09	0.15	0.001
Mercury compounds	2.24E-02	3.10E-04			0.09	0.003
Methanol	37.46	5.18E-01			4000.00	0.000
Methyl ethyl ketone (MEK)	1.23	1.70E-02			5000.00	0.000
Methyl tert butyl ether	4.99E-01	6.90E-03	2.6E-07	1.79E-09	3000.00	0.000
Methylene chloride	102.58	1.42E+00	4.7E-07	6.66E-07	3000.00	0.000
Naphthalene	5.50E-04	7.60E-06	3.4E-05	2.58E-10	3.00	0.000
n-Hexane	15.54	2.14E-01			200.00	0.001
Nickel compounds	2.05E-03	2.83E-05	2.4E-04	6.79E-09	0.20	0.000
Nitrobenzene	1.60E-03	2.12E-05			30.00	0.000
Pentachloronitrobenzene	9.00E-04	1.24E-05	7.4E-05	9.18E-10		
Pentachlorophenol	2.40E-02	3.31E-04	5.1E-06	1.69E-09	100.00	0.000
Phenol	2.55E-03	3.53E-05			200.00	0.000
Polychlorinated biphenyl compounds (PCBs)	2.30E-03	3.18E-05	1.0E-04	3.18E-09	0.07	0.000
Selenium compounds	5.00E-04	6.91E-06			20.00	0.000
Styrene	4.00E-04	5.53E-06			1000.00	0.000
Toluene	3.23	4.40E-02			400.00	0.000
Triethylamine	2.46E-01	3.40E-03			7.00	0.000
Vinyl Acetate	8.50E-04	1.18E-05			200.00	0.000
Vinyl chloride	4.50E-04	6.22E-06	8.8E-06	5.47E-11	100.00	0.000
Xylenes	9.17E-02	1.27E-03			100.00	0.000
Total(TPY)	**309.97**		**Cumulative Cancer Risk**	**1.09E-06**	**Hazard Index**	**0.290**

* Further information on URFs and RfCs can be found at the following EPA website: http://www.epa.gov/ttn/atw/toxsource/chronicsources.html

The Hazard Index for the project does not exceed 1. Pollutants with a Hazard Quotient (HQ) greater than 1 are considered to be at concentrations that could represent a health concern. Hazard Quotients above 1 do not represent areas where adverse health effects will be observed but indicate that the potential exists.

The additive cancer risk estimate from all HAPs is 1.09 additional cancer cases in a million people. This means if an individual was exposed to these HAPs continuously for 70 years, the risk of getting cancer from this exposure would be 1.09 in a million. The US EPA considers one in ten thousand (1.0E-04) excess cancer risks to be the upper range of acceptability with an ample margin of safety. The probability for the general public to be exposed to these HAPs for 24 hours a day, seven days a week, 52 weeks a year for 70 years is minimal. No single pollutant has an additional cancer risk of one in a million.

The short term or acute affects were also analyzed. No short term affects are anticipated from the renewal of this flexible operating permit

Part E – Qualitative Analysis

Additional Impact Analysis

All PSD permit applicants must prepare additional impacts analysis for each pollutant subject to regulation under the Act. This analysis assesses the impacts on growth, soils and vegetation, endangered species and visibility caused by any increase in emissions of any regulated pollutant from the source. The Eli Lilly modeling submittal provided an additional impact analysis performed by ERM.

Economic Growth

The purpose of the growth analysis is to quantify project associated growth and estimate the air quality impacts from this growth either quantitatively or qualitatively.

No new construction is part of this application. No commercial growth is anticipated to occur. Since the area is predominately rural, it is not expected the growth impacts will cause a violation of the NAAQS.

Soils and Vegetation Analysis

A list of soil types present in the general area was determined. Soil types include the following: Loamy Glacial Till, Moderate Thick Loess over Loamy Glacial Till and Thin Loess over Loamy Glacial Till.

Due to the agricultural nature of the land, crops in the Tippecanoe County area consist mainly of corn, sorghum, wheat, soybeans, and oats (2002 Agricultural Census for Tippecanoe County). The maximum modeled concentrations for Eli Lilly are well below the threshold limits necessary to have adverse impacts on the surrounding vegetation such as autumn bent, nimblewill, barnyard grass, bishopscap and horsetail, and milkweed (Flora of Indiana – Charles Deam). Livestock in Tippecanoe County consist mainly of hogs, cattle, and sheep (2002 Agricultural Census for Tippecanoe County) and will not be adversely impacted from the facility. Trees in the area are mainly hardwoods. These are hardy trees and no significant adverse impacts are expected due to modeled concentrations.

Federal and State Endangered Species Analysis

Federal and state endangered or threatened species are listed by the U.S. Fish and Wildlife Service; Division of Endangered Species for Indiana and includes 5 amphibians, 27 birds, 10 fishes, 7 mammals, 15 mollusks, and 15 reptiles. Of the federal and state endangered species on the list, 2 reptiles, 12 mollusks, 11 birds, and 2 mammals have habitat within Tippecanoe County. The mollusks, fish, amphibians and certain species of birds and mammals are found along rivers and lakes while the other species of birds and mammals are found in forested areas. The facility is not expected to have any additional adverse effects on the habitats of the species than what has already occurred from the industrial, farming, and residential activities in the area.

Federal and state endangered or threatened plants are listed by the U.S. Fish and Wildlife Service, Division of Endangered Species for Indiana. They list 13 state endangered species of plants. At this time no federally endangered plant species are found in Tippecanoe County. The endangered plants do not thrive in industrialized and residential areas. The facility is not expected to adversely affect any plant on the endangered species list.

Additional Analysis Conclusions

Finally, the results of the additional impact analysis conclude the operation of the facility will have no significant impact on economic growth, soils or vegetation in the immediate vicinity or on any Class I area. CO is not a pollutant that affects visibility. The visibility analysis was not necessary for this application.

Part F - Summary of Air Quality Analysis

ERM prepared the modeling portion of the PSD application. Tippecanoe County is designated as attainment for all criteria pollutants. CO and Fluoride emission rates associated with the renewal application exceeded the respective significant emission rates. Modeling results taken from the latest version of the AERMOD model showed CO impacts were not predicted to be greater than the significant impact levels. Eli Lilly did trigger the preconstruction monitoring threshold level for Fluorides but satisfied the preconstruction monitoring requirement with an area wide air quality dispersion modeling analysis. The nearest Class I area is Mammoth Cave National Park in Kentucky over 400 kilometers away from the source. An additional impact analysis was required but the continued operation of the facility will have no significant impact.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

We Protect Hoosiers and Our Environment.

Mitchell E. Daniels Jr.
Governor

Thomas W. Easterly
Commissioner

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

SENT VIA U.S. MAIL: CONFIRMED DELIVERY AND SIGNATURE REQUESTED

TO: Shelly Shope
Eli Lilly & Company
1650 Lilly Road TL72
Lafayette, Indiana 47909

DATE: October 6, 2009

FROM: Matt Stuckey, Branch Chief
Permits Branch
Office of Air Quality

SUBJECT: Final Decision
Title V
157-26577-00006 & 157-26575-00006

Enclosed is the final decision and supporting materials for the air permit application referenced above. Please note that this packet contains the original, signed, permit documents.

The final decision is being sent to you because our records indicate that you are the contact person for this application. However, if you are not the appropriate person within your company to receive this document, please forward it to the correct person.

A copy of the final decision and supporting materials has also been sent via standard mail to:
Lawrence J. McShane
OAQ Permits Branch Interested Parties List

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178, or toll-free at 1-800-451-6027 (ext. 3-0178), and ask to speak to the permit reviewer who prepared the permit. If you think you have received this document in error, please contact Joanne Smiddie-Brush of my staff at 1-800-451-6027 (ext 3-0185), or via e-mail at jbrush@idem.IN.gov.

Final Applicant Cover letter.dot 11/30/07

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

We Protect Hoosiers and Our Environment.

Mitchell E. Daniels Jr.
Governor

Thomas W. Easterly
Commissioner

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

October 6, 2009

TO: Tippecanoe County Public Library

From: Matthew Stuckey, Branch Chief
Permits Branch
Office of Air Quality

Subject: **Important Information for Display Regarding a Final Determination**

Applicant Name: Eli Lilly & Company
Permit Number: 157-26577-00006 & 157-26575-00006

You previously received information to make available to the public during the public comment period of a draft permit. Enclosed is a copy of the final decision and supporting materials for the same project. Please place the enclosed information along with the information you previously received. To ensure that your patrons have ample opportunity to review the enclosed permit, **we ask that you retain this document for at least 60 days.**

The applicant is responsible for placing a copy of the application in your library. If the permit application is not on file, or if you have any questions concerning this public review process, please contact Joanne Smiddie-Brush, OAQ Permits Administration Section at 1-800-451-6027, extension 3-0185.

Enclosures
Final Library.dot 11/30/07

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

We Protect Hoosiers and Our Environment.

Mitchell E. Daniels Jr.
Governor

Thomas W. Easterly
Commissioner

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

TO: Interested Parties / Applicant

DATE: October 6,2009

RE: Eli Lilly & Company / 157-26577-00006 & 157-26575-00006

FROM: Matthew Stuckey, Branch Chief
Permits Branch
Office of Air Quality

In order to conserve paper and reduce postage costs, IDEM's Office of Air Quality is now sending many permit decisions on CDs in Adobe PDF format. The enclosed CD contains information regarding the company named above.

This permit is also available on the IDEM website at:
http://www.in.gov/ai/appfiles/idem-caats/

If you would like to request a paper copy of the permit document, please contact IDEM's central file room at:

Indiana Government Center North, Room 1201
100 North Senate Avenue, MC 50-07
Indianapolis, IN 46204
Phone: 1-800-451-6027 (ext. 4-0965)
Fax (317) 232-8659

Please Note: *If you feel you have received this information in error, or would like to be removed from the Air Permits mailing list, please contact Patricia Pear with the Air Permits Administration Section at 1-800-451-6027, ext. 3-6875 or via e-mail at PPEAR@IDEM.IN.GOV.*

Enclosures
CD Memo.dot 11/14/08

Mail Code 61-53

IDEM Staff	DPABST 10/6/2009 Eli Lilly & Company 157 - 26577 - 00006 & 157 - 26575 - 00006 (final)			AFFIX STAMP HERE IF USED AS CERTIFICATE OF MAILING
Name and address of Sender	▶	Indiana Department of Environmental Management Office of Air Quality – Permits Branch 100 N. Senate Indianapolis, IN 46204	Type of Mail: **CERTIFICATE OF MAILING ONLY**	

Line	Article Number	Name, Address, Street and Post Office Address	Postage	Handing Charges	Act. Value (If Registered)	Insured Value	Due Send if COD	R.R. Fee	S.D. Fee	S.H. Fee	Rest. Del. Fee Remarks
1		Shelly Shope Eli Lilly & Company-Tippecanoe Labs 1650 Lilly Rd, TL72 Lafayette IN 47909 (Source CAATS)									
2		Lawrence J McShane Gen Mgr Eli Lilly & Company-Tippecanoe Labs 1650 Lilly Rd, TL05 Lafayette IN 47909 *(RO CAATS)*									
3		Ms. Anna Cicirelli P.O. Box 289, 102 Tipton Street Battleground IN 47920 *(Affected Party)*									
4		Mr. Charles L. Berger Berger & Berger, Attorneys at Law 313 Main Street Evansville IN 47700 *(Affected Party)*									
5		Tippecanoe County Commissioners 20 N 3rd St, County Office Building Lafayette IN 47901 *(Local Official)*									
6		Tippecanoe County Health Department 20 N. 3rd St Lafayette IN 47901-1211 *(Health Department)*									
7		Lafayette City Council and Mayors Office 20 North 6th Street Lafayette IN 47901-1411 *(Local Official)*									
8		Tippecanoe County Public Library 627 South Street Lafayette IN 47901-1470 *(Library)*									
9		Ms. Sharon McKnight 909 Southernview Drive North Lafayette IN 47909 *(Affected Party)*									
10		Ms. Dorothy Whicker 2700 Bonny Lane Lafayette IN 47904 *(Affected Party)*									
11		Tom Pierce Sr. 2029 Hall Street Lafayette IN 47904 *(Affected Party)*									
12		Ms. Geneva Werner 3212 Longlois Drive Lafayette IN 47904-1718 *(Affected Party)*									
13		Mr. Thomas Ruzicka 3509 Pine Lane Lafayette IN 47905 (Affected Party)									
14		Mrs. Phyllis Owens 3600 Cypress Lane Lafayette IN 47905 *(Affected Party)*									
15		Kevin Carnes 1816 Beechwood Drive Lafayette IN 47905 *(Affected Party)*									

Total number of pieces Listed by Sender	Total number of Pieces Received at Post Office	Postmaster, Per (Name of Receiving employee)	The full declaration of value is required on all domestic and international registered mail. The maximum indemnity payable for the reconstruction of nonnegotiable documents under Express Mail document reconstructing insurance is $50,000 per piece subject to a limit of $50, 000 per occurrence. The maximum indemnity payable on Express mil merchandise insurance is $500. The maximum indemnity payable is $25,000 for registered mail, sent with optional postal insurance. See ***Domestic Mail Manual*** **R900, S913**, and **S921** for limitations of coverage on inured and COD mail. See ***International Mail Manual*** for limitations o coverage on international mail. Special handling charges apply only to Standard Mail (A) and Standard Mail (B) parcels.
14			

FACSIMILIE OF PS Form 3877

Mail Code 61-53

IDEM Staff	DPABST 10/6/2009 Eli Lilly & Company 157 - 26577 - 00006 & 157 - 26575 - 00006 (final)			AFFIX STAMP HERE IF USED AS CERTIFICATE OF MAILING
Name and address of Sender	▶	Indiana Department of Environmental Management Office of Air Quality – Permits Branch 100 N. Senate Indianapolis, IN 46204	Type of Mail: **CERTIFICATE OF MAILING ONLY**	

Line	Article Number	Name, Address, Street and Post Office Address	Postage	Handing Charges	Act. Value (If Registered)	Insured Value	Due Send if COD	R.R. Fee	S.D. Fee	S.H. Fee	Rest. Del. Fee / Remarks
1		Jerry 1901 King Eider Ct West Lafayette IN 47906 (Affected Party)									
2		Ms. Rose Filley 5839 Lookout Drive West Lafayette IN 47906 *(Affected Party)*									
3		Mr. William Cramer 128 Seminole Drive West Lafayette IN 47906 *(Affected Party)*									
4		Mr. Robert Kelley 2555 S 30th Street Lafayette IN 44909 *(Affected Party)*									
5		West Lafayette City Council and Mayors Office 609 W. Navajo West Lafayette IN 47906 *(Local Official)*									
6											
7											
8											
9											
10											
11											
12											
13											
14											
15											

Total number of pieces Listed by Sender	Total number of Pieces Received at Post Office	Postmaster, Per (Name of Receiving employee)	
5			The full declaration of value is required on all domestic and international registered mail. The maximum indemnity payable for the reconstruction of nonnegotiable documents under Express Mail document reconstructing insurance is $50,000 per piece subject to a limit of $50, 000 per occurrence. The maximum indemnity payable on Express mil merchandise insurance is $500. The maximum indemnity payable is $25,000 for registered mail, sent with optional postal insurance. See ***Domestic Mail Manual*** **R900, S913**, and **S921** for limitations of coverage on inured and COD mail. See ***International Mail Manual*** for limitations o coverage on international mail. Special handling charges apply only to Standard Mail (A) and Standard Mail (B) parcels.

FACSIMILIE OF PS Form 3877